IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.,** **a Private Limited Company** **of the United Kingdom,** **Defendants.**	)	**Civil No. 04-12457 PBS**

DEPUY MITEK'S BRIEF IN SUPPORT OF ITS CLAIM CONSTRUCTION OF THE HUNTER PATENT -- U.S. PATENT NO. 5,314,446

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I. INTRODUCTION

This case involves a patent directed to surgical sutures of a particular construction – the Hunter Patent, U.S. Patent No. 5,314,446 ("Mitek's 446 Patent") (Ex. 1).

The sutures claimed in Mitek's 446 Patent are formed from a braided construction of at least two sets of yarns. The inventors departed from tradition and discovered that by braiding two multifilament yarns from the different materials in a certain configuration a braid could be made with improved properties compared to a braid of just one of the materials. In the configuration, at least one yarn from the first set is in direct intertwining contact with a yarn from the second set (*id*. at 2:49-66). The patent teaches that "it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid" (*id*. at 2:58-62).

DePuy Mitek is asserting Claims 1, 2, 8, 9, and 12 of Mitek's 446 Patent against Arthrex. Claim 1 is the independent claim, and reads as follows (with the disputed terms in bold):

> 1. A surgical suture **consisting essentially of** a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and
>
> a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and **PE**; and
>
> b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and
>
> c) optionally a core.

Arthrex's FiberWire suture, accused of infringement, is constructed from a core of ultra high molecular weight polyethylene ("ultra high molecular weight PE") surrounded by a braided

sheath of ultra high molecular weight PE and polyethylene terephthalate (PET). The braided suture is then coated with silicone (Ex. 2).

The claim terms in dispute are:

(i) the transitional term, "consisting essentially of," and whether the use of this transitional term excludes sutures that are coated; and

(ii) the term "PE," and whether it encompasses ultra high molecular weight PE (polyethylene).

The parties agree on the construction of two other claim terms:

(a) "direct intertwining contact" means the mechanical interlocking or weaving of the individual yarns that make up the suture braid; and

(b) "volume fraction of the first set of yarns in the braided sheath and core" (in Claim 9) means the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross sectional area of all the yarns in the surgical suture.

II. MITEK'S 446 PATENT

A. The Specification

Braided sutures were known before the Hunter invention (Ex. 1 at 1:8-25), but there was a need to improve the properties of such sutures (*id.* at 1:26-31). Some of the prior art efforts to improve the properties of braided sutures are disclosed in Mitek's 446 Patent specification.

For example, composite sutures (*i.e.*, sutures made of at least two different materials) were looked at in an attempt to improve suture properties (*id.* at 1:55-2:2). But these efforts failed because, in this kind of suture, the fibers were essentially melted together so that the suture mimicked the properties of a monofilament and not the more desirable properties of a multifilament braid (*id.*). This problematic, monofilament-like structure also occurred with certain coatings (*id.* at 1:18-25). Certain coatings investigated in an attempt to improve suture properties flaked off or required additional processing steps that made them undesirable (*id.* at 1:43-54).

The inventors of Mitek's 446 Patent inventors posited that problems with these prior art efforts to improve braided suture properties failed because they failed to appreciate the importance of fiber-to-fiber friction or mobility – *i.e.*, the effect of fibers in the suture moving against each other (*id.* at 2:14-28). The inventors discovered that, by braiding two yarns, formed of multifilaments of the different materials recited in the claims, in a certain configuration where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, a braid could be made with improved properties. By "mechanically blending" the multifilament yarns of different materials, the inventors disclosed that the resulting heterogeneous braids

> may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns.

(*id*. at Abstract & 2:49-52).

In a preferred embodiment, the sutures have improved handling properties compared to prior art braids, without sacrificing the braid's physical properties (*id.* at 2:22-66). The inventors noted that the properties of the braid could be further enhanced by using a coating, although it noted that coatings used would preferably not restrict fiber-to-fiber mobility (*id.* at 6:5-17).

III. LAW OF CLAIM CONSTRUCTION

It is a "bedrock" principle of claim construction that "the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (citation omitted). It is the words of the claims themselves that define the scope of the patented invention. *Id*. Thus "the analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to 'particularly point[] out and distinctly claim [] the subject matter which the

patentee regards as his invention.'" *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) (quoting 35 U.S.C. § 112, ¶2).

Claim terms cannot be construed completely in vacuum; they must be understood in the context of the written description of the patent specification and the prosecution history before the Patent Office. *Phillips*, 415 F.3d at 1313. Relevant sources of meaning include "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id*. (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004)). Claim terms should be defined in a way that "stays true to the claim language and most naturally aligns with the patent's description of the invention." *Id*. at 1316 (quotation omitted).

When construing claim terms, there is a "heavy presumption" that they carry their ordinary meaning, as understood by a person of ordinary skill in the art at the time of the invention. *Id.* at 1313; *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Claims should be given the full scope of their plain and customary meaning, *Vitronics Corp.*, 90 F.3d at 1582, with the goal being to ascertain what one of "ordinary skill in the art" would understand the terms of a claim to mean at the time the application for patent was filed. *Phillips,* 415 F.3d at 1313. In some cases, the ordinary meaning of a claim term may be readily apparent, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. *Id.* at 1314. More often, however, it is necessary to consider the context in which a claim term has been used to ascertain its legally operative

meaning. That context is provided by the "intrinsic evidence," which is of primary importance in claim construction. *Id.* at 1314-17.

Although the emphasis in claim construction is appropriately placed on the intrinsic evidence, a court is permitted to consider extrinsic evidence in the claim construction process, *e.g.*, expert and inventor testimony, dictionaries, and learned treatises. *Id.* at 1317. Dictionaries and learned treatises may provide help in understanding the underlying technology involved and the way in which those in the field might ordinarily use the claim terms. *Id.* at 1318. Inventor and expert testimony can be useful for a variety of purposes, "such as to provide background on the technology at issue, to explain how an invention works, to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id.; Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1309 (Fed. Cir. 1999) (noting value of scientific testimony to construction of technical terms or terms of art).

In some cases, the presumption that claims take on their ordinary meaning can be rebutted. For example, an inventor can act as his own lexicographer and set forth a special definition for a term in the specification. *CCS Fitness*, 288 F.3d at 1366; *Vitronics*, 90 F.3d at 1582. Or the patentee can specifically disavow or disclaim claim scope, but this intentional disavowal must be made clear by the use of expressions of manifest exclusion or restriction. *See Phillips*, 415 F.3d at 1316. "Where a specification does not *require* a limitation, that limitation should not be read from the specification into the claim." *E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988) (emphasis in original) (citation omitted).

The prosecution history of a patent is also intrinsic evidence that can sometimes provide indications of how the inventor understood the invention at the time it was prosecuted before the Patent Office. *Phillips*, 415 F.3d at 1317. The prosecution history can show if the inventor clearly disclaimed any claim scope during prosecution. *Id.*

When construing the claims in light of the intrinsic and extrinsic evidence, there is a fine line between simply interpreting the claims and improperly importing extraneous limitations into the claims. Too much reliance on evidence outside the claim language itself can result in a claim construction that is too narrow or that strays from the plain meaning of the claim terms. In sum, claim construction should focus on the plain language of the claims, reading them in light of the specification but carefully avoiding the unnecessary grafting of extraneous limitations onto the claim language.

Further, "although the specification often describes very specific embodiments of the invention," district courts have been "repeatedly warned against confining the claims to those embodiments." *Phillips*, 415 F.3d at 1323. In claim construction, "interpreting what is *meant* by a word *in* a claim is not to be confused with adding an extraneous limitation appearing in the specification, which is improper." *Intervet Am., Inc. v. Kee-Vet Labs., Inc.*, 887 F.2d 1050, 1053 (Fed. Cir. 1989) (internal quotations omitted). Accordingly, the Federal Circuit has "expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." *Phillips*, 415 F.3d at 1323 (*citing Gemstar-TV Guide Int'l, Inc. v. Int'l Trade Comm'n*, 383 F.3d 1352, 1366 (Fed. Cir. 2004)). The disclosure of preferred embodiments or implementing examples should not be used to limit the scope of the claims absent a clear disavowal by the inventor. *See Nazomi Comm., Inc. v. ARM Holdings, PLC*, 403 F.3d 1364, 1369 (Fed. Cir. 2005); *Teleflex, Inc. v. Ficosa N.*

Am. Corp., 299 F.3d 1313, 1327 (Fed. Cir. 2002); *see also CCS Fitness*, 288 F.3d at 1366-67. It is "not just because section 112 of the Patent Act requires that the claims themselves set forth the limits of the patent grant, but also because persons of ordinary skill in the art rarely would confine their definitions of terms to the exact representations depicted in the embodiments." *Phillips*, 415 F.3d at 1323.

IV. INTERPRETATION OF MITEK'S 446 PATENT CLAIMS

A. The Transitional Language -- "Consisting Essentially of"

1. The Law Relating to "Consisting Essentially of"

The language "consisting essentially of" is a transition term. There are generally three transitional terms used in patent claims: 1) "comprising," which is considered to be an "open" term; 2) "consisting of," which is considered to be a closed term; and 3) "consisting essentially of," which is considered to be a "partially open" term. The Federal Circuit has stated that when a claim includes the language "consisting essentially of," that claim can be construed to include elements other than those recited in the claim, provided the additional elements do not materially affect the basic and novel properties of the invention. *See, e.g. AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1239-40 (Fed. Cir. 2003) (citations omitted). In other words, a product can infringe such a claim if the product contains, in addition to the recited claim elements, additional elements that do not materially affect the basic and novel properties of the invention. *W.E. Hall Co., Inc. v. Atlanta Corrugating, LLC*, 370 F.3d 1343, 1353 (Fed. Cir. 2004).

The claim construction issue for the court is what are the "novel and basic properties of the invention." This is properly a claim construction issue because Mitek's 446 Patent defines the novel and basic properties of the invention with clarity. *AK Steel*, 344 F.3d at 1239-40 (when specification clear on novel and basic characteristics then determining what that means is claim construction issue for the court); *BASF Corp. v. Eastman Chem. Co.*, No. 95-746-RRM, 1998

U.S. Dist. LEXIS 23054, *24-*30 (D. Del. Mar. 24, 1998) (basic and novel characteristics derived from the specification and claim language) (Ex. 10); *Momentus Golf, Inc. v. Swingrite Golf Corp.*, 312 F. Supp. 2d 1134, 1140-1141 (S.D. Iowa Mar. 15, 2004) (basic and novel properties discerned from patent claims), *rev'd on other grounds.*, No. 05-1614, 2006 U.S. App. LEXIS 16665 (Fed. Cir. June 30, 2006) (unpublished) (Ex. 11) (vacated and remanded because district court erred in finding a disclaimer attached to amendment adding "consisting essentially of" language and erred in relying on ambiguous statements in prosecution history for disclaimer).

2. DePuy Mitek's construction

Claim Language	DePuy Mitek's Interpretation
A surgical suture ***consisting essentially of*** **a** heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set	The "novel and basic characteristics" of the invention are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the materials claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. *Consisting essentially of* excludes sutures that contain bioabsorbable materials as the first and second fiber-forming materials.

a) The specification explains the "novel and basic characteristics" of the invention

DePuy Mitek's construction of the novel and basic characteristics of the invention -- a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid -- is well-grounded in the specification and claims.

The concept of braiding different materials to achieve a "mechanical blend" of the differing properties of the materials is first referenced in the Abstract of Mitek's 446 Patent:

> Heterogeneous braided multifilament of first and second set of yarns **mechanically blended by braiding**, in which first and second set of yarns are composed of different fiber-forming materials.

(Ex. 1 at Abstract, emphasis added).

The inventive aspect, of utilizing the different properties of different fiber-forming materials, by braiding discrete, multifilament yarns of the different materials so that they are in direct intertwining contact, is discussed in the Summary of the Invention portion of Mitek's 446 Patent:

> The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. ***At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.***
>
> Surprisingly***, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns***. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the ***integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns.*** . . . For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

(*id*. at 2:40-44, 49-66, emphasis added).

The inventors emphasized the braid structure again in the Detailed Description of the Invention portion of Mitek's 446 Patent. They disclosed that the first and second set of yarns are to be "mechanically blended" and that this mechanical blending is accomplished through "intertwining the dissimilar yarns in a braided construction" (*id.* at 3:21-25). The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. This

direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid (*id.* at 3:40-51).

Thus, the disclosure in Mitek's 446 Patent supports the conclusion that the "basic and novel" characteristics of the claimed invention are, as DePuy Mitek asserts, a heterogeneous braid of dissimilar non-bioabsorbable yarns of the materials claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid.

b) "Consisting essentially of" was added to the claims to exclude certain bioabsorbable materials, *not* to exclude coatings

Although the language "consisting essentially of" tends to automatically invoke the novel-and-basic-characteristics-of-the-invention standard, the language is not to be looked at in a vacuum. The language should also be considered in connection with why it was added to the claims. *Water Technologies Corp. v. Calco, Ltd.*, 850 F.2d 660, 666-67 (Fed. Cir. 1988) (court looked to prosecution history to determine what was excluded by "consisting essentially of" language"); *BASF*, 1998 U.S. Dist. LEXIS 23054 at *24-*30 (considered prosecution history to determine what "consisting essentially of" language excluded based on prior art rejection) (Ex. 10); *Rheox, Inc. v. Entact, Inc.*, No. 98-3731 (MLC), 2000 U.S. Dist. LEXIS 21851, *21-*23 (D. N.J. Aug. 21, 2000) ("consisting essentially of" added in response to prior art rejection, claim interpreted to exclude material from prior art) (Ex. 12); *University of Florida Research Foundation, Inc. v. Orthovita, Inc.*, No. 1:96-cv-82-MMP, 1998 U.S. Dist. LEXIS 22648, *14-*16 (N.D. Fla. Apr. 20, 1998) ("consisting essentially of" added to narrow claim to exclude particle sizes disclosed in the prior art) (Ex. 13).

Mitek's 446 Patent's prosecution history leaves no doubt that "consisting essentially of" was added to the claims to exclude bioabsorbable materials as the first and second set of fiber-forming materials. DePuy Mitek's proposed construction takes this into account.

The claims that ultimately issued in Mitek's 446 Patent (Claim 1 was originally Claim 21), as originally filed, did not specify the fiber-forming materials (Ex. 3 at DMI000033, 35). The examiner rejected the claims based on two references – Doddi and Kaplan – directed to, per the examiner, braids of dissimilar materials necessarily including bioabsorbable materials (*id.* at DMI000247-249).

Despite the various differences between the claimed invention and the Kaplan and Doddi disclosures, Applicants amended the claims to excluded biomaterials as the first and second fiber-forming materials and to further distance themselves from this art (*id.* at DMI000258-260). The amended claim was as follows:[1]

> 21 (claim 1 as issued). A surgical suture [comprising] consisting essentially of a [the] heterogeneous braid [of claim 1] composed of a first and second set of continuous and discrete yarns in a sterilized braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and
>
> a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP, and PE; and
>
> b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and
>
> c) optionally a core.

(*id.* at DMI000258).

The remarks accompanying the amendment reinforced that the "consisting essentially of" language was added to the claims to specifically exclude certain bioabsorbable materials. For

[1] Material in [] deleted and underlined material added.

example, in the remarks, the Applicants stated that the claims as amended were patentable over Doddi and Kaplan because the amended claims were directed to using nonbioabsorbable yarns as the first and second fiber-forming materials (*id.* at DMI00259). They emphasized that the references did not disclose nonbioabsorbable yarns as the first and second fiber-forming materials, as now claimed (*id.* at DMI000259-260).

Notably, one inventor, Dennis Jamiolkowski, was removed as a named inventor after this claim amendment, because his contribution to the invention as originally claimed had related to using bioabsorbable materials as the first and second fiber-forming materials (Ex. 4 at 114:13-22 & Ex. 5 at 65:1-66:13). This further evidences that incorporation of the "consisting essentially of" language served to exclude certain bioabsorbable materials from the claimed sutures.

Arthrex, however, contends that the language "consisting essentially of" excludes sutures with coatings from the scope of Mitek 446's Patent claims, even though coatings are expressly contemplated by the specification (Ex. 1 at 6:5-14), and even though coatings were not the basis for the examiner's rejection and were never raised during the prosecution of Mitek 446's Patent. As explained in the next section, Arthrex's position is unsupported and misguided.

3. Arthrex's Overly Restrictive Construction is Not Supported by the Intrinsic Evidence

Per Arthrex, the novel and basic characteristics of the invention are a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties and doing this *without a coating* (Ex. 6 at 8-9). Arthrex's position is unsupported by the intrinsic evidence and contrary to the principles of claim construction.

The specification states that

> In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties.

> More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

(Ex. 1 at 3:29-37). But the specification nowhere states that coatings could not be used on the claimed sutures. In fact, the specification shows the contrary – *i.e.*, that the inventors specifically contemplated coatings.

The specification states:

> If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness.

(*id.* at 6:5-13). Arthrex's overly restrictive construction of "consisting essentially of," as limiting the claims to *uncoated* sutures, flies in the face of this express disclosure in Mitek's 446 Patent.

Arthrex's excuse for ignoring this clear language in the specification appears to be its misguided view that the discussion in the Background of the Invention criticizing certain kinds of prior art coatings trumps the clear and unequivocal statement in the Detailed Description of the Invention. But for Arthrex to show that coatings are someone how excluded from the claim, it needs to show an unambiguous, express, clear, and unequivocal disclaimer. *Sorensen v. Int'l Trade Comm'n*, 427 F.3d 1375, 1377-80 (Fed. Cir. 2005) (amendments to claims to add "different characteristics" and statements in prosecution history did not disavow "broad scope of claim language and specification that permit any difference in characteristics, including color" and ALJ erred in limiting characteristics to molecular characteristics); *Cordis Corp. v. Medtronic Ave, Inc.*, 339 F.3d 1352, 1359 (Fed. Cir. 2003) (disclaimer must be clear and unequivocal). There is no such disclaimer on this intrinsic record.

In support of its restrictive construction, Arthrex also appears to be relying on the discussion in Mitek's 446 Patent of a *preferred embodiment*. The specification states that in a preferred embodiment,

> the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

(Ex. 1 at 2:62-66). However, the claims may not properly be limited to a disclosed embodiment or preferred embodiment absent a clear disclaimer. The Federal Circuit has "expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." *Phillips*, 415 F.3d at 1323 (citing *Gemstar-TV Guide Int'l*, 383 F.3d at 1366). The disclosure of preferred embodiments or implementing examples should not be used to limit the scope of the claims absent a clear disavowal by the inventor. *See Nazomi Comm.*, 403 F.3d at 1369. Arthrex's position invites legal error and should be rejected.

B. "PE"

1. DePuy Mitek's construction

Claim Language	DePuy Mitek's Construction
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and ***PE***	**"PE"** includes any polymer formed from a repeating ethylene monomer (*i.e.* "PE" – means all types of polyethylene (PE) including ultra high molecular weight polyethylene).

2. "PE" is a term of art

The fiber-forming materials recited in Claim 1 – PTFE, FEP, PFA, PDVF, PETFE, PP and PE – are all polymeric materials. In other words, they are molecules formed of repeating

chemical units, called "monomers" (Ex. 7 at ¶6). Polyethylene, for example, is formed from repeating units of the monomer ethylene, $(CH_2=CH_2)_n$, where n = a whole number (*id*.).

The length of the chain of repeating units in a polymer (*i.e.*, how high a number "n" is) determines the "molecular weight" of the polymer. The longer the chain (the higher "n" is), the higher the molecular weight of the polymer (*id*. at ¶7). Polymers are frequently referred to as having "low," "high," or, in some situations, "ultra high" molecular weights (*id*.).

There is no dispute that "PE," recited in Mitek's 446 Patent claims, is polyethylene. The dispute lies in the fact that Arthrex contends that, despite the absence of any disclaimer or disavowal in Mitek's 446 Patent or its prosecution history, "PE" does not include *all* polyethylenes. Specifically, Arthrex contends that "PE" encompasses "low" molecular weight polyethylene and "high" molecular weight polyethylene, but does not encompass ultra high molecular weight polyethylene. Limiting the claims in this way would be error.

3. The relevant evidence supports DePuy Mitek's construction

Mitek's construction of PE, as any polymer formed from a repeating ethylene monomer (*i.e.* "PE" – means all types of polyethylene (PE) including ultra high molecular weight polyethylene), is consistent with its plain meaning to those skilled in the art and is supported by the intrinsic record.

a) Extrinsic evidence of the understanding of one skilled in the art supports DePuy Mitek's construction of "PE"

Since "PE" or "polyethylene" is a term of art, it is proper to consider extrinsic evidence of how one or ordinary skill in the art would have understood the term at the time the application for patent was filed. *Phillips*, 415 F.3d at 1317; *Pfizer, Inc. v. Teva Pharms.USA, Inc*., 429 F.3d 1364, 1374-75 (Fed. Cir. 2005) (relying on extrinsic evidence in the form of technical dictionaries, treatises, and expert testimony to support conclusion drawn from patent

specification that one of skill in the art would understand term "saccharides" to encompass more than just sugars, and included polysaccharides). Extrinsic evidence, such as expert and inventor testimony, dictionaries and learned treatises, may provide help in understanding the underlying technology involved and the way in which those in the field might ordinarily use the claim terms to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art. *Id.; Phillips,* 415 F.3d at 1318. The Federal Circuit's decision in *Pfizer, Inc. v. Teva Pharmaceuticals* is instructive on the use of extrinsic evidence and particularly apropos to the facts here.

In *Pfizer*, the Federal Circuit was faced with the construction of the term "saccharides." The defendant was arguing for a narrow definition of the "saccharides" limiting it to "sugars" with up to ten monosaccharide units, and to exclude polysaccharides, such as microcrystalline cellulose (part of the accused product), with more than ten monosaccharide units. Both the district court and the Federal Circuit rejected that construction relying on the claims, specification, and extrinsic evidence. *Pfizer*, 429 F.3d at 1374-75.[2]

The Federal Circuit found that the extrinsic evidence -- technical dictionaries, treatises, and expert testimony -- supported the conclusion that one of skill in the art would understand "saccharides" to encompass more than sugars. The Federal Circuit noted that the district court weighed the disclosures of the competing references and testimony and concluded that the "general view" was that the saccharides included polysaccharides. *Pfizer*, 429 F.3d at 1374-75.

[2] This claim construction came to the Federal Circuit *via* an appeal from the granting of a preliminary injunction motion in favor of *Pfizer*. Interestingly, in a previous case, the parties had stipulated to a narrower definition of the term "saccharides." *Pfizer*, 429 F.3d at 1370-71 (that case involved Warner-Lambert of which Pfizer is the parent). The Federal Circuit rejected the stipulated construction in favor of the broader construction. *Id.* at 1376.

Pfizer compels the conclusion here that PE in the claims is not limited to any particular kind of PE. The extrinsic evidence establishes that those skilled in the art of polymer chemistry recognize "PE" (polyethylene) as a generic term that includes polymers of low, medium, or high molecular weight containing an ethylene monomer, or substituted or unsubstituted polyethylenes, and that "PE" includes ultra high molecular weight PE (Ex. 7 at ¶9).

In particular, in 1987, the Encyclopedia of Polymer Science and Engineering 2nd edition volume 10 recognized polyethylene as the "common (source-based)" name for all polymers made from ethylene (*id.* at Tab B). Further, the International Union of Pure Applied Chemistry (IUPAC), which has long been recognized as the world authority on chemical nomenclature, officially recognized that "PE" is the accepted abbreviations for all types of polyethylene (*id.* at ¶8 and Tab C). Ultra high molecular weight PE has the same chemical formula as any other polyethylene, ($(CH_2CH_2)_n$) (*id*. at ¶7). "High molecular weight" or "ultra high molecular weight" PE is just a longer chain of this polymer (*i.e.*, *n* is a higher number) than "low molecular weight" or "medium molecular weight" PE (*id.*).

As explained below, nothing in Mitek's 446 Patent specification or prosecution history warrants placing any limitation on the plain meaning of the term "PE."

b) DePuy Mitek's construction of "PE" is consistent with the patent specification

Mitek's 446 Patent's description of PE is consistent with all types of polyethylene, including ultra high molecular weight polyethylene (*id*. at ¶11). Mitek's 446 Patent describes the first set of yarns as being made from fiber forming materials (Ex. 1 at 4:30-32). PE, including ultra high molecular weight PE, is a fiber forming material (Ex. 7 at ¶12). Mitek's 446 Patent states that, in a preferred embodiment, the first set of yarns acts as lubricating yarns (Ex. 1 at 4:11-12). PE, including ultra high molecular weight PE, is a lubricious material (Ex. 7 at ¶11 &

at Tab E, Ex. 8 at 239:10-13, Ex. 9 at 52:24-53:1). Mitek 446's Patent states that the first set of yarns may be derived from "non-absorbable polymers." (Ex. 1 at 4:9-11). PE, including ultra high molecular weight PE, is a non-absorbable polymer (Ex. 7 at ¶12).

Mitek's 446 Patent does not specify any molecular weight for the PE, implying that any type of PE can be used to make the claimed sutures. In fact, the patent refers to a number of *other* polymeric materials -- such as PTFE, FEP, PFA, PVDF, PETFE, and PP – and Arthrex's experts admitted that the invention placed no limitations on the particular kind of polymers that are included within the scope of these polymers (Ex. 8 at 296:17-301:25). It makes no sense to apply a different standard to the "PE" recited in the claims and to exclude ultra high molecular weight PE from the claim scope. It also makes no sense to require an inventor to list in the specification every single polymer that is included within the broad class (*e.g.*, generic term) of polymers listed in the specification. Again, the *Pfizer* case is instructive.

Per the Federal Circuit, because the claims recited "saccharides" and did not distinguish between saccharides having ten or less monosaccharide units and polysaccharides having more than ten monosaccharide units, the defendant's narrow construction was improper. *Pfizer*, 429 F.3d at 1373. The Federal Circuit in *Pfizer* looked to the specification to support the construction of saccharide. *Id*. at 1373-74. The Federal Circuit reasoned that there was no basis for limiting the claims as the defendant proposed. *Id*. at 1374. Per the Federal Circuit, because the specification recited that "mannitol, lactose, and other sugars are preferred" the patentee identified sugars only as preferred saccharides, the inventors contemplated a broader class of substances that were still "saccharides." *Id*. The same is the case here.

The claims merely recite PE as one of the first fiber-forming materials. Just as in *Pfizer*, because the claims do not distinguish between low, medium, high, or ultra-high molecular

weight PE, limiting the claims to exclude particular polymers, as Arthrex advocates, would be improper. The Mitek 446 Patent specification supports this construction. The specification is clear that the inventors contemplated that the broad classes of polymers recited as the first-fiber forming materials were within the scope of the invention. If the inventors intended to limit the polymers within the broad generic class of PE, for example, they would have done so by express language in the patent, just as the inventors in *Pfizer*. They did not. *Pfizer*, 429 F.3d at 1374 (inventors expressly stated that saccharides should be compatible with alkali or alkaline-earth containing stabilizers).

c) "PE" was used in the prosecution history to encompass ultra high molecular weight PE

The prosecution history of the patent is also consistent with PE including ultra high molecular weight PE. During prosecution of the patent claims, the examiner rejected the claims over a Burgess patent relating to fishing line made from a braid of ultra high molecular weight PE. The Examiner twice referred to the ultra high molecular weight PE disclosed in Burgess as "polyethylene" (Ex. 3 at DMI000189). DePuy Mitek's attorney prosecuting Mitek 446's Patent application, Mr. Goodwin, also referred to the ultra high molecular weight PE disclosed in Burgess generically as "polythene," which is the British name for polyethylene (*id.* at DMI000064). Thus, both the Examiner and the applicants understood "PE" to include ultra high molecular weight PE, and one reading the prosecution history would therefore also understand "PE" to encompass ultra high molecular weight PE.

4. The Applicants did not disavow ultra high molecular weight PE

Applicants made arguments distinguishing their claims from the Burgess reference. Arthrex tries to spin those arguments into evidence that the inventors somehow disclaimed or disavowed ultra high molecular weight PE, but this argument is without merit. Disclaimers

based on disavowing actions or statements during prosecution must be both clear and unmistakable. *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325-26 (Fed. Cir. 2003); *Northern Telecom Ltd. v. Samsung Elecs. Co.*, 215 F.3d 1281, 1294-95 (Fed. Cir. 2000) (declining to apply doctrine because the infringer had not shown "that the patentees--with reasonable clarity and deliberateness--defined 'plasma etching' as excluding ion bombardment") (citation omitted); *Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 833 (Fed. Cir. 2003) ("We therefore do not consider the applicants' statement to be a clear and unambiguous disavowal of claim scope as required to depart from the meaning of the term provided by the written description."); *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1369 (Fed. Cir. 2003) ("The prosecution history does not show any clear and unambiguous disavowal of steps in advance of the step of growing *E. coli* cells in the claimed temperature range"). There is no evidence of a clear, unmistakable, and unambiguous disavowal of ultra high molecular weight PE in Mitek's 446 Patent prosecution history.

The Applicants responded to the rejection of their claims over the Burgess fishing line patent by pointing to the different design needs of sutures and fishing lines. Their attorney, Mr. Goodwin, pointed out that an important characteristic of sutures is knot strength, which is not mentioned in Burgess. He explained that knot strength is important for sutures because, if the suture knot fails, the suture could not work for its intended purpose (Ex. 3 at DMI000195-196). He further noted that the Burgess fishing line had some filaments composed of high tensile polyethylene thread which, although having good strength properties, has poor knot strength properties (*id*.).

Arthrex has suggested that Mr. Goodwin disclaimed ultra high molecular weight PE because he allegedly argued that, if a medical designer were to build a suture using an ultra high

molecular weight PE and polyester, "he would inevitably design an unacceptable suture" (Ex. 6 at 6). The problem with this argument is that Mr. Goodwin did not make such a statement. He said that if a suture designer *used the teachings of the fishing line art* to modify a suture, then he would inevitably design an unacceptable suture:

> In view of the dissimilarities in property requirements between sutures and fishing line, there would be no incentive for a medical designer who wishes to improve the properties of a braided suture to study the art related to braided fishing lines. Even if he did use the teachings of the fishing line art to modify a suture, then he would inevitably design an unacceptable suture.

(Ex. 3 at DMI000196-197). Mr. Goodwin argued that the suture claims were not obvious over the Burgess reference because the fishing line art was nonanalagous to the suture art -- *not* that one could never make a usable suture from ultra high molecular weight PE. And, following receipt of Mr. Goodwin's arguments, the Examiner dropped the rejection of the claims over the Burgess reference (*id.* at DMI000204).

Indeed, Mr. Goodwin's argument was consistent with what the patent examiner himself had said earlier, in issuing a restriction requirement. In issuing that restriction requirement, the examiner restricted had indicated that fishing line and sutures were patentably distinct inventions and were classified in different art classes (*id*. at DMI000187-188). Mr. Goodwin's arguments were consistent with the examiner's earlier statements.

At best (for Arthrex), the statements in the prosecution history regarding Burgess are ambiguous and "subject to multiple reasonable interpretations," [and thus] they do not "constitute a clear and unmistakable departure from the ordinary meaning of the term" PE. *Cordis*, 339 F.3d at 1359. There is nothing in the specification or prosecution history of Mitek 446's Patent to support a departure from the plain and ordinary meaning of "PE," and DePuy Mitek's construction should therefore be adopted.

V. CONCLUSION

In view of the foregoing, DePuy Mitek's construction of PE and consisting essentially of should be adopted:

> ***Consisting essentially of*** was added to the claim to distinguish over prior art disclosing certain bioabsorbable materials. This language excludes sutures that contain bioabsorbable materials as the first and second fiber-forming materials. The "novel and basic characteristics" of the invention are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid.
>
> ***PE*** includes any polymer formed from a repeating ethylene monomer (*i.e.* "PE" – means all types of polyethylene (PE) including ultra high molecular weight polyethylene).

Dated: August 11, 2006

DEPUY MITEK, INC.,
By its attorneys,
_/s/ Erich M. Falke_____
Dianne B. Elderkin
Lynn A. Malinoski
Michael J. Bonella
Erich M. Falke
WOODCOCK WASHBURN LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
(215) 568-3100

Daniel J. Gleason (BBO #194900)
Michelle Chassereau Jackson (BBO #654825)
Nutter McClennen & Fish LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA. 02210-2604

CERTIFICATE OF SERVICE

I certify that I am counsel for DePuy Mitek, Inc. and that a true and correct copy of **DEPUY MITEK'S BRIEF IN SUPPORT OF ITS CLAIM CONSTRUCTION OF THE HUNTER PATENT -- U.S. PATENT NO. 5,314,446** was served on counsel for Defendants Arthrex, Inc. and Pearsalls Ltd. on this date via the Court's e-mail notification with the following recipients being listed as filing users for Defendants:

Charles W. Saber
Dickstein Shapiro
1825 Eye Street, NW
Washington, DC 2006
saberc@dicksteinshapiro.com

Raymond P. Ausrotas
Todd & Weld LLP
28 State Street, 31st Floor
Boston, MA 02109
rausrotas@toddweld.com

Dated: August 11, 2006

/s/ Erich M. Falke
Erich M. Falke

US005314446A

United States Patent [19]

Hunter et al.

[11] Patent Number: 5,314,446

[45] Date of Patent: May 24, 1994

[54] STERILIZED HETEROGENEOUS BRAIDS

[75] Inventors: **Alastair W. Hunter**, Bridgewater; **Arthur Taylor, Jr.**, Plainfield, both of N.J.; **Mark Steckel**, Maineville, Ohio

[73] Assignee: **Ethicon, Inc.**, Somerville, N.J.

[21] Appl. No.: **838,511**

[22] Filed: **Feb. 19, 1992**

[51] **Int. Cl.**[5] **D04C 1/00**

[52] **U.S. Cl.** **606/231**; 606/228; 87/7; 87/9; 428/370

[58] **Field of Search** 606/228, 230, 231; 87/7, 8, 9; 428/225

[56] **References Cited**

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Primary Examiner—George F. Lesmes
Assistant Examiner—Chris Raimund
Attorney, Agent, or Firm—Hal Brent Woodrow

[57] **ABSTRACT**

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

12 Claims, 3 Drawing Sheets

FIG-1

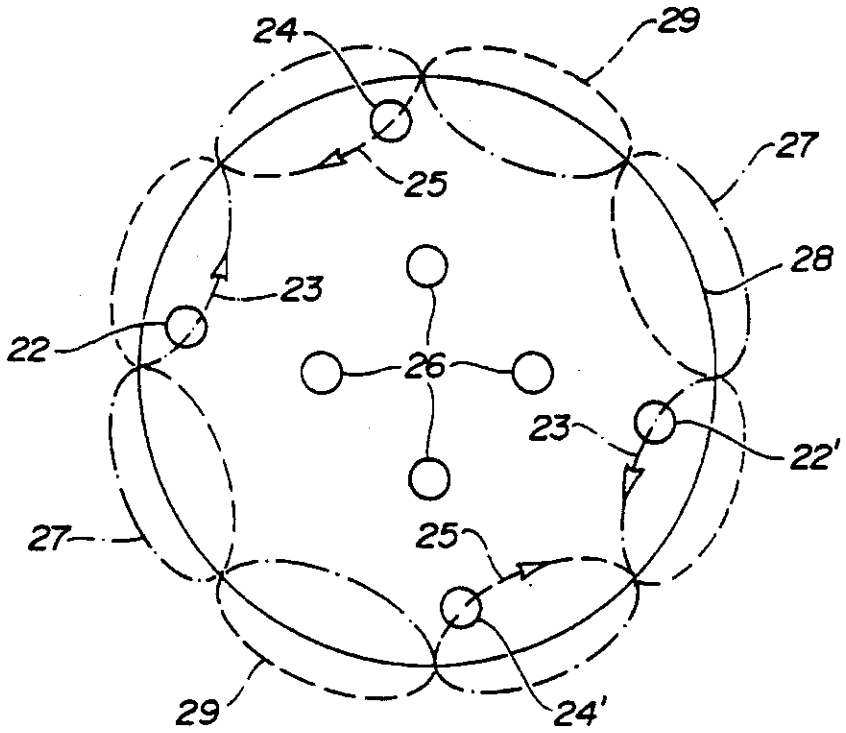


FIG-2

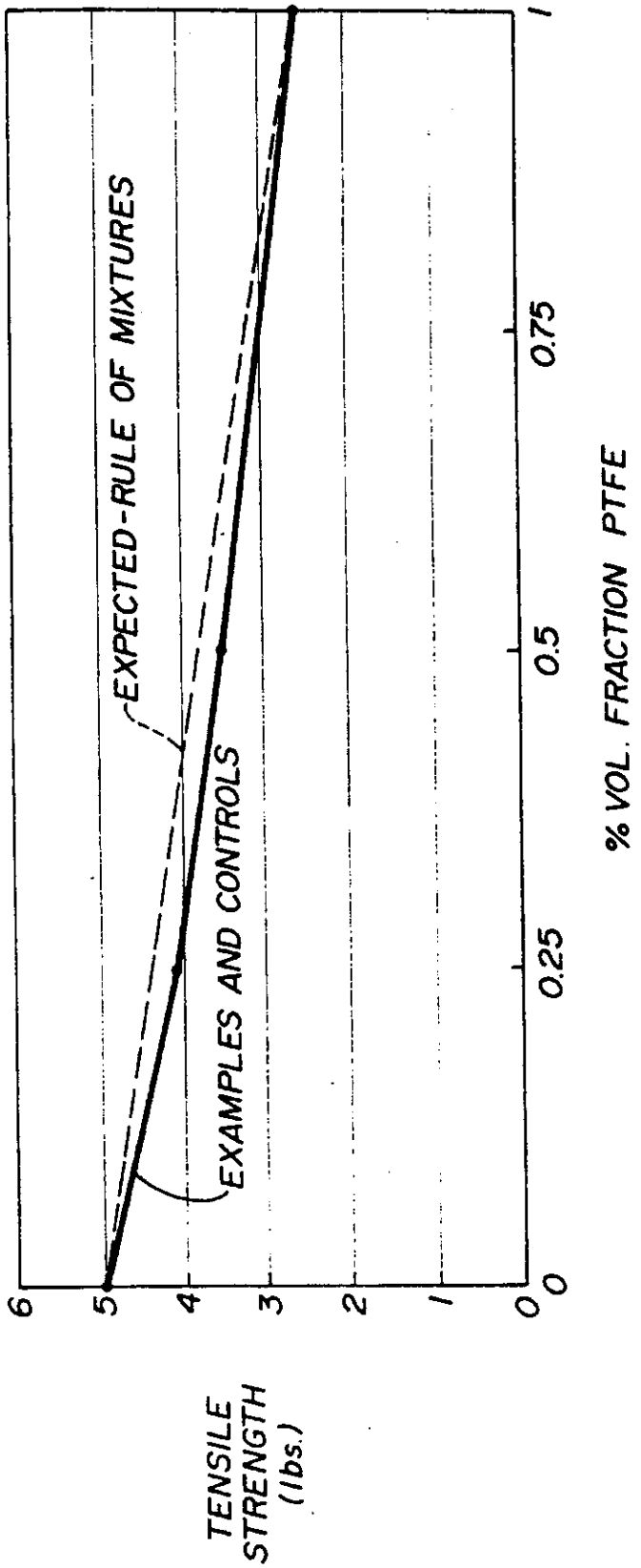
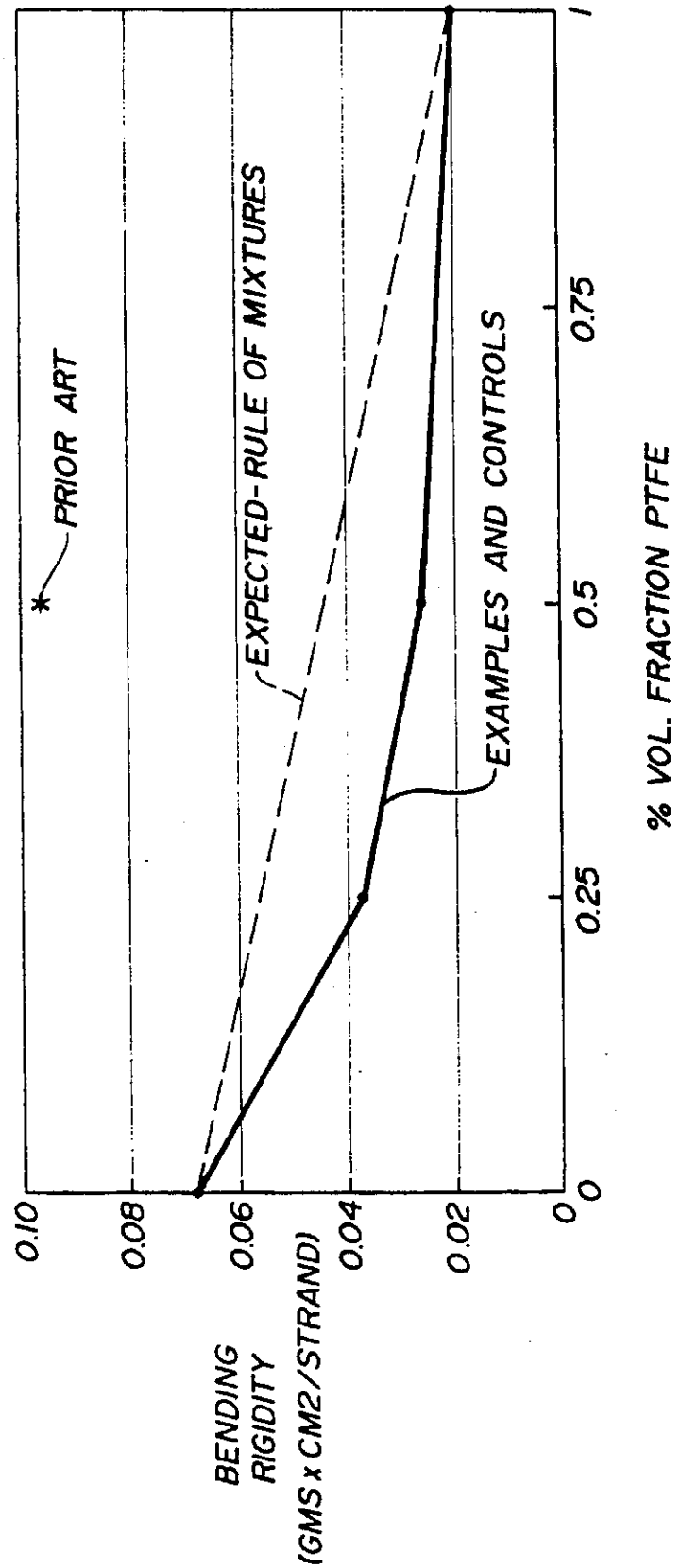

EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
TENSILE STRENGTH (lbs.)
6
5
4
3
2
1
0
0
0.25
0.5
0.75
1
% VOL. FRACTION PTFE

FIG-3


PRIOR ART
EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
0.10
0.08
0.06
0.04
0.02
0
0.25
0.5
0.75
1
BENDING RIGIDITY (GMS x CM2/STRAND)
% VOL. FRACTION PTFE

STERILIZED HETEROGENEOUS BRAIDS

BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid,. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutilate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ-caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Pat. 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Pat. No. 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by FIG. 3 which is described in detail below),

apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for

the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

FIG. 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

FIG. 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Pat. Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Pat. Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns, respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone, ε-caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluorethylene copolymers (PETFE), the polycholorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of FIG. 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and

24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of FIG. 1 are dispensed upward with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in FIG. 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g. the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, than the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tieing a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tieing knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Pat. No. 4,470,941.

CONTROL I

FIBER MATERIALS: An 8×0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225° C.

CONTROL II

FIBER MATERIALS: An 8×0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

FIBER MATERIALS: An 8×0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300° C. and for a longer residence time to facilitate melting of the PET fibers.

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gm × cm^2)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.81			0.0966	

As may be expected, the tensile strengths of the heterogeneous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c=(Vf_a)(P_a)+(Vf_b)(P_b)$$

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and Vf_a and Vf_b are the volume fractions of components a and b. This behavior is clearly observed in FIG. 2, which shows a plot of tensile strength versus volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in FIG. 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the *bending moment-radius of curvature* plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Pat. No. 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and FIG. 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

What is claimed is:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core.

2. The surgical suture of claim 1 wherein the suture is attached to a needle.

3. The surgical suture of claim 1 wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.

4. The surgical suture of claim 3 wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.

5. The surgical suture of claim 4 wherein the first set of yarns is PTFE.

6. The surgical suture of claim 5 wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

7. The surgical suture of claim 6 wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

8. The surgical suture of claim 1 wherein the second set of yarns is PET.

9. The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

10. The surgical suture of claim 9 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

11. The surgical suture of claim 1 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

12. The surgical suture of claim 8 wherein the suture is attached to a needle.

* * * * *

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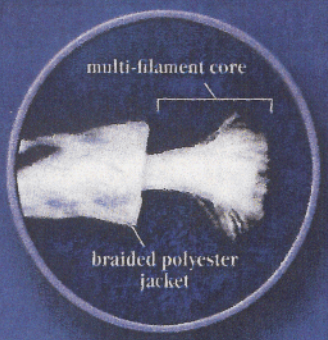

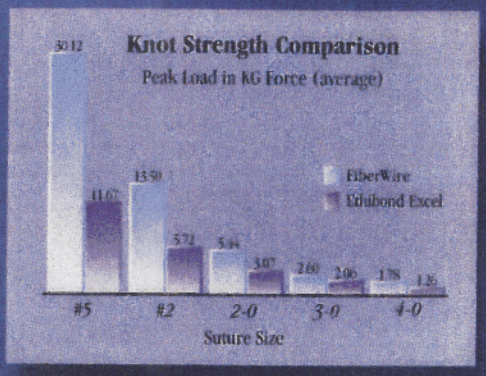

Exceptional Strength

A unique blend of a UHMW polyethylene multi-filament core with braided polyester jacket gives FiberWire suture exceptional strength, virtually eliminating intraoperative suture breakage. FiberWire #2 is actually stronger than #5 polyester suture.

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FiberStick™

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February 04, 2005

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APPLICATION NUMBER: *07/838,511*
FILING DATE: *February 19, 1992*
PATENT NUMBER: *5,314,446*
ISSUE DATE: *May 24, 1994*

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

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Certifying Officer

PART (/) OF (A) PART(S)

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000010

07 838511

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SERIAL NUMBER	FILING DATE	CLASS	SUBCLASS	GROUP ART UNIT
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APPLICANTS

ALASTAIR W. HUNTER, BRIDGEWATER, NJ; ARTHUR TAYLOR JR., PLAINFIELD, NJ; MARK STECKEL, MAINEVILLE, OH.

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Verified and Acknowledged Examiner's initials		NJ	3	24	1	$770.00	ETH-782

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

STERILIZED HETEROGENEOUS BRAIDS

U.S. DEPT. of COMM.-Pat. & TM Office— PTO-436L (rev. 10-78)

RTS OF APPLICATION
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NOTICE OF ALLOWANCE MAILED	PREPARED FOR ISSUE	CLAIMS ALLOWED
11-18-93	CHRIS RAIMUND, Assistant Examiner; E. Simms, Docket Clerk; 11/29/93	Total Claims: 12; Print Claim: 1

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PTO-436
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DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000011

BAR CODE LABEL

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APPLICANT

ALASTAIR W. HUNTER, BRIDGEWATER, NJ; DENNIS D. JAMIOLKOWSKI, LONG VALLEY, NJ; ARTHUR TAYLOR JR., PLAINFIELD, NJ; MARK STECKEL, MAINEVILLE, OH.

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NJ	3	24	1	$ 770.00	ETH-782

ADDRESS

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

TITLE

STERILIZED HETEROGENEOUS BRAIDS

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07 838511

PATENT APPLICATION SERIAL NO.

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
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PTO-1556
(5/87)

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07/838511

Case Docket No.: ETH-782

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Sir:

Transmitted herewith for filing is the patent application of

Inventor: Alastair Hunter et al.

For : STERILIZED HETEROGENEOUS BRAIDS

Enclosed are:

[X] Three (3) sheets of drawings (Formal).

[X] Two signed Declarations and Powers of Attorney.

[X] Two assignments of the invention to Ethicon, Inc.

[ ] A certified copy of a _____ application.

[ ] Associate Power of Attorney.

[X] Information Disclosure Statement.

[X] One stamped, self-addressed postcard for the PTO Mail Room date stamp.

CLAIMS AS FILED

(1)	(2)	(3)	(4)	(5)
FOR:	NUMBER FILED	NUMBER EXTRA	RATE	BASIC FEE $690.00
TOTAL CLAIMS	24 - 20 =	4	x 20.00	$ 80.00
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Matthew S. Goodwin
Attorney of Record
Reg. No. 32,839

Matthew S. Goodwin
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2791
February 19, 1992

VIA EXPRESS MAIL NO. HB346860118
MAILED FEBRUARY 19, 1992



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Alastair Hunter et al.

For : STERILIZED HETEROGENEOUS BRAIDS

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#1 838511

TITLE OF THE INVENTION

STERILIZED HETEROGENEOUS BRAIDS

BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid,. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

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MAILED FEBRUARY 19, 1992

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000016

U.S. Patent 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutilate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Patent 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ-caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Patent 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Patent 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite

sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by Figure 3 which is described in detail below), apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000018

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying

the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

DRCL

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

Figure 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

Figure 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

DECL

DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at

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least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Patent Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Patent Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns,

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respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone, ϵ-caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle

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of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluorethylene copolymers (PETFE), the polycholorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below

about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of Figure 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and 24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of Figure 1 are dispensed upward

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with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in Figure 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

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Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing

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stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, than the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Patent 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tieing a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tieing knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is

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determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Patent 4,470,941.

CONTROL I

FIBER MATERIALS: An 8x0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each

carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225 C°.

CONTROL II

FIBER MATERIALS: An 8x0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

FIBER MATERIALS: An 8x0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm.

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The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300 C° and for a longer residence time to facilitate melting of the PET fibers.

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The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY ($gmXcm^2$)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.87			0.0966	

As may be expected, the tensile strengths of the heterogenous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c = (Vf_a)\ (P_a) + (Vf_b)\ (P_b)$$

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and Vf_a and Vf_b are the volume fractions of components a and b. This behavior is clearly observed in Figure 2, which shows a plot of tensile strength versus

volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in Figure 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the bending moment-radius of curvature plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Patent 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and Figure 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

WHAT IS CLAIMED IS:

1. A heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and:

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

2. The heterogeneous braid of claim 1 wherein the first and second fiber-forming materials are nonmetallic.

3. The heterogeneous braid of claim 2 wherein the first and second fiber-forming materials are synthetic fiber-forming polymers.

4. The heterogeneous braid of claim 3 wherein the synthetic fiber-forming polymers are bioabsorbable.

5. The heterogeneous braid of claim 4 wherein the bioabsorbable polymers are derived from a monomer selected from the group consisting of glycolic acid, glycolide, lactide, p-dioxanone, ϵ-caprolactone, trimethylene carbonate, and mixtures thereof.

6. The heterogeneous braid of claim 3 wherein the fiber-forming polymers are nonabsorbable.

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7. The ~~heterogeneous braid~~ surgical suture of claim ~~6~~ 1 wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.

8. The ~~heterogeneous braid~~ surgical suture of claim ~~7~~ 3 wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.

9. The heterogeneous braid of claim 8 wherein the first set of yarns is PTFE, FEP, PFA, PVDF, PETFE, PP or PE.

10. The ~~heterogeneous braid~~ surgical suture of claim ~~9~~ 4 wherein the first set of yarns is PTFE.

11. The ~~heterogeneous braid~~ surgical suture of claim ~~10~~ 5 wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

12. The ~~heterogeneous braid~~ surgical suture of claim ~~11~~ 6 wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

13. The heterogeneous braid of claim 12 wherein the second set of yarns is PET, nylon or aramid.

14. The ~~heterogeneous braid~~ surgical suture of claim ~~13~~ 12 wherein the second set of yarns is PET.

15. The heterogeneous braid of claim 14 wherein each yarn from the first set is in direct intertwining contact with a yarn from the second set.

16. The heterogeneous braid of claim 15 wherein the braid encloses a core of longitudinally extending yarns.

17. The heterogeneous braid of claim 16 wherein the longitudinally extending yarns are PET.

18. The ~~heterogeneous braid~~ surgical suture of claim ~~17~~ 14 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

19. The ~~heterogeneous braid~~ surgical suture of claim ~~18~~ 9 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

20. The ~~heterogeneous braid~~ surgical suture of claim ~~1~~ 24 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

21. A surgical suture comprising the heterogeneous braid of claim 1.

22. A surgical suture comprising the heterogeneous braid of claim 19.

23. The surgical suture of claim ~~21~~ 1 wherein the suture is attached to a needle.

24. The surgical suture of claim ~~22~~ 14 wherein the suture is attached to a needle.

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ABSTRACT

SA

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

PA

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

EA

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[redacted]

DOCKET NO. ETH-838511

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

STERILIZED HETEROGENEOUS BRAIDS,

the specification of which

(check one) [X] is attached hereto.

[ ] was filed on as Application Serial No. and was amended on . (if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed: NONE

VIA EXPRESS MAIL NO. HB346860118
MAILED FEBRUARY 19, 1992

Prior Foreign Application(s):

Country	Application Number	Date of Filing	Priority Claimed Under 35 U.S.C. 119
		Day/Mo./Year	[ ] YES [ ] NO
		Day/Mo./Year	[ ] YES [ ] NO
		Day/Mo./Year	[ ] YES [ ] NO

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.	Filing Date	Status (patented, pending, abandoned)
Application Serial No.	Filing Date	Status (patented, pending, abandoned)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith as well as to file equivalent patent applications in countries foreign to the United States including the filing of international patent applications in accordance with the Patent Cooperation Treaty: Robert L. Minier (Reg. #20,083), Audley A. Ciamporcero, Jr. (Reg. #26,051), Steven P. Berman (Reg. #24,772), Jason Lipow (Reg. #25,509), and Matthew S. Goodwin (Reg. #32,839), One Johnson & Johnson Plaza, New Brunswick, NJ 08933.

(5)

Address all telephone calls to Matthew S. Goodwin at telephone no. (908) 524-2791.

Address all correspondence to Robert L. Minier, One Johnson & Johnson Plaza, New Brunswick, NJ 08933-7003.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

1 Inventor's Signature: Alastair W. Hunter
Full Name of Sole or First Inventor: Alastair W. Hunter

Date: 2/18/92

Citizenship: U.S.A.
Residence: 516 Spring Valley Drive, Bridgewater, New Jersey 08807 NJ
Post Office Address: Same as above

2 Inventor's Signature: Dennis D. Jamiolkowski
Full Name of Second Joint Inventor, If Any: Dennis D. Jamiolkowski

Date: 2/18/92

Citizenship: U.S.A.
Residence: 20 Fawnridge Drive, Long Valley, New Jersey 07853 NJ
Post Office Address: Same as above

3 Inventor's Signature: Arthur Taylor, Jr.
Full Name of Third Joint Inventor, If Any: Arthur Taylor, Jr.

Date: 2/18/92

Citizenship: U.S.A.
Residence: 1217 East Second Street, Plainfield, New Jersey 07062 NJ
Post Office Address: Same as above

(Supply similar information and signature for fourth and subsequent joint inventors.)


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DOCKET NO. [redacted]

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

STERILIZED HETEROGENEOUS BRAIDS,

the specification of which

(check one) [X] is attached hereto.

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Application Serial No.	Filing Date	Status (patented, pending, abandoned)
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H

Inventor's Signature: _____
Full Name of Sole or First Inventor: Mark Steckel

Date: 2/17/92

Citizenship: U.S.A.
Residence: 8919 Farmdale Way, Maineville, Ohio 45039 OH
Post Office Address: Same as above

Inventor's Signature: _____
Full Name of Second Joint Inventor, If Any

Date: _____

Citizenship:
Residence:
Post Office Address:

Inventor's Signature: _____
Full Name of Third Joint Inventor, If Any

Date: _____

Citizenship:
Residence:
Post Office Address:

(Supply similar information and signature for fourth and subsequent joint inventors.)


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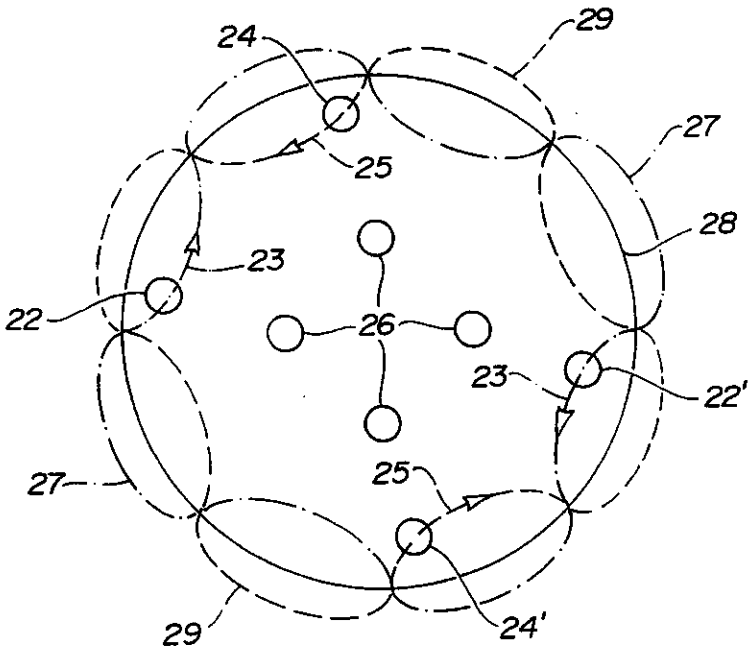
FIG-1



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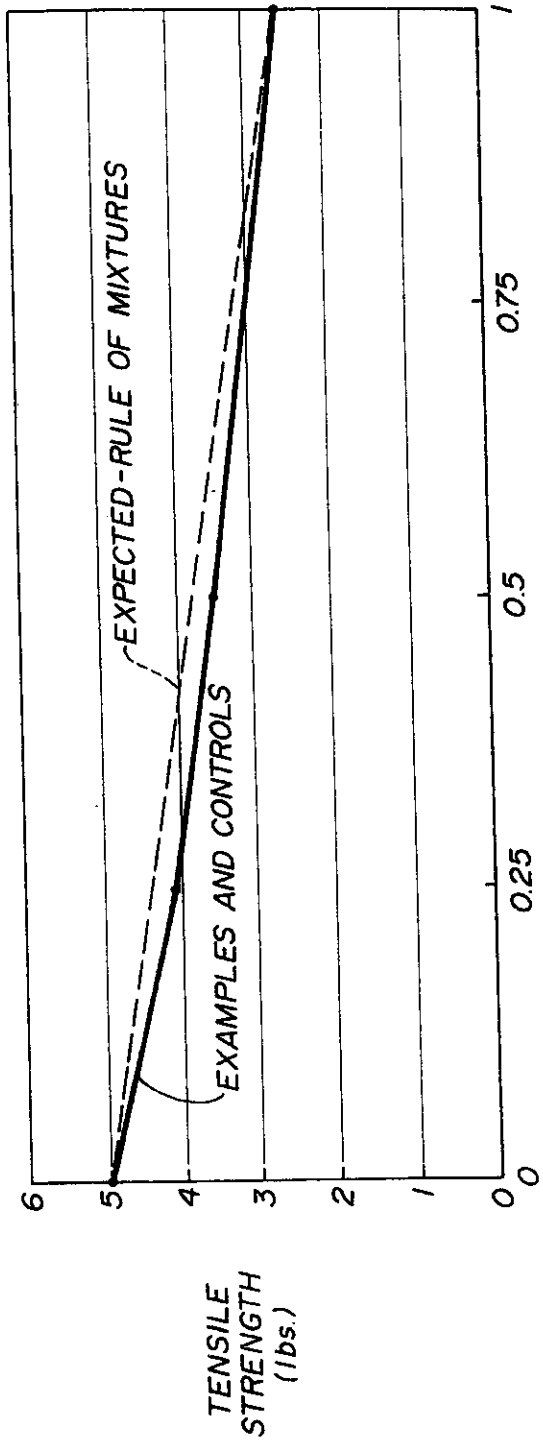

FIG-2


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1992
PAT. & TRADEMARK OFF.

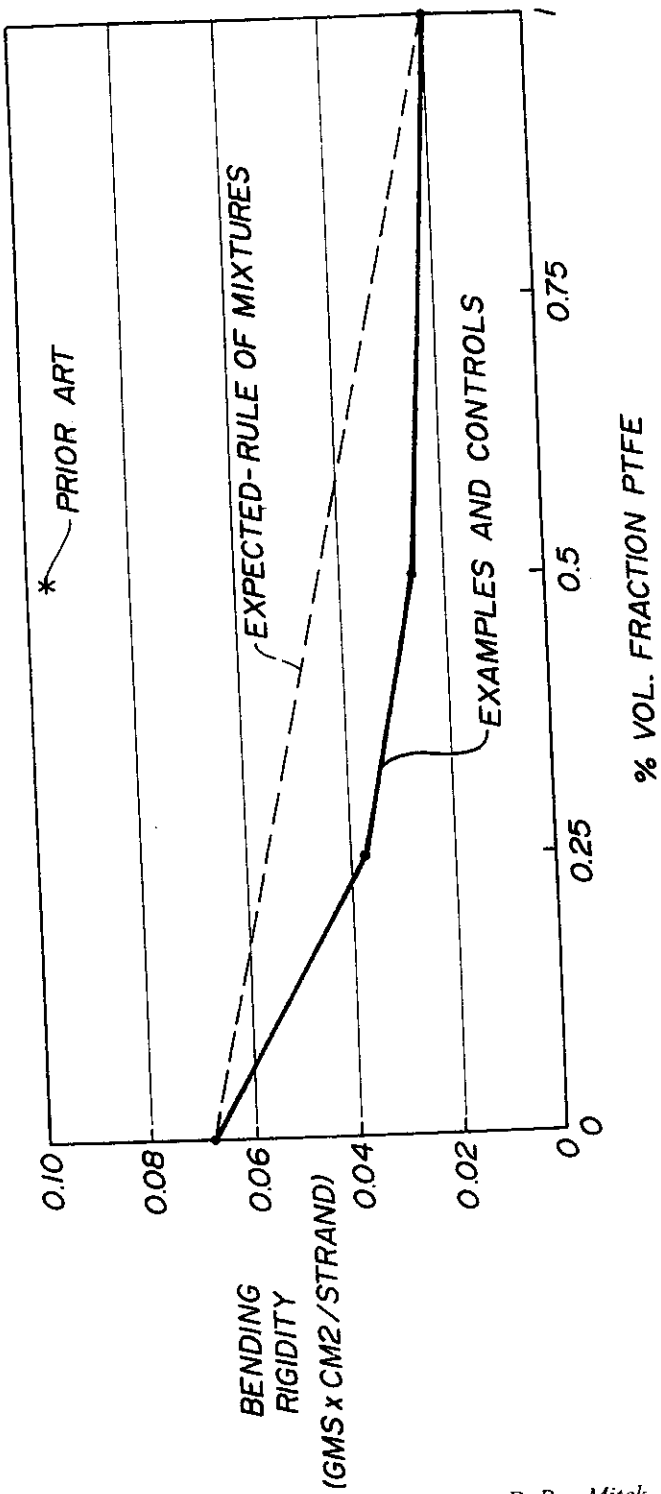

PRIOR ART
EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
0.10
0.08
0.06
0.04
0.02
0
0.25
0.5
0.75
1
BENDING RIGIDITY (GMS x CM2/STRAND)
% VOL. FRACTION PTFE

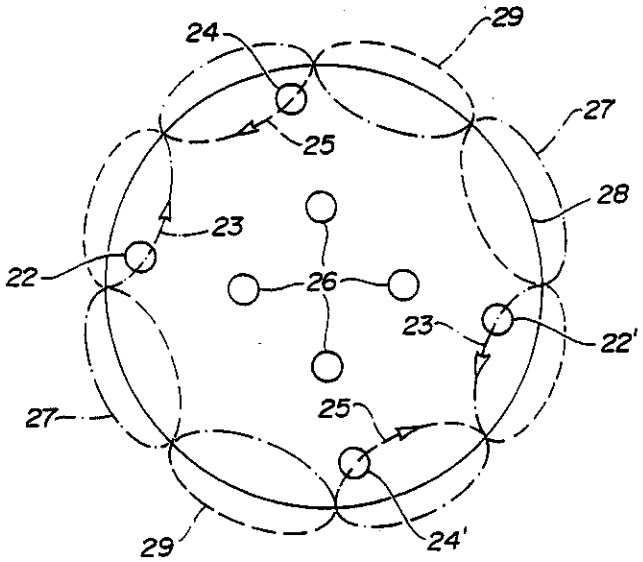
FIG-3



83
96)

As Originally Filed
838511

FIG-1



Pat 838511

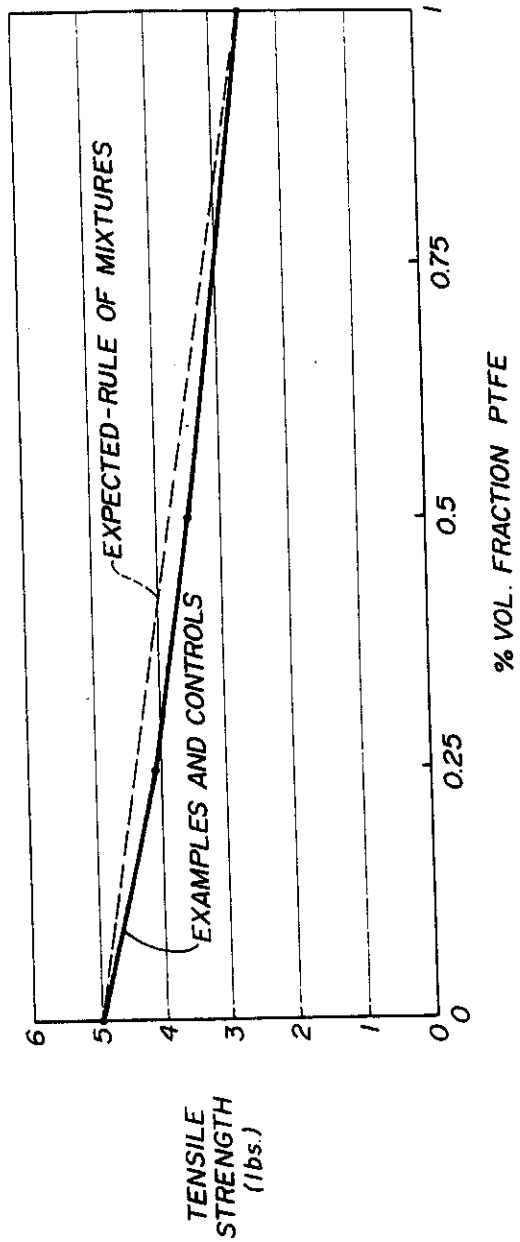
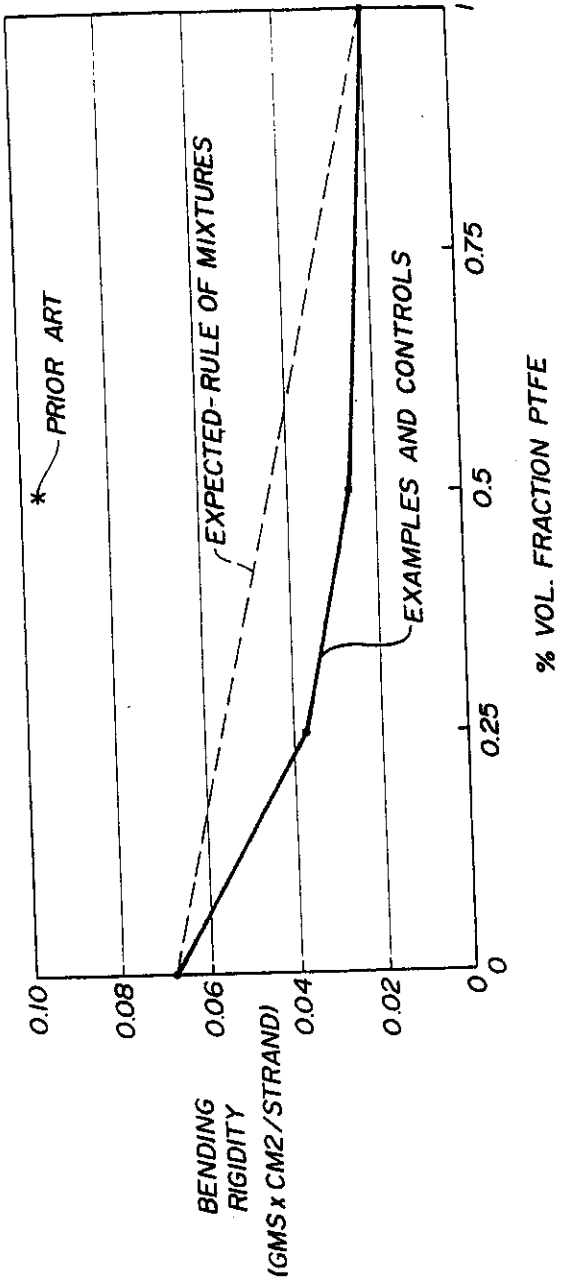


FIG-2

EL 838511

FIG-3



US005314446A

United States Patent [19]

Hunter et al.

[11] Patent Number: 5,314,446

[45] Date of Patent: May 24, 1994

[54] STERILIZED HETEROGENEOUS BRAIDS

[75] Inventors: Alastair W. Hunter, Bridgewater; Arthur Taylor, Jr., Plainfield, both of N.J.; Mark Steckel, Maineville, Ohio

[73] Assignee: Ethicon, Inc., Somerville, N.J.

[21] Appl. No.: 838,511

[22] Filed: Feb. 19, 1992

[51] Int. Cl.[5] D04C 1/00

[52] U.S. Cl. 606/231; 606/228; 87/7; 87/9; 428/370

[58] Field of Search 606/228, 230, 231; 87/7, 8, 9; 428/225

[56] References Cited

U.S. PATENT DOCUMENTS

3,187,752	6/1965	Glick	128/335.5
3,463,158	8/1969	Schmitt et al.	606/228
3,527,650	9/1970	Block	117/7
3,636,956	1/1972	Schneider	128/335.5
3,942,532	3/1976	Hunter et al.	128/335.5
4,043,344	8/1977	Landi et al.	128/335.5
4,047,533	8/1977	Perciaccante et al.	128/335.5
4,052,988	10/1977	Doddi et al.	128/335.5
4,141,087	2/1979	Shalaby et al.	3/1
4,470,941	9/1984	Kurtz	264/136
4,624,256	11/1986	Messier et al.	128/335.5
4,946,467	8/1990	Ohi et al.	606/228
4,959,069	9/1990	Brennan et al.	606/228
4,979,956	12/1990	Silverstrini	623/13
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WO86/00020	1/1986	PCT Int'l Appl.	A61L 17/00
2082213	8/1980	United Kingdom .	
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Primary Examiner—George F. Lesmes
Assistant Examiner—Chris Raimund
Attorney, Agent, or Firm—Hal Brent Woodrow

[57] ABSTRACT

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

12 Claims, 3 Drawing Sheets

FIG-1

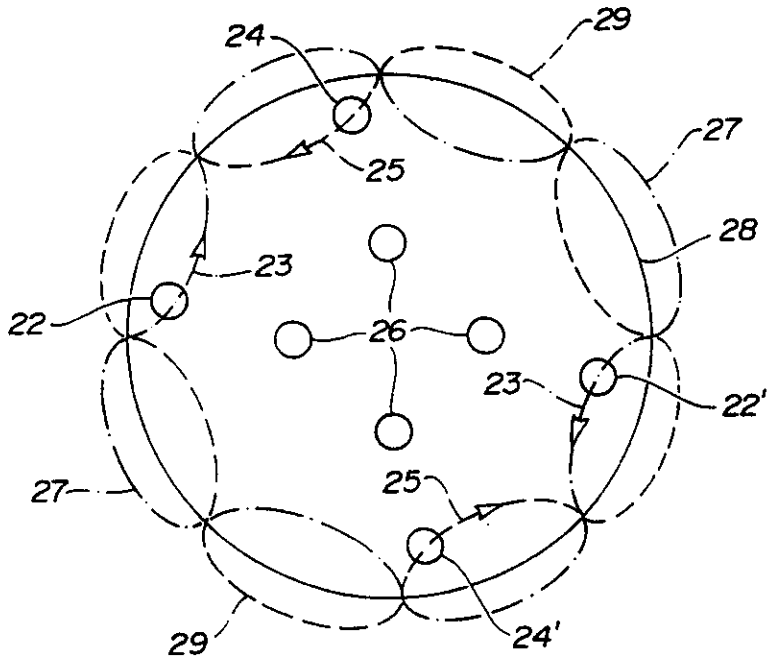


FIG-2

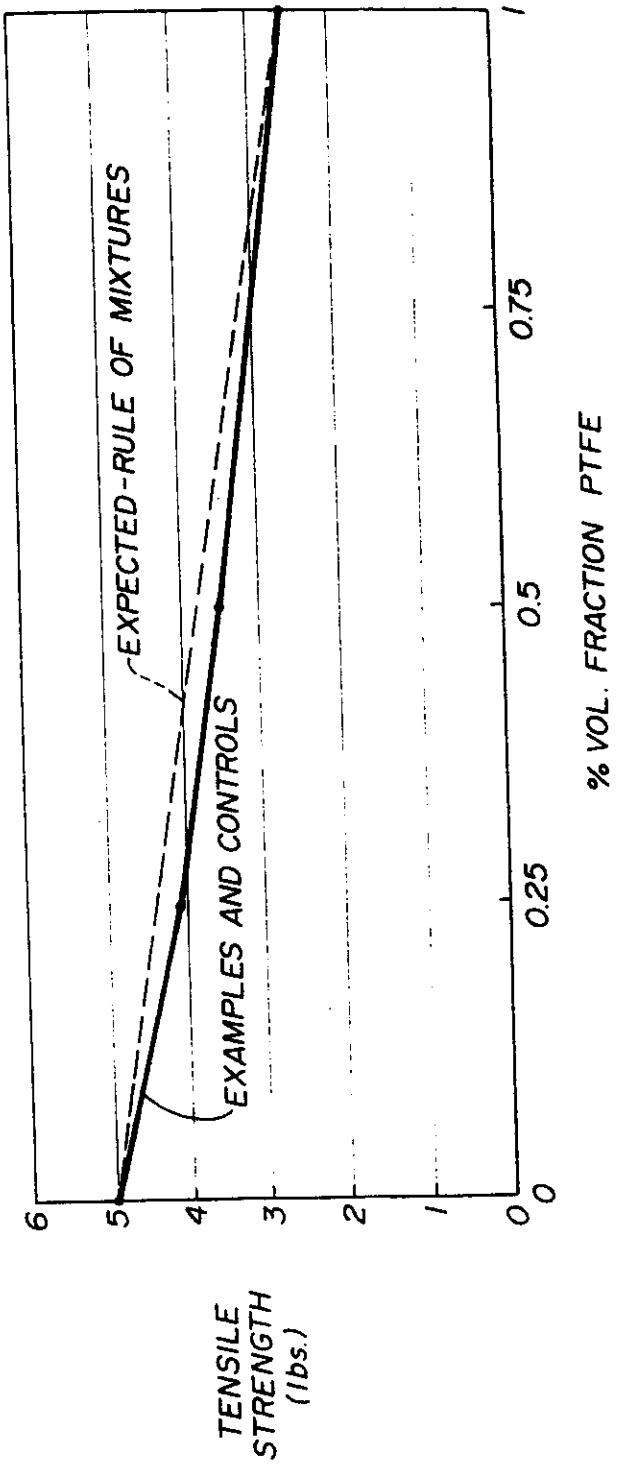
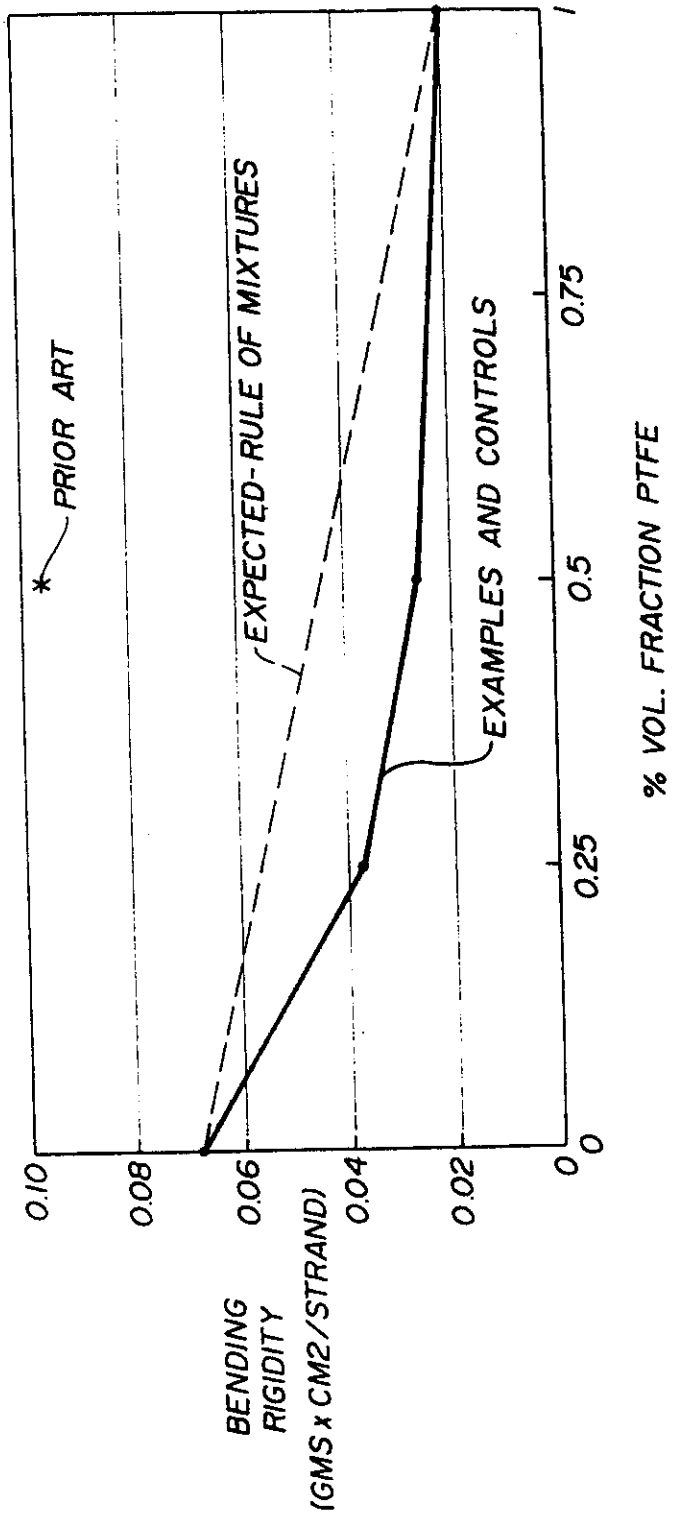

EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
TENSILE STRENGTH (lbs.)
6
5
4
3
2
1
0
0
0.25
0.5
0.75
1
% VOL. FRACTION PTFE

FIG-3


PRIOR ART
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% VOL. FRACTION PTFE

STERILIZED HETEROGENEOUS BRAIDS

BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid,. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutilate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ-caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Pat. 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Pat. No. 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by FIG. 3 which is described in detail below), apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for

the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

FIG. 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

FIG. 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Pat. Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Pat. Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns, respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone, ε-caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluorethylene copolymers (PETFE), the polycholorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of FIG. 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and

CONTROL I

FIBER MATERIALS: An 8×0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225° C.

CONTROL II

FIBER MATERIALS: An 8×0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

FIBER MATERIALS: An 8×0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300° C. and for a longer residence time to facilitate melting of the PET fibers.

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gm × cm²)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.81			0.0966	

As may be expected, the tensile strengths of the heterogenous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c = (Vf_a)(P_a) + (Vf_b)(P_b)$$

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and Vf_a and Vf_b are the volume fractions of components a and b. This behavior is clearly observed in FIG. 2, which shows a plot of tensile strength versus volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in FIG. 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the *bending moment-radius of curvature* plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Pat. No. 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and FIG. 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

What is claimed is:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of FIG. 1 are dispensed upward with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in FIG. 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention. moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example. "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g. the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, than the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tieing a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tieing knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Pat. No. 4,470,941.

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core.

2. The surgical suture of claim 1 wherein the suture is attached to a needle.

3. The surgical suture of claim 1 wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.

4. The surgical suture of claim 3 wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.

5. The surgical suture of claim 4 wherein the first set of yarns is PTFE.

6. The surgical suture of claim 5 wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

7. The surgical suture of claim 6 wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

8. The surgical suture of claim 1 wherein the second set of yarns is PET.

9. The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

10. The surgical suture of claim 9 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

11. The surgical suture of claim 1 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

12. The surgical suture of claim 8 wherein the suture is attached to a needle.

* * * * *

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838511 [redacted]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair Hunter et al.

Serial No.: Art Unit:

Filed : Examiner:

For : STERILIZED HETEROGENEOUS BRAIDS

#2

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

The following references are discussed in the Background of the Invention:

U.S. Patent 3,942,532 (Hunter, et al., issued March 9, 1976).

U.S. Patent 4,624,256 (Messier et al., issued November 25, 1986).

U.S. Patent 3,527,650 (Block, A., issued September 8, 1970).

U.S. Patent 4,470,941 (Kurtz, L., issued September 11, 1984).

WO 86/00020 (Kurtz et al., issued January 3, 1986).

The following additional references may be relevant to the examination of the above-identified application:

U.S. Patent 3,187,752 (Glick, A., issued June 8, 1965), discloses a tightly braided nonabsorbable suture coated with a polymeric silicone.

U.S. Patent 4,043,344 (Landi et al., issued August 23, 1977), discloses a nonabsorbable suture coated with a polyoxyethylene-polyoxypropylene copolymer.

VIA EXPRESS MAIL NO. HB346860118
MAILED FEBRUARY 19, 1992

U.S. Patent 4,047,533 (Periaccante et al., issued September 13, 1977), discloses an absorbable suture coated with a polyoxyethylene-polyoxypropylene copolymer.

U.S. Patent 4,946,467 (Ohi et al., issued August 7, 1990), discloses a suture having a core of one synthetic fiber material and a covering sheath of silk strands.

U.K. Patent Application GB 2 218 312A, discloses a fishing line of braided construction, some braid filaments being composed of polythene and other filaments composed of polyester and/or nylon.

German Patent DE 2949920, discloses a suture having a core of fibers composed of platinum or gold, and a braided sheath of fibers composed of polytetrafluoroethylene.

A completed Form PTO-1449 and a copy of each cited reference is attached herewith.

Respectfully submitted,

Matthew S. Goodwin
Reg. No. 32,839
Attorney for Applicants

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08903
(908) 524-2791
February 19, 1992

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000064

United States Patent [19]
Hunter et al.

[11] 3,942,532
[45] Mar. 9, 1976

[54] BRAIDED SUTURE

[75] Inventors: Alastair Wilson Hunter; Darrell R. Thompson, both of Somerville, N.J.

[73] Assignee: Ethicon, Inc., Somerville, N.J.

[22] Filed: Aug. 15, 1974

[21] Appl. No.: 497,596

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 303,588, Nov. 3, 1972, abandoned.

[52] U.S. Cl. 128/335.5; 428/375
[51] Int. Cl.² A61L 17/00
[58] Field of Search ..... 128/335.5; 161/175, 176; 117/139.5 F, 161 R

[56] References Cited

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3,527,650	9/1970	Block	128/335.5 X
3,694,257	9/1972	Dumont	117/139.5 F
3,754,069	8/1973	Adams et al.	128/335.5 X
3,776,766	12/1973	Smerz et al.	117/139.5 F X
3,839,524	10/1974	Adams et al.	128/335.5 X

Primary Examiner—Dalton L. Truluck
Attorney, Agent, or Firm—Wayne R. Eberhardt

[57] ABSTRACT

The tie-down characteristics of braided sutures are improved by applying to the surface thereof a polymeric ester of a dibasic acid and a glycol.

16 Claims, 3 Drawing Figures

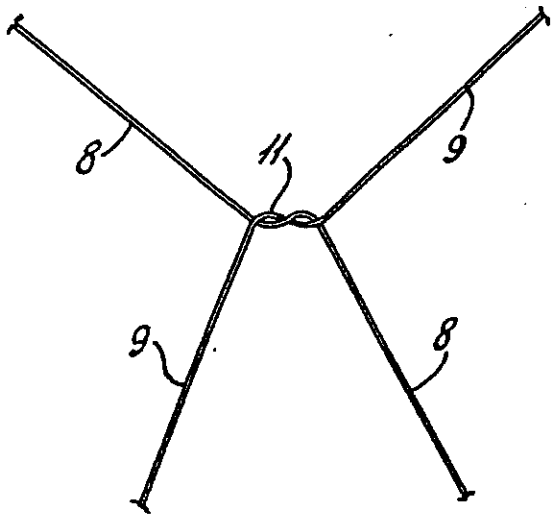


Fig. 1.

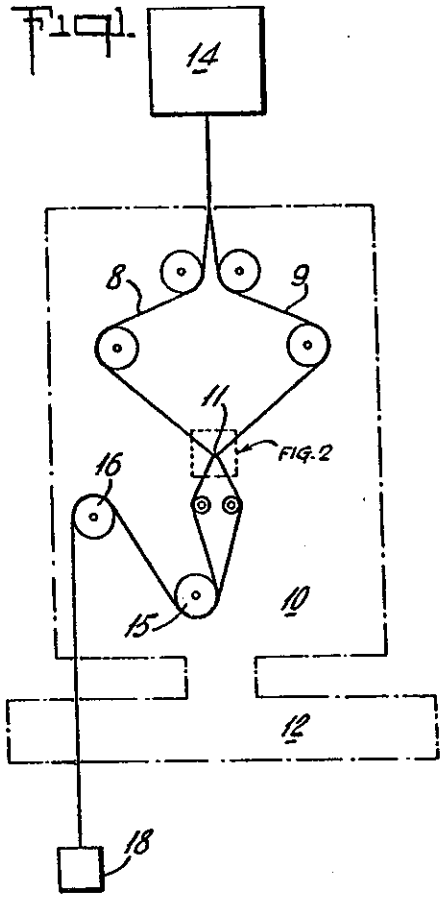


Fig. 2.

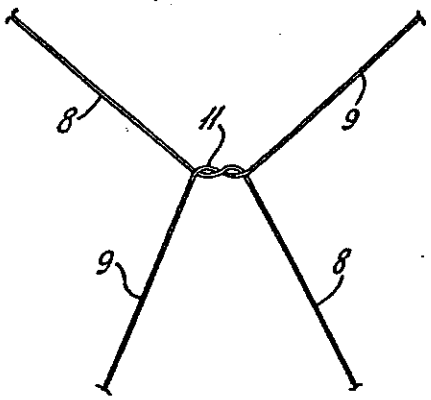
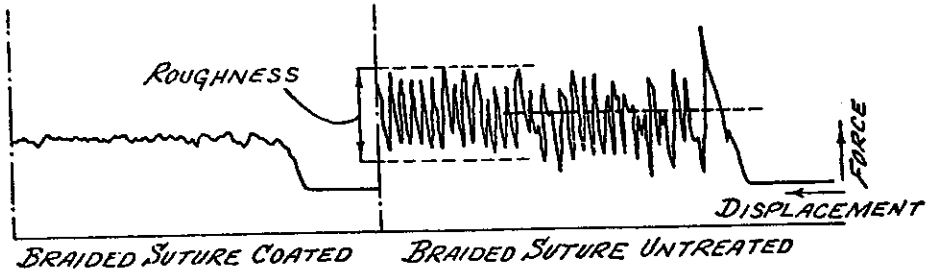


Fig. 3.



BRAIDED SUTURE

BACKGROUND OF THE INVENTION

This application is a continuation-in-part of my co-pending U.S. application Ser. No. 303,588, filed Nov. 3, 1972 now abandoned.

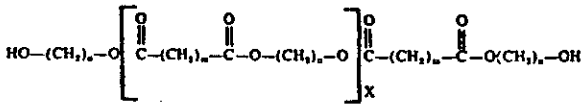
The present invention relates to surgical sutures and more specifically to multifilament sutures. Braided polyester multifilament sutures have been used by many surgeons for their strength and lack of tissue reactivity. Other surgeons prefer to use waxed silk when a non-absorbable suture is required because of its excellent hand, ease of knotting, and ease of passage through tissue.

An important characteristic of sutures in deep wound surgery is the ease of sliding a single throw knot down the suture into place. This behavior, sometimes referred to as the "tie-down performance" may be evaluated subjectively by tying a suture around a suitable mandrel. A single throw knot is formed and while pulling on the two free ends, the knot is forced to slide along the suture. The roughness or smoothness of this sliding action is an important criterion of performance.

Uncoated braids such as a braided polyethylene terephthalate suture give a very rough, jerky behavior while sutures coated with TEFLON, as described in U.S. Pat. No. 3,527,650 and wax-coated braided silk sutures are very smooth. Fortunately, the roughness or smoothness of tie-down can be measured and assigned a numerical value that will enable one to predict performance in the hands of the surgeon without reliance upon the subjective test referred to in the preceding paragraph. A method of using an INSTRON Universal Testing Instrument to determine tie-down performance is described below.

The present invention is directed to improving the tie-down characteristics of a braided suture by applying a surface coating of a non-toxic and physiologically inert polymer that does not adversely affect the hand or tensile properties of the suture.

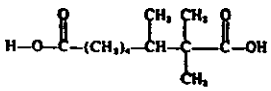
It has now been discovered that the tie-down performance of braided, twisted, or covered multifilament sutures may be improved (the roughness decreased) by applying to the surface thereof polyesters derived from the polymerization of lactones or obtained by esterifying low molecular weight glycols with a dimeric acid. Preferred coating compositions are polyesters characterized by a melting point above room temperature and have the formula:



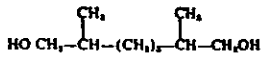
wherein n is an integer larger than 1 and smaller than 13, m is an integer larger than 1 and smaller than 9 and X is the degree of polymerization. Thus, stoichiometric quantities of succinic, glutaric, adipic, pimelic, suberic, azelaic, sebacic acid, or mixtures thereof may be condensed with ethylene glycol, propylene glycol, butanediol, pentanediol, hexanediol, nonanediol, decanediol, undecanediol, dodecanediol, or mixtures thereof to obtain a polyester suitable for application as a surface coating. Polyesters of the above formula having a molecular weight in the range of approximately 1,000 to

15,000 and characterized by having at least two carbon atoms between the ester linkages in the polymer chain have been found to give the best lubricant and handling properties on silk and polyester sutures. Particularly preferred polyesters are those derived from 1,4-butanediol (n=4) and adipic acid (m=4) having a molecular weight of 2,000–3,000.

It will be understood that branched chain acids such as α,α,β-trimethylsuberic acid having the formula:

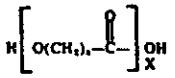


3,7-dimethyloctadienoic acid; 1,4-cyclohexanecarboxylic acid; mesatonic acid; β,β-dimethyl glutaric acid; and dimer acid; and branched chain diols such as diisononyl glycol having the formula:

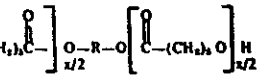


and glycols having a secondary hydroxyl group such as 1,2-propylene glycol may be added to the reaction mixture in small amounts as comonomers to produce polyesters suitable as coating materials that have a melting point above room temperature. The addition of larger amounts of such comonomers to the reaction mixture will result in low melting polyesters that are unsuitable for use in the present invention.

Polyesters that are useful in the manufacture of coated sutures in accordance with the present invention may also be prepared by polymerizing lactones. Such polyesters are characterized by a melting point above room temperature, and have the formula:



wherein n is an integer larger than 2 and X is the degree of polymerization. Particularly preferred is the polyester characterized by a molecular weight of about 2,000 obtained by polymerizing ϵ-caprolactones in the presence of a poly-methylenediol and having the formula:



wherein R is a polymethylene group derived from the poly-methylenediol and x is the degree of polymerization.

The polyester coating compositions described above are non-toxic and may be applied to the multifilament suture from solution. The multifilament suture may be

of braided, twisted, or covered construction. The construction of a covered suture is described in U.S. Pat. No. 3,791,388. The suture is then air dried to remove solvent and form a continuous surface coating.

The amount of the polyester coating composition applied to the suture may be varied depending upon the suture size and composition. Thus, the surface coating on a size 710 braided polyester suture may amount to from about 5 percent to as much as 7 percent of the weight of the suture. Sutures of larger size (size 5/0 – 5) require a smaller amount of the polyester coating composition (about 0.4 percent to 1 percent based upon the weight of the suture).

The surface coating composition (0.4 percent to about 7 percent based on suture weight) has no detrimental effect on tensile strength or stability. While the application of an excess of the surface coating composition has an effect on lubricity, it may detract from other physical properties of the suture, particularly knot stability.

A numerical value may be assigned to the tie-down performance of any braided suture when tested in accordance with the following procedure. In describing the test for tie-down performance reference is made to the accompanying drawings wherein:

FIG. 1 is a diagrammatic representation of an INSTRON Tester and shows two braided suture strands in position for testing;

FIG. 2 is an enlarged perspective view of the single throw knot illustrated in FIG. 1;

FIG. 3 is a reproduction of the tracing of an oscillographic recorder.

All tie-down measurements reported in the tables are made on a Table-Model INSTRON Tensile Tester using a Type B tension cell, full-scale range 100 to 2,000 grams. The INSTRON instrument is manufactured by the Instron Corporation of Canton, Massachusetts. A high-speed SANBORN Oscillographic Recorder (Model 7702A, manufactured by Hewlett-Packard, Waltham, Massachusetts) is substituted for the standard INSTRON Recorder which would be too slow to follow the rapid changes in force that result as the sutures under test slide against each other. A high-gain DC Amplifier (Hewlett-Packard Model 8803A, manufactured by Hewlett-Packard, Waltham Division, Waltham, Massachusetts) is used to interface this recorder with the INSTRON Transducer and a low-voltage DC power supply is provided to excite the transducer. The measurements are made in an air-conditioned laboratory at 72°F. and 50 percent relative humidity. To hold the specimen suture strands, a line contact jaw is used. The INSTRON machine is operated at a cross-head speed of 50 inches per minute and the chart speed of the oscillographic recorder is 20 millimeters per second.

Subjective tests for tie-down involved the suture configuration 11 shown in FIG. 2 (a single throw knot). The same configuration is produced by a pulley arrangement that is supported by a steel plate 10 shown in FIG. 1. The steel plate is attached to the cross-head 12 of the INSTRON Tester.

To perform tie-down measurements, two strands 8 and 9 of the same suture are attached at one end to the B cell transducer 14 of an INSTRON Tester. The sutures are threaded through the pulley arrangement as shown in FIGS. 1 and 2. The other end of the suture strands are brought together, passed around the pulleys 15 and 16, and attached together to a weight 18 which provides tension similar to that applied in a subjective test. A weight of 2.5 pounds is used in the standard procedure.

FIG. 3 shows actual recorder traces for a braided polyethylene terephthalate suture before and after coating with a polymer to improve tie-down performance. The roughness values are measured along the ordinate and throughout the specification and examples are recorded in pounds (roughness). When relatively smooth samples are compared, the amplitude of the oscillographic recorder can be increased by a factor of 20.

The present invention will be further illustrated by the following examples which illustrate preferred embodiments of the inventive idea.

EXAMPLE I

A condensation polymer is prepared by reacting 42.5 weight percent of 1,4-butanediol with 57.5 weight percent of adipic acid. The polymer so obtained is a firm, waxy solid having a viscosity of 1475 cps. at 60°C., a molecular weight of 2150, an acid number of 1.7, and a hydroxyl number of 52.1.

The polyester prepared as described in the preceding paragraph (4.84 parts by weight) is dissolved in 95.16 parts by weight of toluene and the solution is applied to a braided, size 2/0 polyethylene terephthalate suture strand using an ATLAB Yarn Finish Applicator manufactured by Precision Machine & Development Company, P.O. Box 645, New Castle, Delaware. The braid is coated under the following conditions:

Speed of Yarn	30 feet per minute
Hypodermic Syringe Size	30 cc.
Motor Drive Rate	10 r.p.m.
Hysteresis Tension	5 pounds.

The coated, braided strand is dried in forced air at 70°–80°F. to evaporate the solvent and is then collected on a take-up drum. No curing of the adipic ester is required. The coating is continuous over the entire surface of the suture and amounts to 1 percent by weight (based on the weight of the untreated suture). The coated braid is sterilized by exposure to cobalt-60 irradiation without significant loss of straight tensile strength or knot strength. The physical characteristics of the braided polyethylene terephthalate suture before and after coating are summarized in Table I.

TABLE I

	Braided Size 2/0 Polyethylene Terephthalate Suture (Untreated)	Braided Size 2/0 Polyethylene Terephthalate Suture (Coated)
Tensile Strength		
Non-Sterile	100,200 p.s.i.	99,100 p.s.i.
Sterile	99,400 p.s.i.	98,800 p.s.i.
Knot Strength		
Non-Sterile	53,900 p.s.i.	53,500 p.s.i.
Sterile	52,100 p.s.i.	55,000 p.s.i.

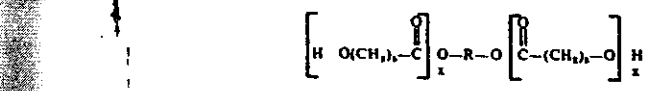
TABLE 1-continued

	Braided Size 2/0 Polyethylene Terephthalate Suture (Untreated)	Braided Size 2/0 Polyethylene Terephthalate Suture (Coated)
Roughness	3.67 lbs.	0.31 lbs.

Similar results are obtained when the polyester resin described in this Example is used to coat braided silk, cotton, and collagen sutures. However, higher levels of coating solids should be used for the hydrophilic substrates such as cotton and silk. The coated sutures made according to this example have excellent knot holding properties.

EXAMPLE II

A linear polymer of ϵ-caprolactone characterized by an average molecular weight of about 2,000 and having the structural formula:



wherein R is a polymethylene group derived from a polymethylenediol and x represents the degree of polymerization, was purchased from the Union Carbide Corporation, Chemical Division, 270 Park Avenue, New York City, New York. This polycaprolactone has a molecular weight of about 2,000 and is sold under the trade name NIAX POLYOL D-560.

The polycaprolactone identified above was dissolved in toluene to obtain a 3.8 percent by weight solution. This solution is applied to a braided, size 2/0 polyethylene terephthalate suture strand using an ATLAB Yarn Finish Applicator. The braid is coated under the conditions as described in Example I above and dried in forced air at 75°F. The coated braid, after evaporation of the solvent is collected on a take-up drum. No curing of the polycaprolactone is required. The coating is continuous over the entire surface of the suture and amounts to 1 percent by weight (based on the weight of the untreated suture). The coated braid is sterilized by exposure to cobalt-60 irradiation without appreciable loss of straight tensile strength or knot strength. The physical characteristics of the braided polyethylene terephthalate suture before and after coating are summarized in Table 2.

TABLE 2

	Braided Size 2/0 Polyethylene Terephthalate Suture (Untreated)	Braided Size 2/0 Polyethylene Terephthalate Suture (Coated)
Tensile Strength		
Non-Sterile	96,300 p.s.i.	92,000 p.s.i.
Sterile	95,100 p.s.i.	91,500 p.s.i.
Knot Strength		
Non-Sterile	53,900 p.s.i.	51,700 p.s.i.
Sterile	54,700 p.s.i.	51,700 p.s.i.
Roughness	2.77 lbs.	0.67 lbs.

Similar results are obtained when the polycaprolactone is used to coat braided silk, cotton, and collagen sutures of size 2/0 through 6/0. The polyesters of the present invention may also be used to coat absorbable synthetic sutures such as those described in U.S. Pat. No. 3,297,033 and 3,636,956 with a resulting improvement in tie-down characteristics.

What is claimed is:

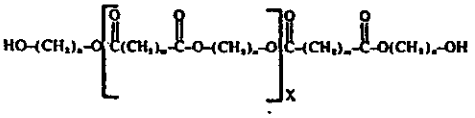
1. A suture having improved tie-down performance comprising a multifilament, the outer surface of the multiflament being coated with from about 0.4 percent to about 7 percent based on suture weight of an aliphatic polyester that is a solid at room temperature; said polyester having from 2 carbon atoms to about 12 carbon atoms between the ester linkages in the polymer chain and said polyester having a molecular weight in the range of 1,000 to 15,000.

2. The suture of claim 1, characterized by a braided construction.

3. The suture of claim 1, characterized by a twisted construction.

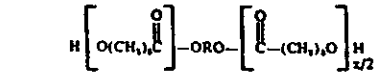
4. The suture of claim 1, characterized by a covered construction.

5. The multifilament suture of claim 1, wherein the polyester has the formula:



wherein *n* is an integer larger than 1 and smaller than 13, *m* is an integer larger than 1 and smaller than 9 and X is the degree of polymerization.

6. The multifilament suture of claim 1, wherein the polyester has the formula:



wherein R is a polymethylene group and X represents the degree of polymerization.

7. The multifilament suture of claim 1, wherein the polyester is a condensate of adipic acid and 1,4-butanediol having a molecular weight of about 2,000–3,000.

8. The suture of claim 7, wherein said multifilament is a silk multifilament and the polyester coating

amounts to about 5 p. ..nt of the weight of the untreated suture.

9. The suture of claim 7, wherein said multifilament is a polyethylene terephthalate multifilament, and the polyester coating amounts to about 1 percent of the weight of the untreated suture.

10. The multifilament suture of cliam 6, wherein the polyester coating has a molecular weight of about 2,000.

11. The suture of claim 10, wherein said multifilament is a polyethylene terephthalate multifilament and the polyester coating amounts to about 1 percent of the weight of the untreated suture.

12. The su...e of claim 10, wherein said multifilament is a silk multifilament and the polyester coating amounts to about 5 percent of the weight of the untreated suture.

13. The multifilament suture of claim 1, characterized by a roughness of less than 1 pound.

14. The multifilament suture of claim 2, characterized by a roughness of less than 1 pound.

15. The multifilament suture of claim 3, characterized by a roughness of less than 1 pound.

16. The multifilament suture of claim 4, characterized by a roughness of less than 1 pound.

* * * * *

United States Patent [19]
Messier et al.

[11] **Patent Number: 4,624,256**
[45] **Date of Patent: Nov. 25, 1986**

[54] **CAPROLACTONE POLYMERS FOR SUTURE COATINGS**

[75] Inventors: **Kenneth A. Messier**, Jewett City; **Joseph D. Kiss**, Old Lyme, both of Conn.

[73] Assignee: **Pfizer Hospital Products Group, Inc.**, New York, N.Y.

[21] Appl. No.: 774,636

[22] Filed: Sep. 11, 1985

[51] Int. Cl.⁴ A61L 17/00
[52] U.S. Cl. 128/335.5
[58] Field of Search 132/335.5

[56] **References Cited**

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4,201,216	5/1980	Mattei	128/335.5

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Sagarin, Cosmetics Science & Technology, 1957, pp. 104–105.

Primary Examiner—Gregory E. McNeill
Attorney, Agent, or Firm—Charles J. Knuth; Peter C. Richardson; Gezina Holtrust

[57] **ABSTRACT**

High molecular weight caprolactone polymers are coated on surgical sutures to improve suture properties such as smooth surface, single knot slipdown, two throw knot slipdown for repositioning, and three throw knot security.

8 Claims, No Drawings

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000071

CAPROLACTONE POLYMERS FOR SUTURE COATING

BACKGROUND OF THE INVENTION

The invention relates to surgical sutures comprising a braided multifilament of a biocompatible material coated with a lubricating agent. More particularly, the invention relates to sutures coated with high molecular weight polycaprolactone or a high molecular weight copolymer of at least 90% by weight of caprolactone.

Coating of braided sutures with lubricating agents to improve knot slipdown properties is known in the art. For instance, U.S. Pat. No. 4,080,969 discloses coating braided polyglycolic acid filaments with diglycolate polyesters. U.S. Pat. No. 4,027,676 provides a coating for sutures comprising a bioabsorbable film-forming polymer, the bioabsorbable lubricant polyalkylene glycol and a hydrophobic material. U.S. Pat. No. 3,867,190 relates to polyglycolic acid sutures coated with a copolymer of lactic and glycolic acid. This patent also mentions incorporation of caprolactone in glycolide sutures. The formed copolymer contains not more than 15% by weight of caprolactone. Use of such copolymer in coating of sutures is not suggested.

U.S. Pat. No. 3,942,532 describes polyester multifilament sutures coated with polycaprolactone Niax Polyol D-560 having a low molecular weight of about 2,000 and a melt viscosity at 60° C. of 500 centipoise.

It is an object of the invention to provide a suture having a smooth surface, good single knot slipdown, two throw knot slipdown for repositioning, and three throw knot security.

SUMMARY OF THE INVENTION

In accordance with the invention, there is provided a surgical suture of a braided multifilament biocompatible, bioabsorbable material coated with a lubricating agent selected from the group consisting of high molecular weight polycaprolactone, a high molecular weight copolymer derived from at least 90% by weight of caprolactone and the remainder another biodegradable monomer, and a blend of at least 50% by weight of said polycaprolactone or said copolymer and up to 50% by weight of another biodegradable lubricating agent, based on the combined weights of the lubricating agents. The homopolymer or copolymer of caprolactone has a melt viscosity at 60° C. of at least about 50,000 centipoise (cps) or is a solid.

Generally, the lubricating agent or agents are present in an amount of about 0.5 to 10% by weight based on the suture.

The invention also provides for a needled surgical suture wherein a novel coated suture as described above is threaded through or fitted with a surgical needle, and a surgical suture package comprising a sterile enclosure containing a sterile needled coated surgical suture as previously described.

DETAILED DESCRIPTION OF THE INVENTION

According to the invention, any conventional bioabsorbable suture material may be used. Sutures must be biocompatible such that they do not cause any adverse reactions in living tissue. The sutures of the invention are bioabsorbable such that they are slowly absorbed in living tissue. Examples of suitable bioabsorbable suture materials are collagen, poly(glycolic acid), poly(lactic acid), poly(hydroxybutyric acid), chitosan, chitin, carboxymethylcellulose etc. Preferably, the suture is made of poly(glycolic acid) or a glycolic acid copolymer containing at least 85% glycolic acid units.

The primary lubricating agent of the invention is high molecular weight polycaprolactone or a high molecular weight copolymer of at least 90% by weight of caprolactone and at most 10% by weight of another biodegradable monomer. Examples of such biodegradable monomers are glycolic acid, a glycolide, lactic acid, a lactide, p-dioxanone, valerolactone and other lactones derived from linear aliphatic hydroxycarboxylic acids, α-hydroxybutyric acid, ethylene carbonate, ethylene oxide, propylene oxide, propylene carbonate, malic acid ester lactones, succinic acid, adipic acid and other linear aliphatic dicarboxylic acids, and linear aliphatic diols such as butanediol and hexanediol.

High molecular weight polycaprolactone may be made by conventional methods for the polymerization of ε-caprolactone. Suitable polycaprolactones are commercially available, e.g. PCL-300 and PCL-700 of Union Carbide Corporation, also known by the brand names Tone P-300 and Tone P-700, respectively, having weight average molecular weights of about 15,000 and about 40,000, respectively, as reported by the manufacturer. Copolymers of caprolactone and another monomer may be made by conventional polymerization techniques, e.g. as described in U.S. Pat. No. 4,190,720.

When reference is made hereafter to polycaprolactone, this will include the above-described copolymers of caprolactone containing 10% or less of a biodegradable comonomer.

The high molecular weight polycaprolactone is applied to the multifilament suture generally from a solution in a solvent for polycaprolactone such as methylene chloride. Other known solvents for polycaprolactone may be used such as carbon tetrachloride, chloroform, ethyl acetate, cyclohexanone, methyl ethyl ketone, toluene, and xylene. The concentration of the polycaprolactone in the solvent may range from 1 to 10% by weight based on the solvent. Generally, about 5 g commercially available polycaprolactone per 100 ml of solvent is used. The preferred concentration will provide a readily flowable composition the solvent of which is not difficult to evaporate after the coating is applied, and will deposit the desired amount of polycaprolactone on the suture.

The sutures are immersed in the coating solution for 0.1 to 10 minutes, preferably about 0.2–3 minutes, and air dried at room temperature or, if desired, at slightly higher temperatures. The immersion may be carried out by batch dipping a skein or by continuously passing a continuous length of yarn through the coating solution.

The primary lubricating agent, high molecular weight polycaprolactone, may be mixed with other lubricating agents in an amount of up to 50% by weight of the combined lubricating agents. Examples of such other lubricating agents are poly(ethylene oxide), partially oxidized polyethylene wax, N,N'-ethylene diamine bis-stearamide, C_{10}–C_{30} fatty acid esters of sterols such as cholesterol and lanosterol, and polyalkylene glycols such as a copolymer of ethylene glycol and propylene glycol.

The coating composition may also contain other components for other purposes including dyes, stabilizers against oxidation or degradation caused by radiation, antibiotics, antiseptics, analgesics, anesthetics, anti-

inflammatory agents, growth or healing promoting agents and other pharmaceutically active ingredients.

Polycaprolactone is known to be a non-toxic material that degrades slowly in living tissue to form an innocuous metabolizable intermediate.

The following examples illustrate the invention. Examples 1–15 and 20 are comparative examples and Examples 16–19 are examples according to the invention.

EXAMPLES 1–19

Uncoated sutures of polyglycolic acid (18 inch long) were immersed in 100 ml of coating solution. The solvent, percentage by weight of coating material in solution, percentage coating by weight on the coated suture, and the size of the sutures are listed in Table 1.

The sutures were immersed in the coating solution for 2 to 3 minutes and air dried at room temperature. The percentage coating was calculated by weighing the suture on an analytical balance before and after coating and is given in Table I as percent of total weight of the coated suture. After air drying, the coated sutures were stored in a desiccator.

TABLE 1

Example	Suture size	Coating material	Solvent	% Coating material in solvent	% Coating on suture
1	2-0	PEO 8000	CH_2Cl_2	3	1.4
2	2-0	PGA powder	CH_2Cl_2	5	1.3
3	2-0	PEO 8000-PGA powder (5:1)	CH_2Cl_2	3.5	1.5
4	2-0	Pluracol P-4010	$CHCl_3$	3	1.0
5	3-0	PVP	$CHCl_3$	2	6.9
6	3-0	PVP	$CHCl_3$	2	1.7
7	3-0	PVA	H_2O	3	6.5
8	3-0	PEO 8000-calcium stearate (2:1)	CH_2Cl_2	3	3.4
9	2-0	Petrac 15	$CHCl_3$	5	3.5
10	2-0	Petrac 165	$CHCl_3$	5	2.9
11	2-0	PEG-100 stearate	CH_2Cl_2	5	4.4
12	2-0	PEG-40 stearate	CH_2Cl_2	5	3.9
13	2-0	Carnauba wax	$CHCl_3$	5	3.9
14	2-0	Kemamide W-40	$CHCl_3$	5	2.3
15	4-0	Cholesteryl palmitate	$CHCl_3$	5	2.5
16	1-0	PCL (Tone P300)	CH_2Cl_2	5	5.7
17	1-0	PCL (Tone P700)	CH_2Cl_2	5	6.1
18	1-0	PCL (Tone P700) Super Sterol Ester (1:1)	CH_2Cl_2	5	2.4
19	1-0	PCL (Tone P700) Super Sterol Ester (4:1)	CH_2Cl_2	5	3.1

The abbreviations and trademarks in Table I stand for the following:
PEO: poly(ethylene oxide)
PGA: poly(glycolic acid)
Pluracol P-4010: poly(propylene glycol)
PVA: poly(vinyl pyrrolidone)
Petrac 165: wax
Petrac 215: partially oxidized polyethylene wax (Petrochemicals Company Inc.)
PEG: poly(ethylene glycol)
Kemamide: N,N'—ethylene diamine bis-stearamide
PCL: polycaprolactone
Super Sterol Ester: cholesterol and lanosterol esters of a mixture of C_{10}—C_{30} fatty acids esters, supplied by CRODA Inc.

The melt viscosity of PCL (Tone P300) was measured with a Brookfield RVT viscometer having a No. 7 spindle at 20 and 50 rpm. The polymer was melted in a beaker and surrounded by a temperature controlled water bath, the temperature of which was measured with an electronic thermometer sensitive to ±0.1° C. The viscosity was 51,200 cps at 60° C. PCL (Tone P700)) is solid at 60° C. The molecular weight of PCL (Tone P700) was determined by gel permeation chromatography and was found to be 100,000 (polystyrene equivalent in dichloromethane).

Table 2 sets out the properties of the coated sutures of Table 1.

The general texture and feel of a suture such as flexibility, smoothness and hardness was observed by handling the suture and drawing between fingers. Typical observations as set out in Table 2 are stiff, silky, waxy.

The slipdown property of a suture was determined by tieing tightly a two-throw square knot, then grasping the long ears and pulling apart. If the suture was drawn through the knot, giving the appearance of the knot slipping down the braid, it was marked as excellent (exc.), good, or acceptable (acc.) depending on the ease of slipdown. If the knot seized or was difficult to slip down, the suture was marked as locks, poor, or rachety, depending on the difficulty of slip down.

The slipdown property was also tested under wet conditions by immersion of the unknotted suture in water for 5 seconds and immediately testing thereafter.

The knot security of a suture was tested by tying firmly a triple throw square knot and pulling the suture from a patient's side until the knot slipped or the suture broke. If the knot slipped, knot security was marked poor. If the suture broke without slip, the knot was sufficient to hold the suture at the knot and was marked acceptable in Table 2.

The knot security was tested under wet conditions by immersion of the unknotted suture in water for 5 seconds and immediately testing thereafter.

The wet knot slipdown was tested by tieing tightly a two-throw granny knot and slipping down the knot. The knot was then wetted by rubbing with fingers dipped in water. An attempt was then made to slip the knot down further. If the knot slipped both dry and wet, the suture was marked as acceptable, good, or excellent depending on the ease of the slip. If the knot slipped dry but not wet, the suture was marked as locking. If the slip was poor wet and dry and locking was difficult to determine, the suture was marked poor, or rachety.

TABLE 2

Example	Texture	2 throw square slipdown dry	2 throw square slipdown wet	3 throw square slipdown dry	3 throw square slipdown wet	2 throw granny slip-down, wet knot	Comments
1	stiff	exc.	poor	acc.	acc.	locks	exc. dry, poor wet
2	powdery smooth	poor	locks	acc.	acc.	locks	poor lubr. overall
3	stiff	exc.	poor	acc.	acc.	locks	exc. dry, poor wet
4	silky	acc.	acc.	acc.	acc.	locks	acc. lubr. but locks
5	very stiff	poor	locks	acc.	acc.	locks	very poor lubr., locks
6	very stiff	locks	locks	acc.	acc.	locks	as 5
7	stiff, rough	rach-ety	locks	acc	acc.	poor	poor lubr. esp. wet
8	silky	exc.	poor, rachety	acc.	acc.	locks	exc. slip-down dry, but not when wet

TABLE 2-continued

Example	Texture	2 throw square slipdown dry	2 throw square slipdown wet	3 throw square slipdown dry	3 throw square slipdown wet	2 throw granny slip-down, wet knot	Comments
9	stiff, rough	exc.	exc.	acc.	acc.	exc., no locking	excellent
10	very rough	rach-ety	rachety	acc.	acc.	rachety	poor lubr., not affected by water
11	stiff, waxy	very good	good	acc.	acc.	rachety	fairly good, not much affected by water
12	stiff, smooth	rach-ety	rachety	acc.	acc.	rachety	poor lubr., not affected by water
13	rough	fine to rach-ety	good	acc.	acc.	acc.	rachety dry, good wet
14	waxy, rough	good	good	acc.	acc.	good	good, not affected by water
15	rough	poor	poor	acc.	acc.	poor	poor lubr. overall
16	stiff, waxy	exc.	exc.	acc.	acc.	exc.	as 14
17	stiff, waxy	exc.	exc.	acc.	acc.	exc.	as 14
18	silky, good feel	exc.	exc.	acc.	acc.	exc.	exc. good feel, good lubr., not affected by water
19	stiff	exc.	exc.	acc.	acc.	exc.	as 18.

"lubr.": lubricant

COMPARATIVE EXAMPLE 20

An uncoated suture of polyglycolic acid (54 inch long), size 3-0 was immersed in 100 ml of coating solution comprising 95.0 ml methylene chloride and 5.00 g of Tone polyester 0240 (formerly Niax Polyol D560) of Union Carbide Corporation. The manufacturer specifies a molecular weight of 2000 and a viscosity of 500 cps at 60° C. for Tone polyester 0240. The coating solution was obtained by dissolving the Tone polyester 0240 at room temperature in a 200 ml beaker in 3 minutes using a magnetic stirrer.

The suture was immersed in the coating solution for one minute and air-dried at room temperature. The % coating on the suture was 5.9.

Knot slip and knot security were determined as follows.

Knot	Result
2 throw square slip down	slips about 0.5 inch.
3 throw square slipdown	locks and breaks locks
2 throw granny slipdown (dry)	acceptable slip
2 throw granny slipdown (wet)	acceptable slip

I claim:

1. A surgical suture comprising a braided multifilament of poly(glycolic acid or a copolymer containing at least 85% glycolic acid units coated with a lubricating agent selected from the group consisting of a high molecular weight homopolymer of caprolactone, a high molecular weight copolymer of at least 90% by weight of caprolactone and the remainder another biodegradable monomer, and a blend of at least 50% by weight of said homopolymer of said copolymer of caprolactone and up to 50% by weight of another biodegradable lubricating agent, said homopolymer or copolymer of caprolactone having a melt viscosity at 60° C. of at least about 50,000 centipoise or being solid.

2. A suture according to claim 1 wherein said other biodegradable lubricating agent is a mixture of sterol esters of C_{10}–C_{30} fatty acids.

3. A suture according to claim 2 wherein said sterol is a mixture of cholesterol and lanosterol.

4. A suture according to claim 1 wherein said lubricating agent is present in an amount of 0.5 to 10% by weight based on the weight of the suture.

5. A needled surgical suture comprising at least one filament of poly(glycolic acid) or a copolymer containing at least 85% glycolic acid units coated with a lubricating agent selected from the group consisting of a high molecular weight homopolymer of caprolactone, a high molecular weight copolymer of at least 90% by weight of caprolactone and the remainder another biodegradable monomer, and a blend of at least 50% by weight of said homopolymer or said copolymer of caprolactone and up to 50% by weight of another biodegradable lubricating agent, said homopolymer or copolymer of caprolactone having a melt viscosity of 60° C. of at least about 50,000 centipoise.

6. A needled surgical suture according to claim 5 wherein said other biodegradable lubricating agent is a mixture of sterol esters of C_{10}–C_{30} fatty acids.

7. A surgical suture package comprising a sterile enclosure containing a sterile needled surgical suture, the suture comprising at least one filament of poly(glycolicacid) or a copolymer containing at least 85% glycolic acid units coated with a lubricating agent selected from the group consisting of a high molecular weight homopolymer of caprolactone, a high molecular weight copolymer of at least 90% by weight of caprolactone and the remainder another biodegradable monomer, and a blend of at least 50% by weight of said homopolymer of said copolymer of caprolactone and up to 50% by weight of another biodegradable lubricating agent, said homopolymer or copolymer of caprolactone having a melt viscosity at 60° C. of at least about 50,000 centipoise or being solid.

8. A package according to claim 7 wherein said other biodegradable lubricating agent is a mixture of sterol esters of C_{10}–C_{30} fatty acids.

* * * * *

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3,527,650

SUTURE COATING OF POLYETHYLENE OR POLYTETRAFLUOROETHYLENE

Edward A. Block, Somerville, N.J., assignor to Ethicon, Inc., a corporation of New Jersey

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Int. Cl. A61l 17/00
U.S. Cl. 117—7 8 Claims

ABSTRACT OF THE DISCLOSURE

The hand and lubricity of a braided polyethylene terephthalate suture are improved by applying to the surface thereof polymers of polyethylene or polytetrafluoroethylene having a lower coefficient of friction than the suture and a styrene-acrylic ester copolymer resin binder therefor.

The present invention relates to nonabsorbable surgical sutures and more specifically to braided multifilament sutures of polyethylene terephthalate. Braided polyethylene terephthalate sutures have been used by many in the surgical profession for years and actually are preferred over silk by many surgeons for their strength and lack of tissue reactivity. Other surgeons prefer to use waxed silk when a nonabsorbable suture is required because of its excellent hand, ease of knotting, and ease of passage through tissue.

It is a known disadvantage of polyethylene terephthalate sutures that the knot may slip unless repeated knots are tied. Attempts have been made to improve the knotability of polyethylene terephthalate by modifying the surface thereof to decrease lubricity. One method of doing this is described in U.S. Pat. No. 3,307,971, which issued to Leonard D. Kurtz in March of 1967.

The present invention is directed to increasing the lubricity of a braided polyethylene terephthalate suture by applying a surface coating of a nontoxic and physiological inert resin that has a lower coefficient of friction than the polyethylene terephthalate, such as, polytetrafluoroethylene or polyethylene.

Polytetrafluoroethylene has been applied to braided polyethylene terephthalate sutures for the purpose of filling the interstices of the braided structure and achieving the characteristics of a solid monofilament. U.S. Pat. No. 3,322,125 described in Example I impregnating a braided 4/0 polyethylene terephthalate suture with a suspension of polytetrafluoroethylene particles having a particle size of about 0.2 micron. The suture is dried and stretched at 450° F. whereby the particles of polytetrafluoroethylene are trapped within the body of the suture.

The process described in U.S. Pat. No. 3,322,125, however, does not produce a satisfactory surface coating of polytetrafluoroethylene because the polytetrafluoroethylene particles do not adhere to the surface of the suture material. The particles can flake off and produce foreign body reactions near the suture site. It has now been discovered that polytetrafluoroethylene and other resinous particles having a coefficient of friction lower than that of the braided polyethylene terephthalate surface may be cemented to the surface of the braided polyethylene terephthalate suture with a binder resin which prevents flaking of the resinous particles.

Binder resins that are suitable for use in securing polytetrafluoroethylene and similar resinous particles having a lower coefficient of friction than polyethylene terephthalate to the surface of a braided polyethylene terephthalate suture are the non-ionic, self-cross linking, or cross-linkable acrylic polymers, such as Rhoplex HA–12 and Rhoplex B–15, manufactured by Rohm and Haas Company, Philadelphia, Pa., and thermoplastic acrylic

polymers, such as Hycar 2601, manufactured by B. F. Goodrich Chemical Company of Cleveland, Ohio and copolymers of an acrylic ester and styrene, such as Aerotex Resin 134, manufactured by the American Cyanamid Company, Bound Brook, N.J.

In the practice of the present invention, a braided polyethylene terephthalate suture is passed through an aqueous mixed dispersion of an acrylic latex of the type identified above and polytetrafluoroethylene particles or polyethylene particles. The ratio of acrylic latex to polytetrafluoroethylene particles in the dispersion is about 1:3 but may be increased to improve the adhesion of the lubricating particles to the surface of the suture or decreased to increase the lubricity of the surface coating. The dwell time of the braided suture with the polytetrafluoroethylene dispersion is just sufficient to coat the surface as penetration of the lubricant particles into the interstices of the suture is not necessary or desired. The braided polyethylene terephthalate after it leaves the coating bath is dried and heat cured. The structure of the braided polyethylene terephthalate suture is altered by the shrinkage that occurs during the curing process. To restore the original close braided structure and control the size (diameter), the coated, braided suture after cooling is heated and stretched under tension. The coated, braided strand may be conveniently heated by moving it one or more times past a steel plate maintained at a temperature between 350° F. and about 440° F. at the rate of 50 to 100 yards per minute. The smaller size sutures, e.g., size 6/0, may be stretched in this manner about 25 percent to 40 percent. The larger sutures, e.g., size 2, are stretched as as much as 40 percent to 60 percent.

It is an important aspect of the present invention that the binder resin is flexible and bound to the braided suture in such a manner that it does not crack, flake, or come off of the suture during the heat-stretching step.

The product so obtained has an improved hand and surface lubricity. Yet the knot will not slip if a double square knot is tied. The surface lubricity of a coated polyethylene terephthalate suture may be demonstrated by the following test:

To the cross bar of an Instron tester is secured a 3½" pulley and a 2" pulley. Using a B cell and the associated upper jaw (red), the instrument is calibrated with a 100 gram weight on the B cell clamp to full scale deflection on the ×1 scale.

To determine the surface lubricity of a coated strand, a 45" length of suture is clamped in the center of the upper jaw; the free end is passed counterclockwise around the 3½" diameter pulley, and a counterclockwise single throw is made approximately 1½" above the face of the 3½" diameter pulley wheel. The free end of the suture is then passed over the 2" diameter pulley wheel and secured to a 50 gram weight. The distance from the periphery of the pulley face to the bottom of the B cell clamp is 2½".

In operation, the ×10 scale on the Instron tester is used (1,000 grams full scale) and the crosshead speed and chart speed are 20" per minute.

As the suture passes over itself, a curve is plotted on the graph paper. Since a braided suture has braid protrusions and is somewhat elliptical in cross-section, a smooth curve does not appear. The "stick" portion of a stick-slip curve is produced when it is easier for the suture to stick to itself and elongate than to slip. As the suture is elongated more and more, the tension continues to build up until either the yield point of the suture is reached or until the cohesive force is overcome and the suture slips. This cycle is repeated producing a saw-tooth pattern on the chart.

The surface lubricity of the braided suture may be determined from the maximum and minimum friction

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peaks on the graph in accordance with the following equation:

$$\text{average lubricity} = \text{minimum peak} + \frac{(\text{maximum peak} - \text{minimum peak})}{2}$$

The lubricity of the surface as determined by the test described above may be confirmed subjectivly (by feel).

Microscopic examination of the surface coated braided sutures confirms that the surface coating does not scuff or flake off on tie-down.

The invention will be understood from the following examples which illustrate preferred embodiments of the inventive idea.

EXAMPLE I

A braided skein of polyethylene terephthalate (Dacron) multifilament, size 2/0[1], passed beneath two nylon rollers immersed in a trough containing a polytetrafluoroethylene resin dispersed in a thermosetting acrylic latex (Emralon 312, manufactured by Achesin Collids Company, Port Huron, Mich.). The polytetrafluoroethylene resin constitutes about 50 percent of the total resin solids. The braided multifilament moves through the trough at the rate of about 16 yards per minute, the surface of the skein being in contact with the liquid dispersion for about 0.6 to 0.9 seconds. The concentration of resin solids in the trough was maintained at 50±5 percent throughout the run.

After coating, the skein is heated in an over for ½ hour at 300° F. and heat stretched 40 percent by passing the moving skein 12 times under tension in close proximity to an 18-inch plate heated to 440° F.

The product so obtained has utility as a suture. It has an excellent hand and a smooth, resinous surface coating amounting to 3 percent of the total suture weight.

The surface lubricity, as measured by the Instron surface lubricity test described above, is 500 grams. The coated suture does not slip when tied with a double square knot.

EXAMPLE II

A braided skein of polyethylene terephthalate (Dacron) multifilament, size 2/0, is coated by passing it though one foot in length that contains a resinous dispersion having the following composition:

	Parts
Acrylic resin 45 percent solids (Rhoplex HA-12)	707
Polytetrafluoroethylene resin 60 percent solids (Teflon 30 manufactured by E. I du Pont de Nemours and Company, Inc., Wilmington, Del.)	1,588
Water	7,705

The skein moves through the trough at a speed of 20 feet per minute and is heated in an oven for ½ hour at 300° F. and heat stretched 35 percent by passing the moving skein 12 times under tension in close proximity to an 18-inch plate heated to 440° F.

The product so obtained has utility as a suture. It has an excellent hand and a smooth, resinous surface coating amounting to 3.8 percent of the total suture weight. The surface lubricity, as measured by the Instron surface lubricity test described above, is 550 grams. The coated suture does not slip when tied with a double square knot.

EXAMPLE III

A braided skein of polyethylene terephthalate (Dacron) multifilament, size 2/0, is passed beneath two nylon rollers immersed in a trough containing 340 parts of a polytetrafluoroethylene resin containing 60 percent resin solids and 151 parts of a thermosetting acrylic latex (45 percent solids). The acrylic latex is an interpolymer of 90 parts of 2-ethylhexyl acrylate, 12 parts glycidyl acrylate, 90 parts styrene, and 8 parts methacrylic acid. The braided multifilament moves through the trough at the rate of about 16 yards per minute, the surface of the skein being in contact with the liquid dispersion for about 0.6 to 0.9 second.

After coating, the skein was heated in an oven for ½ hour at 275° F. and heat stretched 45 percent by passing the moving skein 12 times under tension in close proximity to an 18-inch plate heated to 440° F.

The product so obtained has utility as a suture. It has an excellent hand and a smooth, resinous surface coating amounting to 2.6 percent of the total suture weight.

The surface lubricity, as measured by the Instron surface lubricity test described above, is 530 grams. The coated suture does not slip when tied with a double square knot.

EXAMPLE IV

A braided skein of polyethylene terephthalate (Dacron) multifilament, size 2/0, is coated by passing it through a trough one foot in length that contains a resinous dispersion having the following composition:

	Parts
Acrylic resin 46 percent solids (Rhoplex B-15)	832
Polytetrafluoroethylene resin 60 percent solids (Teflon 30)	1,868
Water	7,300

The skein moves through the trough at a speed of 20 feet per minute and is heated in an oven for ½ hour at 300° F. and heat stretched 50 percent by passing the moving skein 12 times under tension in close proximity to an 18-inch plate heated to 440° F.

The product so obtained has utility as a suture. It has an excellent hand and a smooth, resinous surface coating. The surface lubricity, as measured by the Instron surface lubricity test described above, is 490 grams. The coated suture does not slip when tied with a double square knot.

EXAMPLE V

A braided skein of polyethylene terephthalate (Dacron) multifilament, size 2/0, is passed beneath two nylon rollers immersed in a trough containing 1,494 parts of a tetrafluoroethylene resin containing 60 percent resin solids (Teflon 30); 1,192 parts of a styrene acrylate copolymer resin latex (Aerotex Resin 134); and 7,314 parts of water. The braided multifilament moves through the trough at the rate of about 20 feet per minute.

After coating, the skein was heated in an oven for ½ hour at 300° F. and heat stretched 55 percent by passing the moving skein 12 times under tension in close proximity to an 18-inch plate heated to 440° F.

The product so obtained has utility as a suture. It has an excellent hand and a smooth, resinous surface coating amounting to 3.94 percent of the total suture weight.

The surface lubricity, as measured by the Instron surface lubricity test described above, is 466 grams. The coated suture does not slip when tied with a double square knot.

EXAMPLE VI

A braided skein of polyethylene terephthalate (Dacron) multifilament, size 2/0, is coated by passing it through a trough one foot in length that contains a resinous dispersion having the following composition:

	Parts
Polyethylene resin 50 percent solids Valsof K070 manufactured by Valchem Chemical Division of United Merchants and Manufacturers, Inc., New York, N.Y.	126
Acrylic resin (45 percent solids) (Rhoplex HA-12)	126
Water	748

[1] Diameter 10–13 mils as determined by the method described at p. 918 of the U.S. Pharmacopeia, vol. XVII.

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The skein moves through the trough at a speed of 20 feet per minute and is heated in an oven for ½ hour at 300° F. and heat stretched 40 percent by passing the moving skein 12 times under tension in close proximity to an 18-inch plate heated to 440° F.

The product so obtained has utility as a suture. It has an excellent hand and a smooth, resinous surface coating amounting to 3.3 percent of the total suture weight. The dry straight tensile strength is 9.1 pounds, and the dry knot strength is 6.4 pounds. The coated suture does not slip when tied with a double square knot.

EXAMPLE VII

A braided skein of polyethylene terephthalate (Dacron) multifilament, size 2/0, is coated by passing it through a trough one foot in length that contains a resinous dispersion having the following composition:

	Parts
Polyethylene resin 30 percent solids Valspex N-123 manufactured by the Valchem Division of United Merchants and Manufacturers, Inc., New York, N.Y.	3,375
Non-crosslinking acrylic resin (Hycar 2601)	675
Water	5,950

The skein moves through the trough at a speed of 20 feet per minute and is heated in an oven for ½ hour at 300° F. and heat stretched 45 percent by passing the moving skein 12 times under tension in close proximity to an 18-inch plate heated to 440° F.

The product so obtained has utility as a suture. It has an excellent hand and a smooth, resinous surface coating amounting to 3.5 percent of the total suture weight.

EXAMPLE VIII

A braided skein of polyethylene terephthalate (Dacron) multifilament, size 2/0, is coated by passing it through a trough one foot in length that contains a resinous dispersion having the following composition:

	Parts
Acrylic resin 50 percent solids (Hycar 2601)	720
Polytetrafluoroethylene resin 60 percent solids (Teflon 30)	1,868
Water	7,412

The skein moves through the trough at a speed of 20 feet per minute and is heated in an oven for ½ hour at 300° F. and heat stretched 40 percent by passing the moving skein 12 times under tension in close proximity to an 18-inch plate heated to 440° F.

The product so obtained has utility as a suture. It has an excellent hand and a smooth, resinous surface coating. The surface lubricity, as measured by the Instron surface lubricity test described above, is 553 grams. The coated suture does not slip when tied with a double square knot.

The invention described and illustrated herein before and secured by this Letters Patent is defined in the following patent claims.

What is claimed is:

1. A braided polyethylene terephthalate suture having a surface coating of a first resin selected from the group consisting of tetrafluoroethylene and polyethylene and a second binder resin comprising a styrene-acrylic ester copolymer, the weight ratio of said first resin to said second resin being between about 1:1 and about 3:1.

2. The suture of claim 1, wherein said first resin is polytetrafluoroethylene.

3. The suture of claim 1 wherein said acrylic ester copolymer is a copolymer of 2-ethylhexyl acrylate.

4. The suture of claim 1, wherein said first resin is polyethylene.

5. A method of improving the hand and surface lubricity of a braided polyethylene terephthalate suture comprising the steps of immersing the suture in an aqueous dispersion of a first resin selected from the group consisting of tetrafluoroethylene and polyethylene and a second binder resin comprising a styrene-acrylic ester copolymer, the weight ratio of said first resin to said second resin being between about 1:1 and about 3:1, for a time sufficient to wet the surface of said suture but not sufficient for said resins to substantially penetrate into the interstices of said suture, drying the suture, curing the binder resin, and heating and stretching the suture at an elevated temperature, whereby a resinous coating is formed on the surface of the suture.

6. The method of claim 5, wherein said first resin is polytetrafluoroethylene.

7. The method of claim 5, wherein said suture is heated at about 300° F. for about one-half hour.

8. The method of claim 5, wherein said first resin is polyethylene.

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ALFRED L. LEAVITT, Primary Examiner

A. GRIMALDI, Assistant Examiner

U.S. Cl. X.R.

117—138.8, 139.5, 161; 128—335.5

United States Patent [19]

Kurtz

[11] **Patent Number: 4,470,941**

[45] **Date of Patent: Sep. 11, 1984**

[54] **PREPARATION OF COMPOSITE SURGICAL SUTURES**

[75] Inventor: **Leonard D. Kurtz, Woodmere, N.Y.**

[73] Assignee: **BioResearch Inc., Farmingdale, N.Y.**

[21] Appl. No.: **384,245**

[22] Filed: **Jun. 2, 1982**

[51] Int. Cl.³ **B29B 3/02**

[52] U.S. Cl. 264/136; 128/335.5; 264/108; 264/134; 264/171; 264/174; 264/288.8; 264/290.5; 264/345

[58] Field of Search ..... 428/397, 375, 372; 425/113, 192 R; 264/174, 562, 108, 288.8, 134–137, 345, 210.8, 290.5, 171, 210.7; 128/335.5

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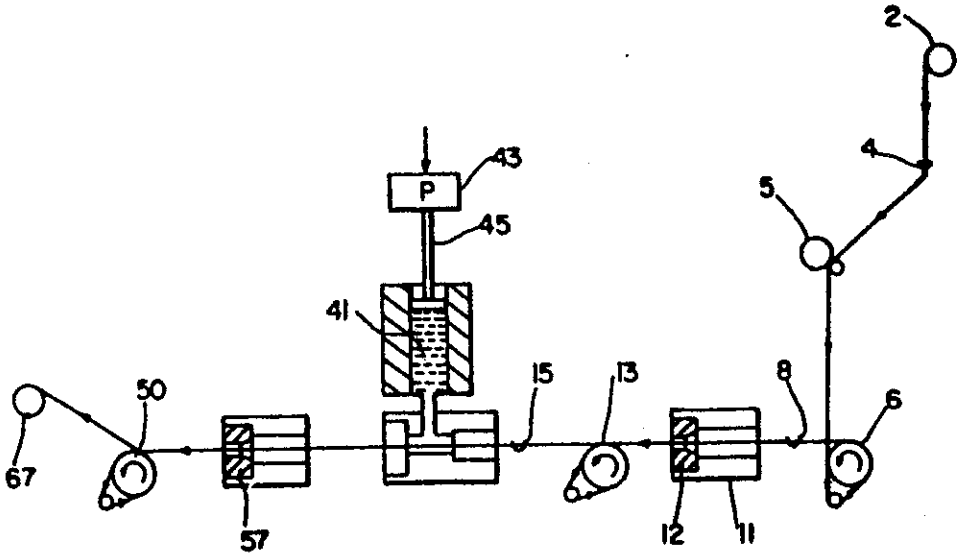
Primary Examiner—Jeffery Thurlow
Attorney, Agent, or Firm—Larson and Taylor

[57] **ABSTRACT**

Composite sutures of dissimilar synthetic polymer materials are prepared by forming a thread comprisised of a plurality of fibers of a first synthetic polymer, said thread further comprising a second synthetic ppolymer in intimate association with and present uniformily along the length of said first synthetic polymeer, softening the second synthetic polymer to cause it tto flow, applying pressure to the softened polymer to redistribute it throughout the plurality of fibers, and into the interstices thereof and sterilizing the thread tto form a suture thereof.

33 Claims, 2 Drawing Figures



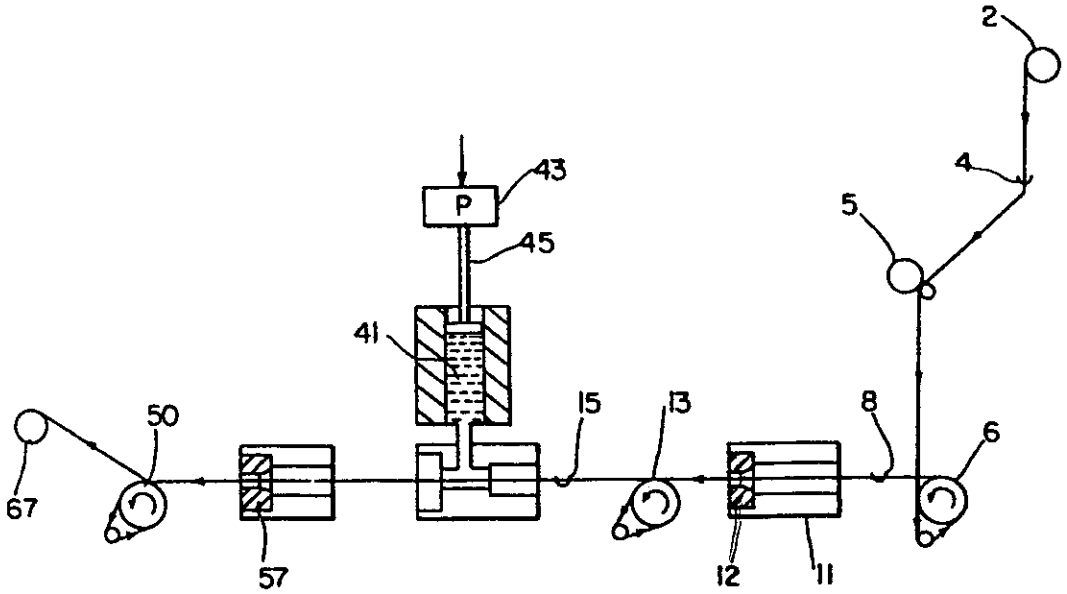

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FIG. 1

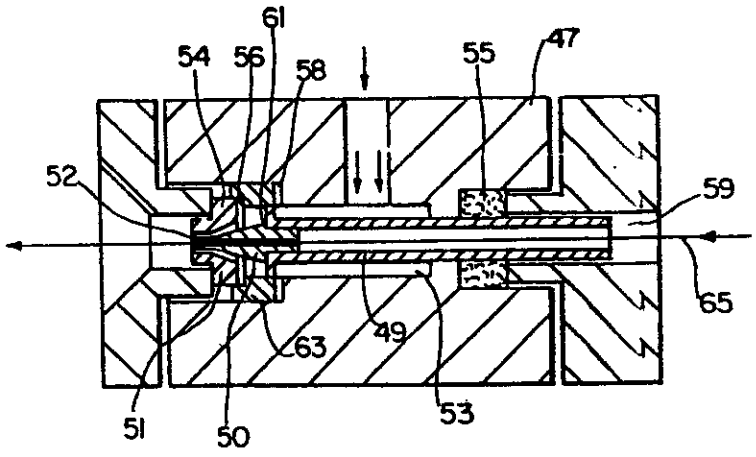
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FIG. 2

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PREPARATION OF COMPOSITE SURGICAL SUTURES

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to a method for preparing composite surgical sutures. More particularly, the invention is directed to methods by which composite sutures of improved lateral strength are obtained.

2. Brief Description of the Prior Art

Composite sutures offer a number of advantages recognized by the prior art. For instance, there are many synthetic fibers which per se are unsuitable for use in sutures because they lack one or more of the properties required in surgical sutures but which possess, nevertheless, certain other properties considered desirable in sutures. By way of example, fibers drawn from many synthetic polymers are too stiff and do not satisfy the knottability requirements of sutures. At the same time these synthetic polymers may possess a tensile strength that renders their use in sutures highly desirable. It is not surprising, therefore, that there have been numerous attempts to combine the best properties of different synthetic materials by compositing them in various ways. These compositing attempts have not been without shortcomings, however.

The principal difficulties involved in the preparation of composite sutures have resided in the fact that polymers whose properties render them desirable for compositing often lack cohesiveness for one another and are otherwise unable to adhere to each other. Many have attempted to remedy these problems by resorting to chemical adhesion through reactive groups provided the polymer components and/or chemical additives to assist in the binding of one polymer component to the other. These techniques, in addition to being costly have in large part proved unsuccessful.

Other attempts to integrate multi-components strands in the production of strings for athletic rackets has been described, for example, in U.S. Pat. No. 4,275,117 to Steven J. Crandall and involves subjecting a fibrous strand composed of fibrous materials having differing melting points to heating conditions sufficient to melt some but not all of the fibrous materials. While perhaps satisfactory for tennis string production or the like, this method of forming composites, as in the case of other aforementioned prior art methods, provides unsatisfactory surgical sutures in that they are found to possess poor lateral strength manifested by a lack of stability against abrasion, kinking and fibrillation during knotting.

Accordingly, it is an object of the present invention to provide a method whereby composite sutures of synthetic polymers having improved lateral strength, that is, composite sutures stabilized against abrasion, kinking and/or fibrillation during knotting are obtained.

Yet another object of the invention is to provide a method of enabling preparation of composite sutures whose surface characteristics, tensile strength and/or knot strength can be tailored to desired specifications.

A further object of the invention is to provide a method of preparing a composite suture whereby one synthetic polymer is tenaciously anchored to the other without the use of chemical adhesion, chemically reactive groups or additives to bind one polymer to the other.

A still further object of the invention is to provide a method for composite suture preparation which enables the use of synthetic fibers heretofore unsuitable for use in suture manufacture.

Another subject of the invention is to provide a method of manufacturing a composite suture having monofilament characteristics which is free of flaking on its outer surface and which retains in large part the flexibility, knottability, knot retention and tensile strength that characterizes multifilament sutures.

SUMMARY OF THE INVENTION

These and other objects of the invention are obtained by forming a thread having interstices therein, comprised of a plurality of fibers of a first synthetic polymer, said thread further comprising a second synthetic polymer in intimate association with and present along the length of at least one of said plurality of fibers, softening said second synthetic polymer to cause flow thereof, applying sufficient pressure to the softened polymer for a time sufficient to redistribute it throughout the plurality of fibers of said first synthetic polymer and into the interstices thereof.

Absolutely essential to the construction of the composite sutures is the pressure step of the method for without it composite sutures having acceptable lateral strength are not obtained. The pressure can be applied to the softened polymer component of the thread in any suitable way with the only proviso being that sufficient pressure be used for a time sufficient to redistribute the softened polymer throughout the fibers of the first synthetic polymer and substantially fill the voids in the thread. According to one preferred embodiment of the invention the pressure is applied by placing the thread under tension during the softening operation. Another preferred method by which the pressure can be applied in the method of the invention is to pass the thread immediately after the softening operation through a compression die having a reduced diameter relative to that of the diameter of the thread so that the necessary pressure can be applied. Although unnecessary, it is preferred in the latter case to use a compression die heated to above the melting point of the polymer component softened. If desired, both forms of pressure application can be utilized as by first effecting the pressure by placing the thread under tension followed by passing the thread through the compression die of reduced diameter.

Since the thread is under pressure, the softened dissimilar polymer exudes into and through interstices existing in the plurality of unsoftened fibers, substantially filling same and forming an internal cast within the matrix of unsoftened fibers upon resolidification. The internal cast of the softened polymer may be continuous or discontinuous and will appear in cross-section in the composite suture as a homogeneous, solid phase throughout the plurality of unsoftened fibers. In most instances, it will be preferred to use an amount of softened polymer sufficient to form upon redistribution throughout the plurality of fibers of the unsoftened synthetic fiber an external cast extending continuously throughout the thread.

Also, where enough of the polymer component softened is present, the liquified polymer exudes through the interstices of the unsoftened fibers and onto the surface of the thread so as to form a coating thereon.

In all instances, however, the internal cast formed within the matrix of unsoftened fibers serves as a tena-

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cious "anchor" onto which additional softened synthetic polymer can be secured as by coating, if desired.

Composite sutures prepared by the present invention having coatings of the exuded synthetic polymer component are preferably smoothed, for instance, by passing them through a heated smoothing die. The smoothed composite thread may then be sterilized if desired to form a surgical suture. In many instances, it may be necessary to further coat the smoothed composite with additional similar synthetic polymer as by extrusion or melt coating to seal and further strengthen the composite thread formed. In addition where the thread is in braided form, subsequent coating tends to eliminate any undulating effect that results as a consequence of the braid and provide a flexible, composite polyfilamentous composite suture having a monofilament-like structure exhibiting improved knottability and knot retention. The improvement in knottability and knot retention characteristics is obtained by virtue of the fact that when a knot is "thrown" and tied down, the suture undergoes a marked deformation in the knot due to the "hills and dales" of the underlying thread.

DETAILED DESCRIPTION OF THE INVENTION

By the term "softening" as used herein and the appended claims is meant any operation by which one of the synthetic polymer components of the thread treated but not the other is brought from a solid or highly viscous state to a viscosity causing flow of the synthetic polymer under the prevailing conditions. This "softening" can be achieved by a variety of ways such as by the use of heat, selective solvents, high energy sources such as lasers, etc. Other suitable ways of effecting the softening will readily come to the mind of those of ordinary skill in this art.

In the aspect of the invention wherein the softening is induced by heating, the thread, comprised of a matrix of a plurality of fibers of a first synthetic polymer and a second solid, dissimilar synthetic polymer having a melting point lower than the melting point of said first synthetic polymer is heated at a elevated temperature sufficient to melt and liquify the dissimilar synthetic polymer, to a viscosity permitting flow throughout the matrix.

Similarly, where the "softening" is induced by a solvent, the thread of dissimilar synthetic polymer components is contacted at a temperature and with a solvent capable of solubilizing or softening the second synthetic polymer but not the first at the contact temperature. The contact time will vary depending principally upon the particular synthetic polymer to be softened and the solvent and contact temperature employed. In all instances, however, the contact time will be sufficient to cause one of the synthetic polymer components to flow, that is, to reduce the viscosity of the polymer to where it flows under the external pressure applied according to the invention and through the remaining, or unsoftened synthetic fibers so as to fill the voids or interstices therein. There is thus formed an internal cast throughout the thread which is dried to resolidify the exuded softened polymer component.

The thread softened in accordance with the present invention can assume a variety of structures and the polymer component to be softened can be present during the softening in any desired form such as a film or fiber, or as a coating on the polymer not softened. In one embodiment, for example, the thread is comprised of lower melting point synthetic polymer fibers in a plied, twisted, braided or commingled construction with synthetic polymer fibers of higher melting point. A preferred form of this embodiment involves heating under tension a thread comprised of a cover of a polyfilamentous synthetic polymer surrounding a core of at least one but preferably a plurality of fibers of a dissimilar synthetic polymer having a lower melting point than the synthetic polymer of said cover.

Alternatively, the thread to be heated pursuant to the present invention can comprise, at least in part, a plurality of synthetic polymer fibers coated with a dissimilar synthetic polymer having a melting point lower than that of the synthetic polymer fiber substrate, which coated fibers are in a plied, twisted, braided, commingled or simply aligned construction.

The proportions of lower melting point synthetic polymer component to higher melting point synthetic polymer component employed in the thread heated in accordance with the invention will vary depending principally upon the particular components selected, whether or not a continuous or discontinuous internal cast is desired and whether or not a composite coated with melted components is the intended product. In all instances, however, the component melted should be present in amounts at least sufficient to provide adequate anchoring sites for additional like synthetic polymer material that may be subsequently applied as by coating to the composite thread formed.

In general, the ratio of higher melting point synthetic polymer material to lower melting point synthetic polymer material in the initial thread required to achieve adequate anchoring sites is at least 0.5:1 on a volume bases. Ratios of melted to unmelted synthetic polymers in excess of 1:10 up to 2:1 are generally required, however, if it is desired to not only fill all the interstices of the thread but to coat the thread as well. Proportions in excess of about 12:1, can create processing difficulties due to thread line non-uniformities.

Heating of the precursor thread of multiple synthetic polymer components to temperatures above the melting point of one of the synthetic components can be conducted in any suitable manner as by passing it through a suitable oven preferably under an inert gas such as nitrogen. As the composite thread passes through the oven, the synthetic component of lower melting point melts and under the applied pressure exudes through the voids present in the plurality of higher melting fibers remaining leaving them substantially filled. Preferably the softened polymer exudes onto the surface under the tension applied.

Any excess melted synthetic polymer can then be trimmed off manually but it is preferred that the thread structure thus formed be passed through a heated die which trims nubs from the thread and otherwise smooths the external surface of the thread. If the thread thus formed is to be coated, it is important to select a die in this operation which provides a precoated yarn that is at least 20–40 microns thinner than the suture class limits in order to leave room for the coating. Again, it is preferred that this operation be conducted under an inert gas such as nitrogen. Stretch may also be applied during the smoothing operation. The thread may be passed through the heating oven and/or smoothing die as many times as is necessary to obtain a smooth, nub-free surface. Advantageously, in smoothing down the nubs not only should excess surface polymer be removed, but some of it should be used to fill the ups and

downs of the thread's surface in order to obtain a sufficiently smooth undercoat structure. If this is not done, the polymer remaining on the surface follows the contours of the thread and any subsequently applied polymer coating will follow these contours.

The temperature employed in the heating oven will vary depending on the polymer components and the speed at which the thread is passed through the oven. As aforementioned, the temperatures should be raised above the melting point of the polymer of lower melting point to a level at which the polymer melts and reaches a viscosity permitting it to exude through the thread as a gelatinous mass which can then be seen on the surface of the thread when it cools. Excessively high temperatures which then the lower melting polymer to a point where it runs off should be avoided as they tend to exude too much polymer and fail to produce a solid cast structure.

Regardless of the method utilized to induce the required pressure, the actual or optimum pressure applied will vary depending principally upon the particular synthetic polymer components that make up the thread, the softening conditions, the flow viscosity of the softened polymer compound and the nature of the thread construction, i.e. braid, twist, yarn, etc. It is important to note, however, that giving the thread a high level of stretch during the heating operation reduces or eliminates the necessity of applying stretch in any subsequent coating and final sizing stages that may be employed.

The optimum heating temperature employed in a softening operation wherein one of the polymer components is melted will not only depend upon the particular polymer of lower melting point employed but also on the melting point and/or the zero strength temperature of the higher melting polymeric component forming the matrix. In the case of polymers having high crystallinity, the more important consideration is not so much the melting point of the lower melting polymer but rather the temperature at which the polymer reaches a fluidity or viscosity that facilitates exudation. In the case of non-crystalline polymers, on the other hand, only the last criterion applies since non-crystalline polymers do not have a melting point. Usually this temperature is in excess of the melting point of the polymer. For example, to obtain acceptable fluidity with isotactic polypropylene which melts at about 160° C., the polymer should be heated at a temperature within the range of about 180° to 280° C. depending on its molecular weight. Fiber-forming polyethylenes will generally process in the range of about 160° to 275° C. Nylon 66 (polyhexamethylene adipamate) usually will require a heating temperature of about 280° to 295° C. and polyethylene terephthalate a heating temperature of about 270° to 320° C.

Smoothing die temperatures will also be above the melting point of the lower melting synthetic polymer and usually below the melting point of the dissimilar synthetic polymer component. In most instances, the smoothing die temperatures will conform closely to the temperature employed in the heating, i.e. structure formation/precoating stage. Preferably the smoothing die temperature about 5 to 15 degrees below that used in the structure formation/precoating stage.

In a preferred embodiment of the invention, the smooth composite suture structure formed is subjected to coating stage wherein polymer is melt extruded onto the structure. Any of the conventional extrusion apparatuses can be employed for this purpose. The smooth composite suture structure is simply fed through the extrusion coating die and coated with additional polymer of the same type as used in the structure formation, i.e. precoating stage. Optionally, a smoothing operation can follow this stage using a heated die as described above.

The extrusion temperatures employed in the coating stage depend upon the polymer added and generally will conform to those employed in the heating operation. It has also been found that when the coating is done with apparatus of the melt flow rheometer type the higher the coating temperature, other conditions being equal the greater the finished suture diameter. This is due to decreased melt viscosity with increased temperatures which results in increased polymer flow under a given applied force. The thickness of the polymer coating can be easily regulated by changing the applied extrusion force. If the coated suture is to be subjected to a final sizing operation this thickness should be 30–40 microns larger than the required final size.

After a coating stage, the coated thread preferably undergoes a final size stage. Ordinarily, a thread leaving the coating stage is thicker than the USP size limits. In order to bring it to USP size requirements, a size or calibration process is carried out. The final sizing in such cases is made by passing the coated suture through the calibration die, preferably a non-split die. In addition to its sizing function the calibration die has additional operations: (a) all possible homogenicities in the coating are eliminated (b) squeezing the coated suture through the hot calibration die results in additional co-melting of the polymer in the sheath with the polymer on the surface of the precoated thread, thus improving the adhesion of the coating to the thread and (c) if for some reason the flow rate of the polymer melt changes at extrusion during the coating stage, it results in increased thickness of the coating. The calibration die will control the final thickness by scraping off excess polymer coating.

The coated suture should contact the walls of the calibration die while still in the molten state, in order to prevent abrasion of cold polymer coating passing through the calibration die. The distance between the outlet of the coating die and the calibration die should be minimal in order to secure a coated suture which is sufficiently rigidified so that when it goes through the calibration die it takes the shape of the die but at the same time it should be soft enough to give a smooth finish. Distances of 5 to 7 cm have been found suitable. On leaving the coating die the coating thickness of the suture should be significantly larger (by 30–40 m) than the inner diameter of the calibration die in order that the space in the capillary part of the die and the entrance to the die will always be filled by the polymer melt. On the other hand, too heavy a coating will cool faster leaving the coating die and will not be heated up rapidly enough to pass through the calibration die. This will disturb the scraping action and will produce breaks in the suture or a rough surface.

When softening of the second synthetic is effected by the use of solvent, the solvent selected will depend, of course, upon the nature of the first component of thread treated since the latter must not soften during the operation. The following are illustrative of solvents generally suitable for use in softening exemplary types of synthetic polymers:

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Polyesters—mixtures of halogenated hydrocarbons (e.g. methylene chloride) and halogenated alkanols (e.g. hexafluoroisopropanol).

Aromatic polyamides—strong acids and bases

Nylons—phenols

Polyolefins—aromatic hydrocarbons (e.g. xylene, toluene)

The synthetic/polymer components selected for compositing in accordance with the present invention are without limitation provided they are toxicologically acceptable, fiber- or film-forming polymers, possessing softening points sufficiently distant from each other to permit softening of one without softening or otherwise degrading the other. Thus, the synthetic polymers can be thermoplastic or non-thermoplastic polymer materials illustrative of which are homopolymers and copolymers of a olefins of 1–6 carbons, e.g. polyethylene, polypropylene, polybutene, polyisobutylene, copolymers of ethylene and propylene and the like; polyacrylates such as polymethacrylate, polyethacrylate, and the like; polyamides such as Nylon 66, i.e. poly(hexamethylene adipamide), Nylon 610, i.e. (polyhexmethylene sebacamide), Nylon 6, i.e. polycaprolactam; aromatic polyamides, such as those described in U.S. Pat. Nos. 3,063,966; 3,600,350; 3,671,542 and 3,819,587, all incorporated herein by reference, particularly poly(p-benzamide); poly(p-phenylene terephathalamide); poly(2-chloro-p-phenylene terephthalamide; poly(2,6,-dichloro-p-phenylene-2, 6-naphthalamide; poly(p-phenylene-p,p-biphenyldicarboxamide; poly(p, p'-phenylene benzamide and poly(1,5-naphthylene terephthalamide); copoly(p,p'-diaminobenzanilide terephthalamide; polyesters of difunctional carboxylic acids and diols such as polyethylene terephthalate, poly(1,4-cyclohexylene dimethylene terephthalate); polystyrene; poly(acrylonitrile); polyurethane, polyethers, polyvinyls, polypeptides such as polylactides, polyglycolides and copolymers of lactide and glycolide with each other and with other reactive monomers such as those described, for instance, in U.S. Pat. Nos. 3,636,952 and 2,683,136, incorporated by reference herein; and polymers of p-aminobenzoic acid.

Illustrative of suitable composite threads for treatment in accordance with the present invention are set forth in the following Table I:

TABLE I

Composite	Matrix	Extruding Polymer
1	polyethylene terephthalate	isotactic polypropylene
2	Kevlar[1]	polypropylene
3	Kevlar[1]	polyethylene
4	Kevlar[1]	polyethylene terephthalate
5	chain extended polyethylene[2]	atatic polypropylene
6	Kevlar[1]	polyglycolic acid
7	Nylon 66	isotactic polypropylene
8	Nylon 66	polyisobutylene
9	polyethylene terephthalate	Nylon 11

[1]aromatic polyamide product of DuPont Corporation

[2]high strength polyolefin yeae having straight pull tenacity of approximately 25-50 g/denier described in Keller A. and Barham, P. J., "High Modulus Fibres", Plastics and Rubber International, Feb. Vol. 6, No. 1 (1981) incorporated herein by reference.

The following examples are included to further illustrate preparation of composite sutures of the invention. In the examples, reference is made to the following brief description of the drawings wherein:

FIG. 1 is a schematic drawing of an apparatus useful in the three stage melting method of the present invention and

FIG. 2 is a schematic drawing in section of a spinneret useful in the extrusion coating of the formed composite suture employed in the apparatus of FIG. 1.

EXAMPLE I

Structure Formation or Precoating Stage

Directing attention to the drawings, using a conventional New England Butt braider machine polyethylene terephthalate (PET) strands of 40 denier are braided around a single core of 265 denier isotactic polypropylene to form a 4/0 raw or precursor thread with 4 ends of 40 denier PET in the cover and 1 end of 165 denier polypropylene in the core. The raw braid, wound around a reel 2, is fed through a guide 4, between nip rollers 5 about a feed roll (Godet) 6, through guide 8 into a heated 10 cm long tubular over inside Spinneret I designated 11 in FIG. 1. The lumen of Spinneret I without polyolefin feed serves this purpose, Heated Zone I in FIG. 1. A roll (Godet) 13 pulls the raw braid through the oven at a stretch ratio (SR) of 1.24. The heating oven is maintained at a temperature of 230° C. Under these conditions all the polypropylene melts and is entirely distributed throughout the braid interstices and onto the surface of the braid. No solid polypropylene core residue remains.

As the braid emerges from Spinneret I, large quantities of excess polypropylene which has melted out and formed nubs on the surface is trimmed off by a smoothing die 12 having an internal diameter (ID) of 0.180 mounted at the outlet of Spinneret I. The braid then continues through a Guide 15 to Spinneret II designated 39 which is an extrusion coating die apparatus shown in detail in FIG. 2.

Coating Stage

The smoothed precoated braid is pulled through Spinneret II by a roll (Godet) 50. Tension is let down on roll 50 so that some overfeed, i.e. a stretch ratio (SR) of approximately 0.9 is applied. Isotactic polypropylene chips are melted in heated reservoir 41 maintained at a temperature of 260° C. and the melt is forced by means of extruding weights 43 applying a force of 0.233 kg to a piston 45 into and through the tubing-type extrusion coating die apparatus 39.

Directing particular attention to FIG. 2, the extruding coating apparatus 39 is comprised of a holder indicated generally as 47 which houses a hollow guide tube 49 and a die holder 50 which retains a die 51. Die 51 has an outlet 52. The guide tube 49 is essentially positioned within the holder 47 so as to provide an annular chamber 53. A Teflon gasket 55 seals one end of the guide tube 49 within the holder while the other end is connected to die 51 and sealed by aluminum gaskets 54, 56 and 58. The guide tube contains an inlet 59 and an outlet 61. Between outlet 61 and outlet 52 of the die 51 is positioned a hollow needle 63. The polypropylene melt from heated reservoir 41 is forced by piston 45 through channel 65, into annular chamber 53 and over needle 63. The impregnated/precoated thread 65 passes consecutively through guide tube 49, hollow needle 59, outlet 52 and is coated with the melt as it emerges from the due 51. The coating die is maintained at a coating temperature of 230° C.

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Final Sizing or Calibration Stage

The coated thread is passed to a Spinneret III designated 66 whose design is like that of Spinneret I except that a calibration die 67 (see FIG. 1) having an internal diameter of 0.220 mm is employed so as to provide a finished 4/0 suture. Spinneret III is positioned approximately 5 cm from the outlet of Spinneret II so as to provide a coated thread cooled to a rigidity that allows the coated thread when it enters Spinneret III to take the shape of calibration die 67 but is soft enough to give a smooth finish. The working temperature of Spinneret III is 220° C. Some overfeed (Stretch Ratio, SR approximately 0.9) is applied in the finishing stage as in the coating stage so as to improve the smoothness of the final product.

The finished suture is finally wound around receiving reel 69 and identified in the Table II below as CK suture 4–0.

Sutures of 3–0, 5–0 and 6–0 diameter size were similarly prepared and the mechanical properties of these sutures, identified below as CK sutures 3–0, 5–0 and 6–0 as well CK Suture 4–0 are reported in Table II. Also included for purposes of comparison are the mechanical properties of commercial sutures of like size.

TABLE II

No.	Type of Suture	Knot-pull Tensile Strength, P_{knot} (g) Required by USP*	Knot-pull Tensile Strength, P_{knot} (g) Measured	Percent Elongation (%)	Knot Security K_{sec}	Knot Security $n_{knot}-1/5$	Gurley Stiffness G.S. (mg)
1	CK Suture 3-0	1200	1456	15.0	2	—	8.2
2	Prolene 3-0 (from Ethicon)	"	1504	58.3	3	$n_2/5 = 5$	19.8
3	PP Yellow Monofil. 3-0 (from Thiokol)	"	1430	39.4	3	$n_2/5 = 5$	24.9
4	Nylon White Monofil. 3-0 (from Deknatel)	"	1434	50.4	4	$n_3/5 = 5$	22.8
5	PET Monofil. 3-0	"	2430	76.1	3	$n_2/5 = 5$	52.0
6	CK Suture 4-0	750	930	12.8	2	—	5.9
7	Prolene 4-0 (from Ethicon)	"	946	56.7	3	$n_2/5 = 5$	9.9
8	PP Blue Monofil. 4-0	"	841	29.1	3	$n_2/5 = 5$	14.4
9	Nylon White Monofil. 4-0 (from Deknatel)	"	950	47.8	4	$n_3/5 = 5$	12.6
10	PET Green Braid Suture 4-0	"	1146	16.5	4	$n_3/5 = 1$	3.0
11	CK Suture 5-0	500	649	14.2	2	—	2.2
12	Prolene 5-0 (from Ethicon)	"	646	44.9	3	$n_2/5 = 5$	3.1
13	PP Blue Monofil. 5-0	"	532	31.5	3	$n_2/5 = 3$	5.9
14	Nylon White Monofil. 5-0 (from Deknatel)	"	577	51.0	4	$n_3/5 = 5$	5.4
15	PET Green Braid Suture 5-0 (from Deknatel)	"	770	25.2	4	$n_3/5 = 1$	0.6
16	Suture 6-0	250	318	11.0	2	—	0.4
17	Prolene 6-0 (from Ethicon)	"	270	50.0	3	$n_2/5 = 4$	0.6
18	PP Blue Monofil. 6-0	"	192	29.9	3	$n_2/5 = 5$	1.1
19	PET Monofil. 6-0	"	485	37.0	3	$n_2/5 = 5$	3.3

*The limits on P_{knot} apply to non-sterile sutures.

RESULTS

Knot-Pull Tensile Strength

Sizes 3–0, 4–0 and 5–0 CK Sutures have the same F knot as Prolene and Nylon Monofilaments (the differences being within the limits of 3% except for Nylon 5–0 which is 12% weaker than CK Suture 5–0). It should be noted that the values of 5–0 sutures are 20–30% higher than required by U.S.P. In size 6–0 the F knot of the CK Suture is 18% higher than that of Prolene. PP monofilament (blue) is remarkably weaker than the CK Suture (the difference increases from 11% in size 4–0 up to 66% in size 6–0).

PET sutures have F knot values higher than CK Sutures. PET Monofilaments of 3–0 and 6–0 have F knot values 50–60% higher than CK Sutures of the same size. For PET Braid Suture 4–0 and 5–0 the difference is about 20%.

Gurley Stiffness

By comparing all materials having the same 3–0 size (samples 1–5, all of them monofilaments) it is seen that the CK Suture 3–0 has the lowest Gurley Stiffness (G.S.). Size 3–0 polypropylene monofilaments (Prolene from ethicon and PP from Thiokol) and nylon monofilament (from Deknatel) have G.S. 2.5–3 times higher than that of similarly sized CK Suture. PET 3–0 monofilament has the highest G.S. —6.3 times higher than that of the CK Suture.

When comparing G.S. of size 4–0 materials (samples 6–10) it can be seen that the G.S. of Prolene 4–0 is still remarkably higher (by 68%) than that of the KC Suture but, on the other hand, the G.S. of PET 4–0 multifilament suture from Deknatel is two times lower than that of CK Suture 4–0. Such a result is not surprising when comparing the stiffness of multifilament with monofilament yarns.

In the size 5–0 the G.S. of CK Suture is 39% lower than that of Prolene, but 3.9 times higher than that of PET 5–0 multifilament.

It may be safely stated that, when comparing CK Suture with other sutures of the same size, the G.S. of CK Sutures is remarkably lower than that of Prolene, PP, PET and Nylon monofilaments. This difference is particularly high when comparing with PET monofilaments of the same size. On the other hand, the G.S. of CK Sutures is remarkably higher than that of PET multifilament sutures. This results from the structure of CK Sutures.

Elongation

The P.E. of CK Sutures of all sizes varies from 11% to 15%. The P.E. of other monifilament sutures is much higher, for example: P.E. of Prolene in all sizes varies

from 45% to 58%; of PP monofilament from 29% to 39%; of Nylon monofilament from 41% to 51%; and of PET monofilament from 37% to 76%. Only P.E. of PET multifilament suture 4-0 (16.5%) is close to the desired value.

Knottability

Knottability results show that the CK Suture has the lowest stiffness and elongation when compared with other monofilament sutures. It can, therefore, be stated on the basis of these two quantitative parameters, that the knottability of the CK Suture is better than that of any other monofilament suture.

Knot Security

It may be seen from the Tables that all investigated materials can be divided into 3 groups with corresponding k_{sec} = 2;3 and 4. CK Sutures belong to the group with k_{sec} = 2. All Prolene sutures, PP monofilaments and PET monofilaments belong to the second group with k_{sec} = 3. PET braids and nylon monofilaments belong to the third group with k_{sec} = 4. It means that with CK Sutures, a secure knot can be tied using only two throws (Square Knot. All other investigated materials need at least one additional throw for secure knot formation and nylon monofilaments and PET braids need even two additional throws.

Microscopic examination (250×) of a cross-section of the finished suture shows virtually no dead spaces present. The finished suture is free of stripping and cracking and possesses the smoothness of a monofilament.

In commercial production, needles may be attached to one end of the composite sutures of the invention and the sutures may be packed in sterile containers. Inasmuch as the sutures are stable for long periods of time without a conditioning fluid, the sutures may be dry packed in glass tubes or plastic envelopes. Conditioning fluid may be used to assure maintenance of sterility or as a rule preventing medium for the needle. Eyeless needles are preferred since they cause less tissue damage. Conveniently, the composite sutures of the present invention are formed at convenient lengths, attached to eyeless needle, wound on reels if desired, and placed in containers such as plastic envelopes. The sutures may then be sterilized with ethylene oxide or other conventional gaseous sterilizing agents in accordance with known practices. Alternatively, the sutures may be sealed in the envelopes and then sterilized by using heat and radiation including x-rays, gamma rays, electrons, neutrons, etc.

EXAMPLES II-IX

Example I is repeated using the following synthetic materials as the matrix and core, i.e. lower melting point component and conducting the heating in Heating Zones I and II as indicated.

Example	Matrix	Core	Spinneret I, °C.	Spinnerette II & III, °C.
II	Kelvar(1)	isotactic polypropylene	220	220
III	Kevlar(1)	polyethylene	225	220
IV	Kevlar(1)	polyethylene terephthalate	265	265
V	chemically crosslinked polyvinylethylene(2)	atactic polypropylene	70	65
VI	Kevlar(1)	polyglycolic acid	238	230

-continued

Example	Matrix	Core	Heating Zone I, °C.	Heating Zone II, °C.
VII	Nylon 66	isotactic polypropylene	230	222
VIII	Nylon 66	polyisobutylene	200	190
IX	polyethylene terephthalate	Nylon 11	237	237

(1) } See Table I, supra
(2) }

It is claimed:

1. A method of preparing a surgical suture comprising forming a thread having interstices therein, comprised of a plurality of fibers of a first synthetic polymer, said thread further comprising second synthetic polymer in intimate association with and present along the length of at least one of said plurality of fibers, said second synthetic polymer having a lower melting point than said first synthetic polymer, heating the thread to a temperature sufficient to liquify the second synthetic polymer but not the first synthetic polymer to cause flow thereof, placing the thread under tension during said melting to compress the thread and redistribute the liquified second polymer throughout the plurality of fibers of said first synthetic polymer so as to substantially fill the interstices of said thread, said liquified polymer being present during said redistribution in an amount sufficient to exude through the interstices of the unmelted fibers and onto the surface of the thread to form a coating thereon and to form an internal cast extending throughout said thread, said internal cast forming an anchor onto which additional second synthetic polymer can be secured, if desired, and sterilizing the resulting thread to form a surgical suture.

2. A method according to claim 1 wherein the second synthetic polymer is in fiber form.

3. A method according to claim 1 wherein the first synthetic polymer is aromatic polyamide.

4. A method according to claim 3 wherein the aromatic polyamide is poly(p-phenylene terephthalamide).

5. A method according to claim 3 wherein the aromatic polyamide is poly(1,4-benzamide).

6. A method according to claim 1 wherein the first synthetic polymer is chain extended, polyethylene having a straight pull tenacity of about 30 to 50 grams/denier.

7. A method according to claim 3 wherein the first synthetic polymer is polyester.

8. A method according to claim 7 wherein the polyester is polyethylene terephthalate.

9. A method according to claim 1 wherein the second synthetic polymer is polyolefin.

10. A method according to claim 9 wherein the polyolefin is polyethylene.

11. A method according to claim 9 wherein the polyolefin is polypropylene.

12. A method according to claim 1 wherein said coating is subjected to smoothing.

13. A method according to claim 12 wherein said smoothing is effected by passing the composite after said heating through a heated smoothing die.

14. A method according to claim 1 wherein the composite formed is coated with the same synthetic polymer as said second synthetic polymer.

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15. A method according to claim 14 wherein the coated composite is subjected to smoothing.

16. A method according to claim 15 wherein said smoothing is effected by passing the composite after said heating through a heated smoothing die.

17. A method according to claim 1 wherein the second synthetic polymer comprises at least one fiber.

18. A method according to claim 17 wherein the second synthetic polymer is polyolefin.

19. A method according to claim 18 wherein the polyolefin is polypropylene.

20. A method according to claim 19 wherein the polyolefin is polypropylene.

21. A method according to claim 1 wherein the first synthetic polymer is a polyamide terephthalate.

22. A method according to claim 21 wherein the polyamide is aromatic polyamide.

23. A method according to claim 22 wherein the aromatic polyamide is poly(p-phenylene terephthalamide).

24. A method according to claim 22 wherein the aromatic polyamide is poly(1,4-benzamide).

25. A method according to claim 21 wherein the polyamide is poly(hexamethylene adipamide).

26. A method according to claim 21 wherein the polyamide is polycaprolactam.

27. A method according to claim 21 wherein the polyamide is poly(hexamethylene sebacamide).

28. A method according to claim 20 wherein the polyamide is poly(w-aminoundecanoic acid).

29. A method according to claim 1 wherein the first synthetic polymer is polyester.

30. A method according to claim 29 wherein the polyester is polyethylene terephthalate.

31. A method according to claim 1 wherein the first synthetic polymer is extended polyethylene having a straight pull tenacity of about 30 to 50 grams/denier.

32. A method according to claim 1 wherein the first synthetic polymer is polypropylene, the second synthetic polymer is polyethylene terephthalate and the softening achieved by heating the composite to a temperature of about 180° to 280° C.

33. A method according to claim 1 wherein the first synthetic polymer is polyethylene terephthalate the second synthetic polymer is polyethylene and the softening is achieved by treating to a temperature of about 160° to 275° C.

* * * * *

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June 8, 1965 A. GLICK 3,187,752

NON-ABSORBABLE SILICONE COATED SUTURES AND METHOD OF MAKING

Filed April 27, 1962

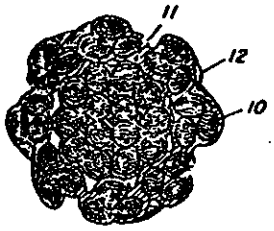

Fig. 1

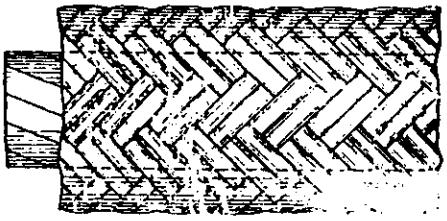

Fig. 2

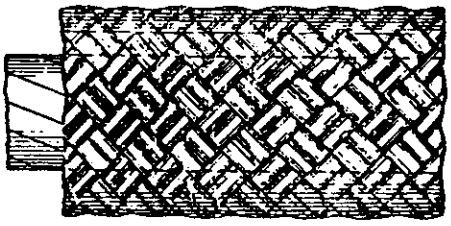

Fig. 3

INVENTOR.
ARTHUR GLICK

BY
Samuel Brand Kelly
ATTORNEY

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3,187,752
NON-ABSORBABLE SILICONE COATED SUTURES AND METHOD OF MAKING
Arthur Glick, Danbury, Conn., assignor to American Cyanamid Company, Stamford, Conn., a corporation of Maine
Filed Apr. 27, 1962, Ser. No. 190,604
26 Claims. (Cl. 128—335.5)

This application is a continuation-in-part of application Serial Number 767,502, filed October 16, 1958 and now abandoned.

This invention relates to a non-absorbable densely constructed suture built up of a plurality of filaments having a serum-proof, moisture-resistant coating on the surface of the individual filaments, which coating contains a silicone resin.

As used in this specification the term "suture" is intended to include both sutures, such are used for the sewing of tissues, and ligatures as used for tying off blood vessels, etc. Different portions of one strand may be used for both purposes in the same operation depending upon the needs of the surgeon at the particular moment.

In surgical practice; and for present purposes, this includes both human and animal surgery, two classes of sutures are commonly used. One is the absorbable suture which is absorbed by the tissues and accordingly loses its identity, such sutures usually being of catgut, etc; and the other form is a non-absorbable suture which in most instances is permitted to remain as such permanently in the tissues, but which is sometimes removed from the tissues at an appropriate phase of the healing process. Such non-absorbable sutures must be strong and should maintain their strength and integrity for prolonged periods while in contact with body tissues and fluids. It is desirable that such sutures be inert, causing a minimum of tissue irritation, and that the diffusion of fluids through the suture by capillarity be at a minimum.

It has been customary to use silk sutures built up as by braiding, weaving, twisting or spinning, hereafter called coordinate configuration, of from a a plurality of individual silk filaments. Synthetic polymers may be used instead of natural silk. These filaments present a construction in which there are fine interstices which by capillary action cause fluids to travel along these length of the suture. This may permit migration of pathogenic organisms.

Accordingly, such sutures have been coated with waxes, such as beeswax, or beeswax mixed with ethyl cellulose, which material reduces the capillarity of the suture and improves the handling characteristics of the suture.

There is some evidence that under some conditions these waxes cause granuloma formation, and have other undesirable side effects.

Additionally the coating material should be inert to all body fluids and heat stable to permit heat sterilization of the suture. It is desirable that the coating be economical and readily applied.

In addition to the physiological properties of inertness the characteristics of handling and of strength of a suture are extremely important. It is desirable that a suture be sufficiently stiff that it can be easily handled and yet readily formable to a a new position. After being bent to a new position, it should maintain this new set position. Many fibrous materials have a plastic "memory," and after being bent to a new position slowly on standing tend to go back to thetheir former shape. A suture should not have plastic "memory" but should when once set maintain that new position.

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Additionally the suture should be easy to tie into a knot and should be resistant to knot-slippage under tension and the knot should remain secure and not slip or unravel itself on standing. Additionally, a suture should have what is known as "throwability." That is, the surgeon should be able to pick up the suture and throw it into a new position, which position is then retained. It is desirable at times to place a suture in a given location or throw it in a given direction with the knowledge that the suture will stay there until positively moved.

In the past a great deal of the handling characteristics have been imparted to a limp suture by the coating material. Beeswax or beeswax mixed with ethyl cellulose used as a coating is responsible for the desirable handling characteristics.

If some other coating material is used with the same filament construction, the sutures may not have satisfactory handling characteristics.

It has now been found that by braiding a suture with a tighter and more dense construction using fewer picnicks, i.e. cross-overs per inch, and by dry stretching the braided filaments, a suture can be formed which has inherently stiffer qualities and improved handleability.

Silk is the usual material used for non-absorbable sutures. Synthetic filaments such as nylon, polypropylene, "Orlon," polyacrylonitrile, "Dacron," a stretched oriented polyester of ethylene glycol and terephthalic acid, etc., or cotton, or linen are sometimes used. Occasionally such materials as stainless steel or horsehair are used. All such materials can be advantageously coated with polymeric silicones, in accordance with this invention, and are braided or spun or formed more tightly for coating with silicones than with conventional coating materials.

Polymeric silicones are applied to this dense structure; such polymeric silicones readily coat the individual filaments increasing the resistance to aqueous fluids thus reducing capillarity. Furthermore, such silicones applied as a coating are heat stable. In at least some instances the coating may be applied in a partially polymerized state and the silicone further polymerized in position on the suture. Fortunately and fortuitously, polymerization catalysts are decomposed by heat sterilization procedures or heat curing so that even if toxic catalysts are used as a component of the silicone coating, the final product is completely inert.

The particular silicone resins themselves are not a part of this invention and standard commercial resins may be used. It is not necessary that the materials be applied as a liquid, as some of these silicone resin containing materials, such as the General Electric "Dri-Film," are volatile and may be applied in the gaseous phase. These materials are among the volatile silicone compounds such as alkyl silicone halides. A material such as dimethyl silicone dichloride is comparatively volatile and may be applied either direct or by allowing it an ethereal solution thereof to evaporate and the vapors contact the suture material.

Frequently, it is more convenient to use a liquid preparation. Such preparations are solvent dispersions of "silicone resins," that is partially polymerized products which will polymerize to a silicone film. For purposes of convenience it is normally easier to purchase the material under trade-names rather than making it, or obtain it to a performance specification. Materials which are sold commercially such as the Dow-Corning silicone "DDC 803" or "DC 804" or General Electric's "9980" give highly satisfactory and useful films. To those skilled in the art of silicone compounding it is comparatively simple to select a heat-curable or potentially heat-curable silicone resin, which either from its inherent characteristics, or

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the addition of a polymerizing catalyst, will set up or cure. As a final check to insure the complete removal of all halide to silicone linkages, ammonia fumes may be used. Usually sufficient moisture is present to insure the hydrolysis of the halogen, but ammonia fumes insure a neutral product. If desired, silicone containing resins may be used in which the silicone atoms are linked through nitrogen, from ammonia, rather than through oxygen as in the silicones, such resins at times being referred to as silamines.

Methods for preparation of silicone resins are well known. Patent No. 2,306,222 to W. I. Patnode, "Method of Rendering Materials Water Repellant," discloses the use of a vapor of an alkyl silicone halide for making glass vapor-proof. The same types of materials as therein described may be used to water-proof and treat sutures. The patent to Safford, No. 2,424,853, and the patent to Tanis, No. 2,408,822, additionally describe siliceous halides and their conversion to resins. There are several methods of preparing such silicone resins, among others are the reaction of Grignard type reagents with a silicone tetrahalide. From the standpoint of costs silicone tetrachloride is normally used and the Grignard may be either alkyl or aryl or a mixture thereof. The amounts of alkyl and aryl groups used affect the brittleness and rate of cure of the resin formed. Normally the product of the reaction of the Grignard reagent with silicone tetrachloride is allowed to react with moisture, allowed to partially polymerize, and the partially polymerized materials are dissolved in a suitable solvent whereby additional polymerization is either inhibited or substantially slowed down. The higher the ratio of lower alkyls, the more rapid the materials will cure and the more brittle will be the film. The more highly branched the chains formed in the resin, which are necessarily formed by the polymerization of the silicone types containing more halide atoms per silicone molecule, the more brittle and polymerized are the resins.

The organo-silicones sometimes referred to as organopolysiloxanes, more particularly the hydrocarbon substituted polysiloxanes are particularly suitable for suture coating. The patent to Wright et al., No. 2,389,477, entitled "Polysiloxane Resins" gives considerable information of this type of resin. Certain of the resins which are described in the patent to Hyde, No. 2,386,466, "Insulated Conductor and Insulation Therefor," if diluted with a solvent may be used in accordance with the instant invention. The patent to Hyde, No. 2,371,050, "Organo-Silicone Polymers and Method of Making Them," describes certain additional methods of preparing such resins. It is not necessary that the resins be prepared from halogen containing compounds as, for example, methods such as set forth by Strain et al. in Patent No. 2,394,642, "Silicic Acid Esters," describes a different form of silicone containing resin. The patent to Iler, No. 2,395,550, "Modified Alkyd Resins," describes still further modifications of silicone containing resins in which the silicone linkages are different than those classified as organo-polysiloxanes.

It is not intended that a treatise be here included on the production of such resins, as such resins are the invention of others and are adequately described in the patent literature, as well as elsewhere. The texts "Introduction to the Chemistry of the Silicones," Eugene G. Rochow, John Wiley & Sons, Inc., New York, 1946, and "Silicones and Their Uses," Rob Roy McGregor, McGraw-Hill Book Company, New York, 1954, give many useful details.

A pamphlet "Silicones in Medicine and Surgery," Rob Roy McGregor, Dow-Corning Corporation, 1957, discloses some of the silicones which may be used, and other medical usages for such silicones.

The silicone acts as a protective layer on the surface of the filaments, and prevents dyes or the surface characteristics of the filaments, such as silk, from interacting with body fluids. In neural surgery, suture materials frequently deleteriously affect regeneration of nerve fibers. Silicone coated silk is the first material known to have been successfully used in suturing nerve fibers which permits the regeneration of the nerves in the spinal column.

Usually silk is braided loose enough for a beeswax coating to impregnate the silk, reduce capillarity, and impart desirable handling qualities. The new silicone coating may not inherently have enough body to give the desired handling qualities. Rather than use a more highly polymerized silicone resin, which is stiffer, it is preferred to use a denser silk construction, with more silk filaments in a given cross-section. This gives a greater strength, and a thinner silicone coating gives a proper inertness to the suture and at the same time prevents capillarity.

One standard test for capillarity is to boil two 3 to 4 inch lengths of the suture in distilled water in a glass container for three successive 20-minute periods, changing the water each time. After the third boiling, the test sutures are allowed to stand for at least 8 hours in an atmosphere having a relative humidity of 65% ±2% at a temperature of 21° ±1° C. The segment of suture is tied to a piece of white silk thread with a square knot, the ends cut close, and suspended by the white silk thread so that the suture dips into a 0.5% aqueous solution of methylene blue, with the knot ¾-inch above the dye solution. After standing for 24 hours, the white silk is inspected for evidence of dye carried up the suture by capillary action. If the white silk is free from dye color, the suture is non-capillary, and passes the test. Both of the duplicate samples should pass.

Sutures of this invention pass this test for capillarity. Sutures which pass this test are non-capillary in tissues of man and animals.

For preventing slippage at knots in the suture, a coating forming a hardened, but flexible silicone film is preferred, using a silicone having a higher ratio of aryl groups. For instance, a polysiloxane having from about 72% to 67% methyl substituents and from 28% to 33% phenyl groups cures to a non-slipping finish that gives excellent knot retention. Usually the suture breaks before the knot slips. Also such polysiloxanes are sufficiently adhesive that spun sutures of silk or other filaments do not unravel, or "broom," and can be threaded into needles.

The silk construction itself rather than the coating can be used to give the handling qualities.

Whereas the number of ends, and total denier, varies with size, it is desirable that a maximum size, and strength be obtained within the overall limits of suture diameter. For the standard United States Pharmacopeia sizes (United States Pharmacopeia Convention, Inc., Distributed by Mack Publishing Co., Easton, Penn., elsewhere abbreviated U.S.P.) this is:

U.S.P. size	U.S.P. diameter, inches, max.	Picks per inch	Denier of raw silk used
6-0	0.004	60	117
4-0	0.006	60	283
3-0	0.008	60	378
2-0	0.010	60	630
00	0.011	50	900
0	0.012	50	1,260

The picks per inch are the number of threads, running in one direction, per lineal inch of suture.

The silk is braided using a smaller number of picks than conventional, and with a larger core size. The braided silk is washed to degum, then dyed, if desired, in skeins in accordance with conventional practice. The silk is dried, and then dry stretched from about 6% to about 11% of its length. This stretching tightens the braid, and gives a more dense, more handleable silk. At least some of the stretching may be accomplished while the silk is wet.

After stretching the silk suture is passed through a solvent bath containing the polymeric silicone. Such solvents as xylene; toluene, benzene, gasoline, or other non-toxic volatile hydrocarbon solvents may be used. In addition to the silicone, beeswax, ethyl cellulose or a low molecular weight polyethylene may be dissolved and used as part of the coating. For the silicone rubbers, a catalyst is usually used to accelerate the curing rate. The standard organic peroxides, of which benzoyl peroxide is the most frequently used, are suitable catalysts, 2% to 20% by weight of the polymer gives good results. The heat which sets the resin decomposes residual peroxides to give non-toxic products. For the hardened, flexible films, having a higher percentage of phenyl groups, heat alone can cure the silicone. Organo metallic driers such as zinc octoate, or iron stearate accelerates the cure. Non-toxic salts of metals with fatty acids are effective.

A 2% to 50% solids bath gives a satisfactory coating.

A 5% to 30% solids concentration in the bath results in easier operating control. A 20% concentration is usually preferred. While an adequate pick up with a single coating bath is obtainable, more uniform distribution and coating can be obtained by using two or more baths, with heat curing between coatings. A cure temperature of at least 150° C. for 30 seconds gives a cure, although longer times at lower temperatures, or a longer cure with less catalysts, etc. in accordance with standard practice in the silicone art may be used.

A total weight of coat of 2% to 20% by weight of the fiber gives good characteristics. This percentage is called the pick up.

The sutures are shown in the attached drawings:

FIGURE 1 is a cross-section of a silicone coated suture.

FIGURE 2 shows a portion of an eight carrier on a 16 capacity carrier braider formed braid.

FIGURE 3 shows a portion of a sixteen carrier braid.

EXAMPLE 1

A silk suture is braided, using 8 carriers, on a sixteen carrier braider, with 3 ends of 13 to 15 denier silk per carrier, and a core of 3 ends of 13 to 15 denier silk, and 40 picks per inch, giving the skipped braid of FIGURE 2. The raw silk used has a total of about 378 denier. (The denier is the weight in grams of 9000 meters of the strand.) The braided suture is washed to degum, then dried, while looped in skeins. The dry silk is stretched 9% of its length, which gives improved stiffness; and increases the density.

A silicone rubber sold as "Silastic 9711" by Dow-Corning is milled into sheets of about ⅛-inch thick, and thereto while milling additionally is added 8.46% by weight of the rubber of a silicone fluid containing 50% by weight benzoyl peroxide (Luperco ASF). After milling for an additional 5 minutes, the sheets are cut into small pieces and soaked overnight in xylene. The swollen silicone is stirred to a cream-like consistency, then diluted to 20% solids, and stirred until uniform.

The braided silk is immersed in a trough of the silicone solution at room temperature, then wiped over a piece of white felt. The coated silk is passed through a three stage heating tunnel, so that the silk is heated for one minute each at 100° C., 125° C., and 150° C. The silk is spooled after air cooling.

This coating procedure is repeated. In the double coating, the silk is found to have picked up 15% by weight of the silicone coating.

The finished suture gauges 0.0077 inch in diameter and is a 4–0 suture.

A conventional braiding of a 4–0 suture gives about 60 to 70 picks per inch, and uses 8 carriers with 2 ends of 20–22 denier each, and no core. Such a silk suture has a total denier of about 336, and if coated with beeswax in accordance with conventional practice gauges .0085 inch.

Other characteristics for comparison are:

	Silk With New Silicone	Silk With Old Reservoir
Picks per inch	40	40
Gauge:		
Raw, inches	.0076	.0081
Sterilized, do	.0077	.0083
Straight pull sterilized, pounds	2.17	2.08
Knot pull sterilized, do	2.04	1.80
Pliability to bend, raw, mgs.	.127	.102
Stiffness—inches self support:		
Horizontal (sterile), inches	2.04	4.75
Vertical (sterile), do	4.00	5.13
Apparent density as braided, gms./cc.	1.127	0.927

The increase in strength after sterilization both straight and over a knot shows the new silicone construction to have marked advantages.

The suture is sterilized either by conventional autoclaving procedures, or by ethylene oxide gas, in accordance with commercial practice in the industry.

The individual silk filaments of the braid are shown at 10, the filaments of the core are shown at 11, and the suture has a silicone coating 12. FIGURE 2 shows the construction of a 000 suture, otherwise the same as above.

EXAMPLE 2

The coating of the suture of Example 1 is repeated using a 15% solids solution of a dimethy silicone polymer of the general formula $((CH_3)_2SiO)_n$ with 5% by weight of the polymer of benzoyl peroxide as catalyst. After two coatings, a readily handleable suture is obtained.

EXAMPLE 3

A multi-filament 4–0 sized silk suture braided as in Example 1 is washed and dyed black in accordance with conventional procedures. The suture is then dry stretched. An alkyl polysiloxane sold by General Electric as "DC-film 88" is diluted with toluene to form a 10% silicone solids solution. The silk suture is immersed in the solution of the silicone resin at 50° C., then drawn through a curing tunnel at a temperature of 130 C., and of such length as to heat the silk suture for two minutes. The suture may be heated longer, so as to sterilize the suture at this time after which it is sterilely packed and handled until used by the surgeon; or after the two-minute heating, the suture may be reeled and packaged using clean but not sterile techniques and finally sterilized by dry heat after packaging and prior to sale, or just prior to use by the surgeon.

EXAMPLE 4

A 4–0 silk suture braided, washed, and dried as described in Example 1 is immersed in a 10% solids solution of the polymerizing silicone resin commercially known as Dow-Corning 804. This resin is a comparatively short chain silicone resin containing both phenyl and methyl substituents on the silicone atoms. The silk suture is immersed in the solution of the silicone, the excess wiped off with a piece of felt, and the coated suture cured by passing through a curing tunnel in which the coated silk is heated to 130° C. for three minutes. The silk suture may be sterilized by heating, as desired, but before use. About 12% by weight of the silk of the silicone remains in the coating.

EXAMPLE 5

The silicone rubber sold as Dow-Corning "Silastic 9711" is milled with 4.2% of benzoyl peroxide for five minutes, cut into small pieces, covered with xylene, and soaked overnight. The swollen material is stirred with additional xylene to obtain a 20% solids concentration. Braided silk prepared as described in Example 1 is passed through the silicone in xylene, wiped with a piece of white

felt, then cured for one minute each at temperatures of 100° C., 125° C., and 150° C. The silk picks up about 10% by weight of silicone solids. The silk suture is heat sterilized before use. The thus prepared suture is used in operations to suture tissues after surgery. The suture is found to be satisfactory and causes a minimum of tissue irritation and deleterious after-effects.

A pigment or dyestuff may be added to the coating solution if desired. Such coloration of the coating is particularly useful for synthetic filaments which are difficult to color.

EXAMPLE 6

A multi-filament size 3–0 braided polyester suture was coated in two passes with a silicone rubber bath containing 17% silicone solids dispersed in xylene. The coating and curing procedure was as described in Example 5. The suture picked up 2.9% by weight of silicone solids. The polyester suture was non-capillary.

EXAMPLE 7

A multi-filament 2–0 silk suture was braided using 16 carriers each containing 3 end 15 denier silk; a core of 14 ends 20–22 denier silk; a pick count of 50; and a total denier of 966. The construction is of the type shown in FIGURE 3. The braided suture was coated with a methyl phenyl polysiloxane which contains about 72% methyl groups and 28% phenyl groups. The coating bath contained 35% silicone solids in xylol. The excess coating was wiped off with a piece of sponge rubber and the coating was cured for one minute each at temperatures of 100° C., 125° C., and 150° C. The silk picked up 7% by weight of silicone solids for one coat. A second coat under the same conditions yielded a total pick up of 12%. The silk at both coating levels was non-capillary, had good hand and showed good resistance to brooming. Surgeon's knots tied in the silk broke before slipping.

EXAMPLE 8

A multi-filament spun, or twisted, 3–0 silk suture was coated with a methyl-phenyl polysiloxane, processed and cured as in Example 7. The spun and twisted silk had a silicone pick up that ranged from 7% for a single coat to 12% for a double coat. The silk did not broom or bush and the filaments were bonded together, so that a needle could be readily threaded.

EXAMPLE 9

A multi-filament size 3–0 braided nylon suture was coated in two passes in a silicone rubber bath containing 17% silicone solids dispersed in xylene. The coating and curing procedure was that described in Example 5. The nylon suture picked up 4.5% by weight of silicone solids and was non-capillary. Good results were obtained when used in surgery.

EXAMPLE 10

A multi-filament braided 3–0 suture was coated with a bath containing 30% solids of a silicone resin commercially sold as Dow-Corning 804. This resin is a comparatively short chain silicone resin containing both phenyl and methyl substitutents on the silicone atoms. Added to this bath was a plasticizer amounting to 20% of the weight of the silicone solids. The silk was immersed in this bath, the excess silicone wiped off with sponge rubber and the silicone was cured in a tunnel for one minute each at temperatures of 100° C., 125° C., and 150° C. The silk for a single coat had a silicone pick up of 7% of the weight of the silk. Silk with two coats had a pick up of 12% silicone resin. Silk coated in this resin bath and the added plasticizer had good hand, was non-capillary and did not broom. Plasticizers used were alkyl aryl phosphates, phthalates, sebacates, citrates, epoxies and polymeric dimethyl siloxanes.

The polysiloxanes containing larger proportions of aryl groups require larger amounts of plasticizers. The pick up can be readily varied by the pressure on the wipers. A slower cure at a lower temperature gives a good coating. A more rapid cure is generally preferred, as the cure most conveniently takes place in a tunnel, and if a slower cure is used the tunnel must be longer for a given production rate and hence is more expensive.

I claim:

1. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 6–0; picks per inch 40; denier of raw silk used 112; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said silicone being present in an amount at least sufficient to impart non-capillarity and not more than 20% of the weight of the uncoated filaments.

2. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 5–0; picks per inch 40; denier of raw silk used 252; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said silicone being present in an amount at least sufficient to impart non-capillarity and not more than 20% of the weight of the uncoated filaments.

3. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 4–0; picks per inch 40; denier of raw silk used 378; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said silicone being present in an amount at least sufficient to impart non-capillary and not more than 20% of the weight of the uncoated filaments.

4. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 3–0; picks per inch 40; denier of raw silk used 630; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said silicone being present in an amount at least sufficient to impart non-capillarity and not more than 20% of the weight of the uncoated filaments.

5. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 00; picks per inch 50; denier of raw silk used 966; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said silicone being present in an amount at least sufficient to impart non-capillarity and not more than 20% of the weight of the uncoated filaments.

6. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 0; picks per inch 50; denier of raw silk used 1560; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said silicone being present in an amount at least sufficient to impart non-capillarity and not more than 20% of the weight of the uncoated filaments.

7. The method of making surgical sutures comprising braiding a plurality of filaments of silk into a hard dense core, washing the gum from the braided silk, drying the braided silk, dry stretching the braided silk about 6 to 11% of its length, immersing the braided silk in a xylene solution of a polymerizable silicone, wiping the braided silk suture, whereby there is a silicone pick up of about

10% to 20% by weight, and drying and polymerizing said silicone.

8. The method of making surgical sutures comprising braiding a plurality of filaments of silk into a hard dense core, washing the gum from the braided silk, drying the braided silk, dry stretching the braided silk about 6 to 11% of its length, immersing the braided silk in a solution of a polymerizable silicone rubber containing a catalyst, wiping the braided silk suture, whereby there is a silicone pick up of about 10% to 20% by weight, and drying and polymerizing said silicone by heat, of at least about 150° C. for at least about 30 seconds, thereby also decomposing the catalyst.

9. The method of making surgical sutures comprising braiding a plurality of filaments of silk into a hard dense core, washing the gum from the braided silk, drying the braided silk, dry stretching the braided silk about 6 to 11% of its length, immersing the braided silk in non-toxic volatile hydrocarbon solvent solution of a polymerizable silicone rubber containing a catalyst, wiping the braided silk suture, drying and polymerizing said silicone, re-immersing in said solution, re-wiping the suture, whereby there is a total silicone pick up of about 10% to 20% by weight, and drying and polymerizing said silicone by heat, of at least about 150° C. for at least about 30 seconds, thereby also decomposing the catalyst.

10. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 6–0; picks per inch 40; denier of raw silk used 112; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said coating weighing from 10% to 20% of the weight of the silk filaments.

11. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 5–0; picks per inch 40; denier of raw silk used 252; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said coating weighing from 10% to 20% of the weight of the silk filaments.

12. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 4–0; picks per inch 40; denier of raw silk used 378; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said coating weighing from 10% to 20% of the weight of the silk filaments.

13. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 3–0; picks per inch 40; denier of raw silk used 630; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said coating weighing from 10% to 20% of the weight of the silk filaments.

14. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 00; picks per inch 50; denier of raw silk used 966; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said coating weighing from 10% to 20% of the weight of the silk filaments.

15. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, with high density, having approximately the following construction: U.S.P. size 0; picks per inch 50; denier of raw silk used 1[illegible]560; and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said coating weighing from 10% to 20% of the weight of the silk filaments.

16. A surgical suture comprising a plurality of individual filaments in coordinate configuration, the filaments being bonded together to hold the filaments in a unitary construction, and hence non-brooming, having a coating on each filament of a non-toxic, physiologically inert, polymeric silicone, whereby the suture is non-capillary and is is inert towards living tissue, the weight of said silicone being from 10% to 20% of the weight of the uncoated filaments.

17. A surgical suture comprising a plurality of individual filaments selected from the group consisting of silk, nylon, polypropylene and stretched oriented polyester, the external filaments being in braided configuration, having a tight braid, and low pick count, with high denesity, thereby imparting surgically handleable characteristics to the uncoated suture, and a coating on each filament of a non-toxic physiologically inert polymeric silicone, whereby the suture is non-capillary and is inert towowards living tissue, the weight of said silicone being from 10% to 20% of the weight of the uncoated filaments.

18. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, and low pick count, with high density, thereby imparting surgically handleable characteristics to the uncoated suture, and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, whereby the suture is non-capillary and is inert towards living tissue, the weight of said silicone being from 10 %to 20% of the weight of these uncoated filaments.

19. A surgical suture comprising a plurality of individual silk filaments in coordinate configuration, each filament having thereon a coating of a polymethyl-polyphenylsiloxane, at least the final polymerization being in situ, the weight of said silicone being from 10% to 20% of the weight of the uncoated filaments, whereby there suture is non-capillary and is inert towards living tissue, and the siloxane coating causes the filaments to cohere to each other, and thereby be free from brooming, around which suture, when tied in a surgeon's knot, breaks rather than slips, on pulling in tension.

20. The method of making surgical sutures comprising braiding a plurality of filaments of silk into a hard dense core, washing the gum from the braided silk, drying the braided silk, dry stretching the braided silk about 6 to 11% of its length, immersing the braided silk in a xylene solution of a polymerizable silicone, wiping the braided silk suture, whereby there is a silicone pick up of an amount sufficient to render the finished suture non-capillary and not more than 20% of the weight of the uncoated filaments, and drying and polymerizing said silicone.

21. The method of making surgical sutures comprising braiding a plurality of filaments of silk into a hard dense core, washing the gum from the braided silk, drying the braided silk, dry stretching the braided silk about 6 to 11% of its length, immersing the braided silk in a solution of a polymerizable silicone rubber containing a catalyst, wiping the braided silk suture, whereby there is a silicone pick up of an amount sufficient to render the finished suture non-capillary and not more than 20% of the weight of the uncoated filaments, and drying and polymerizing said silicone by heat, of at least about 150° C. for at least about 30 seconds, thereby also decomposing the catalyst.

22. The method of making surgical sutures comprising braiding a plurality of filaments of silk into a hard dense core, washing the gum from the braided silk, drying the braided silk, dry stretching the braided silk about 5 to 11% of its length, immersing the braided silk in non-toxic

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volatile hydrocarbon solvent solution of a polymerizable silicone rubber containing a catalyst, wiping the braided silk suture, drying and polymerizing said silicone, re-immersing in said solution, re-wiping the suture, whereby there is a total silicone pick up of an amount sufficient to render the finished suture non-capillary and not more than 20% of the weight of the uncoated filaments, and drying and polymerizing said silicone by heat, of at least about 150° C. for at least about 30 seconds, thereby also decomposing the catalyst.

23. A surgical suture comprising a plurality of individual filaments in coordinate configuration, the filaments being bonded together to hold the filaments in a unitary strand, and hence non-brooming, having a coating on each filament of a non-toxic, physiologically inert, polymeric silicone, said silicone being present in an amount at least sufficient to impart non-capillarity and not more than 20% of the weight of the uncoated filaments, and the suture is inert towards living tissue.

24. A surgical suture comprising a plurality of individual filaments selected from the group consisting of silk, nylon, polypropylene and stretched oriented polyester, the external filaments being in braided configuration, having a tight braid, and low pick count, with high density, thereby imparting surgically handleable characteristics to the uncoated suture, and a coating on each filament of a non-toxic physiologically inert polymeric silicone, said silicone being present in an amount at least sufficient to impart non-capillarity and not more than 20% of the weight of the uncoated filaments, and the suture is inert towards living tissue.

25. A surgical suture comprising a plurality of individual silk filaments, the external silk filaments being in braided configuration, having a tight braid, and low pick count, with high density, thereby imparting surgically handleable characteristics to the uncoated suture, and a coating on each silk filament of a non-toxic physiologically inert polymeric silicone, said silicone being present in an amount at least sufficient to impart non-capillarity and not more than 20% of the weight of the uncoated filaments, and the suture is inert towards living tissue.

26. A surgical suture comprising a plurality of individual silk filaments in coordinate configuration, each filament having thereon a coating of a polymethyl-polyphenyl siloxane, at least the final polymerization being in situ, the weight of said silicone being an amount sufficient to render the finished suture non-capillary and not more than 20% of the weight of the uncoated filaments, and said suture is inert towards living tissue, and the siloxane coating causes the filaments to adhere to each other, and thereby be free from brooming, and which suture when when tied in a surgeon's knot, breaks rather than slips, on pulling in tention.

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RICHARD A. GAUDET, *Primary Examiner.*
JORDAN FRANKLIN, *Examiner.*

United States Patent [19]

Perciaccante et al.

[11] **4,047,533**

[45] **Sept. 13, 1977**

[54] **ABSORBABLE SURGICAL SUTURES COATED WITH POLYOXYETHYLENE-POLYOXYPROPYLENE COPOLYMER LUBRICANT**

[75] Inventors: **Vincent Anthony Perciaccante**, Long Island City; **Henry Patrick Landi**, Yorktown Heights, both of N.Y.

[73] Assignee: **American Cyanamid Company**, Stamford, Conn.

[21] Appl. No.: **724,804**

[22] Filed: **Sept. 20, 1976**

[51] Int. Cl.² A61L 17/00

[52] U.S. Cl. ..... 128/335.5; 128/1 R; 428/375

[58] Field of Search 128/1, 335.5; 428/275

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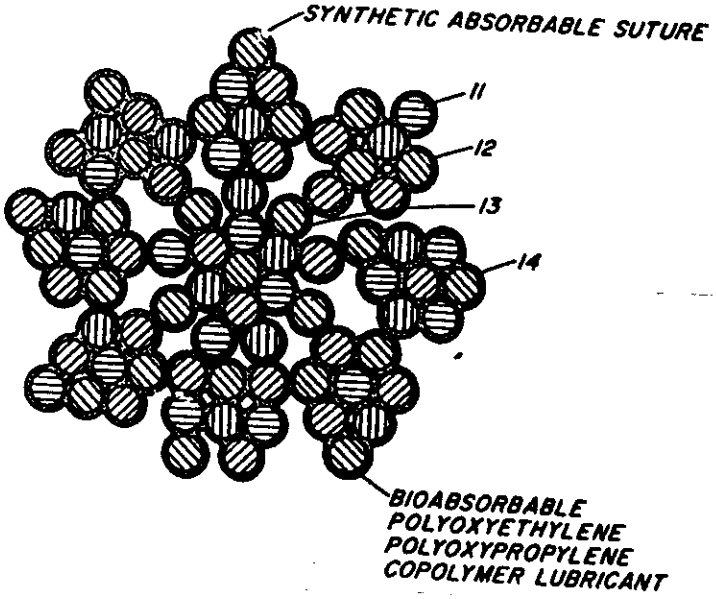
Primary Examiner—Leland A. Sebastian

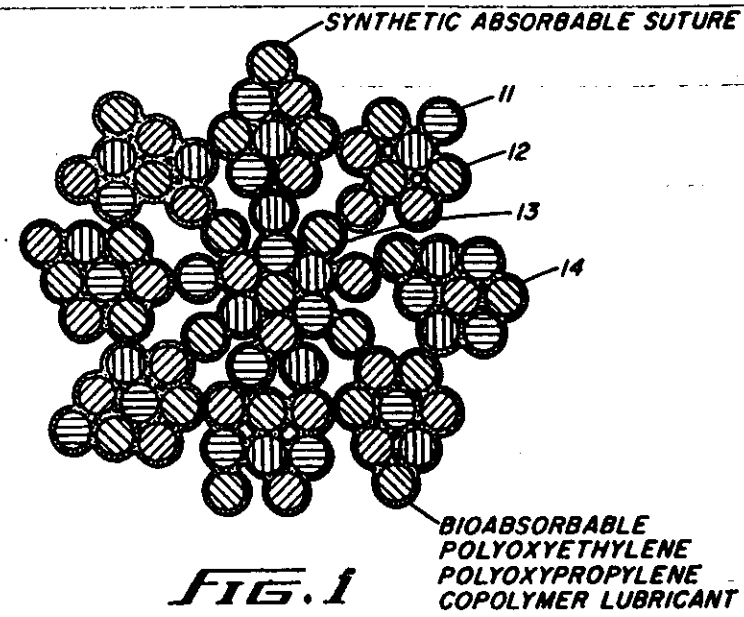
Attorney, Agent, or Firm—Charles F. Costello, Jr.

[57] **ABSTRACT**

The handling characteristics, including particularly the knot run-down, of synthetic absorbable surgical sutures and tissue drag characteristics are improved by a coating of a lubricating film of a bioabsorbable copolymer having polyoxyethylene blocks and polyoxypropylene blocks, and which bioabsorbable copolymer has a molecular weight such that it is pasty to solid at 25° C.

23 Claims, 2 Drawing Figures




SYNTHETIC ABSORBABLE SUTURE
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14
BIOABSORBABLE
POLYOXYETHYLENE
POLYOXYPROPYLENE
COPOLYMER LUBRICANT

FIG. 1

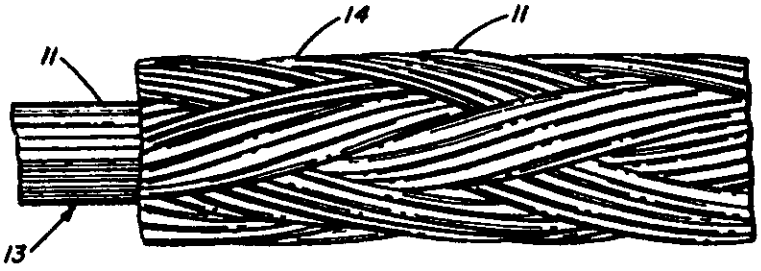
14
11
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FIG. 2

ABSORBABLE SURGICAL SUTURES COATED WITH POLYOXYETHYLENE-POLYOXYPROPYLENE COPOLYMER LUBRICANT

BACKGROUND OF THE INVENTION

The handling characteristics of surgical sutures encompass many factors, some of which factors are at least in part inconsistent or seemingly inconsistent. There is a constant effort to improve the handling characteristics. Among the more important of the handling characteristics are those associated with knot run-down. In many surgical procedures it is necessary that a knot be tied in a suture when the knot is deep inside a surgical or natural opening. For instance, a dental surgeon may need to tie a knot inside a patients mouth. An intravaginal hysterectomy requires suturing in restricted quarters. One technique frequently used is to tie a square knot that can be run-down from an exterior location where the knot is first tied to lie against tissue with a desired degree of tightness. The knot is snugged down so that it is holding with a degree of firmness chosen by the surgeon for a particular situation and then additional throws are tied down against the first throws of the square knot. In some instances, the first throw is a double twist followed by a single throw to form a surgeons knot, with additional throws to form additional square knots on top as needed. As contrasted with the ease of placement, is the necessity of knot security. Each though it is desired that it be easy to tie a knot, it is mandatory that the knot hold without slipping for an acceptable length of time. With buried absorbable sutures, of course, the suture including the knot is eventually absorbed, and the knot need only hold until the tissue is adequately regenerated. This can be merely a few hours for certain types of skin incisions, up to requirements of the order of 15 to 28 days for many types of internal knots. If strength for a longer time or permanent reinforcement is needed, non-absorbable sutures may be used.

Some suture materials are so smooth that a knot runs down very readily and frequently becomes readily untied. Other sutures are of materials in which the knot tends to "lock-up" or refuse to run-down so that it is difficult to snug-down the throws against the tissue and only a few throws are needed, and security is not a problem. Knots in constantly moving tissue, such as adjacent to the heart, have a much greater chance of becoming untied than knots in quiescent tissue such as knots holding together a wound inside a plaster cast.

The problem of improving suture performance under varied conditions has been the subject of much research over a prolonged period.

PRIOR ART

U.S. Pat. No. 1,254,031 — Jan. 22, 1918, Davis, SUTURE AND METHOD OF MAKING THE SAME, shows a braided collagen suture immersed in collagen or glue to cause close adhesion of the braid, to fill up the interstices and provide a smooth uniform coating.

U.S. Pat. No. 2,576,576 — Nov. 27, 1951, Cresswell and Johnstone, LUBRICATED THREAD, shows a lubricated multifilament collagen thread using as a lubricating film a phosphatide such as lecithin. The lecithin should be applied at the time of coagulation or regeneration of collagen as effective lubrication is not obtained if the lubricant is incorporated by adding to a finished thread.

U.S. Pat. No. 2,734,506 — Feb. 14, 1956 - Nichols et al. SILK SUTURES AND LIGATURES shows using poly(alkyl methacrylate as a coating for silk sutures, and a hot coating die system.

U.S. Pat. No. 3,187,752 — June 8, 1956 — Glick, NON-ABSORBABLE SILICONE COATED SUTURES AND METHOD OF MAKING, shows silk or other non-absorbable synthetic filaments such as nylon, cotton or linen coated with a silicone which gives a more inert suture and reduces capillarity.

U.S. Pat. No. 3,209,589 — Oct. 5, 1965 — Schlatter, YARN FRICTION MEASURING INSTRUMENT, describes a machine for measuring the friction of a yarn sliding over itself and describes the variation of friction with speed, and the "slip-stick" variety at slow speeds.

U.S. Pat. No. 3,297,033 — Jan. 10, 1967 - Schmitt and Polistina, SURGICAL SUTURES, shows synthetic surgical sutures of polyglycolic acid and discloses that the surfaces of the fiber can be coated with a silicone, beeswax, or the like to modify the handling or the absorption rate.

U.S. Pat. No. 3,390,681 — July 2, 1968, Kurtz, POLYESTER SUTURE HAVING IMPROVED KNOTTING CHARACTERISTICS, shows improving the knotting characteristics of a polyester such as one formed from a dicarboxylic acid and a diol (Dacron) by depositing on the fibers a polytetrafluoroethylene (Teflon). This patent discloses many of the problems in suture knots, and is hereby incorporated by this reference hereto. This patent also shows the accepted practice of classing "ligatures" under "sutures" for patent disclosure purposes.

U.S. Pat. No. 3,565,077 — Feb. 23, 1971, Glick, DENSIFIED ABSORBABLE POLYGLYCOLIC ACID SUTURE BRAID, AND METHOD FOR PREPARING SAME, shows a suture construction using polyglycolic acid filaments with a compacted structure and a reduced void fraction.

U.S. Pat. No. 3,815,315, June 11, 1974, Glick, ETHYLENE OXIDE STERILIZATION OF MOISTURE SENSITIVE SURGICAL ELEMENTS shows the desirability of maintaining surgical elements of polymers subject to the hydrolytic degradation to non-toxic, tissue-compatible, absorbable components, such as polyglycolic acid sutures, in a desiccated condition in an air tight container impervious to moisture vapor. Suitable desiccating cycles and foil containers to give product which are storage stable for years are disclosed.

U.S. Pat. No. 3,867,190 — Feb. 18, 1975, Schmitt and Epstein, REDUCING CAPILLARITY OF POLYGLYCOLIC ACID SUTURES, shows the coating of polyglycolic acid surgical sutures with a copolymer of from 15-85% glycolic acid with 85-15% lactic acid which coating fills the interstices of a multi-filament polyglycolic acid suture. Example 10 discloses the coating as minimizing capillarity, and improving run-down. Thicker coatings increase stiffness. This patent has 38 references to earlier prior art on sutures and methods of making them, and related fields and is incorporated herein by this reference thereto. A divisional of said 3,867,190 is Ser. No. 489,004, July 16, 1974, REDUCING CAPILLARITY OF POLYGLYCOLIC ACID SUTURES, now U.S. Pat. No. 3,982,543 dated Sept. 28, 1976.

U.S. Pat. No. 3,896,814 — July 29, 1975 — Vivien and Schwartz, COLLAGEN BASED THREADS, shows a collagen or catgut thread which is flexibilized by having therein water and a hygroscopic agent such as a glycerol or a glycol or a low molecular weight (up to 400 m.w.) liquid polyalkalene oxide, and which may additionally be coated with a lipoid or a silicone for surface lubricity.

U.S. Pat. No. 3,942,532 — Mar. 9, 1976 — Hunter and Thompson — BRAIDED SUTURE, discloses an adaptation of an INSTRON Universal Testing Instrument using an oscillographic recorder, to use a single throw between two suture strands to measure surface roughness, as an indication of the ease of sliding a single throw knot down the suture into place, there called "tie-down performance". A coating of 0.4 percent to 7 percent of the suture weight of an aliphatic polyester such as a condensate of adipic acid and 1,4-butanediol having a molecular weight of about 2,000–3,000 is recommended.

U.S. Ser. No. 691,749, filed June 1, 1976 — Casey and Epstein — NORMALLY-SOLID BIOABSORBABLE, HYDROLYZABLE, POLYMERIC REACTION PRODUCT, discloses the use of transesterification product of poly(1,4-propylene diglycolate) and polyglycolic acid and other trans-esterification products of polyglycolic acid and a polyester of diglycolic acid and an unhindered glycol to coat sutures to improve knot run-down and other suture characteristics.

The coating, coloring and conditioning of surgical sutures with polymeric materials in general is well-known. Silicones, wax, polytetrafluoroethylene, and other polymers have been used. Specific coating materials with unique advantages to give improved sutures are constantly being sought.

SUMMARY OF THE INVENTION

It has now been found that the knot run-down characteristics, handleability, tie-down performance and tissue drag characteristics of braided, twisted or covered multifilament synthetic absorbable sutures may be improved by coating with a lubricating biologically absorbable copolymer having polyoxyethylene blocks and polyoxypropylene blocks.

Absorbable polyglycolic acid sutures are described in U.S. Pat. No. 3,297,033, supra. Other synthetic absorbable sutures which absorb in living tissue may be coated with improved results. At present absorbable sutures meeting with market acceptance are those in which the degradation or absorption in tissue results from the hydrolytic degradation of glycolic acid ester linkages. Such materials are presently being sold under the trademarks DEXON® and VICRYL®. The present invention may be used with other synthetic absorbable surgical sutures, described in the prior art, and as they are developed. With synthetic absorbable sutures the problem of a coating to improve knot run-down characteristics is made more difficult by the requirement that the coating must be non-toxic and absorbable.

Absorbable or bioabsorbable as applied to the coating, refers to a coating which by hydrolytic or enzymatic degradation, or by its inherent characteristic, has such molecular weight and solubility properties that it is absorbed from the surface of the suture and is eliminated by the subject either unchanged or in hydrolyzed or degraded form. The exact mechanism of the disposition of the coating in mammalian tissue is not critical to the understanding of the present invention, as long as the coating is non-toxic.

It is also found that the lubricant coating not only aids in the knot run-down characteristics but increases the smoothness and flexibility of the sutures so that they may be more easily drawn through the skin and other tissues during placement of the suture. This reduction in friction is called reduced tissue drag.

Another unexpected and unobvious advantage of the present lubricant coating in that the lubricant copolymers are absorbed from the suture within a few days. The coating that aids in friction reduction in tissue drag and lubricates in knot placement also causes the knot to slip more readily. When the lubricant is comparatively rapidly absorbed in living mammalian tissue, the resistance of the knot to slippage or untieing due to tissue movement is soon increased. As the wound heals the knot security actually improves, up to the time that the synthetic absorbable suture loses strength preliminary to absorption.

The absorbable coating is one or more of a group of compounds having blocks of polyoxyethylene and blocks of polyoxypropylene in their structure. For simplicity and ease of description these compounds are taught, drawn and treated as if there were merely two or three blocks in the chain. However, it is to be understood that non-significant qualities of polyoxypropylene may be present in the polyoxyethylene block and minor quantities of polyoxyethylene may be present in the polyoxypropylene block. From the methods of manufacture it would appear that there may be and probably are such minor admixtures present in the chain. The commercially available grades are acceptable and found to have a low and acceptable degree of toxicity.

The present lubricants may be indicated as having the formula:

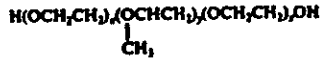
$$R[(CH_2CHO)_n(CH_2CHO)_mH]_c$$
$$\quad\quad\quad

that the oxypropylene chains may have a small amount of ethylene-oxide therein and vice versa. Because of the sources of ethylene oxide and propylene oxide, usually from petroleum fractions, it is to be expected that in commercial practice complete rectification to chemically pure compounds is not obtained. Fortunately the commercial grade may be used on absorbable sutures with excellent results. Said 2,979,528 also points out that as polymers, all molecular species are far from identical—some chains are shorter, some are longer, but on the average the materials are as indicated and it is the physical properties of the lubricants, not the molecular weight spread of the components, which are important.

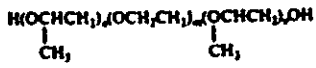
U.S. Pat. No. 3,036,118, May 22, 1962, MIXTURES OF NOVEL CONJUGATED POLYOXYETHYLENE-POLYOXYPROPYLENE COMPOUNDS, D. R. Jackson and L. G. Lundsted, has much disclosure on the addition of polyoxyethylene groups and polyoxypropylene groups to reactive hydrogen compounds having from 2 to 6 reactive hydrogen atoms and not over 6 carbon atoms per molecule. Among other such compounds are listed the group consisting of aliphatic polyhydric alcohols, alkylamines, alkylene polyamines, cyclicamines, amides, and polycarboxylic acids, oxyethylene groups and oxypropylene groups. The reactive hydrogen compound serves as a chain initiator and can be present in such a small proportion that it has minor significance in its own right and serves mainly as a foundation on which the predominantly polyoxyethylene or polyoxypropylene blocks may be added in the chosen order. Whereas Patent 3,036,118 claims primarily the Reverse Pluronics in which the polyoxy-ethylene chains are attached to the nucleus or initiating reactive hydrogen compounds, in the present invention either the Reverse Pluronic with the polyoxyethylene in the center or the regular Pluronics with the polyoxypropylene in the center or the Tetronics with nitrogen in the center may be used for lubricant purposes.

Because the chemistry is previously known, and to avoid unnecessarily extending the length of the present disclosure, the disclosures of each of these three patents is herein hereby incorporated by this reference thereto.

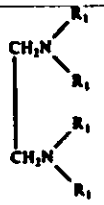
These lubricating bioabsorbable copolymers are often classed as surface active agents as the polyoxyethylene blocks are predominantly hydrophylic and the polyoxypropylene blocks are predominantly hydrophobic. The materials have been sold by the Wyandotte Chemical Company under the trademark of PLURONICS for the formula:



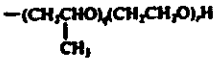
where x, y and z are whole numbers. REVERSE PLURONICS for the formula:



where n, m and o are whole numbers and TETRONICS for the formula:



where R_1 is



where q and r are whole numbers.

For the present purposes as synthetic absorbable suture lubricants, the values of x, y, z, n, m, o, q and r are such that the lubricants are pasty to solid at 25° C.

The pastes are opague semi-solids with melting points above room temperature—preferably above about 40° C.

Those classed as Pluronics are particularly useful for the present invention.

The physical characteristics of these lubricant compounds are affected by their total molecular weight and by the percentage of polyoxyethylene in the molecule. References are made to the commercially available compounds for purposes of convenience. Those which are liquid normally have an L as a primary designator, those which are pasty have a P and those which are solid have an F. For the Pluronics, the first number indicates the typical molecular weight of the polyoxypropylene hydrophobic portion with a number 3 being about 950; 4 being about 1200; 5 being about 1450; 6 about 1750; 7 about 2050; 8 about 2250; 9 about 2750; 10 about 3250; 11 about 3625 and 12 about 4000. The second digit indicates the approximate percentage of the polyoxyethylene hydrophylic units in the total molecular, in units of 10. Thus for example, the formulations of certain commercially available products is approximately that shown in Table I.

As all compositions are mixtures, all values are approximate, and values are subject to some rounding.

Additional data is given in The Journal of the American Medical Association, volume 217, pages 469 to 470 (1971) where the new nonproprietary name of POLOXAMER is established for these compositions as direct food additives.

TABLE I

PLURONIC	Average Molecular Weight	M.W. of each Polyoxyethylene Block	Units of each x and z	% Polyoxyethylene	M.W. of Polyoxypropylene Block	Units of y	M.P. ° C.
P-38	5000	2000	46	80	930	16	45
F-68	8350	3300	75	80	1,750	30	52
F-77	6600	2300	52	70	2,050	35	48
P-85	4600	1200	27	50	2,250	39	40
F-87	7700	2700	62	70	2,250	39	49
F-88	10800	4300	97	80	2,250	39	54
F-98	13500	5400	122	80	2,750	47	55
F-108	14400	5600	128	80	3,150	54	57

TABLE I-continued

F-127	12500	4300	98	70	3,900	67	56
REVERSE PLURONIC			M.W. polyethylene units of m block		M.W. polyoxypropylene block		Units of a and O
10R8	3,000	2000	45	65%	362	9	46
17R8	4,350	2600	59	60%	870	15	83
25R8	9,000	3250	74	57%	1,250	22	56

TETRONIC	Average Molecular Weight	Approximate Molecular Weight of Individual Polyoxyethylene Block	Approximate % Polyoxyethylene	Molecular Approximate Weight of Individual Polyoxypropylene Block	Approximate Polyoxypropylene	Average Approximate length of chains per block Units of r	Units of q
707	12,000	2312	74	673	26	52.5	11
908	26,100	5588	85	923	15	127	15.9
1107	14,500	2438	67	1173	33	55.4	20.2
1307	18,600	3213	69	1423	31	73	24.5
1508	27,000	5063	75	1673	25	115	28.5

In general, the Pluronics with a molecular weight range of from about 4,750 to 16,250 are waxy solids. The polyoxypropylene portion has a molecular weight of 950 to 4,000 and the polyoxyethylene content of about 60–80%.

The pastes in general have a total molecular weight ranging from 3,500 to 5,700 with a polyoxypropylene molecular weight range of 1,750 to 6,500 and polyoxyethylene content of 30 to 50%. The transitions from wax to paste to liquid are not sharp.

COATING

The synthetic absorbable suture is conveniently coated by several conventional procedures including:

Melt Coating

The uncoated suture is placed in a split die whose orifice corresponds to diameter specifications for the particular size suture to be coated. The die is then clamped in a heating block and the polyoxyethylene-polyoxypropylene lubricant bioabsorbable copolymer placed in the die. The die is raised to a temperature about 20° C. above the melting point of said copolymer and after the copolymer has melted, the suture to be coated is slowly pulled downward through the molten material in the die and collected on a take-up spool. The spool is mounted directly below the die a sufficient distance to allow solidification of the coating. A cooling tunnel or a blast of cooling air may be used to increase production speeds. Nichols et al. 2,734,506, supra, describes one useful apparatus for coating.

Solution Coating

The polyoxyethylene-polyoxypropylene lubricant bioabsorbable copolymer is dissolved in chloroform. About twice the percentage by weight is used for coating solution as is desired on the final sutures. A feed loop such as a loop of wire or a ceramic is threaded with the uncoated suture, after which the feed loop is then submerged in the solution and the suture is passed down through the feed loop. It may be passed through a die whose diameter is such that after drying a suture will have the desired diameter. The suture is pulled slowly through the solution and at least partially dried in a drying tunnel. The drying is finished after the suture is wound on a spool. Because variations in equipment, speed, and temperature affect the pick-up of the lubricant bioabsorbable polymer, the concentration in the coating is adjusted based on a preliminary run or experience.

During the following the application of the coating to the synthetic absorbable sutures, contact of the filaments with moisture, or water vapor is minimized. The final coated suture is thoroughly dessicated before packaging in a moisture proof container, such as a metal foil envelope, for long term storage stability. U.S. Pat. No. 3,814,315 supra, discloses methods of dry packaging and sterilizing, and is hereby herein incorporated by this reference thereto.

Other coating techniques which are well known in the coating of polyfilamentary strands may be used. The techniques used for insulating wire may be adapted for large scale suture manufacture. The above are merely two of the more convenient and well known methods for coating. Details are later illustrated in examples.

Toxicity

The low toxicity of the polyoxyethylene-polyoxypropylene compounds of the present invention are shown in such U.S. Pat. Nos. as 3,450,502 which describes the use of a copolymer having a total molecular weight of about 8,750 in isotonic solutions used as a priming agent in a heart-lung apparatus. In sutures even if a maximum of around 25–30% by weight of the suture of copolymer is used, only a very small amount is placed in the subject.

The low toxicity is shown in the following table.

TABLE II

Pluronic No.	Total Molecular Weight	TOXICITY Physical Characteristic	LD 50 (gm/kg) in Mice
F-38	5000	wax	> 5
F-77	6600	wax	4.2
F-87	7700	wax	3.75
F-68	8350	wax	> 5
F-88	10800	wax	> 5
F-127	12500	wax	2.25
F-98	13500	wax	> 5
F-108	14600	wax	1.25
P-65	3400	paste	0.83
P-84	4200	paste	0.4
P-85	4600	paste	0.53
P-94	4600	paste	0.6
P-103	4950	paste	1.4
P-104	5850	paste	0.75
P-123	5750	paste	2.7
P-105	6500	paste	3

The polyoxyethylene-polyoxypropylene compositions used as the lubricant bioabsorbable copolymers have been used in food products; and have been the subject of studies as to their elimination from a mammalian body. In general, they are eliminated in the urine fairly rapidly, and within 48 hours nearly all have been eliminated from the blood stream.

If some of the lubricant bioabsorbable copolymer is trapped in braid pores of a suture, the rate of diffusion into the blood stream may be reduced and hence the

time for elimination somewhat increased. The molecular weight is small enough that the lubricant bioabsorbable copolymers may be eliminated unchanged, although some degradation may occur before elimination. The important thing is that the lubricant bioabsorbable copolymer has no deleterious effect upon healing tissues adjacent to the sutures, and being removed from the surface of the suture by absorption by the body, knot security is improved. As soon as suture placement is completed, the knot run down and tissue drag reduction function is complete, and as the lubricant bioabsorbable copolymer is removed from the suture, knot security improves.

Definitions in the suture and textile trades are sometimes ambiguous or confused. As herein used;

A "filament" is a single, long, thin flexible structure of a non-absorbable or absorbable material. It may be continuous or staple.

"Staple" is used to designate a group of shorter filaments which are usually twisted together to form a longer continuous thread.

An absorbable filament is one which is absorbed, that is digested or dissolved, in living mammalian tissue.

A "thread" is a plurality of filaments, either continuous or staple, twisted together.

A "strand" is a plurality of filaments or threads twisted, plaited, braided, or laid parallel to form a unit for further construction into a fabric, or used per se, or a monofilament of such size as to be woven or used independently.

The term "suture" is used to include the term "ligature" as technically a suture is used with a needle whereas the ligature is merely used to tie without being placed by a needle.

A finished suture has a needle attached and is sterile and ready for use in surgery. For purposes of convenience in nomenclature, the term "suture" is frequently used to refer to the same strand before it is coated and before it is packaged and sterilized. Context indicates whether it is the sterile suture ready for use, or the suture in a manufacturing step which is referred to.

The strand of the suture is used as the basis for weight in determining the quantity of material that is placed on the synthetic absorbable polymer strand in forming the absorbable surgical suture.

The quantity of the lubricating bioabsorbable copolymer is from about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer based on the weight of the uncoated strand forming the suture. It is not necessary that the coating be continuous as a discontinuous coating on the surface aids in reducing friction and chatter. A larger quantity may be present if the lubricating bioabsorbable copolymer penetrates inside the strand, with the various filaments themselves being partially or totally covered.

The wide range of coating weight permits adaptation of the present sutures to many varied uses. Because the strand to be coated to form the suture may have considerable variation in surface roughness, due to the mechanical structure, i.e. braid or twist, etc. as well as being made from filaments which are less than 2 denier per filament to more than 6 denier per filament, with the finer filament sizes giving a smoother surface; and because the filaments may be stretched after the suture is manufactured or in heat treatment, the surface roughness basically can vary. The smoother surfaces require less of the lubricating bioabsorbable copolymer for analogous degrees of slippage.

The various surgical techniques used interact with the desired degree of lubrication. For any given type of knot, a larger quantity of lubricant which for a particular technique increases the ease of run-down, also increases the ease of the knot running back or slipping, called knot security. For some surgical procedures it is highly desirable that the knot be very free in running down, even though the knot slips more readily.

A surgeon in tying knots is confronted with this interaction between the method of tying the knot and the ease of slipping. If a suture is comparatively well lubricated, the surgeon can use a square knot, which is run down readily; with additional squared throws for knot security. On the other hand, if the suture is less well lubricated, the surgeon can use a double half-hitch or some other type of knot which moves more readily to run the knot down to position, after which these double half hitch can be pulled to square the knot, or additional throws can be thrown down against the knot to give adequate knot security. Thus the surgeon can either adapt his knot technique to a particular suture, or can get sutures whose surface lubricity is best adapted to the technique which the surgeon desires to use. Generally, there is an adaptation of each to the other. The surgeon attempts to get a suture whose characteristics are those which he prefers, and then adapts his knot tying techniques to the sutures that he has at the time. Some surgeons make very successful knots with stainless steel wire using a knotting technique that is adapted to such a wire which has very poor run-down. Others prefer a much more readily run-down well-lubricated suture.

Additionally the location of use has influences. Sometimes a suture in passing through tissue picks up tissue fluids. The suture may be coated with tissue fluids which are either fresh or partly dry at the time the knot is tied. In some surgical techniques it is necessary to preplace the sutures, and tie the suture after these coating of tissue fluids on the suture has a chance to become at least partially dried.

Because the ease of knot run-down and knot security are somewhat opposite, it is necessary for the surgeon to use additional throws or such knots as will hold under the particular conditions of a selected surgical procedure. By changing the quantity of the lubricant bioabsorbable copolymer, the run-down can be modified to suit a using surgeons preference.

The time of use of the knots can be quite varied. Some surgeons use a suture to ligate bleeders in a wound with a retention requirement of 30 minutes or less. Such knots can be removed as the surgical procedure is complete, and before wound closure. Others leave the absorbable knots in the tissue even though there is no likelihood that a bleeder would reopen. For such usage, a suture which retains strength for 30 minutes is adequate. For wound closure and some other uses, it is desired that the synthetic absorbable suture maintain strength for at least 15 days to 4 weeks.

Because the present lubricating bioabsorbable copolymer is removed from the suture in living tissue, as the lubricant is removed the knot security increases and after 48 hours more or less, knot security is greatly improved.

The examples following should show the effects of certain different coating and quantities under certain conditions.

The requirements of surgery are extremely varied, and various coating weights permit adaptation of synthetic absorbable sutures to different conditions.

In general, if the surgeon desires a better lubricated suture, a larger quantity of the lubricating bioabsorbable copolymer is used and conversely if the surgeon in willing to accept slightly reduced knot run-down and tissue drag characteristics in favor of greater knot security, the coating level is reduced in favor of this particular compromise.

Usually from 2 percent to 8 percent of the lubricant bioabsorbable copolymer gives a useful range of compromise between the ease of knot run-down and knot security.

A usage of about 5 percent by weight of Pluronic F-68 is a preferred compromise between the knot run-down and knot security requirements for 2 to 6 denier per filament braided sutures of polyglycolic acid.

In the Drawings:

FIG. 1 is a cross-section of a synthetic absorbable suture having on the surface thereof a bioabsorbable polyoxyethylene polyoxypropylene copolymer lubricant.

FIG. 2 is a drawing of a suture showing the parallel filaments in the core and the braided sheath. The lubricant coating appears on the surface.

The drawings are diagrammatic and representative. The filaments 11 of the synthetic bioabsorbable suture are at best some what jumbled in actual configuration but are illustrated as patterned in a somewhat idealized style. The coating 12 of the lubricant bioabsorbable polyoxyethylene-polyoxypropylene copolymer is shown much exaggerated. At a level of from 0.1 to 25 percent, the coating would be so thin as to merely be represented by a blurred line if to accurate scale.

In FIG. 2 the core 13 of the braided suture consists of parallel filaments and the sheath 14 consists of a plurality of filaments, typically braided in configuration. The type of braid shown is representative and diagrammatic. The visability and appearance of the coating varies depending upon the observational technique used to inspect the suture.

The coating 12 in part may bridge the gap between the individual filaments in the finished suture. Depending upon the quantity of coating used, the bridging may be more or less complete but complete filling is not necessary. If the coating level is increased, knot run-down continues to be improved, but knot security is compromised.

EXAMPLE 1

Run Down and Chatter Test

A set of 2/0 USP XIX (diameter 0.339 mm, maximum) polyglycolic acid sutures braided from a 2 denier per filament extrusion, was coated with 7 levels of Pluronic F-68 and a blank, that is no coating, then subjected to a square knot run-down test.

In this test, the suture is tied with a square knot around a cylinder with a 4 inch periphery. The loop thus formed is slipped off the cylinder and placed in the testing machine jaws. The knot is subjected to running-down by pulling on the original free ends in a testing machine which records the pull on a chart as the knot travels down the suture. There is some chatter or variation in knot run-down tension as the knot travels down the suture. This is graphically plotted. Out of a set of runs with various coating levels, the fraction is indicated in which the maximum force for the knot run-down is within the separate ranges given in the table. All of the knots for coated sutures ran down the full length of the suture without breaking. The knot breaking strength of the suture braid was in a range of 7 to 8 pounds. For uncoated braid, the knot locked up and the suture broke in 9 out of 10 tests.

TABLE III

Knot Run-Down on 2/0 Polyglycolic Acid Sutures with Pluronic F-68 Lubricant

Coating Level (percent)	Fraction of trials where maximum resistance was: 0 - 1	1 - 2	2 - 3	3 - 4	4 - 5	5 - 6	6 - 7 lbs.
0.0	broke before run-down in 9 out of 10.						
1.9				2/10	2/10	4/10	2/10
2.8			2/10	3/10	2/10	3/10	
3.9		1/10		1/10	4/10	2/10	2/10
5.0		3/10	2/10	2/10	2/10	1/10	
6.2		2/10	3/10	2/10	3/10		
7.4	3/11	1/11	4/11	3/11			
8.0	5/10	2/10		3/10			
The maximum force for rundown decreases steadily with increasing level. Lower coating levels on a different batch of braid showed							
0.51%	1/10	2/10	2/10	3/10	2/10		
1.09%	5/10	1/10	3/10	1/10			
1.53%	5/10		1/10	1/10	1/10	1/10	1/10

For these coatings, the braid was run through a solution of Pluronic F-68 at a concentration of about twice the percentage of coating on the suture in chloroform.

With other braid constructions and other sizes, the relative ease of knot run-down may be greater or less for the same quantity of coating, or conversely the quantity of the coating may be adjusted to give the desired knot run-down values.

The quantity of the Pluronic in the solvent may be varied, and solvents other than chloroform may be used.

Other organic solvents such as methyl alcohol, ethyl alcohol, isopropyl alcohol, methylene chloride, warm xylene (about 60° C.), tetrahydrofuran, acetone, dimethylformamide, dimethyl sulfoxide, mixtures thereof, and other similar solvents for the lubricant may be used for coating. Flowing the solution onto a moving strand, and letting the surplus drip off is another useful coating technique.

A small amount of water increases the solubility of the lubricants, and aids in coating, but the time of contact with water of the suture should be minimized so that if moisture is present in the coating system, the sutures should be dried and desiccated promptly.

In general it is more convenient to use the solvent coating system at levels below 10 percent pick-up and use a heated die at above about 10 percent pick-up.

EXAMPLE 2

A series of runs was made using a coating of two commercial Pluronics F-68 and F-127 on 2/0 size sutures of 6 dpf braided absorbable polyglycolic acid sutures. The coatings were applied by a solution of the Pluronic in chloroform. The concentration of the Pluronic in the solution used for coating is approximately twice that obtained in the braid. A solution containing about 2.8% Pluronic F-68 in chloroform results in about 1.4% Pluronic F-68 on the braid. An adjustment in concentration can be made to secure any desired level. The strand being coated was braided for a 2/0 size suture using a 6 denier per filament extrusion of polyglycolic acid. An uncoated suture strand of the same lot was used as a control. A standard ATLAB yarn Friction Tester Model CS-151-026, Custom Scientific Instruments, Inc. Whippany, New Jersey 07981, with a Hewlett Packard Model 321 dual channel amplifier recorder was used to record the tension of the strand

feeding into the tester, and coming out of the yarn tester. The chatter factor is the ratio of maximum pull (T_3) to the feed tension (T_1) minus the minimum pull (T_2) to the feed tension, i.e. $(T_3/T_1) - (T_2/T_1)$. The values for friction are of (T_2/T_1) to start slipping.

The values of particular interest are the ratios and percent reduction. With other types of test devices, the numerical values may change, but the relative ratios as an index of improvement are analogous.

In this test, an uncut strand, coated as indicated, was used for the test. For use as a suture, such strand is cut to length, needled, packaged and sterilized using conventional techniques. The friction and chatter is more readily measured on continuous lengths.

Reduction in static friction, chatter and the coefficient of friction are shown for typical coating levels, and sutures in Table IV.

Tests on knot security are dependent on the exact technique of tying knots.

A representative and typical run on knot security showed for a series of tests on size 2/0 polyglycolic acid sutures of 2 denier per filament construction with 4.79% of Pluronic® F-68 coated thereon and different knots, the force in pounds to slip knots or break without slipping to be:

Run	Square Knot	Square + 1 Throw	Square + 2 Throws	Surgeons Knot	Surgeons + 1 Throw	Surgeons + 2 Throws
1	1.70	2.95	Broke	Broke	7.50	Broke
2	2.05	3.90	Broke	6.15	5.15	Broke
3	4.20	4.05	Broke	3.70	Broke	Broke
4	0.70	3.40	Broke	Broke	3.35	Broke
5	3.95	Broke	Broke	1.40	Broke	Broke
Average	2.54	—	—	—	—	—

EXAMPLE 3

A series of runs, including blank, were made with solutions of the Pluronic® R bioabsorbable lubricant copolymers in chloroform, using the procedures of Example II. The following Table V shows the improvement obtained in chatter and friction with a series of polymers and concentrations.

TABLE IV

POLYGLYCOLIC ACID BRAID
Size 2/0

Run No.	Pluronic Coating	Level %	Static Friction	% Reduction	Chatter Factor	% Reduction	Coeff. of Friction $\times 10^{-2}$	% Reduction
1	Blank	0	3.11		0.50		6.109	
2	Blank	0	3.29		0.60		6.2[illegible]	
3	F-68	1.39	2.78	13.1	0.30	45.5	5.7[illegible]	7.0
4	F-68	1.93	2.55	20.3	0.19	65.5	5.468	11.8
5	F-68	4.44	2.54	20.6	0.31	43.6	4.900	20.9
6	F-68	7.29	2.70	15.6	0.33	40.0	5.084	17.9
7	F-68	8.09	2.59	19.1	0.25	54.6	5.424	12.5
8	F-127	1.38	2.55	20.3	0.33	40.0	4.938	20.3
9	F-127	1.57	2.63	17.8	0.24	56.4	5.539	10.6
10	F-127	2.56	2.97	7.2	0.27	50.9	6.104	1.50
11	F-127	5.37	2.76	13.8	0.32	41.8	5.689	8.2
12	F-127	5.62	2.82	11.9	0.40	27.3	5.617	9.4
13	F-127	5.62	2.87	10.3	0.29	47.3	6.007	3.1
14	F-127	8.14	2.81	12.2	0.29	47.3	5.891	4.9
15	F-127	9.83	2.74	14.4	0.29	47.3	5.621	9.3

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TABLE V

POLYGLYCOLIC ACID BRAID
Pluronic® Size 2/0 - 6 denier per filament

Braid	Run	Coating	Level (%)	Static Friction	(%) Reduction	Chatter Factor	(%) Reduction	Coeff. of Friction $\times 10^{-2}$	(%) Reduction
Uncoated	16			3.92		0.31		8.189	
Uncoated	17			3.45		0.21		7.503	
Uncoated	18			2.87		0.27		6.083	
Uncoated	19			2.87		0.18		6.300	
10297B	20	10R8	2.05	2.51	23.4	0.28		5.077	28
10297B	21	10R8	3.00	2.33	28.9	0.16	34.1	4.932	31
10297B	22	10R8	3.96	2.31	29.5	0.21	13.6	4.753	33
10297B	23	10R8	5.31	2.41	26.5	0.23	5.4	4.962	30
10297B	24	10R8	7.49	2.39	27.1	0.25		4.843	32
10297B	25	25R8	2.55	2.34	28.6	0.16	34.1	4.962	30
10297B	26	25R8	3.85	2.40	26.8	0.15	38.3	5.162	27
10297B	27	25R8	6.29	2.23	32.0	0.15	38.3	4.662	34
10297B	28	25R8	7.15	2.31	29.5	0.13	46.5	4.990	30
10297B	29	25R8	8.74	2.37	27.7	0.11	54.7	5.175	27
10297B	30	31R4	2.18	2.53	22.8	0.15	38.3	5.520	22
10297B	31	31R4	3.42	2.53	22.8	0.17	30.0	5.466	23
10297B	32	31R4	4.51	2.57	21.6	0.14	42.4	5.652	23
10297B	33	31R4	5.53	2.61	20.4	0.17	30.0	5.705	20
10297B	34	31R4	7.26	2.51	23.4	0.11	54.7	5.782	19
10297B	35	17R8	2.12	2.45	25.3	0.19	21.8	5.218	27
10297B	36	17R8	3.13	2.45	25.3	0.25		5.019	30
10297B	37	17R8	5.02	2.33	28.9	0.20	17.7	4.782	33
10297B	38	17R8	6.32	2.36	28.0	0.25		4.723	34
10297B	39	17R8	8.60	2.33	28.9	0.15	38.3	4.962	30

EXAMPLE IV

A braided polyglycolic acid strand, of a size to form a 2/0 USP suture is dipped in a 10% solution of Pluronic F-68 in chloroform, and dried. The pick-up is about 5% by weight of the weight of the strand itself.

The dried coated strand is cut into 54" segments, needled, packaged, sterilized and dried in accordance with conventional procedures.

The thus prepared sutures were used in surgical procedures. When used to approximate tissue at a wound, a suture is placed in an appropriate location, and tied with a square knot. The square knot readily ran down to pull the edges of the wound to the degree of tightness desired by the using surgeon. The suture sh. ws low tissue drag, and excellent knot run down. When a knot is at a desired final location, three additional squared throws are placed to secure the knot. Knots buried in tissue have the lubricant bioabsorbable copolymer removed from the suture surface within 48 hours, which gives additional knot security. The suture itself maintains tissue retaining strength for at least 15 days, and is substantially absorbed in 90 days.

Whereas exemplified and tested with square knots, the ease of knot run-down and reduced tissue drag are useful in most suture placements and for knot retention. The amount of coating, and the relative values for knot run-down and reduced tissue drag, is variable to suit the requirement of a particular surgical situation.

The needling, packaging and sterilizing of the coated sutures is in accordance with conventional procedures.

We claim:

1. An absorbable surgical suture having improved knot run-down characteristics and reduced tissue drag comprising a polyfilamentary synthetic absorbable polymer strand having thereon a thin lubricating coating of a lubricating absorbable copolymer comprising polyoxyethylene blocks and polyoxypropylene blocks to aid run-down and handleability, said bioabsorbable copolymer having a molecular weight such that it is pasty to solid at 25° C.

2. The suture of claim 1 in which the lubricating bioabsorbable polymer has the formula:

$$R[(CH_2CHO)_n(CH_2CHO)_mH]_c$$
$$\quad\quad R_1 \quad\quad R_2$$

where one of R_1 and R_2 is methyl and the other hydrogen, and n and m are sufficiently large that the compound is pasty to solid at 25° C., R is the residue of a relatively low molecular weight reactive hydrogen compound having from 2 to about 6 reactive hydrogen atoms and having not over 6 carbon atoms in said compound, and c is the number of reactive hydrogens on the compound forming R.

3. The suture of claim 1 in which the lubricating bioabsorbable copolymer has effectively the formula:

$$H(OCH_2CH_2)_x(OCHCH_2)_y(OCH_2CH_2)_zOH$$
$$\quad\quad\quad

15. The suture of claim 3 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

16. The suture of claim 4 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

17. The suture of claim 7 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

18. The suture of claim 8 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

19. The suture of claim 9 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

20. The suture of claim 10 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

21. The suture of claim 11 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

22. The suture of claim 12 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

23. A method of closing a wound in living tissue which comprises: sewing edges of a wound in living tissue with the sterile absorbable surgical suture of claim 1,

tying the suture into a square knot,

running down the square knot to approximate the tissues in a desired location,

placing additional throws on the square knot, and

within less than about 48 hours bioabsorbing and removing the lubricant absorbable copolymer from the suture thereby increasing knot security and,

leaving the absorbable surgical suture in living tissue until the suture strand is absorbed by living tissue during the healing process, the suture providing useful tissue retention strength for at least 15 days and absorption being substantially complete within 90 days.

* * * * *

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000104

United States Patent [19]

Landi et al.

[11] **4,043,344**

[45] **Aug. 23, 1977**

[54] **NON-ABSORBABLE SURGICAL SUTURES COATED WITH POLYOXYETHYLENE-POLYOXYPROPYLENE COPOLYMER LUBRICANT**

[75] Inventors: **Henry Patrick Landi**, Yorktown Heights; **Vincent Anthony Perciaccante**, Long Island City, both of N.Y.

[73] Assignee: **American Cyanamid Company**, Stamford, Conn.

[21] Appl. No.: **724,876**

[22] Filed: **Sept. 20, 1976**

[51] Int. Cl.[2] A61L 17/00

[52] U.S. Cl. ..... 128/335.5; 128/1 R; 428/375

[58] Field of Search ..... 128/1 R, 335.5; 428/375

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,061,470	10/1962	Kuenmerer	428/375 X
3,432,898	3/1969	Stanley et al.	428/396 X

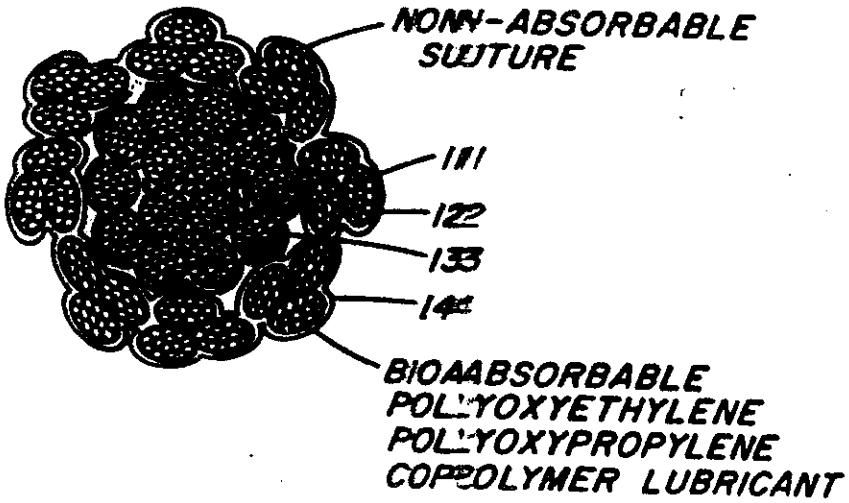
Primary Examiner—Leland A. Sebastian

Attorney, Agent, or Firm—Charles F. Costello, Jr.

[57] **ABSTRACT**

The handling characteristics, including particularly the knot run down and tissue drag characteristics, of non-absorbable surgical sutures are improved by a coating of a lubricating film of a bioabsorbable copolymer having polyoxyethylene blocks and polyoxypropylene blocks, and which bioabsorbable copolymer has a molecular weight such that it is pasty to solid at 25° C. This lubricant coating is absorbed in tissue in less than about 48 hours—which results in improved long term knot security.

17 Claims, 2 Drawing Figures



U.S. Patent Aug. 23, 1977 4,043,344

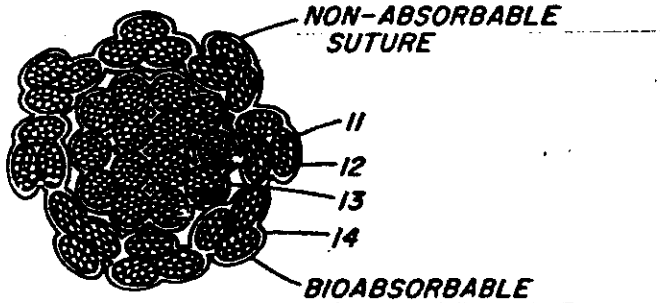


FIG. 1

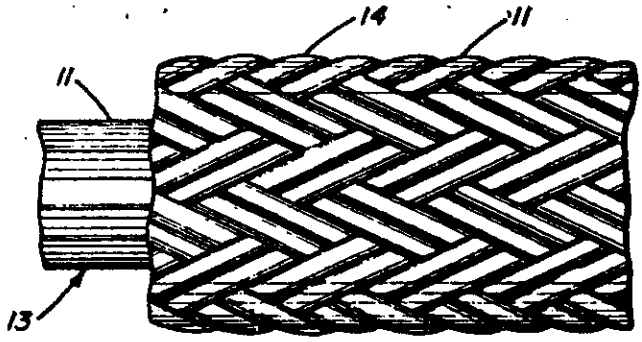


FIG. 2

NON-ABSORBABLE SURGICAL SUTURES COATED WITH POLYOXYETHYLENE-POLYOXYPROPYLENE COPOLYMER LUBRICANT

BACKGROUND OF THE INVENTION

The handling characteristics of surgical sutures encompass many factors, some of which factors are at least in part inconsistent or seemingly inconsistent. There is a constant effort to improve the handling characteristics. Among the more important of the handling characteristics are those associated with knot run-down. In many surgical procedures it is necessary that a knot be tied in a suture when the knot is deep inside a surgical or natural opening. For instance, a dental surgeon may need to tie a knot inside a patients mouth. An intravaginal hysterectomy requires suturing in restricted quarters. One technique frequently used is to tie a square knot that can be run-down from an exterior location where the knot is first tied to lie against tissue with a desired degree of tightness. The knot is snugged down so that it is holding with a degree of firmness chosen by the surgeon for a particular situation and then additional throws are tied down against the first throws of the square knot. In some instances, the first throw is a double twist followed by a single throw to form a surgeons knot, with additional throws to form additional square knots on top as needed. As contrasted with the ease of placement, is the necessity of knot security. Even though it is desired that it be easy to tie a knot, it is mandatory that the knot hold without slipping for an acceptable length of time.

With buried absorbable sutures, the suture including the knot is absorbed, and the knot need only hold until the suture is absorbed. This can be a few hours for certain types of skin incisions, up to 15 to 28 days for some internal knots.

Non-absorbable sutures are used, if strength for a longer time or permanent reinforcement is desired.

Some suture materials are so smooth that a knot run downs very readily and frequently becomes readily untied. Other sutures are of materials in which the knot tends to "lock-up" or refuse to run-down so that it is difficult to snug-down the throws against the tissue and only a few throws are needed, and security is not a problem. Knots in constantly moving tissue, such as adjacent to the heart, particularly if a non-absorbable suture, have a much greater chance of becoming untied than knots in quiescent tissue such as knots holding together a wound inside a plaster cast.

For knots in non-absorbable sutures which are buried in tissue, the problem of knot security for years has been a problem.

PRIOR ART

U.S. Pat. No. 1,254,031 — Jan. 22, 1918, Davis, SUTURE AND METHOD OF MAKING THE SAME, shows a braided collagen suture immersed in collagen or glue to cause close adhesion of the braid, to fill up the interstices and provide a smooth uniform coating.

U.S. Pat. No. 2,576,576 — Nov. 27, 1951, Cresswell and Johnstone, LUBRICATED THREAD, shows a lubricated multifilament collagen thread using as a lubricating film a phosphatide such as lecithin. The lecithin should be applied at the time of coagulation or regeneration of collagen as effective lubrication is not obtained if the lubricant is incorporated by adding to a finished thread.

U.S. Pat. No. 2,734,506 — Feb. 14, 1956 — Nichols et al. SILK SUTURES AND LIGATURES shows using poly(alkyl) methacrylate as a coating for silk sutures, and a hot coating die system.

U.S. Pat. No. 3,187,752 — June 8, 1956 — Glick, NON-ABSORBABLE SILICONE COATED SUTURES AND METHOD OF MAKING, shows silk or other non-absorbable synthetic filaments such as nylon, cotton or linen coated with a silicone which gives a more inert suture and reduces capillarity.

U.S. Pat. No. 3,209,589 — Oct. 5, 1965 — Schlatter, YARN FRICTION MEASURING INSTRUMENT, describes a machine for measuring the friction of a yarn sliding over itself and describes the variation of friction with speed, and the "slip-stick" variety at slow speeds.

U.S. Pat. No. 3,297,033 — Jan. 10, 1967 — Schmitt and Polistina, SURGICAL SUTURES, shows synthetic surgical sutures of polyglycolic acid and discloses that the surfaces of the fiber can be coated with a silicone, beeswax, or the like to modify the handling or the absorption rate.

U.S. Pat. No. 3,390,681 — July 2, 1968, Kurtz, POLYESTER SUTURE HAVING IMPROVED KNOTTING CHARACTERISTICS, shows improving the knotting characteristics of a polyester such as one formed from a dicarboxylic acid and a diol (Dacron) by depositing on the fibers a polytetrafluoroethylene (Teflon). This patent discloses many of the problems in suture knots, and is hereby incorporated by this reference thereto. This patent also shows the accepted practice of classing "ligatures" under "sutures" for patent disclosure purposes.

U.S. Pat. No. 3,565,077 — Feb. 23, 1971, Glick, DENSIFIED ABSORBABLE POLYGLYCOLIC ACID SUTURE BRAID, AND METHOD FOR PREPARING SAME, shows a suture construction using polyglycolic acid filaments with a compacted structure and a reduced void fraction.

U.S. Pat. No. 3,815,315, June 11, 1974, Glick, ETHYLENE OXIDE STERILIZATION OF MOISTURE SENSITIVE SURGICAL ELEMENTS shows the desirability of maintaining surgical elements of polymers subject to the hydrolytic degradation to non-toxic, tissue-compatible, absorbable components, such as polyglycolic acid sutures, in a desiccated condition in an air tight container impervious to moisture vapor. Suitable desiccating cycles and foil containers to give products which are storage stable for years are disclosed.

U.S. Pat. No. 3,867,190 — Feb. 18, 1975, Schmitt and Epstein, REDUCING CAPILLARITY OF POLYGLYCOLIC ACID SUTURES, shows the coating of polyglycolic acid surgical sutures with a copolymer of from 15–85% glycolic acid with 85–15% lactic acid which coating fills the interstices of a multi-filament polyglycolic acid suture. Example 10 discloses the coating as minimizing capillarity, and improving run-down. Thicker coatings increase stiffness. This patent has 38 references to earlier prior art on sutures and methods of making them, and related fields and is incorporated herein by this reference thereto. A divisional of said U.S. Pat. No. 3,867,190 is Ser. No. 489,004, July 16, 1974, REDUCING CAPILLARITY OF POLYGLYCOLIC ACID SUTURES, now U.S. Pat. No. 3,982,543 dated Sept. 28, 1976.

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U.S. Pat. No. 3,896,814 — July 29, 1975 — Viviesen and Schwartz, COLLAGEN BASED THREADS, shows a collagen or catgut thread which is flexibilized by having therein water and a hygroscopic agent such as a glycerol or a glycol or a low molecular weight (up to 400 m.w.) liquid polyalkalene oxide, and which may additionally be coated with a lipoid or a silicone for surface lubricity.

U.S. Pat. No. 3,942,532 — Mar. 9, 1976 — Hunteter and Thompson — BRAIDED SUTURE, discloses an adaptation of an INSTRON Universal Testing Instrument using an oscillographic recorder, to use a single throw between two suture strands to measure surface roughness, as an indication of the ease of sliding a surgeon throw knot down the suture into place, there called "tie-down performance." A coating of 0.4 percent to 7 percent of the suture weight of an aliphatic polyester such as a condensate of adipic acid and 1,4-butanediol having a molecular weight of about 2,000–3,000 is recommended.

U.S. Ser. No. 691,749, filed June 1, 1976 — Casey and Epstein — NORMALLY-SOLID BIOABSORBABLE, HYDROLYZABLE, POLYMERIC REEACTION PRODUCT, discloses the use of trans-esterification product of poly(1,4-propylene diglycolate) and polyglycolic acid and other trans-esterification products of polyglycolic acid and a polyester of diglycolic acid and an unhindered glycol to coat sutures to improve knot run-down and other suture characteristics.

The coating, coloring and conditioning of surgical sutures with polymeric materials in general is well-known. Silicones, wax, polytetrafluoroethylene, and other polymers have been used. Specific coating materials with unique advantages to give improved sutures are constantly being sought.

SUMMARY OF THE INVENTION

It has now been found that the knot run-down characteristics, handleability, tie-down performance and tissue drag characteristics of braided, twisted or covered multifilament non-absorbable sutures may be improved by coating with a lubricating biologically absorbable copolymer having polyoxyethylene blocks and polyoxypropylene blocks.

Non-absorbable sutures are sutures which are resistant to biodegradation in living mammalian tissue and remain in the tissue as a foreign body, unless surgically removed (e.g. skin sutures) or extruded. An absorbable suture is degraded in body tissues to soluble products and disappears from the implant site, usually within 2 to 6 months. Non-absorbable sutures retain strength in living mammalian tissue for an extended period, often for the life of the subject. Non-absorbable sutures used for skin closures with the knot above the surface of the skin are removed by the surgeon at a suitable stage of the healing process. For those in which the knot in the non-absorbable suture is buried in living tissue, and are to be left indefinitely, the present lubricant is absorbed from the non-absorbable suture in less than about 48 hours, and hence the lubricating action ceases, and knot security improves.

Non-absorbable sutures are typically of silk, cotton, nylon, a non-absorbable polyester (Dacron ®) polypropylene, polyethylene, or linen. Even metals such as stainless steel, monofilament or braided or tantalum or platinum have been used.

Absorbable or bioabsorbable as applied to the coating, refers to a coating which by hydrolytic or enzymatic degradation, or by its inherent characteristic, has such molecular weight and solubility properties that it is absorbed from the surface of the suture and is eliminated by the subject either unchanged or in hydrolyzed or degraded form.

The lubricant coating not only aids in the knot run-down characteristics but increases the smoothness and flexibility of the sutures so that they may be more easily drawn through the skin and other tissues during placement of the suture. This reduction in friction is called reduced tissue drag. The coating that aids in reduced tissue drag, and lubricates in knot placement also causes the knot to slip more readily.

Another unexpected and unobvious advantage of the present lubricant coating in that the lubricant copolymers are absorbed from the suture within a few days so as the wound heals knot security improves.

The absorbable coating is one or more of a group of compounds having blocks of polyoxyethylene and blocks of polyoxypropylene in their structure. For simplicity and ease of description these compounds are taught, drawn and treated as if there were merely two or three blocks in the chain. However, it is to be understood that non-significant qualities of polyoxypropylene may be present in the polyoxyethylene block and minor quantities of polyoxyethylene may be present in the polyoxypropylene block. From the methods of manufacture it would appear that there may be and probably are such minor admixtures present in the chain. The commercially available grades are acceptable and found to have a low and acceptable degree of toxicity.

The present lubricants may be indicated as having the formula:

$$R[(CH_2CHO)_n(CH_2CHO)_mH]_c$$
$$\quad\quad\quad

from petroleum fractions, it is to be expected that in commercial practice complete rectification to chemically pure compounds is not obtained. Fortunately the commercial grades may be used on sutures with excellent results. Said U.S. Pat. No. 2,979,528 also points out that as polymers, all molecular species are far from identical—some chains are shorter, some are longer, but on the average the materials are as indicated and it is the physical properties of the lubricants, not the molecular weight spread of the components, which are important.

U.S. Pat. No. 3,036,118, May 22, 1962, MIXTURES OF NOVEL CONJUGATED POLYOXYETHYLENE-POLYOXYPROPYLENE COMPOUNDS, D. R. Jackson and L. G. Lundsted, has much disclosure on the addition of polyoxyethylene groups and polyoxypropylene groups to reactive hydrogen compounds having from 2 to 6 reactive hydrogen atoms and not over 6 carbon atoms per molecule. Among other such compounds are listed the group consisting of aliphatic polyhydric alcohols, alkylamines, alkylene polyamines, cyclicamines, amides, and polycarboxylic acids, oxyethylene groups and oxypropylene groups. The reactive hydrogen compound serves as a chain initiator and can be present in such a small proportion that it has minor significance in its own right and serves mainly as a foundation on which the predominantly polyoxyethylene or polyoxypropylene blocks may be added in the chosen order. Whereas U.S. Pat. No. 3,036,118 claims primarily the Reverse Pluronics in which the polyoxyethylene chains are attached to the nucleus or initiating reactive hydrogen compounds, in the present invention either the Reverse Pluronic with the polyoxyethylene in the center or the regular Pluronics with the polyoxypropylene in the center or the Tetronics with nitrogen in the center may be used for lubricant purposes.

Because the chemistry is previously known, and to avoid unnecessarily extending the length of the present disclosure, the disclosures of each of these three patents is herein hereby incorporated by this reference thereto.

These lubricating bioabsorbable copolymers are often classed as surface active agents as the polyoxyethylene blocks are predominantly hydrophylic and the polyoxypropylene blocks are predominantly hydrophobic. The materials have been sold by the Wyandotte Chemical Company under the trademark of PLURONICS for the formula:

$$H(OCH_2CH_2)_x(OCHCH_2)_y(OCH_2CH_2)_zOH$$
$$\quad\quad\quad

TABLE I-continued

REVERSE PLURONIC		M.W. polyethylene units of m block			M.W. polyoxypropylene block	Units of a and O	
10R8	3,000	2000	45	65%	562	9	46
17R8	4,350	2600	59	60%	870	15	53
25R8	9,000	3250	74	57%	1250	22	56

TETRONIC	Average Molecular Weight	Approximate Molecular Weight of Individual Polyoxyethylene Block	Approximate % Polyoxyethylene	Molecular Approximate Weight of Individual Polyoxypropylene Block	Approximate % Polyoxypropylene	Average Approximate length of chains per block Units of r	Units of q
707	12,000	2312	74	673	26	52.5	11
908	26,100	5588	85	923	15	127	15.9
1107	14,500	2438	67	1173	33	55.4	20.2
1307	18,600	3213	69	1423	31	73	24.5
1508	27,000	5063	75	1673	25	115	28.5

In general, the Pluronics with a molecular weight range of from about 4,750 to 16,250 are waxy solids. The polyoxypropylene portion has a molecular weight of 950 to 4,000 and the polyoxyethylene content of about 60–80%.

The pastes in general have a total molecular weight ranging from 3,500 to 5,700 with a polyoxypropylene molecular weight range of 1,750 to 6,500 and polyoxyethylene content of 30 to 50%. The transitions from wax to paste to liquid are not sharp.

COATING

The non-absorbable suture is conveniently coated by several conventional procedures including:

Melt Coating

The uncoated suture is placed in a split die whose orifice corresponds to diameter specifications for the particular size suture to be coated. The die is then clamped in a heating block and the polyoxyethylene-polyoxypropylene lubricant bioabsorbable copolymer placed in the die. The die is raised to a temperature about 20° C. above the melting point of said copolymer and after the copolymer has melted, the suture to be coated is slowly pulled downward through the molten material in the die and collected on a take-up spool. The spool is mounted directly below the die a sufficient distance to allow solidification of the coated. A cooling tunnel or a blast of cooling air may be used to increase production speeds. Nichols et al. U.S. Pat. No. 2,734,506, supra, describes one useful apparatus for coating.

Solution Coating

The polyoxyethylene-polyoxypropylene lubricant bioabsorbable copolymer is dissolved in chloroform. About twice the percentage by weight is used for coating solution as is desired on the final sutures. A feed loop such as a loop of wire or a ceramic is threaded with the uncoated suture, after which the feed loop is then submerged in the solution and the suture is passed down through the feed loop. It may be passed through a die whose diameter is such that after drying a suture will have the desired diameter. The suture is pulled slowly through the solution and at least partially dried in a drying tunnel. The drying is finished after the suture is wound on a spool. Because variations in equipment, speed, and temperature affect the pick-up of the lubricant bioabsorbable polymer, the concentration in the coating is adjusted based on a preliminary run or experience.

Other coating techniques which are well known in the coating of polyfilamentary strands may be used. The techniques used for insulating wire may be adapted for large scale suture manufacture. The above are merely two of the more convenient and well known methods for coating. Details are later illustrated in examples.

TOXICITY

The low toxicity of the polyoxyethylene-polyoxypropylene compounds of the present invention are shown in such U.S. Pats. as U.S. Pat. No. 3,450,502 which describes the use of a copolymer having a total molecular weight of about 8,750 in isotonic solutions used as a priming agent in a heart-lung apparatus. In sutures even if a maximum of around 25–30% by weight of the suture of copolymer is used, only a very small amount is placed in the subject.

The low toxicity is shown in the following table.

TABLE II

TOXICITY

Pluronic No.	Total Molecular Weight	Physical Characteristic	LD 50 (gm/kg) in Mice
F-38	5000	wax	>5
F-77	6600	wax	4.2
F-87	7700	wax	3.75
F-68	8350	wax	>5
F-88	10800	wax	>5
F-127	12500	wax	2.25
F-98	13500	wax	>5
F-108	14400	wax	1.25
P-65	3400	paste	0.83
P-84	4200	paste	0.4
P-85	4600	paste	0.53
P-94	4600	paste	0.6
P-103	4950	paste	1.4
P-104	5850	paste	0.75
P-123	5750	paste	2.7
P-105	6500	paste	3

The polyoxyethylene-polyoxypropylene compositions used as the lubricant bioabsorbable copolymers have been used in food products; and have been the subject of studies as to their elimination from a mammalian body. In general, they are eliminated in the urine fairly rapidly, and within 48 hours nearly all have been eliminated from the blood stream.

If some of the lubricant bioabsorbable copolymer is trapped in braid pores of a suture, the rate of diffusion into the blood stream may be reduced and hence the time for elimination somewhat increased. The molecular weight is small enough that the lubricant bioabsorbable copolymers may be eliminated unchanged, although some degradation may occur before elimination. The important thing is that the lubricant bioabsorbable copolymer has no deleterious effect upon healing tissues adjacent to the sutures, and being removed from the surface of the suture by absorption by the body, knot

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security r is improved. As soon as suture placement is completeted, the knot run down and tissue drag reduction functionn is complete, and as the lubricant bioabsorbable copolymener is removed from the suture, knot security improvesces.

Definitiitions in the suture and textile trades are sometimes ambiguous or confused. As herein used;

A "filamment" is a single, long, thin flexible structure of a non-absosorbable or absorbable material. It may be continuous oor staple.

"Staplele" is used to designate a group of shorter filaments wwhich are usually twisted together to form a longer ccontinuous thread.

An absosorbable filament is one which is absorbed, that is digesteed or dissolved, in living mammalian tissue.

A "threnead" is a plurality of filaments, either continuous or stanaple, twisted together.

A "strarand" is a plurality of filaments or threads twisted, plaited, braided, or laid parallel to form a unit for furtheer coonstruction into a fabric, or used per se, or a monofilfilament of such size as to be woven or used independeciently.

The terrerm "suture" is used to include the term "ligature" as technically a suture is used with a needle whereas tthe ligature is merely used to tie without being placed byy a needle.

A finisished suture has a needle attached and is sterile and readyy for use in surgery. For purposes of convenience inin nomenclature, the term "suture" is frequently used to rerefer to the same strand before it is coated and before it ic is packaged and sterilized. Context indicates whether r it is the sterile suture ready for use, or the suture in a manufacturing step which is referred to.

The strrand of the suture is used as the basis for weight in determmining the quantity of material that is placed on the non-aabsorbable strand in forming the non-absorbable surgicacal suture.

The quuantity of the lubricating bioabsorbable copolymer is frorom about 0.1 to 25 percent by weight of the lubricatingg bioabsorbable copolymer based on the weight ofof the uncoated strand forming the suture. It is not necessaary that the coating be continuous as a discontinuouus coating on the surface aids in reducing friction and cinchatter. A larger quantity may be present if the lubricatingg bioabsorbable copolymer penetrates inside the strandd, with the various filaments themselves being partially oor totally covered.

The wiiide range of coating weight permits adaptation of the presesent sutures to many varied uses. Because the strand to bbe coated to form the suture may have considerable vvariation in surface roughness, due to the mechanical sstructure, i.e. braid or twist, etc. as well as being mmade from filaments which are less than 2 denier per filamesent to more than 6 denier per filament, with the finer filammment sizes giving a smoother surface; and because thesse filaments may be stretched after the suture is manufactuured or in heat treatment, the surface roughness basicacally can vary. The smoother surfaces require less of thhe lubricating bioabsorbable copolymer for analogouus degrees of slippage.

The vaariious surgical techniques used interact with the desired desegree of lubrication. For any given type of knot, a largrger quantity of lubricant which for a particular techniique increases the ease of run-down, also increases thhe ease of the knot running back or slipping, called knoot security. For some surgical procedures it is highly desesirable that the knot be very free in running down, eveven though the knot slips more readily.

A surgeon in tying knots is confronted with the interaction between the method of tying the knot and the ease of slipping. If a suture is comparatively well lubricated, the surgeon can use a square knot, which is run down readily; with additional squared throws for knot security. On the other hand, if the suture is less well lubricated, the surgeon can use a double half-hitch or some other type of knot which moves more readily to run the knot down to position, after which the double half hitch can be pulled to square the knot, or additional throws can be thrown down against the knot to give adequate knot security. Thus the surgeon can either adapt his knot techniques to a particular suture, or can get sutures whose surface lubricity is best adapted to the technique which the surgeon desires to use. Generally, there is an adaptation of each to the other. The surgeon attempts to get a suture whose characteristics are those which he prefers, and then adapts his knot tying techniques to the sutures that he has at the time. Some surgeons make very successful knots with stainless steel wire using a knotting technique that is adapted to such a wire which has very poor run-down. Others prefer a much more readily run-down well-lubricated suture.

Additionally the location of use has influences. Sometimes a suture in passing through tissue picks up tissue fluids. The suture may be coated with tissue fluids which are either fresh or partly dry at the time the knot is tied. In some surgical techniques it is necessary to preplace the sutures, and tie the suture after the coating of tissue fluids on the suture has a chance to become at least partially dried.

Because the ease of knot run-down and knot security are somewhat opposite, it is necessary for the surgeon to use additional throws or such knots as will hold under the particular conditions of a selected surgical procedure. By changing the quantity of the lubricant bioabsorbable copolymer, the run-down can be modified to suit a using surgeons preference.

The time of use of the knots can be quité varied. Some surgeons use a suture to ligate bleeders in a wound with a retention requirement of 30 minutes or less. Such knots can be removed as the surgical procedure is complete, and before wound closure. Others leave the knots in the tissue even though there is no likelihood that a bleeder would reopen.

Because the present lubricating bioabsorbable copolymer is removed from the suture in living tissue, as the lubricant is removed the knot security increases and after 48 hours more or less, knot security is greatly improved.

The examples following should show the effects of certain different coating and quantities under certain conditions.

The requirements of surgery are extremely varied, and various coating weights permit adaptation of non-absorbable sutures to different conditions.

In general, if the surgeon desires a better lubricated suture, a larger quantity of the lubricating bioabsorbable copolymer is used and conversely if the surgeon is willing to accept slightly reduced knot run-down and tissue drag characteristics in favor of greater knot security, the coating level is reduced in favor of this particular compromise.

Usually from 2 percent to 8 percent of the lubricant bioabsorbable copolymer gives a useful range of compromise between the ease of knot run-down and knot security.

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A usage of about 5 percent by weight of Pluronic F-68 is a preferred compromise between the knot run-down and knot security requirements for 2 to 6 denier per filament braided sutures of polyglycolic acid.

In the Drawings:

FIG. 1 is cross-section of a non-absorbable suture having on the surface thereof a bioabsorbable polyoxyethylene polyoxypropylene copolymer lubricant.

FIG. 2 is a drawing of a suture showing the parallel filaments in the core and the braided sheath. The lubricant coating appears on the surface.

The drawings are diagrammatic and representative. The filaments 11 of the non-absorbable suture are at best some what jumbled in actual configuration but are illustrated as patterned in a somewhat idealized style. The coating 12 of the lubricant bioadsorbable polyoxyethylene-polyoxypropylene copolymer is shown much exaggerated. At a level of from 0.1 to 25 percent, the coating would be so thin as to merely be represented by a blurred line if to accurate scale.

In FIG. 2 the core 13 of the braided suture consists of parallel filaments and the sheath 14 consists of a plurality of filaments, typically braided in configuration. The type of braid shown is representative and diagrammatic. The visability and appearance of the coating varies depending upon the observational technique used to inspect the suture.

The coating 12 in part may bridge the gap between the individual filaments in the finished suture. Depending upon the quantity of coating used, the bridging may be more or less complete but complete filling is not necessary. If the coating level is increased, knot run-down continues to be improved, but knot security is compromised.

EXAMPLE 1

Friction and Chatter Tests

A set of 2/0 USP XIX (diameter 0.339 mm, maximum) braided silk sutures was coated with 5 levels of Pluronic F-68; and 12 levels of Pluronic F-127.

4 Blanks were run with no coating, on braid from the same lot, for comparison, and an average of these 4 used for comparative values.

Also 5 runs were made using a commercial silicone coated silk suture, see U.S. Pat. No. 3,187,752, supra, for comparative purposes.

For these coatings, the braid was run through a solution of the Pluronic in chloroform at a concentration of about twice the percentage desired for the coating on the suture, and air dried.

A standard ATLAB yarn Friction Tester Model CS-152-026, Custom Scientific Instruments, Inc. Whippany, New Jersey 07981, with a Hewlett Packard Model 321 dual channel amplifier recorder was used to record the tension of the strand feeding into the tester, and coming out of the yarn tester. The chatter factor is the ratio of maximum pull (T_3) to the feed tension (T_1) minus the minimum pull (T_2) to the feed tension, i.e.$(T_3/T_1) - (T_2/T_1)$. The values for friction are of $(T_3/(T_1)$ to start slipping.

The values of particular interest are the ratios and percent reduction. With other types of test devices, the numerical values may change, but the relative ratios as an index of improvement are analogous.

In this test, an uncut strand, coated as indicated, was used for the test. For use as a suture, such strand is cut to length, needled, packaged and sterilized using conventional techniques. The friction and chatter is more readily measured on continuous lengths.

Reduction in static friction, chatter and the coefficient of friction are shown in Table III.

TABLE III

			Size 2/0 Silk Braid					
Run No.	Pluronic Coating	Level (%)	Static Friction	% Reduction	Chatter Factor	% Reduction	Coeff. of Friction × 10^{-2}	% Reduction
1	Blank	—	3.15	—	0.46	—	6.300	—
2	Blank	—	3.40	—	0.47	—	6.822	—
3	Blank	—	3.32	—	0.46	—	6.690	—
4	Blank	—	3.78	—	0.93	—	6.666	—
5	Silicone	—	3.75	—	0.66	—	7.203	—
6	Silicone	—	3.60	—	0.63	—	6.930	—
7	Silicone	—	3.63	—	0.74	—	6.756	—
8	Silicone	—	3.63	—	0.63	—	7.015	—
9	Silicone	—	3.56	—	0.89	—	6.156	—
10	F-68	2.46	2.85	16.4	0.13	—	6.370	3.77
11	F-68	3.09	2.46	27.*	0.09	—	5.520	16.6
12	F-68	3.51	2.34	31.4	0.07	—	5.190	21.6
13	F-68	3.51	2.44	28.5	0.08	—	5.466	17.4
14	F-68	4.43	2.49	27.0	0.10	—	5.546	16.2
15	F-127	1.68	2.51	26.4	0.08	77.6	5.652	14.6
16	F-127	1.68	2.41	29.3	0.05	91.4	5.466	17.4
17	F-127	2.57	2.51	26.4	0.06	89.7	5.652	14.6
18	F-127	2.57	2.40	29.6	0.09	84.4	5.329	19.5
19	F-127	4.16	2.53	25.8	0.07	87.9	5.782	12.7
20	F-127	4.16	2.39	29.9	0.05	91.4	5.412	18.2
21	F-127	5.16	2.48	27.3	0.06	89.7	5.626	15.0
22	F-127	5.16	2.38	30.2	0.05	91.4	5.357	19.1
23	F-127	5.95	2.45	28.2	0.10	82.8	5.412	18.2
24	F-127	5.95	2.52	26.1	0.07	87.9	5.705	13.8
25	F-127	5.95	2.43	28.7	0.04	93.1	5.520	16.6
26	F-127	7.72	2.43	28.7	0.08	86.2	5.439	17.8

With other braid constructions and other sizes, the relative ease of knot run-down may be greater or less for the same quantity of coating, or conversely the quantity of the coating may be adjusted to give the desired knot run-down values.

The quantity of the Pluronic in the solvent may be varied, and solvents other than chloroform may be used.

Other organic solvents such as methyl alcohol, ethyl alcohol, isopropyl alcohol, methylene chloride, warm xylene (about 60° C.), tetrahydrofuran, acetone, dimethylformamide, dimethyl sulfoxide, mixtures thereof, and other similar solvents for the lubricant may be used for coating. Flowing the solution onto a moving strand, and letting the surplus drip off is another useful coating technique.

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A small amount of water increases the solubility of the lubricants, and aids in coating.

In general it is more convenient to use the solvent coating systems at levels below 10 percent pick-up and use a heated die at above about 10 percent pick-up.

EXAMPLE 2

2/0 Nylon Braided Sutures

Using the procedures described in Example 1, runs were made on nylon braid, sized for a 2/0 suture. The reduction in friction, and chatter factors are shown in Table IV. Both uncoated braids from the same lot, and commercial silicone coated nylon were used for comparison.

The reduction in chatter is particularly outstanding.

TABLE IV

			2/0 NYLON BRAID					
Pluronic Run No.	Level Coating	Static (%)	% Friction	% Chatter Reduction	Chatter Factor	Coeff. of Friction	% Friction × 10^{-2}	% Reduction
1	Blank	—	3.02	—	0.33	—	6.300	—
2	Blank	—	2.89	—	0.53	—	6.205	—
3	Blank	—	3.06	—	0.51	—	5.933	—
4	Silicone	—	2.69	10.0	0.34	26.1	5.466	11.1
5	Silicone	—	2.89	3.34	0.42	8.69	5.762	6.25
6	Silicone	—	3.43	—	0.55	—	6.734	—
7	F-68	2.53	2.24	25.1	0.18	60.9	4.632	24.6
8	F-68	2.53	2.47	17.4	0.23	50.0	5.162	16.0
9	F-68	2.53	2.43	18.7	0.16	65.2	5.218	15.1
10	F-68	4.91	2.41	19.4	0.23	50.0	4.942	19.6
11	F-68	5.60	2.29	23.4	0.18	60.9	4.726	23.1
12	F-68	5.60	2.42	19.1	0.20	56.5	5.077	17.4
13	F-68	5.60	2.46	17.1	0.17	63.0	5.274	14.2
14	F-68	6.09	2.54	15.1	0.22	52.2	5.347	13.0
15	F-127	2.83	2.49	16.7	0.19	58.7	5.302	13.7
16	F-127	3.08	2.32	22.4	0.22	52.2	4.783	22.2
17	F-127	3.36	2.36	21.1	0.17	63.0	4.989	18.8
18	F-127	5.60	2.37	20.7	0.17	63.0	4.989	18.8
19	F-127	5.60	2.36	21.1	0.12	73.9	5.133	16.5
20	F-127	5.60	2.38	20.4	0.13	71.7	5.162	16.0
21	F-127	6.21	2.37	20.7	0.15	67.4	5.077	17.4
22	F-127	6.79	2.45	18.1	0.14	69.6	5.329	13.3
23	F-127	7.57	2.65	11.4	0.28	39.1	5.520	10.2

EXAMPLE 3

2/0 Dacron ®Braid Sutures

Using the procedure of Example 1, runs were made on a polyester braid (Dacron ®) sized for a 2/0 suture. The reduction in friction and chatter factor are shown in Table V.

Both uncoated braid from the same lot and silicone coated braid were used for comparison. An average of the uncoated braid runs was used as a base to show improvement.

TABLE V

				2/0 Dacron Braid				
Run No.	Pluronic Coating	Level (%)	Static Friction	% Reduction	Chatter Factor	% Reduction	Coeff. of Friction × 10^{-2}	% Reduction
1	Blank	—	2.89	—	0.31	—	6.027	—
2	Blank	—	2.65	—	0.34	—	5.310	—
3	Blank	—	2.54	—	0.28	—	5.189	—
4	Silicone	—	2.14	—	0.19	—	4.263	—
5	Silicone	—	2.20	—	0.17	—	4.478	—
6	Silicone	—	2.40	—	0.27	—	4.800	—
7	F-127	2.39	2.60	3.45	0.33	—	5.216	9.30
8	F-127	5.37	2.47	8.28	0.21	32.3	4.996	9.30
9	F-127	5.12	2.36	12.4	0.21	32.3	4.871	11.6
10	F-68	4.03	2.20	18.3	0.19	38.7	4.269	22.5
11	F-68	4.03	2.28	15.3	0.21	32.3	4.628	16.0
12	F-68	5.04	2.45	9.02	0.19	38.7	5.084	7.70
13	F-68	6.26	2.74	16.8	0.18	41.9	4.580	16.8
14	F-68	6.98	2.52	6.42	0.24	22.6	5.247	4.74
15	F-68	8.59	2.26	16.1	0.14	54.8	4.785	13.1

The data in the example is illustrative. Reductions in frictions and improvement in chatter is obtained on all sizes of sutures. With different materials and constructions the results may vary.

The amount of coating and the ease of run-down can be varied to give results desired by the using surgeons.

For sutures, either absorbable or non-absorbable, in which capillarity is a problem, a coating of a phosphatide, preferably purified lecithin, such as taught by U.S. Pat. No. 2,576,576 may be used to reduce capillarity and friction, with the present coating as an additional friction reductant. Lecithin causes tissue irritation under some conditions, particularly if not pure.

EXAMPLE IV

A braided silk suture strand, of a size to form a 2/0 USP suture, is dipped in a 10% solution of Pluronic F-68 in chloroform, and dried. The pick up is about 5% by weight of the weight of the strand itself.

The dried coated strand is cut into 54 inch segments, needled, packaged, sterilized and dried in accordance with conventional procedures.

The thus prepared silk sutures are used in surgical procedures. When used to approximate tissue at a wound, a suture is placed in an appropriate location, and tied with a square knot. The square knot readily runs down to pull the edges of the wound to the degree of tightness desired by the using surgeon. The suture shows low tissue drag, and excellent knot run down.

When a knot is at a desired final location, three additional squared throws are placed to secure the knot. Knots buried in tissue have the lubricant bioabsorbable

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copolymer removed from the suture surface within 48 hours, which gives additional knot security.

When removed from test animals after 48 hours, a square knot, without additional throws shows markedly greater knot security than immediately after placement.

In human tissue, in so far as can be observed, the knot security increases as the bioabsorbable lubricant coating is absorbed in tissue.

Whereas exemplified and tested with square knots, the ease of knot run-down and reduced tissue drag are useful in most suture placements and for knot retention. The amount of coating, and the relative values for knot run-down and reduced tissue drag, is variable to suit the requirement of a particular surgical situation.

The needling, packaging and sterilizing of the coated sutures is in accordance with conventional procedures.

We claim:

1. A non-absorbable surgical suture having improved knot run-down characteristics and reduced tissue drag comprising a polyfilamentary non-absorbable strand having thereon a thin lubricating coating of a lubricating absorbable co-polymer comprising polyoxyethylene blocks and polyoxypropylene blocks to aid run-down and handleability, said bioabsorbable copolymer having a molecular weight such that it is pasty to solid at 25° C.

2. The suture of claim 1 in which the lubricating bioabsorbable polymer has the formula:

$$R[(CH_2\underset{R_1}{\underset{|}{C}}HO)_n(CH_2\underset{R_2}{\underset{|}{C}}HO)_m H]_c$$

where one of R_1 and R_2 is methyl and the other hydrogen, and n and m are sufficiently large that the compound is pasty to solid at 25° C., R is the residue of a relatively low molecular weight reactive hydrogen compound having from 2 to about 6 reactive hydrogen atoms and having not over 6 carbon atoms in said compound, and c is the number of reactive hydrogens on the compound forming R.

3. The suture of claim 1 in which the lubricating bioabsorbable copolymer has effectively the formula:

$$H(OCH_2CH_2)_x(\underset{CH_3}{\underset{|}{O}}CHCH_2)_y(OCH_2CH_2)_z OH$$

where x, y and z are sufficiently large that the lubricating-bioabsorbable copolymer is pasty to solid at 25° C.

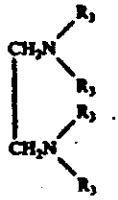
4. The suture of claim 3 in which the lubricating bioabsorbable copolymer has a moelcular weight of about 8350 and x and z are about 75 and y about 30, and the melting point is about 52° C.

5. The suture of claim 1 in which the lubricating bioabsorbable copolymer has effectively the formula:

$$H(\underset{CH_3}{\underset{|}{O}}CHCH_2)_n(OCH_2CH_2)_m(\underset{CH_3}{\underset{|}{O}}CHCH_2)_o OH$$

where n, m and o are sufficiently large that the lubricating bioabsorbable copolymer is pasty to solid at 25° C.

6. The suture of claim 1 in which the lubricating bioabsorbable copolymer has effectively the formula:



where R_3 is

$$-(CH_2\underset{CH_3}{\underset{|}{C}}HO)_q(CH_2CH_2O)_r H$$

where q and r are sufficiently large that the lubricating bioabsorbable copolymer is pasty to solid at 25° C.

7. The suture of claim 1 in which the non-absorbable strand is selected from the group consisting of silk, cotton, nylon, a non-absorbable polyester, polypropylene and polyethylene.

8. The suture of claim 3 in which the non-absorbable strand is selected from the group consisting of silk, cotton, nylon, a non-absorbable polyester, polypropylene and polyethylene.

9. The suture of claim 4 in which the non-absorbable strand is selected from the group consisting of silk, cotton, nylon, a non-absorbable polyester, polypropylene and polyethylene.

10. The suture of claim 1 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

11. The suture of claim 2 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and fricion are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

12. The suture of claim 3 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

13. The suture of claim 4 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

14. The suture of claim 7 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

15. The suture of claim 8 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the

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uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

16. The suture of claim 9 in which the lubricating coating is about 0.1 to 25 percent by weight of the lubricating bioabsorbable copolymer of the weight of the uncoated strand forming the suture, whereby both chatter and friction are reduced sufficiently that a square knot is movable on the suture with control of a wound edge.

17. A method of closing a wound in living tissue which comprises: sewing edges of a wound in living tissue with the sterile non-absorbable surgical suture of claim 1,

tying the suture into a square knot,

running down the square knot to approximate the tissues in a desired location,

placing additional throws on the square knot, in a subcutaneous location, and

within less than about 48 hours bioabsorbing and removing the lubricant absorbable coolymer from the suture thereby increasing knot security, and

leaving the non-absorbable surgical suture in living tissue, thereby reinforcing the tissue.

* * * * *

United States Patent [19]

Ohi et al.

[1111] **Patent Number: 4,946,467**

[4545] **Date of Patent: Aug. 7, 1990**

[54] **SURGICAL SUTURE**

[75] Inventors: **Shigeo Ohi; Masakazu Suzuki; Toru Yamamoto, all of Ayabe, Japan**

[73] Assignee: **Gunze Limited, Ayabe, Japan**

[21] Appl. No.: **320,529**

[22] Filed: **Mar. 8, 1989**

[30] **Foreign Application Priority Data**

Mar. 14, 1988 [JP] Japan ..... 63-34397[U]

[51] **Int. Cl.**[5] **A61B 17/00**

[52] **U.S. Cl.** **606/228**

[58] **Field of Search** 128/335.5; 606/228

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Primary Examiner—Randall L. Green
Assistant Examiner—Gary Jackson
Attorney, Agent, or Firm—Armstrong, Nikaido, Marmelstein, Kubovcik & Murray

[57] **ABSTRACT**

A suture comprising a core of at least one synthetic fiber filament yarns, and a covering layer formed of a plurality of silk strands and sheathing the core, the core and the covering layer having substantially the same elongation at break. The filament yarns have increased modulus of elasticity and increased breaking strength to thereby give the suture improved breaking strength and also have enhanced rigidity to render the suture highly amenable to the correction of its deformation and easier to handle.

10 Claims, 2 Drawing Sheets

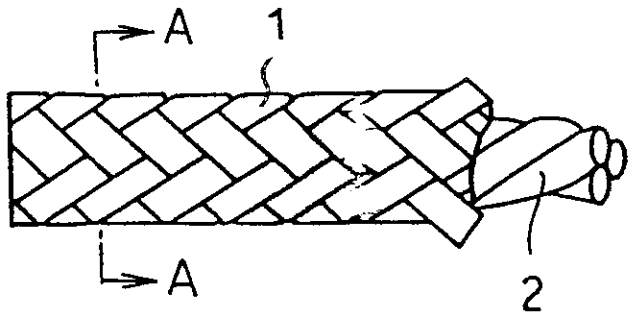


FIG. 1

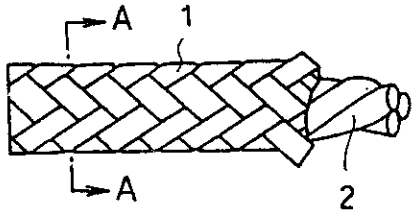


FIG. 2

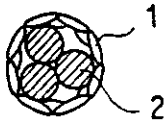


FIG. 3

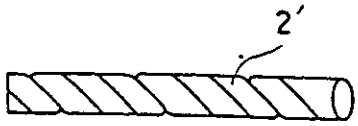
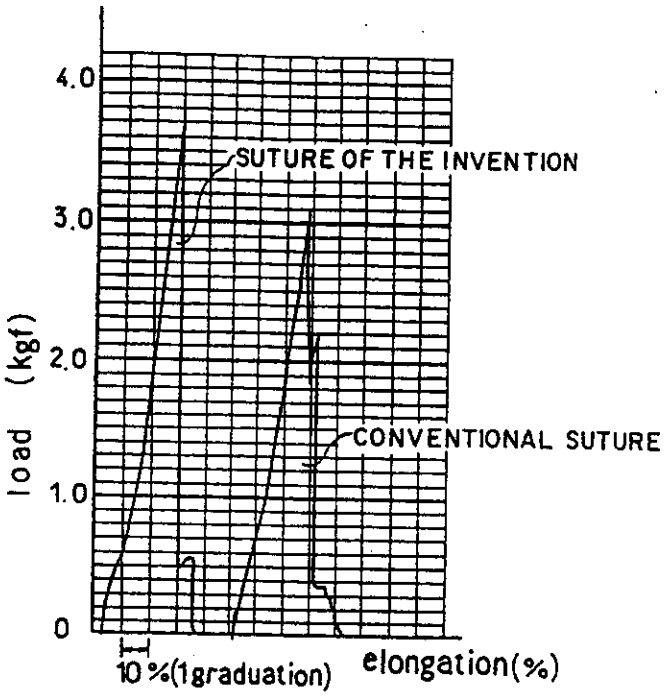


FIG. 4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SUTURE OF THE INVENTION
CONVENTIONAL SUTURE
10%(1graduation)
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SURGICAL SUTURE

BACKGROUND OF THE INVENTION

1. Field of Invention

The present invention relates to sutures for use in surgery.

2. Description of the Prior Art

Sutures of silk have long been known and used for various surgical applications. Conventional sutures are of various types and include those prepared by twisting, braids formed by plaiting, and braids having a core. The known suture is made of silk only and therefore has the drawback of being low in stiffness and having very poor ability to restore itself when deformed. For example, the suture wound on a reel remains helically curled when unwound therefrom and is difficult to straighten to a corrected form. The same difficulty is also encountered with the suture wound around a paper core.

If the suture is used is as curled the suture will coil around the surgeon hand of the surgeon or hang down in a helical form owing to its excessive flexibility and causes great frustration to the surgeon.

To overcome this problem, we have proposed a suture comprising a core of synthetic fiber filament yarn and a braid or the like of silk strands covering the core (Japanese Utility Model Application No. 41670/1987). The proposed suture is given suitable flexibility due to the appropriate rigidity of the filament yarn as afforded by doubled polyester filament strands in combination with the flexibility of the silk strands covering the yarn, whereby the suture is made amenable to the correction of its deformation such as the curl due to winding so as to be easily handled. Furthermore, the suture has a higher breaking strength than those consisting solely of silk strands owing to the presence of the core of synthetic fiber filament yarn. However, the suture still remains to be improved since there is a demand for sutures having a higher strength.

SUMMARY OF THE INVENTION

The main object of the present invention is to provide a surgical suture meeting this demand, and more particularly a suture which has a suitable flexibility and high amenability to the correction of deformation such as the curl due to winding on a reel and is easy to handle and which further has an exceedingly high breaking strength.

To fulfill the above object, the present invention provides a surgical suture characterized in that the suture comprises a core of at least one synthetic fiber filament yarn, and a covering layer formed of a plurality of silk strands and sheathing the core, the core and the covering layer having substantially the same elongation at break.

The core can be formed of a plurality of synthetic fiber filament yarns extending in parallel to one another and each having substantially the same elongation at break as the covering layer.

Furthermore, the core can be formed of single-twisted or plied filament yarns of synthetic fiber and made to have substantially the same elongation at break as the covering layer.

Furthermore, the core can be formed by plaiting a plurality of synthetic fiber filament yarns and made to have substantially the same elongation at break as the covering layer.

The covering layer can be formed by plaiting the plurality of silk strands and made to have substantially the same elongation at break as the core.

The synthetic fiber filament yarn can be made of any of various materials such as nylon, polyester, polypropylene and acrylic, among which polyester which has high breaking strength per denier is especially desirable from the viewpoint of giving improved strength to the suture.

The suture of the present invention has a suitable flexibility due to the rigidity of the core of synthetic fiber filament yarn and because of the flexibility of the covering layer of silk strands, and is thereby given high amenability to the correction of deformation such as the curl due to winding on reels and made easy to handle, hence outstanding advantages. The suture has another advantage; that it is readily deformable to a form suited to suturing during surgery. These great advantages appear attributable also to the fact that slippage occurs more smoothly between the synthetic fiber filament yarn core and the silk strand covering layer than between silk strands.

In the case of the suture already proposed (Japanese Utility Model Application No. 41670/1987) comprising a core of synthetic fiber filament yarn, the filament yarn generally has a higher elongation at break than the silk strands, so that when the suture is stretched under tension, the silk strands reach the limit of elongation (elongation at break) and break first. The force thereafter acts only on the filament yarn to break the yarn. Consequently, the overall breaking strength of the suture is lower than the sum of the individual breaking strengths of the yarn and the silk strands. According to the invention, on the other hand, the core of synthetic fiber filament yarn has substantially the same elongation at break as the covering layer of silk strands, with the result that when the suture breaks under tension, both the core and the covering layer break at the same time. Thus, the sum of the individual breaking strengths of the two is substantially equal to the overall breaking strength of the suture. In this case, synthetic fiber filaments increase in modulus of elasticity as they are made smaller in elongation at break by adjustment through thermal drawing. Accordingly, when the suture comprising such synthetic fiber filaments is compared with the suture comprising usual synthetic fiber filaments, the tensile force acting on the suture when the silk strands are stretched to break is greater on the former suture than on the latter by an amount corresponding to the increase in the modulus of elasticity. Thus, the former suture has a corresponding higher breaking strength. Moreover, the suture has further increased breaking strength because the synthetic fiber filament has higher breaking strength with a decrease in elongation at break. Because of the improved strength, sutures of small diameter are usable for wider application and are advantageous in avoiding injuries to the tissues of the human body to be sutured.

The reduction in the elongation at break gives somewhat increased rigidity to synthetic fiber filaments, makes them more suitable to use and is advantageous in facilitating correction of the deformation of the suture rendering the suture handleable with greater ease.

In the case where the core is formed of synthetic fiber filament yarns extending substantially parallel to one another, it is desirable that the filament yarns be at least 18% to not greater than 24%, more preferably at least 19% to not greater than 21%, in elongation at break

because silk strands are generally 18to 19% in elongation at break and exhibit an elongation at break of 18 to 24%, usually 19 to 21%, when formed into a covering layer by plaiting and so on.

When the core is prepared from synthetic fiber filament yarns by single twisting, plying or plaiting, the core thus formed is adapted to have the same elongation at break as the covering layer, and the elongation is suitably determined in view of twisting or plaiting density, strength, etc.

When the suture to be obtained has a relatively large size of USP2-0 or greater, it is especially desirable to form the core by plying the yarns so that the first twist and the final twist are in opposite directions to offset the torques due to the twists. For sutures of relatively small size of USP3-0 or smaller, single twisting achieves satisfactory results. Although the number of twists for the core is preferably greater to give improved breaking strength to the suture, the filament yarns may be loosely twisted with about 20 to about 50 T/m when made into a compacted ply.

To assure facilitated correction of deformation and improved breaking strength, it is desirable for the suture to have the core in a greater proportion as will become apparent from the following embodiments, especially from the results given in Table 1.

The present invention will become more apparent from the embodiments to be described below with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view partly broken away showing a suture embodying the invention;

FIG. 2 is a view in section taken along the line A—A in FIG. 1;

FIG. 3 is a perspective view showing a core of another embodiment; and

FIG. 4 is a graph showing the relationship between the load and the elongation, as determined for the suture of the invention and a conventional suture and involving a break.

DETAILED DESCRIPTION OF INVENTION

Embodiment 1

Silk strands were each prepared from two scoured silk yarns substantially of 27 denier (median of fineness values involving usual variations) by twisting the yarns together in S direction at about 300 T/m (s27 Naka/2). Silk strands of another type were also prepared each from two silk yarns, the same as those used above, by twisting the yarns together in Z direction at about 300 T/m (z27 Naka/2). A plied yarn serving as a core was prepared by twisting together eight polyester filament yarns (product of Teijin Limited, T300s, 20 denier, composed of 6 filaments, 19% in elongation at break) in S direction at 200 T/m to obtain a twisted unit, and twisting three such twisted units together in Z direction at 137 T/m. The core thus obtained was about 20% in elongation at break. The core was then sheathed with a covering layer by arranging the two types of silk strands alternately on a braiding machine and plaiting the strands, 16 in total number, into a braid at a density of 26 stitches/cm, whereby a suture of USP1-0 in size was obtained. The covering layer formed was about 20% in elongation at break.

The structure of the suture obtained is shown in FIG. 1, in which indicated at 1 is the covering layer formed by plaiting the silk strands, and at 2 is in the core of plied polyester yarn.

The suture prepared in this way had a breaking strength of 2.92 kgf which was 11% higher than that of conventional sutures made of silk yarns only and having the same size. The suture had suitable flexibility (i.e. suitable stiffness), was highly amenable to deformation such as curling and can easily be handled free of trouble. Embodiment 2

A single twist yarn serving as a core 2' as shown in FIG. 3 was prepared from three polyester filament yarns (product of Toray Industries, Inc., S200, 20 denier, composed of 6 filaments, 19% in elongation at break) by twisting the yarns together in S direction at 200 T/m. The core obtained was about 19% in elongation at break. The core 2' was then sheathed with a covering layer which was formed in the same manner as in Embodiment 1 by plaiting twelve silk strands into a braid at a density of 29 stitches/cm, whereby a suture of USP4-0 in size was obtained. The covering layer was about 19% in elongation at break.

The suture thus obtained and having a small size also exhibited excellent characteristics like the suture of Embodiment 1.

Other Embodiments

Sutures of varying sizes were prepared in the same manner as above and tested in comparison with conventional sutures. The results are shown in Table 1, in which the sutures of USP1-0 and USP4-0 in size were made of materials different from those of Embodiments 1 and 2. Accordingly, these sutures were slightly different from the above sutures in the results achieved.

TABLE 1

	USP size	2	1	1-0	2-0	3-0	4-0	5-0	6-0
Invention	Number of component strands of covering layer	16	16	16	16	12	12	8	6
	Core ratio (%)	47	33	33	33	20	20	11	14
	Elongation of break (%)	27.8	25.0	23.7	22.2	20.3	20.0	19.4	18.5
	Breaking strength (kgf)	6.05	3.88	2.92	2.27	1.48	0.95	0.58	0.30
	Flexibility (cm)	18.5	17.5	17.0	17.0	16.0	15.5	12.0	11.0
Prior Art A	Breaking strength (kgf)	5.68	3.76	2.86	2.18	1.41	0.91	0.54	0.28
Prior Art B	Number of component strands of covering layer	16	16	16	16	12	12	8	6
	Core ratio (%)	15	15	15	15	4	4	0	0
	Elongation at break (%)	29.9	27.1	25.2	23.8	22.4	21.8	20.2	19.1
	Breaking strength (kgf)	4.94	3.50	2.79	2.04	1.30	0.83	0.46	0.25
	Flexibility (cm)	16.0	15.0	15.5	15.0	14.0	11.5	9.5	8.0

With reference to Table 1, the core ratio is the ratio of the core to the entire suture in weight as expressed in percentage. The flexibility was determined according to the method of JIS L-1096A. Prior Art (prior-art suture)

A was prepared in the same manner as the suture of the invention except that a usual polyester filament yarn (24% in elongation at break) was used as the core. Prior Art (prior-art suture) B had a silk yarn as the core.

The suture of the invention and a conventional suture comprising a core of usual synthetic fiber filament yarn, both USPI in size, were subjected to a tensile test. FIG. 4 is a graph showing the results. The graph reveals that the suture of the invention has exceedingly higher breaking strength (peak value). The graph also shows that with the conventional suture, the descending line representing a break has an intermediate peak, which indicate that the break involves a time lag between the core and the covering layer. With the suture of the invention, the descending line extends downward almost straight, indicating that the core and the covering layer broke at the same time.

When actually used for operations by surgeons, the sutures of the above embodiments were evaluated as being highly amenable to the correction of curls and like deformations, suitably flexible (suitably stiff), easy to handle to assure an efficient operation and free of any break during handling even when of a reduced size.

The suture of the invention is not limited to the foregoing embodiments but can be modified variously within the scope of the invention defined in the appended claims.

We claim:

1. A surgical suture characterized in that the suture comprises a core of at least one synthetic fiber filament yarn, and a covering layer formed of a plurality of silk strands and sheathing the core, the core and the covering layer having substantially the same elongation at break.

2. A suture as defined in claim 1 wherein the core is formed of a plurality of synthetic fiber filament yarns extending substantially in parallel to one another and each having substantially the same elongation at break as the covering layer.

3. A suture as defined in claim 2 wherein each of the filament yarns is at least 18% to not greater than 24% in elongation at break.

4. A suture as defined in claim 1 wherein the core is formed of a plurality of twisted synthetic fiber filament yarns and made to have substantially the same elongation at break as the covering layer.

5. A suture as defined in claim 4 wherein the synthetic fiber filament yarns are single-twisted.

6. A suture as defined in claim 4 wherein the synthetic fiber filament yarns are plied.

7. A suture as defined in claim 5 which is 9—0 to 3—0 in USP size.

8. A suture as defined in claim 6 which is 2—0 to 10 in USP size.

9. A suture as defined in claim 1 wherein the core is formed of a plurality of braided synthetic fiber filament yarns and made to have substantially the same elongation at break as the covering layer.

10. A suture as defined in claim 1 wherein the plurality of silk strands are braided to form the covering layer and made to have substantially the same elongation at break as the core.

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(71) Applicant
Fly Fishing Technology Limited

(Incorporated in the United Kingdom)

Units 3/4, Ffrwdgrech Industrial Estate, Brecon, Powys, LD3 8LA, United Kingdom

(72) Inventor
Paul David Burgess

(74) Agent and/or Address for Service
Wynne-Jones Laine & James
Morgan Arcade Chambers, 33 St. Mary Street, Cardiff, Glamorgan, CF1 2AB, United Kingdom

(54) Improvements relating to fishing lines

(57) A fishing line of braided construction has some filaments of high tensile polythene. The other filaments are of polyesterer and/or nylon, and the braid may be coated with a sheath of polyurethane.

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"Improvements relating to Fishing Lines"

This invention relates to fishing lines.

Fishing lines require many qualities, such as high tensile strength, while having a small diameter, non-stretchability, resistance to abrasion, smooth running and suppleness. It is the aim of this invention to provide a line embodying most of these not usually very compatible properties.

According to the present invention there is provided a fishing line of braided construction, some braid filaments being of high tensile polythene thread and other filaments being of polyester and/or nylon.

The high tensile polythene gives the line minimal stretchability and will preferably be a high molecular weight polythene, melted in a solvent and drawn at high speed into extremely fine strands. This produces almost perfect alignment of all the molecules in long chains. A suitable product is that sold under the Registered Trade Mark DYNEEMA.

With polyester, multifilaments will generally be used, and the more there are of them in proportion to the polythene the stiffer the line will be. With nylon, monofilaments will preferably be used and the principal effect will be a low coefficient of friction.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000123

It would be possible for certain applications to combine both polyester and nylon with the polythene thread.

The braid may be coated with a thin, supple and smooth sheath of polyurethane and this may be carried out by a simple immersion process in liquid polyurethane. It will alter the characteristics (such as buoyancy and strength) in a predictable manner, but its main purpose is to prevent saturation of the interstices of the braid. In very cold conditions, such as fishing through holes in ice, water having worked its way into the braid will freeze and impart a brittleness that can lead to breakage.

CLAIMS

1. A fishing line of braided construction, some braid filaments being of high tensile polythene thread and other filaments being of polyester and/or nylon.

2. A line as claimed in Claim 1,, wherein the other filaments include polyester multi-filaments.

3. A line as claimed in Claim 1 or 2, wherein the other filaments include nylon monofilaments.

4. A line as claimed in Claim 1., 2 or 3, wherein the braid is coated by a sheath of polyyurethane.

5. A line as claimed in any preeceding Claim, wherein the polythene is that sold undeer the Trade Mark DYNEEMA.

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(71) Applicants
Institut für Textil-und Faserforschung Stuttgart, Burgstrasse 29, D—7410 Reutlingen, Germany, Federal Republic of Germany
(72) Inventors
Heinrich Planck,
Wolfgang Joos
(74) Agents
Marks & Clerk,
57/60, Lincoln's Inn Fields, London WC2A 3LS

(54) **Surgical stitching thread**

(57) Surgical stitching thread, has a sheathing (10) in the form of a tubular braided structure, which is braided from a number of multifilament yarns, each of which consists of smooth uncrimped filaments. For reducing the surface roughness of the sheathing the number of bobbins is increased for the braiding process and the number of braids of the sheathing per axial length is reduced.

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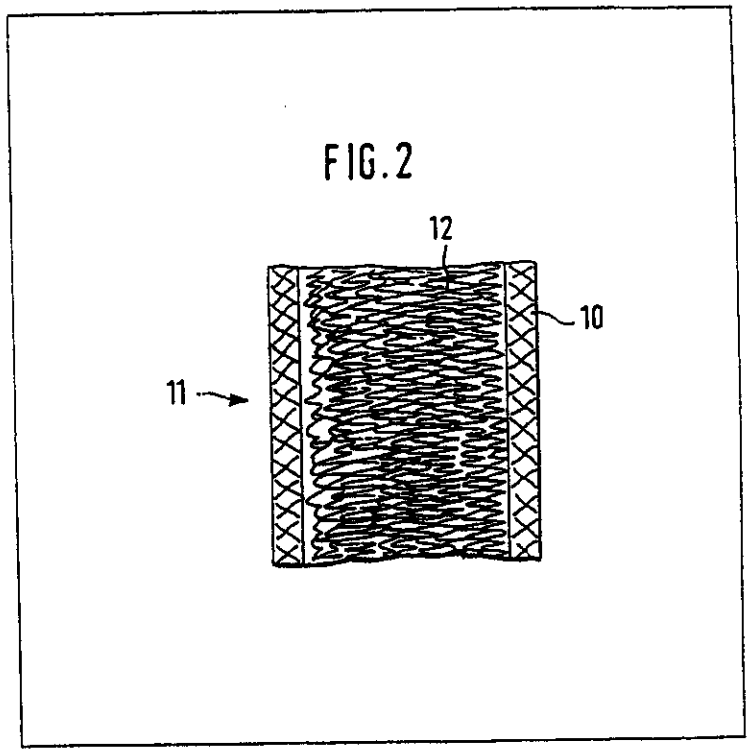

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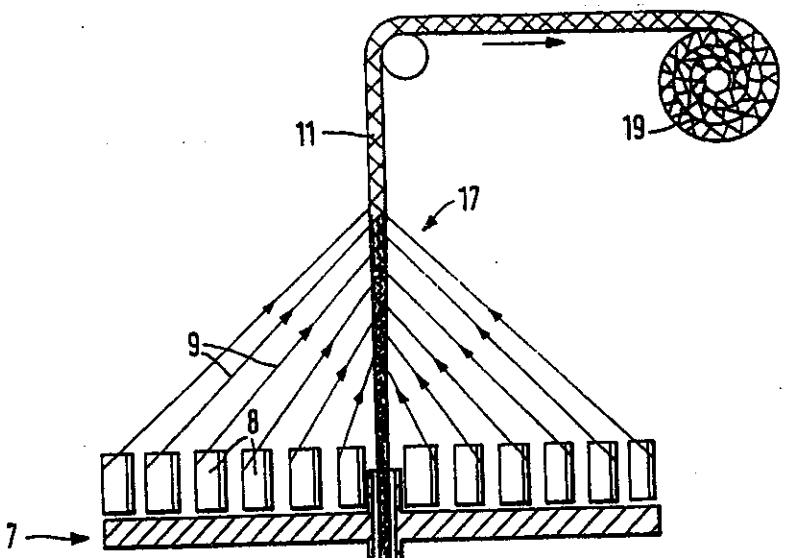

FIG.1

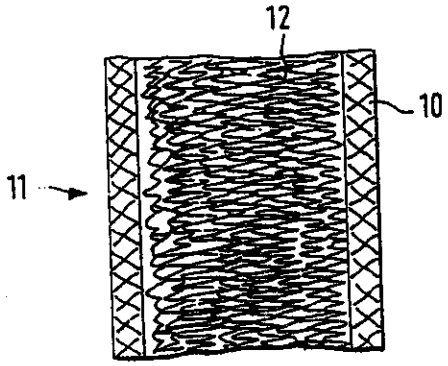

FIG.2

SPECIFICATION

Surgical stitching thread

The invention relates to surgical stitching thread having a tubular braided sheathing composed of a plurality of multi-filaments each of which consists of smooth uncrimped filaments.

Surgical stitching threads of this kind consist of the sheathing alone or of the sheathing and of a core round which this sheathing is wound. The multifilament yarns which are braided together to form the sheathing consists of synthetic plastics filaments which can decompose in the human body (e.g. polyglycolic acid) or synthetic plastics filaments which cannot decompose in the human body (e.g. polyester, polyamide, polypropylene) and/or metal filaments. Filaments of the same materials as for the hitherto known surgical stitching thread can be used for the stitching thread according to the invention. However, filaments from other materials may possibly be considered, in particular materials which are used in the production of synthetic fibres. By "filament" is meant an elongate structure such as can be formed, in the case of synthetic plastics materials, viscose or the like, by means of a hole of a spinning nozzle (spinnaret) or multiple spinning nozzle and, in the case of metal, by means of a hole of a drawing die of a drawing tool. Filaments of synthetic plastics material, viscose or the like are also referred to as endless chemical fibres, elementary fibres or capillaries.

By the hereinafter used term "braid number Z" is meant the number of braids present on a generatrix (also called "edge"), extending axially parallel to the longitudinal axis of the stitching thread, per French inch (equals 27.07 mm).

The following symbols and expressions are used hereinafter:

Z = The number of braids in accordance with the above definition.

K = the number of bobbins (number of bobbins which — in the course of braiding the sheathing — delivered the multi-filament yarns (braiding yarns) which form the multi-filament yarns).

Multifilament yarn = a yarn in the form of a number of filaments.

GT = the count (titre) of the individual yarn, also referred to hereinafter as "individual count", in dtex.

N = the number of yarns of which the core consists.

F = the number of filaments of a multifilament yarn

USP-size = diameter ranges of surgical stitching threads in accordance with United States Pharmacopeiae XIX, pages 486, 665, Pharma Copiae Convention Inc. Meeting at Washington D.C. April 1970, 12601 Twinbrook, USA.

The tubular braided structures of such surgical stitching threads have hitherto been formed with a large number of braids and, in comparison with this a small number of bobbins, and the multifilament yarns which are braided together each had a relatively large individual count (titre); the filaments of the individual yarns also had a relatively large count or titre. Table 1 appended to the end of the specification contains the combinations of values, pertinent to this, of the surgical stitching threads used up to the present time.

Insofar as these known surgical stitching threads had a so-called core, the latter consisted of a ply yarn, which was formed from a number of filament yarns by twisting the latter round one another; the filaments of this ply yarn were uncrimped.

The sheathing forming the outside surface of the surgical stitching thread has relatively high roughness in the case of the numbers of bobbins and numbers of braids which have hitherto been conventional. The result of this, when stitching human or animal tissue by means of these known surgical stitching threads, has been that the stitching threads can cut into the tissue, in the manner of a saw, and thus enlarge the wounds, and delay the healing process. Also, this rough sheathing increases the force required for pulling the surgical stitching thread through the tissue, which makes it more difficult to perform the stitching operation in a sensitive manner.

It is therefore an object of the invention to provide a surgical stitching thread of the type defined at the outset, the outside surface of whose sheathing can be made with lower surface roughness than the surgical stitching threads, made from the same base material, of the same USP size according to Table 1.

According to the invention therefore for the purpose of reducing the surface roughness of the sheathing — the number of bobbins, when braiding the sheathing, in comparison with the known surgical stitching threads, specified in Table 1 of the same diameter range (USP size) is increased, whilst the number of braids of the sheathing in comparison with these known surgical stitching threads is decreased.

To increase the number of bobbins and reduce the number of braids, the outside surface of the surgical stitching thread becomes smoother, that is to say it becomes less rough than is the case with the hitherto conventional stitching threads made from the same basic material and of the same USP size as set forth in Table 1. Consequently, it is possible to pull these surgical stitching threads through human or animal tissue with less force, so that the surgeon can stitch with more sensitivity than hitherto. Also, the human or animal tissue is damaged to a lesser extent by these surgical stitching threads, and so the healing process of the wound is also facilitated.

The individual counts (titres) GT of the yarns of the sheathing of the stitching thread according to

the invention are, due to the increased number of bobbins, smaller than those of the known stitching threads of the same USP size as set out in Table 1.

The material of the filaments of the sheathing of the surgical stitching thread may consist of the materials which have already been referred to above, preferably of synthetic plastics materials, for example polyester, polypropylene, polyglycolic acid or also of other suitable materials, such as for example viscose silk, natural silk, metal or the like.

The diameter of the surgical stitching threads according to the invention is, in particular, within the range of USP sizes 7—0 to 6. It will be appropriate if the stitching threads are without a core within the USP size range 7—0 and 6—0, and if the stitching threads comprise a core within the size range 4—0 to 6. In the intermediate range of USP sizes 5—0 and 4—0 it will preferably be optional whether the stitching threads contain a core or not.

It the stitching thread according to the invention contains a core, the structure and material of its filaments may be conventional, that is to say these filaments will consist of a ply yarn or of an individual yarn. However, in accordance with a modification of the invention, the core may consist of doubled (folded) multifilament yarns, that is to say these multifilament yarns extend parallel to the longitudinal axis of the stitching thread and are not twisted round one another, that is to say they do not form a ply yarn. Also, in the case of the known surgical stitching threads having a core, the filaments of the core were always uncrimped. This may also be the case with the surgical stitching threads according to the invention. However, in accordance with a modification of the invention, at least some, and preferably all, filaments of the core are crimped, as in this way the surgical stitching thread may be made more pliant, so that its stitching performance and compatibility can be further improved.

Generally speaking, it will be satisfactory if the core consists of one or more multifilament yarns. However, in special cases, the core may consist of a single monofilament or of a number of filaments (viz. monofilaments) which are not twisted round one another, that is to say they are doubled (folded). Conveniently, with a view to ensuring that, in this case, the stitching thread has good qualities of pliability and circularity, the monofilament or monofilaments may consist of elastomeric material, preferably of silicone rubber or elastomeric polyurethane.

Preferred bobbin numbers K and braid numbers Z of the tubular sheathing of the surgical stitching threads according to the invention are specified in claims 2 to 13. The surgical stitching threads specified in claims 14 to 25 result, in practice, in optimally smooth surfaces allied to good qualities of pliability and to other favourable properties of the stitching thread.

The yarns (braiding yarns) used for braiding the sheathing of the surgical stitching thread have, in consequence of the higher bobbin numbers and of the lower braid numbers used for the braiding process, smaller individual counts GT than in the case of the hitherto conventional surgical stitching thread set out in Table 1. Multifilament yarns with the highest possible number of filaments have been found to be particularly favourable for braiding the sheathing of the stitching thread according to the invention.

In *Table 2*, appearing at the end of the specification, preferred structural data are given for a number of surgical stitching threads constituted in accordance with the invention; the numbers K of bobbins and numbers Z of braids in accordance with the preferred embodiments as specified in Claims 14 to 25 appear in this table. The individual counts GT, given in Claims 26 to 29 and in Table 2, of the multifilament yarns forming the sheathings and cores are particularly favourable; similarly, the other structural data given for these surgical stitching threads are also particularly favourable.

Normally, when the sheathing is being formed by braiding, one multifilament yarn runs from each bobbin of the braiding machine concerned to the braiding point. However, it is also possible, in the case of the surgical stitching thread according to the invention — and this may lead to a still more smooth surface of the stitching thread — to arrange for a number of multifilament yarns to run, in doubled (folded) fashion, to the braiding point, from at least one of the bobbins, preferably from all of the bobbins, so that the sheathing will be braided from a correspondingly greater number of multifilament yarns. As has already been mentioned, the multifilament yarns of the sheathing are uncrimped.

Thr smooth outer surface of the surgical stitching thread according to the invention is formed by the outside surface of the sheathing, which has been formed by braiding. Moreover, in special instances, provision may be made for providing the outside surface of the sheathing with preparations or the like for achieving special properties.

Further, it will be feasible in special instances, to replace at least one multifilament yarn of the sheathing by a monofilament or by a number of doubled (folded) filaments, that is to say filaments which abut one another in parallel fashion and are not twisted onto one another.

Embodiments of the invention are illustrated in the drawing, in which:

Figure 1 schematically represents a braiding machine for producing a surgical stitching thread constituted according to the invention, and

Figure 2 is a longitudinal cross-section taken through part of a surgical stitching thread in accordance with one embodiment of the invention; this stitching thread section is represented on a greatly enlarged scale.

The braiding machine 7 shown in Figure 1 comprises twelve bobbins 8, viz. yarn bobbins on which non-crimped multifilament yarns 9 are wound, these yarns 9 being braided so as to form the sheathing

10 (Figure 2) of a surgical stitching thread 11 to be produced on this braiding machine. The core 12 of this stitching thread, to be formed by braiding, consists of a number of doubled (folded) yarns 13 which, in this embodiment, are crimped multifilament yarns and are drawn off from bobbins 14 and commonly run to a yarn guide 15, pass through a thread brake 16, which is biased in a variable fashion, whence the yarns 13 pass to the braiding point 17, at which they are enveloped by the braiding yarns 9, that is to say the sheathing 10, which envelopes the core 12, are braided from the braiding yarn 9. The production of this surgical stitching thread takes place continuously, and is wound up into a thread package 19.

The short portion, shown in longitudinal cross-section in Figure 2 of an embodiment of a stitching thread 11 according to the invention has a substantially cylindrical sheathing 10 consisting of a tubular braided structure, in the interior of which lies a core 12 which consists of a number of crimped multifilament yarns which extend axially in the sheathing.

The free circumferential surface of this surgical stitching thread is preferably solely constituted by the multifilament yarns of the sheathing. However, it is also possible to provide this sheathing with a finish, which for example has an anti-bacterial action or imparts other desired properties to the stitching thread.

The individual multifilament yarns of the sheathings and cores of the known stitching threads set out in Table 1 have so-called protective twists, that is to say a small degree of twist (e.g. 10 to 130 turns/meter, according to the individual count or titre in each instance). Conveniently, this may also be the case with the surgical stitching thread according to the invention. In accordance with a modification of the invention somewhat better smoothness of the surface of the sheathing can be achieved by making the multifilament yarns of the sheathing twist free, that is to say they have no twist at all. If the core has one or more multifilament yarns, this provision may also be made for these yarns.

TABLE 1

5107	sheathing braided from uncrimped multi-filament yams			core from non-crimped multi-filament yams
USP-Size	K	Z	Game	N × GT, f GT in dtex
7–0	4	42 to 53	GT 35, f 15 GT 15, f 10	–
6–0	4 to 6	42 to 50	GT 35, f 15 GT 15, f 10	–
5–0	4 to 8	50 to 80	GT 35, f 15 GT 30, f 20	–
4–0	8	59 to 65	GT 49, f 16 GT 76, f 24	–
3–0	8	56 to 68	GT 95, f 24 GT 76, f 24	1 × GT 150, f 24
2–0	6 to 8	50 to 61	GT 190, f 48 GT 76, f 24	2 × GT 80, f 20 (ply yam)
0	8 to 12	55 to 60	GT 190, f 48 GT 111, f 32	–
1	12 to 16	53 to 67	GT 190, f 48	1 × GT 226, f 64
			GT 111, f 32	2 × GT 74, f 18 (ply yam)
2	12 to 16	50 to 67	GT 280, f 72	2 × GT 76, f 18 (ply yam)
			GT 111, f 32	1 × GT 308, f 108
3 and 4	12	50 to 65	GT 280, f 72	3 × GT 180, f 24 (ply yam)
			GT 280, f 50	1 × GT 280, f 50
5	12 to 16	52 to 70	GT 380, f 72	5 × GT 180, f 24 (ply yam)
			GT 340, f 80	3 × GT 455, f 96 (ply yam)
6	12 to 16	52 to 70	GT 380, f 96	6 × GT 180, f 24 (ply yam)
			GT 390, f 66	3 × GT 660, f 20 (ply yam)

TABLE 2

5107	sheathing braided from uncrimped multi-filament yarns				core from doubled (folded), crimped multi-filament yarns		
USP-Size	K	GT (dtex)	f	Z	N	GT (dtex)	f
7–0	8	25	22	8			
6–0	8	25	22	13			
5–0	12	25	22	18			
4–0	12	25	22	20	3	50	24
3–0	12	49	16	18	3	50	24
2–0	16	49	16	23	6	50	24
0	16 or 24	49	16	25	8	50	24
1	18 or 24	49	16	21 or 27	10 or 12	50	24
2	24	49	16	27	12	50	24
3 and 4	20	113	32	25	20	50	24
5	20	113	32	21	30	50	24
6	24	113	32	19	35	50	24
2	18	113	32	21	12	50	24
3 and 4	24	95	24	19	20	50	24
5	24	95	24	19	25	50	24

CLAIMS

1. Surgical stitching thread having a tubular braided sheathing composed of a plurality of multifilament yarns, each of which consists of smooth uncrimped filaments, characterised in that, for reducing the surface roughness of the sheathing, the number of bobbins (K) used for braiding the sheathing is increased in comparison with the known surgical stitching threads, specified in aforesaid Table 1, of the same diameter range (USP-size), and the number of braids (Z) in the sheathing is reduced in comparison with these known surgical stitching threads.

2. Surgical stitching thread of USP-size 7—0 according to claim 1, having its sheathing braided with a number of bobbins K equal to 6, 8 or 10, and with a number of braids Z equal to 8 to 15, in which K is the number of bobbins used for braiding the sheathing and Z is the number of braids per French inch.

3. Surgical stitching thread of USP-size 6—0, according to claim 1, having its sheathing braided with K equal to 8 or 10 and with Z equal to 10 to 20.

4. Surgical stitching thread of USP-size 5—0, according to claim 1, having its sheathing braided with K equal to 10 or 12, and with Z equal to 10 to 20.

5. Surgical stitching thread of USP-size 4—0, according to claim 1, having its sheathing braided with K equal to 10, 12 or 14, and with Z equal to 15 to 25.

6. Surgical stitching thread of USP-size 3—0, according to claim 1, having its sheathing braided with K equal to 10, 12 or 14, and with Z equal to 15 to 25.

7. Surgical stitching thread of USP-size 2—0, according to claim 1, having its sheathing braided with K equal to 12, 14 or 16, and with Z equal to 17 to 27.

8. Surgical stitching thread of USP-size 0, according to claim 1, having its sheathing braided with K equal to 14, 16, 18, 20 or 24, and with Z equal to 17 to 27.

9. Surgical stitching thread of USP-size 1, according to claim 1, having its sheathing braided with

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K equal to 18, 20 or 24 and with Z equal to 17 to 27.

10. Surgical stitching thread of USP-size 2, according to claim 1, having its sheathing braided with K equal to 18, 20, 22, 24 or 26, and with Z equal to 17 to 30.

11. Surgical stitching thread of USP-size 3 and 4, according to claim 1, having its sheathing braided with K equal to 18, 10, 22, 24, 26 and with Z equal to 17 to 30.

12. Surgical stitching thread of USP-size 5, according to claim 1, having its sheathing braided with K equal to 18, 20, 22, 24 or 26, and with Z equal to 17 to 30.

13. Surgical stitching thread of USP-size 6, according to claim 1, having its sheathing braided with K equal to 20, 22, 24 or 26, and with Z equal to 17 to 30.

14. Surgical stitching thread according to claim 2, having its sheathing braided with K equal to 8, and with Z equal to 8.

15. Surgical stitching thread according to claim 3, having its sheathing braided with K equal to 8 and with Z equal to 13.

16. Surgical stitching thread according to claim 4, having its sheathing braided with K equal to 12 and Z equal to 18.

17. Surgical stitching thread according to claim 5, having its sheathing braided with K equal to 12 and Z equal to 20.

18. Surgical stitching thread according to claim 6, having its sheathing braided with K equal to 12 and with Z equal to 18.

19. Surgical stitching thread according to claim 7, having its sheathing braided with K equal to 16 and with Z equal to 23.

20. Surgical stitching thread according to claim 8, having its sheathing braided with K equal to 16 or 24, and with Z equal to 25.

21. Surgical stitching thread according to claim 9, having its sheathing braided with K equal to 18 or 24, and with Z equal to 21 or 27.

22. Surgical stitching thread according to claim 10, having its sheathing braided with K equal to 24 and with Z equal to 27.

23. Surgical stitching thread according to claim 11, having its sheathing braided with K equal to 20 or 24, and with Z equal to 19 or 27.

24. Surgical stitching thread according to claim 12, having its sheathing braided with K equal to 20 or 24, and with Z equal to 19 or 21.

25. Surgical stitching thread according to claim 13, having its sheathing braided with K equal to 24 and with Z equal to 19.

26. Surgical stitching thread according to any of claims 2 to 5 or 14 to 17, having its sheathing braided from multifilament yarns, each of which has an individual count (titre) of 20 to 30 dtex, preferably of about 25 dtex, and preferably at least 22 filaments.

27. Surgical stitching thread according to any of claims 6 to 10 or 18 to 22, having its sheathing braided from multifilament yarns, each of which has an individual count of 40 to 60 dtex, preferably of about 49 dtex, and preferably at least 16 filaments.

28. Surgical stitching thread according to any of claims 11 to 13 or 23 to 25, having its sheathing braided from multifilament yarns, each of which has an individual count of 80 to 120 dtex, preferably 113 dtex, and preferably at least 32 filaments.

29. Surgical stitching thread according to claim 9 or claim 21, having its sheathing braided from multifilament yarns, each of which has an individual count of 60 to 90 dtex, preferably of about 74 dtex, and preferably at least 24 filaments.

30. Surgical stitching thread according to any of the foregoing claims, having at least one filament of its sheathing, and preferably all filaments of its sheathing, made of synthetic plastics material.

31. Surgical stitching thread according to any of the foregoing claims, having at least one filament of its sheathing, and preferably all of its filaments, made of metal.

32. Surgical stitching thread according to any of the foregoing claims, having at least one filament of its sheathing, and preferably all of its filaments, made of viscose or polyglycolic acid.

33. Surgical stitching thread according to any of the foregoing claims, having at least one filament yarn of its sheathing made of natural silk.

34. Surgical stitching thread according to claim 1, having a USP size of from 7—0 to 3—0, and which exclusively consists of the sheathing.

35. Surgical stitching thread according to claim 1, having a USP size of from 4—0 to 6, and in which a core is arranged within its sheathing.

36. Surgical stitching thread according to claim 35, in which its core comprises at least one multifilament yarn, preferably in the form of synthetic plastics material filaments.

37. Surgical stitching thread according to claim 35, having a core which consists of one or more monofilaments which extend parallel to the longitudinal axis of the surgical stitching thread and are of elastomeric material, preferably silicone-rubber or polyurethane.

38. Surgical stitching thread according to claim 36, having a core which consists of a plurality of multifilament yarns which are braided so as to form a tube.

39. Surgical stitching thread according to claim 36, in which its core consists of a plurality of

folded (doubled) multifilament yarns.

40. Surgical stitching thread according to any of claims 36 to 39, in which the filaments of its core are uncrimped.

41. Surgical stitching thread according to any of claims 36 to 39, in which at least one filament of its core, and preferably all of its filaments, are crimped.

42. Surgical stitching thread according to any of the foregoing claims, in which the number of multifilament yarns of which the sheathing consists, corresponds to the number K of bobbins used for braiding the sheathing.

43. Surgical stitching thread according to any of claims 1 to 41, wherein the number of multifilament yarns, of which the sheathing consists, is greater than the number K of bobbins used for braiding the sheathing, this being accomplished by arranging that, when the sheathing is being braided, from at least one bobbin at least two multifilament yarns are guided, doubled (folded) and parallel to one another, to the braiding point.

44. Surgical stitching thread according to any of the foregoing claims, and of which its free outer surface is solely constituted by the multifilament yarns of the sheathing.

45. Surgical stitching thread according to any of claims 1 to 25 or 30 to 44, in which a monofilament or a number of doubled (folded) filaments, which are not twisted round one another, replace at least one multifilament yarn of the sheathing.

46. Surgical stitching thread according to any of the foregoing claims, in which the multifilament yarns of the sheathing and/or of the core have a small twist (so-called protective twist).

47. Surgical stitching thread according to any of claims 1 to 45, in which the multifilament yarns of the sheathing and/or of the core are twist free (without twist).

48. Surgical stitching thread composed substantially as hereinbefore described by reference to the accompanying Tables 1 and 2 and the drawing.

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(71) Anmelder:
Wada, Juro, Prof.; Kabushiki Kaisha Matsuda Ika Kogyo, Tokyo, JP

(74) Vertreter:
Pohlmann, E., Dipl.-Phys.; Schmidt, H., Dipl.-Ing. Dr.-Ing., Pat.-Anw., 8000 München

(72) Erfinder:
Wada, Juro, Prof., Tokyo, JP

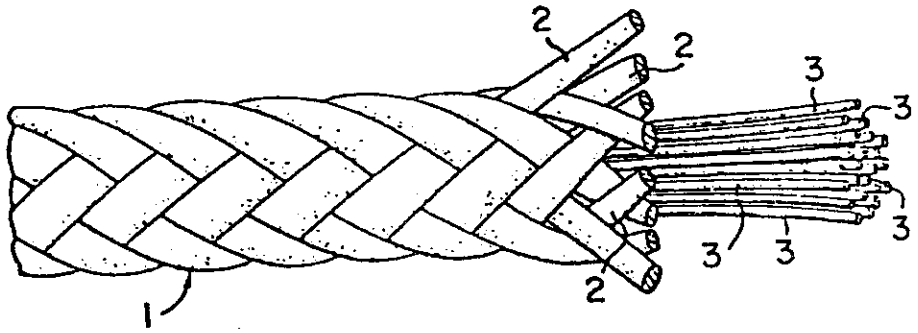
Dr Fritz
Could you provide
a translation of summary please

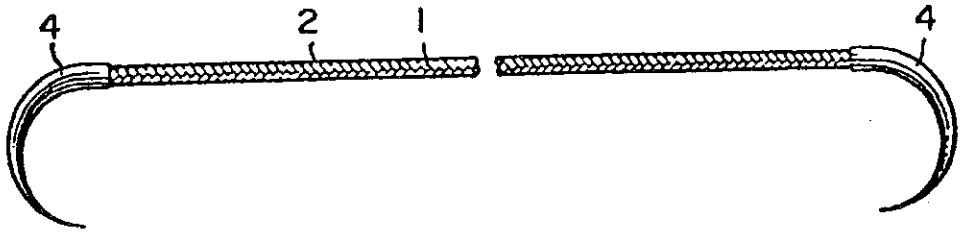
Subject: GERMAN PATENT APPLICATION 29 49 920 AND "MATSUDA MEDICAL"

The claims for this application are as follows:

1. A surgical suture characterized by the fact that it consists of a tubular weave (1) of fine synthetic fibers (2) surrounding fine platinum fibers or pure gold fibers (3) swaged to at least one surgical needle (4).

2. A surgical suture characterized by the fact that the fine synthetic fibers (2) which form the woven (braided) tube (1) consist of polytetrafluoroethylene fibers.





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C. C. FRITZ, Ph.D.

FIG. 1

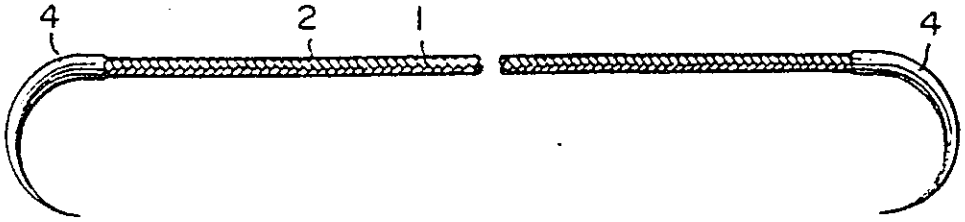


FIG. 2

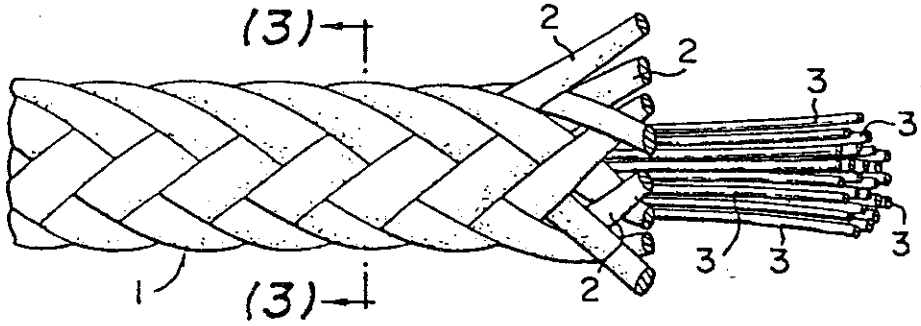
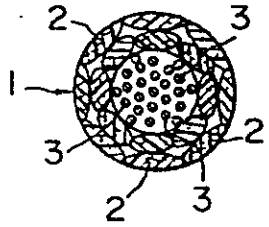


FIG. 3



130012/0575

ROTH, LANN & SCHMIDT
Patentanwälte

Dr. Horst Schmidt (Dipl.-Ing.)
Eckaert Pohlmann (Dipl.-Phys.)
Zugelassene Vertreter
beim Europäischen Patentamt
8000 München 40
Siegfriedstrasse 8
Telefon (089) 39 16 39
Telex 5 213 260 pspa d

2949920

DE 227/228

Juro Wada, Tokyo, Japan
Kabushiki Kaisha Matsuda Ika Kogyo, Tokyo, Japan

Chirurgisches Nahtmaterial

P A T E N T A N S P R Ü C H E

1. Chirurgisches Nahtmaterial, g e k e n n z e i c h n e t durch ein rohrförmiges Geflecht (1) aus sehr dünnen zusammengeflochtenen chemischen Faserfäden (2), durch eine Anzahl von sehr dünnen Platinfäden oder reinen Goldfäden (3), die in das rohrförmige Geflecht (1) über dessen gesamte Länge eingesetzt sind, und durch wenigstens eine chirurgische Nadel (4), die in einem Stück mit einem Ende des rohrförmigen Geflechts (1) verbunden ist.

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2. Chirurgisches Nahtmaterial nach Anspruch 1, dadurch g e k e n n z e i c h n e t , dass die sehr dünnen chemischen Faserfäden (2), die das rohrförmige Geflecht (1) bilden, Polytetrafluoräthylen-Faserfäden sind.

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Beschreibung

Die Erfindung betrifft ein chirurgisches Nahtmaterial.

Als Nahtmaterialien für chirurgische Eingriffe werden bisher in üblicher Weise Materialien aus tierischen Fasern, beispielsweise aus Seide, verwandt. Diese Nahtmaterialien aus tierischen Fasern rufen jedoch eine Reibung mit den inneren Organen bei Bauchoperationen hervor und bringen die Gefahr mit sich, dass die verschiedenen Funktionen der Organe beeinträchtigt werden, was manchmal zu einer Abstossung führt.

Nach der Operation kann darüberhinaus das Nahtmaterial selbst einen Kapillareffekt bewirken. Wenn weiterhin ein künstliches Organ und ein natürliches Organ verbunden werden, besteht die Gefahr, dass das Nahtmaterial selbst mit dem natürlichen Organ verwächst und dessen normale Funktion behindert. Wenn weiterhin eine Infektion auftritt, ist es bisher mit dem Nahtmaterial aus tierischen Fasern unmöglich, die Organfunktion wieder herzustellen, bis das Nahtmaterial entfernt oder körperlich abgestossen ist.

Mit Nahtmaterialien aus Seide oder einem ähnlichen Material war es weiterhin bisher unmöglich, röntgenologisch die miteinander vernähten Teile nach der Operation zu beobachten, so dass es schwierig war, die Funktion des Organs des Körpers nach der Operation zu verfolgen und zu analysieren.

Aufgabe der Erfindung ist daher die Entwicklung eines chirurgischen Nahtmaterials, das die oben beschriebenen Nachteile der bekannten Nahtmaterialien nicht aufweist, d.h. das kein Blut oder andere Körperfluide, Bakterien

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usw. überträgt und sgomit keinen Kapillareffekt zeigt, und das ohne jede beesondere Behandlung bei einer chirurgischen Operattion einsatzbereit ist.

Diese Aufgabe wird eerfindungsgemäss durch ein chirurgisches Nahtmaterial ggelöst, das ein rohrförmiges Geflecht aus sehr dünnen zusammengeflochtenen chemischen Faserfäden, eine Anzahl vvon sehr dünnen Platinfäden oder reinen Goldfäden, die iin das rohrförmige Geflecht über dessen gesamte Länge eingessetzt sind,und wenigstens eine chirurgische Nadel aufweisst, die in einem Stück mit einem Ende des rohrförmigen Geflechts verbunden ist.

Ein besonders bevorzugtes Ausführungsbeispiel des erfindungsgemässen chirurgischen Nahtmaterials zeichnet sich dadurch aus, daass die miteinander vernähten Teile des Körpers nach deer Operation röntgenologisch beobachtet werden können, so daass die Funktion des Organs des Körpers nach der Operation verfolgt und analysiert werden kann.

Im folgenden wird aanhand der zugehörigen Zeichnung ein bevorzugtes Ausführrungsbeispiel der Erfindung näher erläutert:

Fig. 1 zeigt eine teilweise weggebrochene Seitenansicht des Ausführungsbeispiels des erfindungsgemässen Nahtmaterials.

Fig. 2 zeigt eine vergrösserte Teilvorderansicht des Ausführungsbeispiels des erfindungsgemässen Nahtmaaterials, wobei die inneren Metallfäden teilweeise durch Abschneiden und Weglassen des äusseeren Geflechtes freigelegt sind.

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Fig. 3 zeigt eine Schnittansicht längs der Linie 3-3 in Fig. 2.

Wie es in der Zeichnung dargestellt ist, weist das Ausführungsbeispiel des erfindungsgemässen Nahtmaterials ein rohrförmiges Geflecht 1 auf, das aus sehr dünnen zusammengeflochtenen chemischen Faserfäden 2 besteht. Eine Anzahl von sehr dünnen Platinfäden oder reinen Goldfäden 3 ist in das rohrförmige Geflecht 1 über dessen gesamte Länge eingesetzt. Eine chirurgische Nadel 4 ist in einem Stück mit beiden Enden jeweils oder mit einem Ende des rohrförmigen Geflechtes 1 verbunden, das die Platinfäden oder die reinen Goldfäden 3 umschliesst, die in das Geflecht 1 eingesetzt sind.

Als Faserfäden 2, die das rohrförmige Geflecht 1 bilden, können solche Faserfäden, die eine glatte Oberfläche und eine hohe Dauerhaftigkeit, Abbriebfestigkeit, Biegefestigkeit und Zugfestigkeit haben, beispielsweise Polyfluoräthylen-Faserfäden oder Polyester-Faserfäden, verwandt werden.

Das rohrförmige Geflecht 1 ist dadurch gebildet, dass eine Anzahl von Faserfäden 2 mit einer längenbezogenen Masse von $1/9 \cdot 10^2$ tex zusammengeflochten sind, wobei bei dem in den Fig. 2 und 3 dargestellten Ausführungsbeispiel 16 Fäden verwandt sind.

Die sehr dünnen Platinfäden oder die sehr dünnen reinen Goldfäden 3, die in das rohrförmige Geflecht 1 eingesetzt sind, haben eine Stärke von etwa 50 µm im Durchmesser, wobei etwa 20 derartige Fäden verwandt werden. Diese Platinfäden oder diese reinen Goldfäden 3 haben keinen Einfluss auf die

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inneren Organe, wenn sie sich im Körper befinden.

Die chirurgische Nadel 4 besteht aus rostfreiem Stahl oder einem Spezialstahl.

Mit Hilfe des oben beschriebenen Nahtmaterials kann das Ausführen der Naht reibungslos erfolgen, ohne die inneren Organe unnötigerweise zu verletzen, da die Fäden 2, aus denen das Geflecht 1 besteht, glatte Oberflächen haben. Aufgrund der Art seines Materials überträgt das Nahtmaterial darüberhinaus kein Blut oder andere Körperfluide aufgrund des Kapillareffektes. Ohne jede besondere Behandlung des Nahtmaterials können daher ein Anhaften und Fortpflanzen von Bakterien verhindert werden und können selbst dann, wenn Bakterien übertragen werden, die infizierten Bereiche leicht ausgeheilt werden.

Nach dem chirurgischen Eingriff können weiterhin röntgenologische Beobachtungen der Gewebebildung des lebenden Körpers und der Ergebnisse einer Langzeitgewebebildung nach der postoperativen Behandlung, beispielsweise der Nahtbildung, erfolgen und ist es gleichfalls möglich, fortlaufend Änderungen im Zustand des Operationsbereiches mit dessen Wanderung und andere bisher unbekannte Funktionen der Organe des Körpers auf Röntgenfilmen zu beobachten, was für die medizinische Behandlung ausserordentlich nützlich ist.

Das erfindungsgemässe chirurgische Nahtmaterial ist somit am besten für den chirurgischen Einsatz künstlicher Organe geeignet.

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FIG. 1

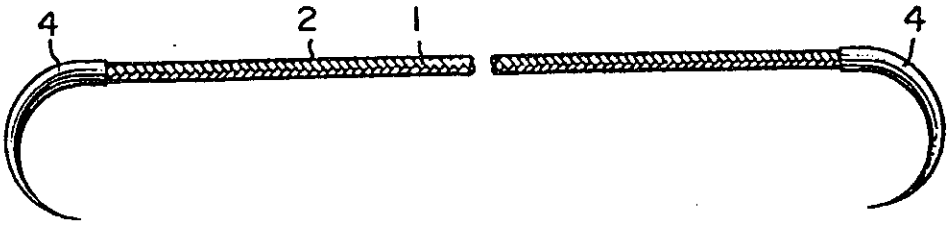


FIG. 2

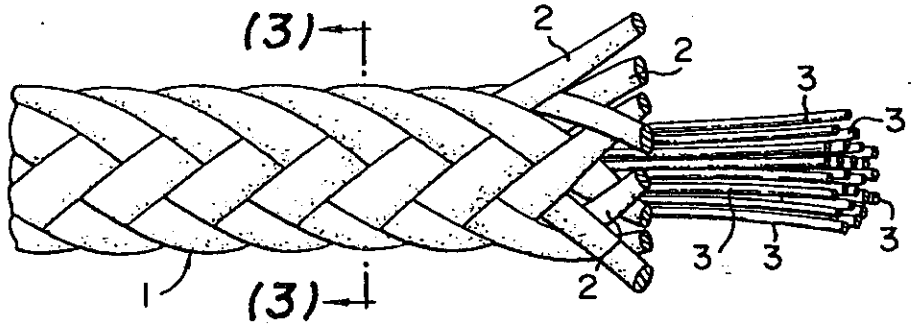
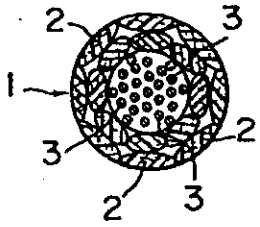


FIG. 3



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ALLEN TRANSLATION SERVICE

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Federal Republic of Germany
German Patent Office

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File No. P2949920.5-41
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Inventor:
Wado, Juro, Prof., Tokyo,JP

Applicant:
Wado, Juro, Prof.; Kabushiki Kaisha Matsuda Ika Kogyo, Tokyo, Japan

Representative:
Pohlmann, E.; Schmidt, H.
Patent Attorneys, 8000 Munich

Subject: German Patent Application 29 49 920 and "Matsuda Medical"

The claims for this application are as follows:

1. A surgical suture characterized by the fact that it consists of a tubular weave (1) of fine synthetic fibers or pure gold fibers (3) swaged to at least one surgiccal needle (4).
2. A surgica suture characterized by the fact that the fine synthetic fibers (2) which form the woven (braided) tube (1) consist of polytetrafluoroethylene fibers.

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POHLMANN & SCHMIDT

DE 227/228

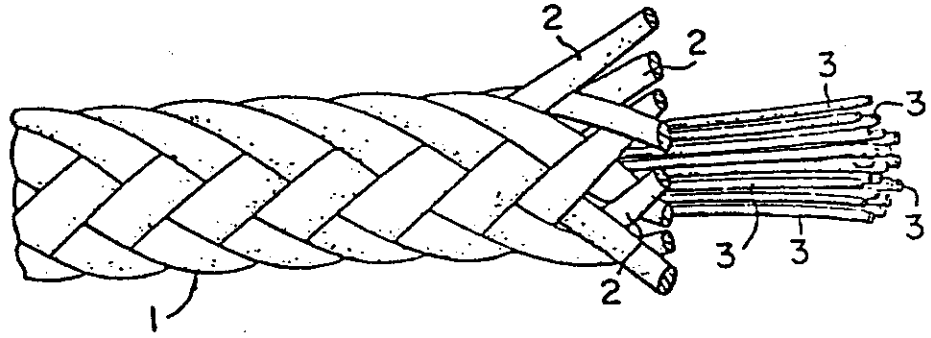
Juro Wada, Tokyo, Japan
Kabushiki Kaisha Matsuda Ika Kogyo, Tokyo, Japan

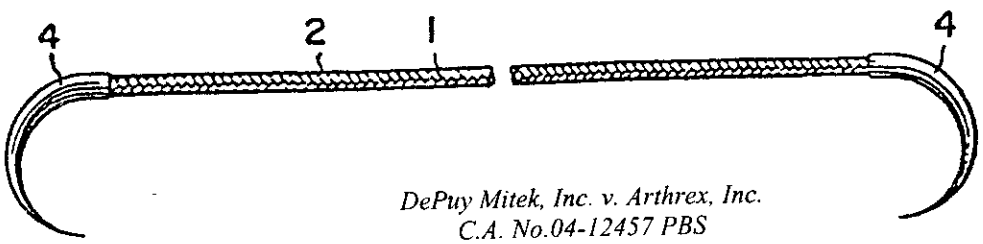
SURGICAL SUTURE MATERIAL

PATENT CLAIMS

1. Surgical suture material characterized by a tubular braid (1) made of very thin synthetic fibers braided together (2), by a number of very thin platinum fibers or pure gold fibers (3) that are inserted into the tubular braid (1) over its entire length, and by at least one surgical needle (4) which is joined integrally to one end of the tubular braid (1).

2. Surgical suture material according to Claim 1, characterized by the fact that the very thin synthetic fibers (2) that form the tubular braid (1) are polytetrafluoroethylene fibers.





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Description

The invention relates to a surgical suture material.

Up to now, materials made from animal fibers, for example silk, have commonly been used as suture materials for surgical operations. These suture materials made of animal fibers, however, cause friction with the internal organs during abdominal operations and are accompanied by a danger that the various functions of the organs will be impaired, which sometimes leads to rejection.

In addition, after the operation, the suture material itself can have a capillary effect. Further, when an artificial organ and a natural organ are joined there is a danger that the suture material itself will be overgrown by the natural organ and hinder its normal functioning. Moreover, when an infection occurs, it has up to now been impossible with animal fiber sutures to restore the organ function until the suture material is removed or physically rejected.

Further, with suture materials made of silk or a similar material, radiological observation of the parts sutured together has been impossible after the operation, so that it has been difficult to observe and analyse the functioning of the body organ after the operation.

The objective of the invention is therefore the development of a surgical suture material that does not have the above-described disadvantages of common suture materials, that is, which does not transport any blood or other body fluids, bacteria, etc., and thus does not display any capillary effect, and that is ready for use in a surgical operation without any special treatment.

This objective is achieved according to the invention by a surgical suture material that has a tubular braid made of very thin synthetic fibers braided together, a number of very thin platinum fibers or pure gold fibers which are inserted into the tubular braid over its entire length, and at least one surgical needle that is joined integrally to one end of the tubular braid.

A particularly preferred example of a realization of the surgical suture material of the invention is characterized by the fact that the parts of the body sutured together can be observed radiologically after the operation, so that the functioning of the body organ can be observed and analysed after the operation.

A preferred realization of the invention is described in more detail below with the aid of the accompanying drawings:

Fig. 1 shows a partially cut away lateral view of the realization of the suture material of the invention..

Fig. 2 shows a magnified partial frontal view of the realization of the suture material of the invention, with the inner metal filaments partially exposed by cutting away or omitting the outer braid.

Fig. 3 shows a sectional view along the line 3-3 in Fig. 2.

As is shown in the drawing, the exemplary realization of the suture material of the invention shows a tubular braid 1, which is composed of very thin synthetic fibers braided together. A number of very thin platinum fibers or pure gold fibers 3 are inserted into the tubular braid 1 over its entire length. A surgical needle 4 is joined integrally with both ends or with one end of the tubular braid 1 which surrounds the platinum fibers or the pure gold fibers that are inserted into the braid 1.

As for fibers 2 that form the tubular braid 1, those fibers can be used that have a smooth surface and a high durability, resistance to abrasion, bending strength and tensile strength, for example, polyfluoroethylene fibers or polyester fibers.

The tubular braid 1 is formed by braiding together a number of fibers 2 with a lengthwise mass of $1/9 \times 10^2$ tex, with 16 fibers being used in the exemplary realization shown in Figs 2 and 3.

The very thin platinum fibers or the very thin pure gold fibers 3 that are inserted into the tubular braid 1 have a diameter of about 50 um, with about 20 fibers of this kind being used. These platinum fibers or these pure gold fibers have no effect on the internal organs when they are in the body.

The surgical needle 4 is composed of stainless steel or a special steel.

By means of the above described suture material, the realization of suturing can take place smoothly without injuring the internal organs unnecessarily, since the fibers 2 of which the braid 1 is composed have smooth surfaces. Furthermore, because of the type of material of which it is composed, the suture material does not transport any blood or other body fluid by capillary action. Adhesion and transmission of bacteria can therefore be hindered without any special treatment of the suture material and even when bacteria are transferred the infected region can be healed easily.

Further, after the surgery, it is possible to make radiological observations of tissue formation in the living body and of the result of long-term tissue formation after the post-operative treatment, for example the formation of an anastomosis, and it is likewise possible to observe on x-ray film progressive changes in the state of the area operated on with its migration and other heretofore unknown functions of the body organs, which is extremely useful for the medical treatment.

The surgical suture material of the invention is thus best suited for the surgical implantation of artificial organs.

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(71) Applicant: BIORESEARCH INC. [US/US]; 315 Smith Street, Farmingdale, NY 11735 (US).

(72) Inventors: KURTZ, Leonard, D., Dr. ; 46 Woodmere Boulevard, Woodmere, NY 11598 (US). ARONOFF, Marvin ; 161-18 65th Avenue, Flushing, NY 11365 (US).

(74) Agent: SARRO, Thomas, P.; Larson and Taylor, 727-Twenty-Third Street, South, Arlington, VA 22202 (US).

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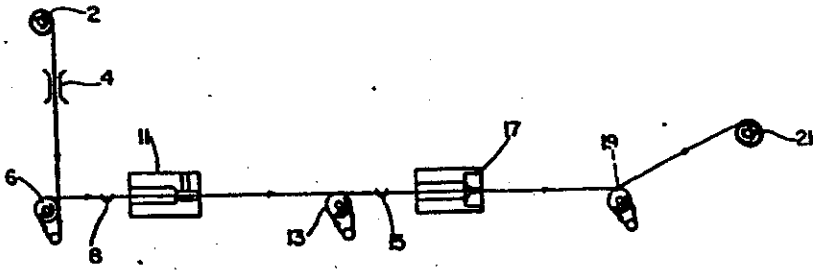

(57) Abstract

A composite surgical suture of extraordinary high knot strength and capable of use over a range of United States Pharmacopeia (USP) suture sizes is prepared by coating or covering a core of a fiber-forming synthetic polymer material having a knot tenacity of at least 7 grams per denier with a conventional suture material. Illustrative of suitable core materials are Kevlar and high strength fully chain-extended crystalline polyethylene.

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COMPOSITE SURGICAL SUTURES

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to improved surgical sutures having extremely high knot strength and to methods for their preparation. More particularly, the invention is directed to composite surgical sutures having a knot strength that enables them to be used over a range of suture sizes classified by the United States Pharmacopeia (USP).

Brief Description of the Prior Art

Surgical sutures are generally divided into two broad classes: (1) absorbable sutures, either natural or synthetic, which are absorbed by the body and (2) non-absorbable sutures, which remain in the body for prolonged periods of time or are removed when the wound heals.

From the patient's viewpoint, whether an absorbable or non-absorbable suture is employed, assuming no toxicity of the suture implant, it is a surgical dictum that the finest suture should be used and that the knot should have the least mass. This dictum is based upon the belief that problems in suture implants are directly related to the size of the suture and the bulk of the mass, i.e., the larger the bulk, the greater the probability of trouble in healing.

Undoubtedly, this was the rational for the original establisnment of the USP classification which divides non-absorbable sutures into seventeen sizes: 10/0, 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5, 6, 7. A few additional

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sizes are used which are not USP. Considering that silk was the most widely used non-absorbable suture in the mid-twenties and thirties, this size differentiation was based upon manufacturing. These seventeen sizes could be differentiated one from another by eye. If a finer differentiation were desired, it would not be accomplished becasue of the variation in the raw material as extruded by the silk worm. This classification has been quite useful. Obviously, the number of sizes cannot be considered "standardization" by any means. The sizes are numerous. Unfortunately, it has not been possible to coalesce size because the finer sizes do not have the adequate knot break strength to substitute for the next size.

A further long term problem in surgery is post-operative hernia. It is a truism that scar tissue never achieves the tensile strength of normal tissue. Hernias have occurred many years post-operably through the scar. If a suture were developed which would leave as a residue a non-absorbable suture to support that scar tissue, it would undoubtedly decrease and most likely eliminate the post-operative hernia as a complication.

Composite sutures having a reinforcing core are known in the prior art. None, however, achieve the aforementioned characteristics desired in a suture.

Accordingly, it is an object of the invention to provide a surgical suture with knot strengths so great that suture of much less foreign material is left in the body.

Another object of the invention is to provide a surgical suture having a knot strength that renders it useful over a range of surgical sizes within the USP classification of graded suture sizes, and thus

having the ability to replace the USP graded scale of sizes with just a few finer sutures whose strength would cover the entire range.

A further object of the invention is to provide a composite suture which leaves a residue of non-absorbable suture to support scar tissue and, therefore, decreases or eliminates post-operative hernia as a complication.

Another object of the invention is to provide a method of preparing surgical sutures having extremely high knot strength whose surface characteristics can be tailored to meet desired properties.

A further object of the invention is to provide composite sutures capable of using needles which more closely approximate the outer diameter of the suture.

A further object of the invention is to provide a composite suture having lateral strength, that is, a suture stabilized against abrasion, kinking and/or fibrillation during knotting.

SUMMARY OF THE INVENTION

These and other objects of the invention are obtained by a sterile, surgical suture having an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier coated with a film and fiber-forming surgical material, said coated core, when constructed into a surgical suture of a particular USP grade size, having a knot strength exhibited by surgical sutures of said suture material at least two USP grade sizes larger.

The elongated core of the sutures of the invention can be formed of any fiber-forming synthetic polymer, such as a polyamide, polyolefin, polyester

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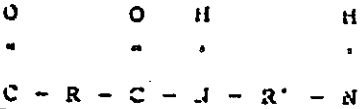
and the like, having a straight pull tenacity of at least 15 grams/denier, preferably up to 70 or more grams/denier and a knot tenacity of at least 7 grams/denier, preferably up to 30 or more grams/denier. By "knot tenacity" as used herein and in the appended claims is meant knot break strength divided by the denier. Unless the synthetic polymer making up the suture core of the invention meets the aforementioned knot tenacity properties, the resulting coated core fails to provide a suture which achieves the desired objects of the invention.

Illustrative of synthetic polymer materials suitable for use as the core of the suture of the invention are fiber-forming aromatic polyamides in which the chain extending bonds from each aromatic nucleus are essentially coaxial or parallel and oppositely directed. The term "aromatic nucleus" is used herein to include individual enchained aromatic rings and fused-ring aromatic divalent radicals. The preferred polymers include carbocyclic aromatic polyamides containing up to 2 aromatic rings, including enchained non-fused rings (e.g. 4, 4'-biphenylene) or fused rings (e.g. 1, 5-naphthalene) per amide linkage. The chain-extending bonds from these aromatic rings are para-oriented and/or essentially coaxial or parallel and oppositely directed.

Highly preferred polyamides are characterized by recurring units of the formula:

(I) 

wherein R and R' (when the chain extending bonds are essentially coaxial) are selected from the group of:

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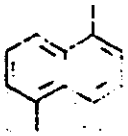
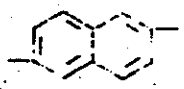
 1,4-phenylene, and

 4,4'-biphenylene

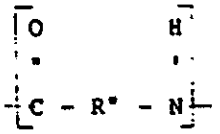
and R and R' (when the chain extending bonds are essentially parallel) are selected from the group of:

 1,5-naphthylene, and

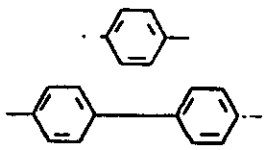
 2, 6-naphthylene

R and R' may be the same or different and may contain substituents on the aromatic nuclei.

Additional highly preferred polyamides of this invention are characterized by recurring units of the formula:

(II) 

wherein R" is selected from the group of:



Similarly R" may contain substituents on the aromatic nuclei.

As previously stated, the aromatic nuclei of the polymers of this invention may bear substituents. These substituents should be non-reactive during the polymerization and preferably also should be non-reactive (e.g. thermally) during subsequent processing of the polymer, e.g., heat treating of a shaped fiber thereof. Such reactivity is undesirable in that it may cause cross-

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linking of the polymer and may adversely effect the dope and/or fiber properties. Among the preferred non-reactive substituents may be names halogens (e.g., methoxy and ethoxy), cyano, acetyl, and nitro. Other suitable substituents non-reactive during the polymerization will be evident to those skilled in the art and are contemplated herein provided such do not adversely affect the desired properties of the dopes and/or fibers of this invention, e.g., due to factors such as steric hindrance. Generally, it is preferred that no more than two (and more preferably no more than one) suitable substituents be present per aromatic nucleus. However, more than two such substituents may suitably be present if the substituent is a relatively small group e.g., methyl.

Both homo-and co-polyamides having substituted or unsubstituted aromatic nuclei, as described above, are well suited for the dopes and fibers of this invention. Random copolymers are preferred copolymers. By the term "random" is meant that the copolymer consists of molecules containing large numbers of units comprised of two or more different types in irregular sequence. The units may be of AB (e.g., from p-aminobenzoyl chloride hydrochloride), AA (e.g., from p-phenylenediamine or 2,6-dichloro-p-phenylene diamine), or BB (e.g., from terephthaloyl or 4,4'-bibenzoyl chloride) type or mixtures of these, provided always that the requirements of stoichiometry for high polymer formation are met. It is not necessary that the relative numbers of the different types of the unit be the same in different molecules or even in different portions of a single molecule.

One or more of these polymers may suitably be

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used in the fibers of this invention, i.e., a single homopolymer; a single copolymer; or homopolymer and/or copolymer blends are suitable herein.

While the polymer chains described above consist essentially of amide links (- CONH -) and aromatic ring nuclei as described above, the polymers useful for preparing the core of this invention may also comprise up to about 10 percent (mole basis) of units not conforming to the above-cited description, e.g., aromatic polyamide-forming units whose chain extending bonds are other than coaxial or parallel and oppositely directed, e.g., they may be metaoriented, or of linkages other than amide, e.g., urea or ester groups.

Among the suitable aromatic polyamides may be named poly(p-benzamide); poly(p-phenylene terephthalamide); poly(2-chloro-p-phenylene terephthalamide); poly(2,6-dichloro-p-phenylene 2,6-naphthalamide); poly(p-phenylene p;p'-biphenyldicarboxamide); poly(p,p'-phenylene benzamide); poly(1,5-naphthylene terephthalamide); ordered aromatic copolyamides such as e.g., copoly(p,p'-diaminobenzanilide terephthalamide), and random copolyamides such as, e.g., copoly(p-benzamide/m-benzamide) (95/5); and many others.

These aromatic polyamides generally have an inherent viscosity and preferably greater than 1.0. Inherent viscosity (ηinh) defined by the following equation:

$$\eta inh = [\ln (\eta rel)/C]$$

wherein (ηrel) represents the relative viscosity and C represents a concentration of 0.5 gram of the polymer in 100 ml of solvent. Exemplary of such aromatic polyamides are those known as the "Kevlar"

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series, products of the DuPont corporation, which generally have a straight pull tenacity of about 18 to 25 grams per denier and a knot tenacity of at least about 7 grams per denier. Further examples of such aromatic polyamides and their methods of preparation can be found, for instance, in U.S. Patent Nos. 3,063,966, 3,600,350, 3,671,542 and 3,919,587 all incorporated herein by reference.

Another example of a synthetic polymer suitable for use as the core of the suture of the invention are high strength polyolefins such as polyethylene which provides fibers having a straight pull tenacity of about 25-50 grams/denier and a knot tenacity of about 7 to 17 grams/denier. These polyolefin fibers are characterized by full chain extension and high crystallization and can be prepared: (1) by ultradrawing of the solidified crystalline polyolefin material that is, by further development of the traditional cold drawing process, and (2) by extending the chains in random state (melt or solution) and inducing them to crystallize in the extended form subsequently. Polyolefins having these characteristics and their method of preparation are described in Keller, A. and Barham, P.J. "High Modulus Fibres", Plastics and Rubber International, February, Volume 6, No. 1 (1981), herein incorporated by reference.

The core of the surgical suture of the invention can be either a monofilament or of multifilament construction. The latter is ordinarily preferred since the coating of suture material subsequently applied generally exhibits stronger adhesion to multifilament cores. The liquified suture material coating tends to penetrate and fill the interstices of a multifilament core as well as

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coating the core, thereby anchoring the coating thereto. Multifilament cores can take the form of braids, twisted polyfilaments, yarns and the like.* It should be noted that while the synthetic polymer materials contemplated for use as the core of the composite sutures of the invention, have high axial strength, they are not ordinarily suitable for use as sutures since they do not possess the necessary lateral strengtn and, therefore, tend to abrade, kink and/or fibrillate during knotting. Coating of the core with a suture material pursuant to the present invention has been found to unexpectedly stabilize, i.e. provide lateral strength resistance against such action thereby rendering suitable for use as sutures these synthetic polymer fibers normally unsuitable for such use.

The surgical suture material used to coat the core can be any film-forming material commonly used in the construction of absorbable and non-absorbable sutures. In general these suture materials when drawn into fibers exhibit straight tensile strengths of about 4 to 10 grams/denier. Examples of the non-absorbable type suture materials are silk (fibroin), polyolefins, such as polyethylene and polypropylene, polyesters such as polyethylene terephthalate and nylon. Examples of absorbable type materials useful as the coating for

* The suture material in the form of multi or monofilament yarn may also be present initially as a core around which the high strength yarn which eventually becomes the core in the finished suture is braided or twisted or it may be formed into a plied, twisted, braided or co-mingled construction with the high strength yarn.

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the core include collagen and the synthetic absorbable materials such as polylactide, polyglycolide and copolymers of lactide and glycolide with each other and with other reactive monomers such as those described, for instance, in U.S. Patent Nos. 3,636,952 and 2,683,136, which patents are herewith incorporated by reference. Such synthetic absorbable polymers are sometimes referred to herein as simply homopolymers and copolymers of lactide and glycolide.

The amount of suture material coated onto the core will vary depending upon the constructon of the core, whether monofilament or multifilament, the number and tightness of braid or twist, the particular tensile strength and knot tenacity of the core, the particular suture material used as the coating and its nature, e.g. melt, solution or solid. In general, when the coating is a non-absorbable suture material, the coating will constitute about 5 to about 10% by weight of the coated core. On the other hand, when the coating is an absorbable suture material, the coating may constitute about 5 to 90% by weight of the coated core.

The coatings can be applied by a variety of suitable techniques well known in the coating art. For example, the coatings can be applied to the core by solution coating, melt coating, extrusion coating and the like.

In melt coating, for example, the uncoated core under tension is slowly passed through a melt of the suture material and then through a die having an orifice smaller than the upper diameter specification for the suture size desired, heated above the melting point of the coating materials, to trim

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off excess coating material and shape the composite. Multiple coatings may be applied if necessary.

In solution coating, the suture material is dissolved in a suitable solvent and the core is slowly passed through the coating solution thus formed. The treated core is then passed continuously through a tubular oven heated to an elevated temperature to evaporate the solvent and coalesce and solidify the suture material that remains.

A preferred coating technique when the core being coated is of multifilament construction comprises initially either solution coating or melt coating the multifilament core while the latter is held under a suitable tension and allowing the liquified coating material to penetrate or infiltrate the interstices of the core, thereby forming roots which help anchor the coating of the core. A second layer of the same suture material may then be applied to the impregnated core by any of the conventional coating methods.

In a typical extrusion coating process the core is passed through the cross-head die of a conventional wire coating extrusion apparatus. Pellets of the coating material are introduced into the plastification zone of the extruder wherein they are plasticized into a melt which is forced through the annular die of the extruder and onto the core.

Which coating technique is employed will usually depend upon the particular core utilized. Aromatic polyamide cores, for example, lend themselves to melt or extrusion coating because of their high melting points. The high strength polyethylene cores, on the other hand, have

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relatively low melting points, e.g. about 145°C, and must be treated differently. With them, solution coating of the monoor multi-filament cores is the chief method.

According to a preferred embodiment of the invention, when the core being coated is an aromatic polyamide, it is subjected to both a precoating stage and finish coating stage, each of which will oe discussed below in more detail.

Impregnation/Precoating Stage

The impregnation/precoating operation of the invention can be conducted using a thread composed of a core made up of multifilaments of a suture material and a plurality of fibers of a synthetic polymer having a tenacity of at least 18 grams/-denier and knot tenacity of at least 7 grams/-denier. The thread can be formed in the usual manner as by twisting, braiding, etc., a plurality of the synthetic polymer fibers around the suture material core. The thread, that is, the covered core is then heated to temperatures above the melting point of the multifilament core material passing it through any suitable oven during which passage the suture material melts and under the tension developed and/or applied exudes upward through the polyfilamentous synthetic polymer component and onto its surface. The amount of coating employed should be sufficient to not only fill all the interstices of the multifilament core component during the melting period but to also coat the surface of the yarn or thread component. Any excess coating material which may have melted out is trimmed off. While the heating of the covered core mixed yarns can be effected with or

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without stretching of the thread in some instances, a better final suture is obtained when the yarn is maintained under tension with little or no stretch applied at this stage. It is at this stage that the basic solid coated core structure is developed.

The impregnated and coated core is then passed through a heated dye which trims coating nubs from the core and otherwise smooths the external surface of the thread. Stretch may also be applied during the smoothing operation, but again, best results are obtained with no or minimum stretch. The thread may be passed through the heating oven or smoothing die as many times as is necessary to obtain a smooth, nub-free surface. Advantageously, in smoothing down the nubs not only should excess surface coating be removed, but some of it should be used to fill the ups and down of the thread's surface in order to obtain a sufficiently smooth undercoat structure. If this is not done, the coating remaining on the surface follows the contours of the thread and any subsequently applied coating will follow these contours.

The temperatures employed in the heating oven will vary depending on the coating employed, the proportions of coating material to core, the speed at which the core is passed through the oven and whether the heating and/or smoothing is conducted under stretch conditions. As aforementioned, the temperature should be raised above the melting point to a level at which the coating material exudes through the thread as a gelatinous mass which can then be seen on the surface of the thread when it cools. Excessively high temperatures which thin the coating material to a point where it runs off should be avoided as they tend to exude too

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much coating material and fail to produce a solid case structure.

Generally speaking, when the impregnation/precoating operation is conducted under stretch conditions, distribution of the coating material throughout the thread and exudation to the surface occurs at lower temperatures than when no stretch is applied. It is important to note, however, that giving the core a high level of stretch in the impregnation/precoating operation reduces or eliminates the ability to apply stretch in the subsequent finish coating stage, in accordance with the preferred embodiment of the invention described below, where it may be used to adjust finished suture properties such as break elongation by additional heat treatment of the highly stretched precoated thread.

The optimum melting temperatures employed in the impregnation/precoating operation will depend primarily upon which suture coating material is employed. The smoothing die temperature will also be above the melting point of the coating material and below the melting point of the core. Usually it will conform closely to the temperature employed in the impregnation/precoating stage preferably about 5 to 15 degrees below that used in the impregnation/precoating stage.

Finish Coating Stage

In the preferred embodiment of the invention, the final stage in obtaining the composite suture structure is to melt extrude coating material onto the smoothed impregnated/precoated thread. Any of the conventional extrusion apparatuses can be employed for this purpose. The smooth precoated

thread is simply fed through the extrusion coating die and coated with additional coating material of the same type as used in the impregnation/ precoating stage. As aforementioned, it is important to note that the smooth impregnated/ precoated thread subjected to the coating stage be essentially free of an undulating surface. The extrusion temperatures employed in the impregnation/ precoating stage although it has been found that the higher the extrusion coating temperature, other conditions being equal, the greater the finished suture diameter. This is due to decreased melt viscosity with increased temperature which results in increased polymer flow under a given applied force.

The following examples are included to further illustrate the novel composite sutures of the invention and their preparation. In the examples, reference is made to the following drawings wherein: Fig. 1 is a schematic drawing of an apparatus useful in the impregnation/precoating stage of the present invention; Fig. 2 is a schematic drawing of an apparatus useful in the extrusion coating of the suture impregnated and precoated by use of the apparatus of Fig. 1; and Fig. 3 is a cross-section of the extrusion die in Fig. 2 on a larger scale.

Example I

Directing attention to the drawings, using a conventional New England Butt braider machine 4 strands of "Kevlar", a tradenamed material of DuPont DeNemours, of 30-50 denier having a straight pull tenacity of approximately 7.5 grams per denier are braided around a single core of continuous 40 denier polypropylene having a straight pull tenac-

ity of approximately 4 grams/denier. The raw braid thus formed is wound around a reel 2, and fed through a tensioner 4, about a feed roll (Godet) 6, guide 8 and into a heated 10 cm long tubular oven. The lumen of an extrusion coating die without feed serve this purpose and is designated Heated Zone I in Fig. 1. A draw roll (Godet) 13 pulls the raw braid through the oven without stretch, that is, at a stretch ratio (SR) of 1:1. The Heated Zone I is maintained at a temperature of 230°C. Under these conditions all the polypropylene melts and is entirely distributed throughout the braid interstices and onto the surface of the braid. No solid polypropylene core residue remains.

As the braid emerges from Heated Zone I, large quantities of excess polypropylene which have melted out are trimmed off manually. The braid then continues through a Guide 15 to Heated Zone II which contains a smoothing die 17 having a 0.2 mm diameter that trims and smooths down nubs that are formed on the braid. Heated Zone II is maintained at a temperature of about 220°C for the smoothing operation. The smoothed braid is pulled through Heated Zone II by a draw roll (Godet) 19 and onto receiving reel 21. The speed at which the braid passes through both Heated Zone I and II is approximately 1-1.8 M/min. The precoated braid is passed through the smoothing die 17 three times so as to obtain an impregnated/precoated braid of the desired smoothness.

Referring to Fig. 2, reel 31 of smooth impregnated/precoated braid prepared as above is passed through a tensioner 33, to feed roll (Godet) 35 which feeds the braid through guide 37 into extrusion coating die apparatus indicated generally

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as 39. Polypropylene chips are melted in heated reservoir 41 maintained at a temperature of 260°C and the melt is forced by means of extruding weights 43 applied at a force of 0.233 kg to a piston 45 into and through the extrusion coating die.

Directing particular attention to Fig. 3, the extruding coating apparatus is comprised of a holder indicated generally as 47 which houses a hollow lumen member 49 a spinneret 57 having an outlet 52. The lumen member 49 essentially positioned within the holder 47 so as to provide an annular chamber 53. A gasket 55 seals one end of the member 49 within the holder while the other end is supported by slotted plate 60. The lumen member contains an inlet 59 and an outlet 61. Between outlet 61 and outlet 52 of the spinneret 57 is positioned a hollow needle 63. The impregnated/precoated thread 65 passes consecutively through lumen member 49, hollow needle 59, outlet 52 and is coated with melt as it emerged from the die. The coating die is maintained at a coating temperature of 235°C.

The coated filament is then taken up on draw roll 48 which applies stretch. Tension is let down on draw roll 50 which is run more slowly than draw roll 48. The yarn velocity is 1.43 M/min. and the total stretch ratio (SR) is 1.02. The finished suture is finally wound around receiving reel 51.

The result is a finished composite suture with a 5/0 diameter "Kevlar" core accounting for approximately 90% of the cross-sectional area and exhibiting a knot break strength of about 3.2 pounds. A knot break strength of 3.2 pounds is equivalent to USP limits of size 2.0 monofilament suture. Thus,

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the composite suture prepared can be used as a 5/0, 4/0, or 3/0 suture.

Example II

The process of Example I is repeated substituting a polyethylene terephthalate core for polypropylene core and extrusion coating in extrusion coating die apparatus 39 with polyethylene terephthalate. The result is a composite suture having a 5/0 diameter "Kevlar" core accounting for approximately 90% of the cross-sectional volume coated with polyethylene terephthalate exhibiting a knot break strength of about 3.5 pounds which is a knot brek strength above the USP limits for a 2/0 size suture. Therefore, the composite suture prepared could be used for sizes 5/0, 4/0, 3/0 and 2/0 according to the physician's wishes.

Example III

Fibroin (silk) is dissolved in a aqueous solution of 62% zinc chloride to give a solution having fibroin weight % concentrations in the range of 5-20%. The resulting solution is maintained at approximately its boiling point and "Kevlar" yarn of Example I is pulled through the solution at a constant rate as to fully impregnate and coat the yarn. The impregnated and coated yarn is then dried by passing it through a tubular oven maintained at heating temperatures up to 130°C. The heat treatment evaporates the solvent and helps to form a continuous fibroin film. The composite suture is then washed with cold water to remove residual zinc chloride.

The resulting composite suture with a size 5/0 "Kevlar" core containing approximately 5% by weight fibroin exhibits a knot break strength of approximately 3.5 pounds which is equivalent to a silk

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suture of size 2.0. In other words, the silk-coated "Kevlar" composite suture could be used instead of silk in the following sizes: 5/0, 4/0, 3/0 and 2/0.

Example IV

A size 5/0 high strength fully chain-extended polyethylene multifilament yarn having a straight pull tenacity of 50 grams/denier and a knot tenacity of 15 grams/denier is pulled through a 10% solution of polyethylene terephthalate in a solvent mixture of methylene chloride containing 31% by weight hexafluoroisopropanol and then passed through a die to trim off excess solution. The coated core is dried in air and the process repeated to build up the coating to a final composite suture containing 10% by weight polyethylene terephthalate. The composite is washed with water and dried again. The resulting composite suture could be used for sizes 5/0, 4/0, 3/0, 2/0 and 1/0.

Example V

Example I is repeated substituting a polyglycolic acid (PGA) core for the polypropylene core and PGA resin for the polypropylene chips. The resulting "Kevlar"/polyglycolic acid composite has a minimum knot break strength in the range of 1550-1700 grams. Since commercial non-absorbable "Prolene" sutures of size 3/0 has a knot strength of 1550-1650 grams, this means that a size 3/0 "Kevlar"/polyglycolic acid suture will retain the knot break strength of 3/0 "Prolene" after absorption of all the polyglycolic acid. Thus, the "Kevlar"/polyglycolic acid suture prepared could be used for sized 3/0, 4/0 and 5/0.

When 6/0 size "Kevlar" reinforcing core is used with a non-reinforcing PGA coating, the core by

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itself will give a knot strength midway between size 4/0 and 5/0 based on "Prolene" knot strength but above the USP standards for 4/0. Thus, PGA coated "Kevlar" composites with a 6/0 core could be used for size 6/0, 5/0 and possible size 4/0.

With size 7/0 reinforcing core and PGA non-supportive coating 6/0 strength is obtained. Thus, PGA coated, 7/0 core "Kevlar" can be used for sizes 6/0 and 7/0.

Using high strength, extended chain polyethylene having 50 gram/denier straight breaking tenacity, with approximately 1/3 of this converting to knot tenacity, a 5/0 size reinforcing high strength polyethylene core of about 0.140 mm in diameter will impart at least the knot strength of a 2/0 suture to the composite. Thus, a PGA-coated high strength polyethylene 5/0 core can be used to make sizes 2/0, 3/0, 4/0 and 5/0 absorbable, non-absorbable composite sutures.

With high strength polyethylene 6/0 size reinforcing core of about 0.90 mm diameter and a non-supporting PGA coating, the core itself will provide enough knot strength for sizes 4/0, 5/0 and 6/0 based on the knot strength of "Prolene".

With high strength polyethylene 7/0 size reinforcing core of about .060 - .065 mm in diameter and non-reinforcing PGA coating, the core itself will give knot strength sufficient for 5/0, 6/0 and 7/0 composites based on the knot strengths of "Prolene".

With higher strength materials or by increasing the knot strength of the materials mentioned here, a wider spectrum of sizes could be covered with the same fine sized reinforcing core.

In commercial production, needles may be

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attached to one end of the composite sutures of the invention and the sutures may be packed in sterile containers. Inasmuch as the sutures are stable for long periods of time witnout a conditioning fluid, the sutures may be dry packed in glass tubes or plastic envelopes. Conditioning fluid may be used to assure maintenance of sterility or as a rust preventing medium for the needle. Eyeless needles are preferred since they cause less tissue damage. Conveniently, the composite sutures of the present invention are formed at convenient lengths, attached to eyeless needle, wound on reels if desired, and placed in containers such as plastic envelopes. The sutures may then be sterilized with ethylene oxide or other conventional gaseous sterilizing agents in accordance with known practices. Alternatively, the sutures may be sealed in the envelopes and then sterilized by using heat and radiation including x-rays, gamma rays, electrons, neutrons, etc.

Another advantage offered by the composite sutures of the invention is that needles of smaller diameter can be attached thereto. In accordance with this feature of the invention the outside cover or coating of suture material at the end of the composite suture is removed by any suitable means as, for instance, by dissolving the cover using a solvent which solubilizes the cover but not the core. The core at the end of the suture is thereby exposed and onto the core is attached as, for instance, by swagging a needle of smaller outer diamter than would be used with a suture of the same outer diameter. The following example illustrates this feature of applicants' invention:

Example VI

The end of a composite suture prepared according to the general procedure of Example I and having an outer diameter of approximately 0.012 inch is dipped one-eighth inch into boilin xylene until the polypropylene cover softens. The polypropylene cover is then manually scrapped off to expose the 5/0 "Kevlar" core. A 0.014 inch diameter needle is swagged onto the core to provide a suture with a needle having a cross-sectional area reduced approximately two-thirds that of needles required for sutures having a 0.012 inch diameter.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000173

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IT IS CLAIMED:

1. A sterile, surgical suture comprising an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams per denier coated with a film and fiber-forming surgical suture material, said coated core, when constructed into a surgical suture of a particular USP grade size, having a knot strength exhibited by surgical sutures of said suture material at least two USP grade sizes larger.

2. A sterile, surgical suture according to claim 1 wherein the synthetic polymer is an aromatic polyamide.

3. A sterile, surgical suture according to claim 1 wherein the aromatic polyamide is poly(p-phenylene terephthalamide).

4. A sterile, surgical suture according to claim 1 wherein the aromatic polyamide is poly(1,4-benzamide).

5. A sterile, surgical suture according to claim 1 wherein the synthetic polymer is a fully chain-extended polyethylene having a straight pull tenacity of about 30 to 50 grams/denier.

6. A sterile, surgical suture according to claim 1 wherein the surgical suture material is fibroin.

7. A sterile, surgical suture according to claim 1 wherein the surgical suture material is polyester.

8. A sterile, surgical suture according to claim 1 wherein the polyester is polyethylene terephthalate.

9. A sterile, surgical suture according to claim 1 wherein the surgical suture material is polyolefin having a straight pull tenacity of about

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21. A sterile, surgical suture according to claim 2 wherein the core is a plurality of fibers of said synthetic polymer in a twisted yarn or braided construction.

22. A sterile, surgical suture according to claim 20 wherein the aromatic polyamide is poly(p-phenylene terephthalamide).

23. A sterile, surgical suture according to claim 1 wherein the coating of film-forming suture material comprises 5 to 10% by weight of the suture.

24. A sterile, surgical suture according to claim 13 wherein the coating of film-forming suture material comprises 5 to 90% by weight of the suture.

25. A method of producing a surgical suture having a knot strength rendering it useful over a range of USP suture grade sizes comprising coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier, with a fiberand film-forming surgical suture material, said coated core when constructed into a surgical suture of a particular USP grade size, having a knot strength exhibited by surgical sutures of said suture material at least two USP grade sizes larger.

26. A method according to claim 25 wherein said coating is effected by solution coating.

27. A method according to claim 25 wherein said coating is effected by melting coating.

28. A method according to claim 25 wherein the coating comprises heating under tension a thread conprised of a plurality of synthetic polymer fibers having a knot tenacity of at least 7 grams/denier in the form of a cover and at least one fiber of a meltable surgical suture material in the form of a core, at an elevated temperature sufficient to melt and liquify the fiber or fibers

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4 to 10 grams/denier.

10. A sterile, surgical suture according to claim 1 wherein the polyolefin is polyethylene.

11. A sterile, surgical suture according to claim 1 wherein the polyolefin is polypropylene.

12. A sterile, surgical suture according to claim 1 wherein the surgical suture material is collagen.

13. A sterile, surgical suture according to claim 1 wherein the surgical suture material is a film-forming absorbable synthetic polymer.

14. A sterile, surgical suture according to claim 13 wherein the absorbable synthetic polymer is selected from the group consisting of film-forming homopolymers and copolymers of lactide and glycolide.

15. A sterile, surgical suture according to claim 14 wherein the absorbable synthetic polymer is a homopolymer of glycolide.

16. A sterile, surgical suture according to claim 14 wherein the absorbable synthetic polymer is a homopolymer of lactide.

17. A sterile, surgical suture according to claim 1 wherein the core is in monofilament construction.

18. A sterile, surgical suture according to claim 2 wherein the core is in monofilament construction.

19. A sterile, surgical suture according to claim 18 wherein the aromatic polyamide is poly(p-phenylene terephthalamide).

20. A sterile, surgical suture according to claim 1 wherein the core is a plurality of fibers of said snythetic polymer in a twisted yarn or braided constructon.

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of surgical suture material but not the fibers of said cover, permitting the liquified surgical suture material to distribute itself throughout the interstices of the cover and onto the surface thereof so as to form a coating on said cover, which is thereby converted to the core of the finished composite suture, then smoothing said coating.

29. A method according to claim 28 wherein said smoothing is effected by passing said heated thread through a heated smoothing die.

30. A method according to claim 28 wherein the surgical suture material is selected from polyolefin and polyester.

31. A method according to claim 25 wherein the coating comprises heating under tension a thread comprised of a plurality of synthetic polymer fibers having a straight pull tensile strength of at least 18 grams/denier and a knot tenacity of at least 7 grams/denier in the form of a cover and at least one fiber of a meltable surgical suture material in the form of a core, at an elevated temperature sufficient to melt and liquify the fiber or fibers of surgical suture material but not the fibers of said cover, permitting the liquified surgical suture material to distribute itself throughout the interstices of the cover and onto the surface thereof so as to form a coating on said cover, which is thereby converted to the core of the finished composite suture, smoothing said coating and melt extruding similar surgical suture material onto said smoothed coating.

32. A method according to claim 31 wherein the surgical suture material is selected from polyolefin and polyester.

33. A method according to claim 25 wherein the coating is effected by solution coating.

34. A method of producing a surgical suture having a knot strength rendering it useful over a range of USP suture grade sizes comprising coating an elongated core of synthetic polymer having a knot tenacity of at least 7 grams/denier and a lateral strength insufficient to prevent abrasion, fibrillation or kinking on knotting with a film and fiber-forming surgical material in an amount sufficient to increase the lateral strength of said core and provide resistance against said abrasion, fibrillation or kinking on knotting, said coated core, when constructed into a surgical suture of a particular USP grade size, having a knot strength exhibited by surgical sutures of said suture material at least two USP grade sizes larger.

35. A sterile, surgical suture according to claim 1 having a needle attached to said core.

36. A sterile, surgical suture according to claim 35 wherein the synthetic polymer is an aromatic polyamide.

37. A sterile, surgical suture according to claim 35 wherein the aromatic polyamide is poly(p-Phenylene terephthalamide).

38. A sterile, surgical suture according to claim 35 wherein the aromatic polyamide is poly(1,4-benzamide).

39. A sterile, surgical suture according to claim 35 wherein the synthetic polymer is a fully chain-extended polyethylene having a straight pull tenacity of about 30 to 50 grams/denier.

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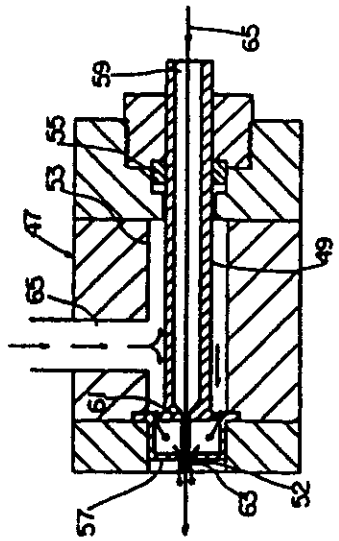

FIG. 3

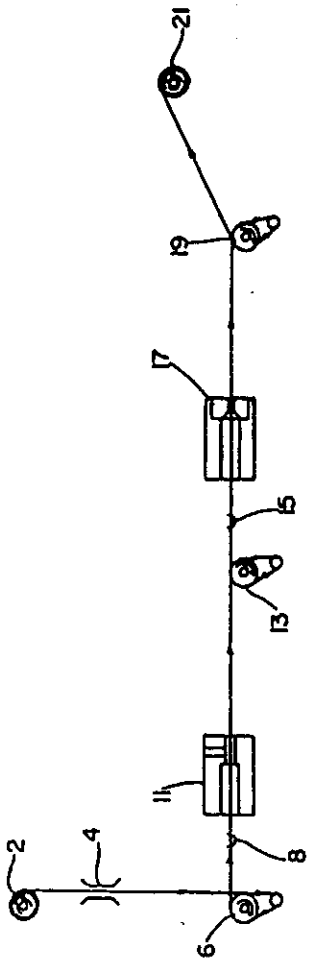

FIG. 1

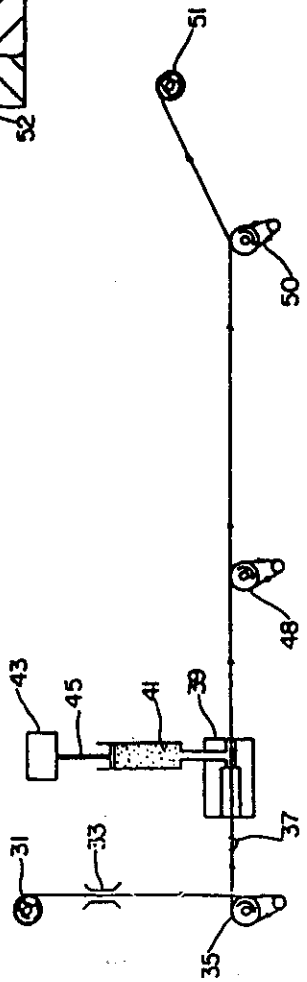

FIG. 2

INTERNATIONAL SEARCH REPORT

International Application No PCT/US84/00918

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int Cl [3] A61L 17/00
US CL 128/335.5

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
US	128/329R, 334R-335.5, Dig. 8, Dig. 18 28/140, 165, 166, 169 66/169R-170, 202 8/Dig. 21 8/490, 529-533, 115.5-115.7, 130.1-132, Dig. 3,

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

cont'd Dig. 9

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]		Relevant to Claim No. [18]
X, Y	US, A, 3,791,388	12 February 1974 HUNTER	1, 6-9, 11-17, 20, 23-35
Y	US, A, 4,014,973	29 March 1977 THOMPSON	23, 24, 31
Y	US, A, 3,359,983	26 December 1967 NORTHEY	5, 10, 23, 24, 39
Y	US, A, 3,630,205	28 December 1971 LISTNER	5, 10, 23, 24, 39
X, Y	US, A, 4,204,542	27 May 1980 BOKROS	23, 24, 35-38
X, Y	US, A, 4,336,357	22 June 1982 BARTOLI	23, 24, 35-38

* Special categories of cited documents: [15]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
31 JULY 1984	17 AUG 1984
International Searching Authority [1]	**Signature of Authorized Officer [20]**
ISA/US	C. FRED ROSENBAUM

Form PCT/ISA/210 (second sheet) (October 1981)

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000180

International Application No PCT/US84/00918

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [10]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers . because they relate to subject matter [12] not required to be searched by this Authority, namely:

2. ☐ Claim numbers . because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [13], specifically:

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [11]

This International Searching Authority found multiple inventions in this international application as follows:

Claims 1-24 and 35-39 are drawn to a surgical suture.

Claims 25-34 are drawn to a method of making a surgical suture.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☒ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (supplemental sheet (2)) (October 1981)

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

February 04, 2005

THIS IS TO CERTIFY THAT ANNEXED IS A TRUE COPY FROM THE RECORDS OF THIS OFFICE OF THE FILE WRAPPER AND CONTENTS OF:

APPLICATION NUMBER: *07/838,511*
FILING DATE: *February 19, 1992*
PATENT NUMBER: *5,314,446*
ISSUE DATE: *May 24, 1994*

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

N. WOODSON
Certifying Officer

PART 2 OF 2 PART(S)

Form PTO-1449 — List of Prior Art Cited by Applicant

MAIL ROOM FEB 19 1992 PAT. & TRADEMARK OFFICE

Attorney Docket No. ETH-782 | Serial No. 07/838,911

Applicant Alastair Hunter et al.

Filing Date 2-19-92 | Group 1504

U.S. PATENT DOCUMENTS

Exam'r Init.		Document No.	Date	Name	Class	Sub Class	File Date
CWR	AA	3,942,532	3/9/76	Hunter et al.	128	335.5	8/15/74
CWR	AB	4,624,256	11/25/86	Messier et al.	128	335.5	8/11/85
CWR	AC	3,527,650	9/8/70	Block, A.	117	7	12/21/67
CWR	AD	4,470,941	9/11/84	Kurtz, L.	264	136	6/2/82
CWR	AE	3,187,752	6/8/65	Glick, A.	128	335.5	4/27/62
CWR	AF	4,043,344	8/23/77	Landi et al.	128	335.5	9/20/76
CWR	AG	4,047,533	8/13/77	Perciaccante et al.	128	335.5	9/20/76
CWR	AH	4,946,467	8/7/90	Ohi et al.	606	228	3/8/89
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

Exam'r Init.		Document No.	Date	Country	Class	Sub Class	Translate Yes	Translate No
CWR	AL	GB 2 218 312A	11/15/89	United Kingdom	A01K	91/00	✓	—
CWR	AM	DE 2949920	3/19/81	Germany	A61F	1/00	✓	—
CWR	AN	WO 86/00020	1/3/86	PCT	A61L	17/00	✓	—
	AO							
	AP							

OTHER REFERENCES (include author, title, date, pertinent pages, etc.)

	AR		
	AS		
	AT		

Examiner	Date Considered
CHRIS RAIMUND	JUNE 25, 1992

*Examiner: See note on original PTO form concerning initialing and MPEP 609 compliance. Include copy of this form with next communication to applicant.

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address : COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/828,511	02/19/92	HUNTER A	ETH-782

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
RAIMUND J.C	3
ART UNIT	PAPER NUMBER
1504	

DATE MAILED: 07/08/92

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☑ Notice re Patent Drawing, PTO-948.
3. ☑ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☑ Claims 1 - 24 are pending in the application.
   Of the above, claims 1 - 20 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 21 - 24 are rejected.
5. ☐ Claims _____ are objected to.
6. ☑ Claims 1 - 24 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____ has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 9-89)

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-20, drawn to a heterogeneous braid, classified in Class 57, subclass 243.

II. Claims 21-24, drawn to a surgical suture, classified in Class 600, subclass 231.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as mutually exclusive species in intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (M.P.E.P. § 806.04(b), 3rd paragraph), and the species are patentably distinct (M.P.E.P. § 806.04(h)).

In the instant case, the intermediate product is deemed to be useful as a fishing line and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Matthew S. Goodwin on June 23, 1992 a provisional election was made without traverse to prosecute the invention of Group II, claims 21-24. Affirmation of this election must be made by applicant in responding to this Office action. Claims 1-20 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 21-24 are rejected under 35 U.S.C. § 103 as being unpatentable over Burgess (U.K. Patent Application No. 2,218,312A).

Burgess discloses a fishing line of braided construction comprising filaments of polyethylene and filaments of polyester or nylon. Such a braid is disclosed to have the low stretchability of polyethylene and the low coefficient of friction of polyester. (See page 1). It is therefore known to braid filaments of two dissimilar polymers together to form a structure which embodies the desirable properties of each fiber.

Braided sutures are well known in the art. Many of the requirements of sutures are comparable to those of fishing line- strength, low stretchability, flexibility, low coefficient of friction etc. Indeed, many of the same materials are used for both of these applications. It would therefore have been

obvious, in view of Burgess, to use a heterogeneous braid for a suture. Claims 21 and 23 are therefore unpatentable over Burgess.

Synthetic, fiber forming polymers are widely employed as filaments in braided sutures. In German Patent Application DE 2949920A1, for example, surgical sutures made from braided polytetrafluoroethylene (PTFE) fibers or polyester fibers are disclosed. As polyester fibers are noted for their strength and PTFE fibers for their low coefficient of friction, it would have been obvious to use a braid comprising both types of filaments as a suture.

It is also known in the art to a braid around longitudinally extending core filaments. Ohi et al, for example, disclosure a core comprising a plurality of synthetic fiber filaments (column 1, lines 57-60). Polyester filament are specifically disclosed (column 2, lines 4-9). It would therefore have been obvious to dispose a heterogeneous braid comprising polyester and polytetrafluoroethylene fibers around a core of polyester fibers to form a suture. Claims 22 and 24 are therefore unpatentable over Burgess.

Any inquiry concerning this communication should be directed to Chris Raimund at telephone number (703) 308-3452.

Chris Raimund:jp
July 06, 1992

GEORGE F. LESMES
SUPERVISORY PATENT EXAMINER
GROUP 150

PTO FORM 948
(Rev 5-91)

U.S. DEPARTMENT OF COMMERCE
Patent and Trademark Office

ATTACHMENT TO PAPER NUMBER 3

APPLICATION NUMBER 838511

GROUP 1504

NOTICE OF DRAFTSMAN'S PATENT DRAWING REVIEW

The PTO Draftsmen review all originally filed drawings regardless of whether they were designated as informal or formal.

The drawings filed 2/19/92

A. ☒ are approved.

B. ☐ are objected to under 37 CFR 1.84 for reason(s) checked below. The examiner will require submission of new, corrected drawings at the appropriate time. Corrected drawings must be submitted according to the instructions listed on the back of this Notice.

1. Paper and ink. 37 CFR 1.84(a)
   - ☐ Poor Quality Paper. Must Be White. Transparent Paper Not Allowed. Sheet(s) _____

2. Size of Sheet and Margins. 37 CFR 1.84(b)

Acceptable Paper Sizes and Margins

Margin	Paper Size: 8 1/2 by 14 inches	8 1/2 by 13 inches	DIN size A4 21 by 29.7 cm.
Top	2 inches	1 inch	2.5 cm.
Left	1/4 inch	1/4 inch	2.5 cm.
Right	1/4 inch	1/4 inch	1.5 cm.
Bottom	1/4 inch	1/4 inch	1.0 cm.

   - ☐ Proper Size Paper Required. All Sheets Must be Same Size. Sheet(s) _____
   - ☐ Proper Margins Required. Sheet(s) _____
     - ☐ Top ☐ Right
     - ☐ Left ☐ Bottom

3. Character of Lines. 37 CFR 1.84(c)
   - ☐ Lines Pale, Rough and Blurred, or Jagged. Fig(s) _____
   - ☐ Solid Black Shading Not Allowed. Fig(s) _____

4. ☐ Photographs Not Approved. _____

5. Hatching and Shading. 37 CFR 1.84(d)
   - ☐ Shade Lines are Required. Fig(s) _____
   - ☐ Criss-Cross Hatching Not Allowed. Fig(s) _____
   - ☐ Double Line Hatching Not Allowed. Fig(s) _____
   - ☐ Parts in Section Must be Hatched Properly. Fig(s) _____

6. Reference Characters. 37 CFR 1.84(f)
   - ☐ Reference Characters Poor or Rough and Blurred. Fig(s) _____
   - ☐ Minimum 1/8 inch (3.2 mm.) in height is required. Fig(s) _____
   - ☐ Figure Legends Poor or Placed Incorrectly. Fig(s) _____

7. Views. 37 CFR 1.84(i) & (j)
   - ☐ Figures Must be Numbered Separately. _____
   - ☐ Figures Must Not be Connected Fig(s) _____

8. Identification of Drawings. 37 CFR 1.84(l)
   - ☐ Extraneous Matter or Copy Machine Marks Not Allowed. Fig(s) _____

9. ☐ Changes Not Completed from Prior PTO-948 dated _____

☐ Comments:

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000191

Telephone inquires concerning this review should be directed to the Chief Draftsman at telephone number (703) 557-6404.

_____ 3/6/92
Reviewing Draftsman — Date

PTO Copy

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. **Correction of Informalities—37 CFR 1.85**
File new drawings with the changes incorporated therein. The art unit number, serial number and number of drawing sheets should be written on the drawings in accordance with 37 CFR 1.84(l). Applicant may delay filing of the new drawings until receipt of the "Notice of Allowability" (PTOL-37). If delayed, the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for response in the "Notice of Allowability" (PTOL-37). Extensions of time may be obtained under the provisions of 37 CFR 1.136 The drawing should be filed as a separate paper with a transmittal letter addressed to the Official Draftsman.

   Timing of Corrections
   Applicant is required to submit **acceptable** corrected drawings within the three month shortened statutory period set in the "Notice of Allowability" (PTOL-37). Within that three month period, two weeks should be allowed for review by the Office of the correction. If a correction is determined to be unacceptable by the Office, applicant must arrange to have acceptable correction re-submitted within the original three month period to avoid the necessity of obtaining an extension of time and paying the extension fee. Therefore, applicant should file corrected drawings as soon as possible.

   Failure to take corrective action within set (or extended) period will result in **ABANDONMENT** of the Application.

2. **Corrections other than Informalities Noted by the Draftsman on the PTO-948**
All changes to the drawings, other than informalities noted by the Draftsman, **MUST** be made in the same manner as above except that, normally, a red ink sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

MAIL ROOM FEB 16 19 64 PAT. & TRAD

ETH 782
Batch No. 567

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : **STERILIZED HETEROGENOUS BRAIDS**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

February 14, 1994
(Date of Deposit)

Hal Brent Woodrow
Name of applicant, assignee, or Registered Representative

Hal Brent Woodrow
(Signature)

February 14, 1994
(Date of Signature)

9200 ordered 5/18/94

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

AMENDMENT UNDER 37 CFR §312

Dear Sir:

This is responsive to the Examiner's Amendment attached to the Notice of Allpwance dated November 15, 1993, at which time a shortened statutory period for response of three months was set.

In the Claims

Please amend the claims as follows:

In Claim 10 after "claim" and before "wherein" please delete "8" and insert therefor -- 21 -- .

OK to enter - 9/7/94

Hal Brent Woodrow
Hal Brent Woodrow
Reg. No. 32,501
Attorney for Applicant(s)

MAIL ROOM AUG 10

ETH-78

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair Hunter et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

August 6, 1992
(Date of Deposit)

Matthew S. Goodwin
Name of applicant, assignee, or Registered Representative

(Signature)

August 6, 1992
(Date of Signature)

RECEIVED
AUG 17 1992
GROUP 150

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

AMENDMENT

Dear Sir:

Responsive to the Office Action of July 8, 1992, please reconsider the above-identified application in view of the following remarks.

REMARKS

1. Restriction to the invention of either Group I, claims 1-20, or Group II, claims 21-24, was required. Applicants reaffirm without traverse to prosecute the invention of Group II, claims 21-24. This election is made without prejudice to Applicants' right to file a divisional application directed to the non-elected invention of Group I, claims 1-20.

2. Claims 21-24 were rejected under 35 USC §103 as being unpatentable over Burgess. The Examiner has asserted that it would have been obvious in view of Burgess to use a heterogeneous braid for a suture. Applicants respectfully traverse this rejection.

The Examiner mistakenly believes that the requirements for a braided suture are comparable to those of a fishing line. However, nothing could be further from the truth.

One of the most important requirements for a braided suture is that it have outstanding knot strength when a knot is secured on the suture braid. Indeed, this requirement may be the most important requirement for a braided suture. This is so because the suture knot is what keeps a stitched wound intact. If the knot fails, then the wound can reopen and consequently the braided suture has failed as well.

Applicants recognized the importance of knot strength when attempting to overcome the shortcomings of the braided sutures disclosed in the art. In preferred embodiments of the invention, Applicants' claimed suture exhibits improved handling properties without sacrificing physical strength or knot security (see the specification at page 5, lines 4-7). In addition, numerous braided sutures were tested to determine their knot strength and knot security (see the examples at the end of the specification). The determination of knot security is described in the specification at page 12, lines 26-33.

In contrast, knot strength is not even mentioned in Burgess. Although it may be argued that it may be necessary to secure a knot on a fishing line to hold the hook to the line, the security and strength of the knot are not nearly as critical for this application. In fact, the fishing line of Burgess would have poor knot strength properties because of its braided construction, as set forth in more detail below.

Some of the braid filaments of the Burgess fishing line are composed of high tensile polythene thread. This thread gives the line minimal stretchability (see Burgess at page 1, lines 12-13). Although this thread has great strength properties, it suffers from

low elongation and, in turn, poor knot strength properties. This is a good idea for a fishing line because high strength and low elongation, or low stretchability, are important criteria. Low elongation is an important requirement for a fishing line because it makes it possible for the fisherman to apply force on the hook when, for example, the fish is caught. If the line were stretchable, then the force exerted by the fisherman would be taken up by the stretching action of the line. This would clearly be an undesirable property for a fishing line to exhibit. Therefore, the property requirements for fishing line yield a braid with poor knot strength and security, and the requirements for sutures yield a braid which has by necessity excellent knot strength and security.

In addition to the contrasting requirements for braided sutures and fishing line resulting from the critical need to tie strong and secure knots on braided sutures, other requirements concerning the knot make the braid for a fishing line unsuitable for use as sutures. For example, a surgeon must be able to make a conventional square knot at a very fast pace for patient safety. Clearly, a knot on a fishing line for a hook can be made at a much slower pace, and with a much more complex knot. Also, it is necessary during suturing to form a pre-knot on the braided suture, and the pre-knot must be subsequently slid down the suture until it is adjacent the body tissue desired to be stitched. Once the knot is placed at the desired location, additional throws on the knot can be added for knot security. This requires a braided suture which is stretchable and resilient so that this operation can be performed. Obviously, there is no such similar requirement for a fishing line.

In view of the dissimilarities in property requirements between sutures and fishing line, there would simply be no incentive for a medical designer who wishes to improve the properties of braided sutures to study the art related to braided fishing lines. Even if he did use the teachings of the fishing line art to modify a

suture, then he would inevitably design an unacceptable suture. Accordingly, Applicants respectfully submit that the rejection is in error and therefore it should be withdrawn.

It is noted that the Examiner has discussed German Patent Application DE 2949920 A 1 and Ohi et al. as evidence of the state of the art concerning the types of filaments used in braided sutures, and core/sheath braid construction. Applicants do not wish to rely on these specific limitations set forth in claims 22 and 24 for patentability, but instead rely on the inventive features set forth in the broader independent claim, claim 21.

Accordingly, for the reasons set forth above, Applicants respectfully request the Examiner to withdraw the rejection of claims 21-24 under 35 USC 103 as being unpatentable over Burgess.

3. Since all formal requirements appear to have been met, except for the submission of formal drawings, and claims 21-24 are patentable over the art of record, Applicants respectfully solicit a Notice of Allowability.

Respectfully submitted,

Matthew S. Goodwin
Attorney for Applicant
Reg. No. 32,839

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933-7003
(908) 524-2791
August 6, 1992

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& TRADEMARK OFF.

Case Docket No.: ETH-782

In application of Alastair Hunter et al.

Ser. No. 838,511

Filed February 19, 1992

For STERILIZED HETEROGENEOUS BRAIDS

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Sir:

Transmitted herewith is an amendment in the above-identified application.

[ ] No additional fee is enclosed because this application was filed prior to October 25, 1965 (effective date of Public Law 89-83).

[X] No additional fee is required.

[X] One stamped, self-addressed postcard for the PTO Mail Room date stamp.

[ ] Petition For Extension of Time and charge to Deposit Account of Appropriate Fee.

The fee has been calculated as shown below.

CLAIMS AS AMENDED

(1)	(2)	(3)	(4)	(5)	(6)	(7)
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDITIONAL FEE
TOTAL CLAIMS	* XX	minus	** XX	= 0	x $20	= $ XXX.XX
INDEP. CLAIMS	* XX	minus	*** XX	= XX	x $72	= $ XXX.XX
			TOTAL ADDITIONAL FEE FOR THIS AMENDMENT			$ XXX.XX

* If the entry in Col.2 is less than the entry in Col.4, write "0" in Col.5
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

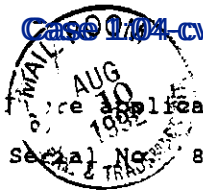
[ ] Charge $ ###.## to Deposit Account No. 10-750/DOCKET NO/ATTY. Three copies of this sheet are enclosed.

[X] Please charge any additional fees in connection with the filing of this communication, or credit overpayment, to Deposit Account No. 10-750/ETH-782/MSG. Three copies of this sheet are enclosed.

[ ] A check in the amount of $ _____ is attached.

Matthew S. Goodwin
Attorney of Record
Reg. No. 32,839

Matthew S. Goodwin
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933-7003
(908) 524-2791
August 6, 1992



Case Docket No.: ETH-782

In re application of Alastair Hunter et al.

Serial No. 838,511

Filed February 19, 1992

For STERILIZED HETEROGENEOUS BRAIDS

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

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[ ] Petition For Extension of Time and charge to Deposit Account of Appropriate Fee.

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CLAIMS AS AMENDED

(1)	(2)	(3)	(4)	(5)	(6)	(7)
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDITIONAL FEE
TOTAL CLAIMS	* XX	minus	** XX	= 0	x $20	= $ XXX.XX
INDEP. CLAIMS	* XX	minus	*** XX	= XX	x $72	= $ XXX.XX
			TOTAL ADDITIONAL FEE FOR THIS AMENDMENT			$ XXX.XX

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** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

[ ] Charge $ ***###.##*** to Deposit Account No. 10-750/DOCKET NO/ATTY. Three copies of this sheet are enclosed.

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[ ] A check in the amount of $ _____ is attached.

Matthew S. Goodwin
Attorney of Record
Reg. No. 32,839

Matthew S. Goodwin
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933-7003
(908) 524-2791
August 6, 1992

MAIL ROOM AUG 19 1992 PAT. & TMK. OFF.

Case Docket No.: ETH-782

In re application of Alastair Hunter et al.

Serial No. 838,511

Filed February 19, 1992

For STERILIZED HETEROGENEOUS BRAIDS

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AUG 1 7 1992
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THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Sir:

Transmitted herewith is an amendment in the above-identified application.

[ ] No additional fee is enclosed because this application was filed prior to October 25, 1965 (effective date of Public Law 89-83).

[X] No additional fee is required.

[X] One stamped, self-addressed postcard for the PTO Mail Room date stamp.

[ ] Petition For Extension of Time and charge to Deposit Account of Appropriate Fee.

The fee has been calculated as shown below.

CLAIMS AS AMENDED

(1)	(2)	(3)	(4)	(5)	(6)	(7)
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDITIONAL FEE
TOTAL CLAIMS	* XX	minus	** XX	= 0	x $20	= $ XXX.XX
INDEP. CLAIMS	* XX	minus	*** XX	= XX	x $72	= $ XXX.XX
			TOTAL ADDITIONAL FEE FOR THIS AMENDMENT			$ XXX.XX

* If the entry in Col.2 is less than the entry in Col.4, write "0" in Col.5
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

[ ] Charge $ ###.## to Deposit Account No. 10-750/DOCKET NO/ATTY. Three copies of this sheet are enclosed.

[X] Please charge any additional fees in connection with the filing of this communication, or credit overpayment, to Deposit Account No. 10-750/ETH-782/MSG. Three copies of this sheet are enclosed.

[ ] A check in the amount of $ _____ is attached.

Matthew S. Goodwin
Attorney of Record
Reg. No. 32,839

Matthew S. Goodwin
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933-7003
(908) 524-2791
August 6, 1992

Address : COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ART UNIT	ATTORNEY DOCKET NO.
07/755,111	9/5/91	HUNTER A	1811	JNJ 2

RAIMUND, C
EXAMINER

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

5
PAPER NUMBER

11/02/92
DATE MAILED:

This is a communication from the examiner in charge of your application
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☑ Responsive to communication filed on August 6, 1992 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ___ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☑ Claims 1 - 24 are pending in the application.
   Of the above, claims 1 - 20 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 21 - 24 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev.9-89)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21 and 23 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Doddi et al.

Doddi et al disclose a surgical suture comprising filaments of two different polymers in a braided configuration (column 9, lines 47-56). The suture is specifically disclosed attached to a needle (column 11, lines 53-54). Claims 21 and 23 are therefore unpatentable over Doddi et al.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 22 and 24 are rejected under 35 U.S.C. § 103 as being unpatentable over Kaplan et al taken with Doddi et al.

Kaplan et al discloses a ligament prosthesis comprising a core component and a braided sheath component (see Figure 3). The core component is "made up of one or more biocompatible, essentially non-bioasborbable..." filaments (column 9, lines 1-3). The sheath yarn component may be fabricated "from individual filaments having more than two different chemical compositions, one or more of which optionally being nonbioabsorbable" (column 9, lines 25-28).

Doddi et al disclose suitable biocompatible, non-absorbable fibers to include PET and PTFE (column 9, lines 51-53). It would have been obvious to form the device of Kaplan with a sheath component of PTFE and PET and a core component of PET. PTFE is known to impart improved knot run down properties to sutures (see Block U.S. Patent No. 3,527,650). PET is noted for its low cost

and high strength. Claims 22 and 24 are therefore unpatentable over Kaplan et al taken with Doddi et al.

Applicant's arguments with respect to claims 21-24 have been considered but are deemed to be moot in view of the new grounds of rejection.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication should be directed to Chris Raimund at telephone number (703) 308-3452.

Chris Raimund:jp
October 29, 1992

GEORGE F. LESMES
SUPERVISORY PATENT EXAMINER
GROUP 150

TOP AND BOTTOM EDGES SNAP-APART AND DISCARD CARBON

FORM PTO-892 (REV. 2-92) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

NOTICE OF REFERENCES CITED

SERIAL NO.	GROUP ART UNIT	ATTACHMENT TO PAPER NUMBER
838,511	1504	

APPLICANT(S): Hunter et al.

U.S. PATENT DOCUMENTS

*		DOCUMENT NO	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
	A	4052988	10/1977	Dodd et al.	128	335.5	—
	B	5147400	09/1992	Kaplan et al.	623	13	09/1990
	C	5116360	05/1992	Pinchuk et al.	623	1	12/1990
	D						
	E						
	F						
	G						
	H						
	I						
	J						
	K						

FOREIGN PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUB-CLASS	PERTINENT SHTS DWG	PERTINENT PP. SPEC.
	L								
	M								
	N								
	O								
	P								
	Q								

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

R

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EXAMINER: CHRIS RAIMUND

DATE: OCT. 26, 1992

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DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000205

XR 4,052,988

United States Patent [19]

Doddi et al.

[11] 4,052,988

[45] Oct. 11, 1977

[54] SYNTHETIC ABSORBABLE SURGICAL DEVICES OF POLY-DIOXANONE

[75] Inventors: Namassivaya Doddi; Charles C. Versfelt, both of Somerville; David Wasserman, Springfield, all of N.J.

[73] Assignee: Ethicon, Inc., Somerville, N.J.

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[51] Int. Cl.² A61L 17/00

[52] U.S. Cl. ..... 128/335.5; 3/1; 128/92 B; 128/92 D; 260/78.3 R

[58] Field of Search 128/335.5, 92; 260/78.3; 3/1

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U.S. PATENT DOCUMENTS

3,063,967	11/1962	Schultz	260/78.3
3,063,968	11/1962	Schultz	260/78.3
3,190,858	6/1965	Cox et al.	260/78.3
3,297,033	1/1967	Schmitt et al.	128/335.5
3,636,956	1/1972	Schneider et al.	128/335.5
3,645,941	2/1972	Snapp et al.	260/78.3
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Primary Examiner—Dalton L. Truluck
Attorney, Agent, or Firm—Wayne R. Eberhardt

[57] ABSTRACT

Synthetic absorbable sutures and other surgical devices are prepared from polymers of p-dioxanone and 1,4-dioxepan-2-one, and alkyl substituted derivatives thereof. Monofilament sutures of oriented fibers are characterized by good tensile and knot strength and a high level of flexibility and softness. The sutures have good in vivo strength retention and are slowly absorbed without significant tissue reaction.

39 Claims, 5 Drawing Figures

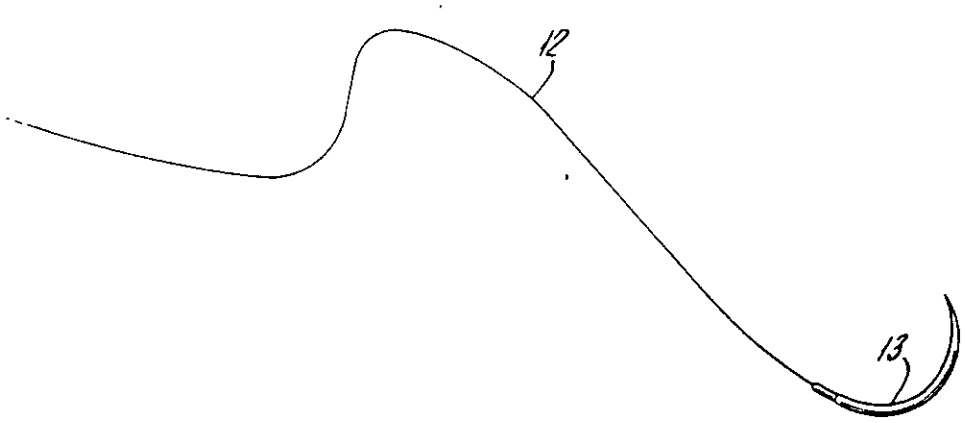


Fig. 1.

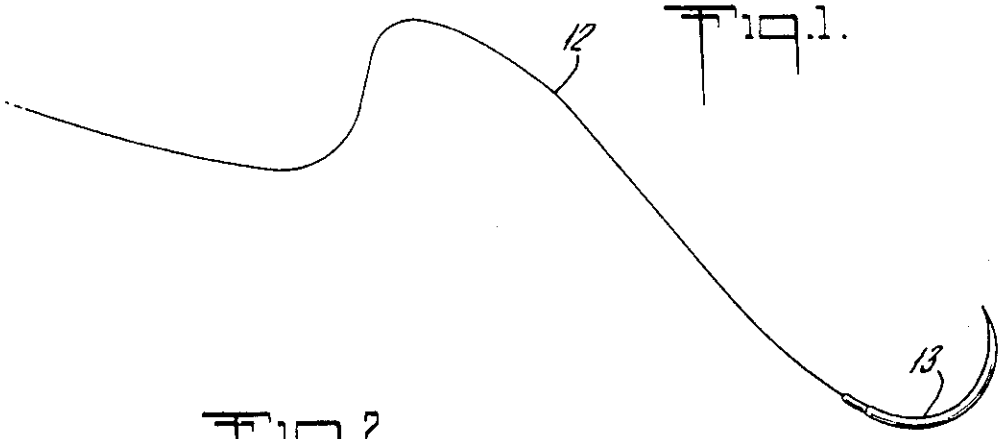


Fig. 2.

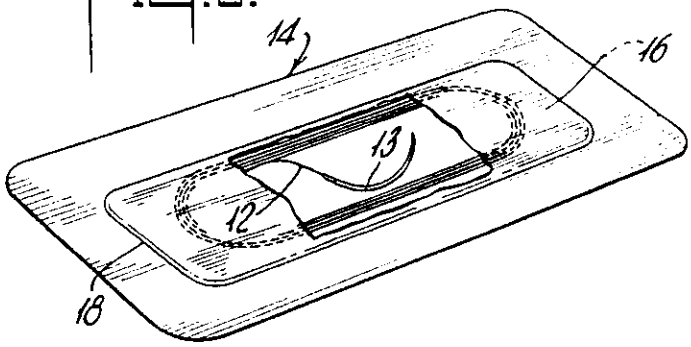


Fig. 3.

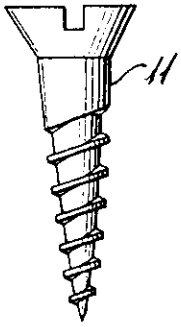


Fig. 4.

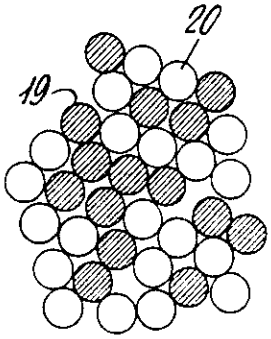
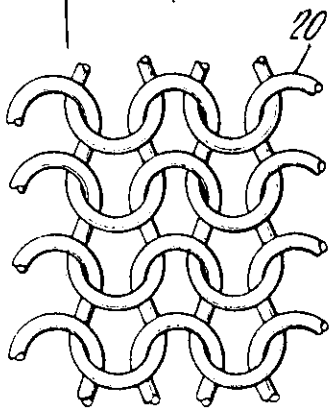


Fig. 5.



SYNTHETIC ABSORBABLE SURGICAL DEVICES OF POLY-DIOXANONE

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to synthetic absorbable sutures, and more particularly, to synthetic absorbable sutures comprising extruded and oriented filaments of polymers of p-dioxanone or 1,4-dioxepan-2-one.

2. Description of Prior Art

Absorbable suture materials have traditionally been natural collagenous materials obtained from sheep or beef intestine, commonly known as catgut. More recently, it has been proposed to manufacture synthetic absorbable sutures from polyesters of hydroxycarboxylic acids, notably polylactide, polyglycolide, and copolymers of lactide and glycolide. Such synthetic absorbable sutures are described in U.S. Pat. Nos. 3,636,956, 3,297,033 and elsewhere in the literature.

Among the requirements of an ideal absorbable suture are that it should have good handling properties, should approximate and hold tissue for proper healing with minimal tearing and tissue damage, should have adequate straight tensile and knot strength, should be controllably uniform in properties including dimensional stability within the body, should be sterilizable, should be absorbable by living tissue, preferably at a constant rate regardless of the place in the body or the condition of the patient, without causing such unfavorable tissue reactions as walling off, granuloma formation, excessive edema, etc., and finally should be capable of being properly and easily tied into surgical knots.

While multifilament sutures manufactured from polymers of lactide and glycolide fulfill the above requirements to a large degree, monofilament sutures of these materials are considerably less flexible than catgut and these synthetic sutures are accordingly generally limited to a multifilament, braided construction. Sutures of glycolide polymers are also not suitable for sterilization by radiation without suffering severe degradation of physical properties.

The present invention provides synthetic absorbable sutures having a high degree of softness and flexibility which allows the sutures to be used in monofilament form. The sutures can also be sterilized with cobalt 60 radiation without serious loss of suture strength. It is accordingly an object of the present invention to provide synthetic absorbable sutures having unique and desirable properties not available with the sutures of the prior art.

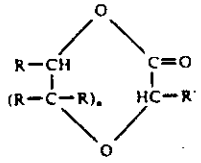
We have discovered that polymers of p-dioxanone and 1,4-dioxepan-2-one prepared from monomers of very high purity can be melt extruded into pliable, monofilament fibers which are slowly absorbed in animal tissue without significant adverse tissue reaction. The fibers have good tensile and knot strength and good in vivo strength retention, and can be sterilized with cobalt 60 without serious loss of these properties.

Polymers of p-dioxanone and fibers extruded therefrom have been known in the art. U.S. Pat. Nos. 3,063,967 and '968 for example, describe the polymerization of p-dioxanone and the preparation of films and fibers therefrom. The low tensile strength of fibers prepared in accordance with the teachings of these references, however, make these fibers generally unsuitable for use as surgical sutures. Moreover, there was no appreciation in these references of the absorbability of such fibers which were reported to be resistent to the effects of saline and distilled water.

Other references dealing with the polymerization of p-dioxanone include, but are not limited to, U.S. Pat. Nos. 3,190,858, 3,391,126 and 3,645,941 which disclose various catalysts for the polymerization of lactones such as p-dioxanone, and U.S. Pat. No. 3,020,289 which describes the polymerization of p-dioxanone in the presence of sulfuric acid. None of these references suggest polymers of p-dioxanone or 1,4-dioxepan-2-one for use in the preparation of synthetic absorbable sutures in accordance with the present invention.

SUMMARY

Synthetic absorbable sutures are prepared from polymers of monomers having the formula:



wherein R' and each R are hydrogen, methyl or ethyl and n is 1 or 2, provided that when n is 2, at least two R groups are hydrogen.

Polymers prepared by the polymerization of very pure monomers are melt extruded into filaments suitable for use as synthetic absorbable sutures. The filaments are characterized by high tensile and knot strength, good strength retention in vivo, and a Young's modulus of less than about 600,000 psi corresponding to a high degree of softness and flexibility.

DESCRIPTION OF DRAWINGS

FIG. 1 is a perspective view of a needle-suture combination;

FIG. 2 is a perspective view of a suture-needle combination within a hermetically sealed container;

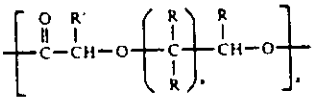
FIG. 3 illustrates a screw machined from the polymer of the present invention;

FIG. 4 is a cross-sectional view of a composite yarn containing filaments of different composition and;

FIG. 5 is a plan view of a surgical fabric knitted from fibers of the present invention.

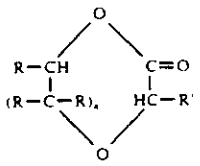
DESCRIPTION OF PREFERRED EMBODIMENTS

Polymers of the present invention are comprised of units having the general formula:



wherein R' and R are individually hydrogen, methyl, or ethyl, n is 1 or 2 provided that when n is 2 at least two R groups are hydrogen, and x is the degree of polymerization resulting in a fiber forming polymer.

The polymer is conveniently prepared from highly purified monomer, i.e., monomer of at least about 98 percent purity, having the formula:



wherein R, R' and n are as defined above. When n is 1, the monomer is preferably p-dioxanone, methyl-p-dioxanone, or dimethyl-p-dioxanone. When n is 2, the monomer is preferably 1,4-dioxepan-2-one.

A particularly preferred monomer is p-dioxanone, and the following description and examples which are presented by way of illustration are directed primarily to the preparation and polymerization of that monomer, it being understood that certain variations may apply to other monomers and polymers encompassed by the above formula as will be readily apparent to those skilled in the art. Para-dioxanone monomer is conveniently prepared by reacting ethylene glycol, metallic sodium, and chloroacetic acid as hereinafter described in detail. The resulting monomer is preferably purified to 99+% purity by multiple distillations and recrystallizations. We have discovered that high monomer purity is necessary to obtain a high molecular weight polymer and ultimately, a fiber of good tensile and dry knot strength.

The purified monomer is polymerized at a temperature of 20° to 130° C, most preferably above 75° C, in the presence of an organometallic catalyst as hereinafter described in detail to obtain a high molecular weight polymer of p-dioxanone characterized by an inherent viscosity of at least about 0.50 measured as a 0.1% solution in tetrachloroethane at 25° C, and a crystallinity of at least about 20% as determined by X-ray diffraction.

The polymer is melt extruded through a spinneret in a conventional manner to form one or more filaments which are subsequently drawn about 4x to 6x in order to achieve molecular orientation and improve tensile properties. The resulting oriented filaments have good tensile and dry knot strength and good in vivo strength retention.

To further improve dimensional stability and tensile strength retention, the oriented filaments may be subjected to an annealing treatment. This optional annealing treatment consists of heating the filaments to a temperature of from about 50° to 105° C, most preferably from about 50° to 80° C while restraining the filaments to prevent any substantial shrinkage. The filaments are held at the annealing temperature for a few seconds to several days or longer depending on the temperature and processing conditions. In general, annealing at 50° to 80° C for up to about 24 hours is satisfactory for p-dioxanone. Optimum annealing time and temperature for maximum improvement in fiber in vivo strength retention and dimensional stability is readily determined for each fiber composition.

Since the function of a suture is to join and hold severed tissue until healing is well along, and to prevent separation as a result of movement or exercise, a suture must meet certain minimum standards of strength. It is particularly important that strength be maintained when knots are tied and during the actual procedure of drawing tight a suitable knot. Oriented filaments of the present invention are characterized by a straight tensile strength of at least about 40,000 psi and a knot strength of at least about 30,000 psi, although significantly higher strengths are possible as will be apparent from the following examples.

The preparation of high molecular weight oriented filaments of poly-p-dioxanone and other polymers of the present invention is further illustrated by the following examples where all percentages are by weight unless otherwise noted.

EXAMPLE I

A. Preparation of p-dioxanone

Metallic sodium is dissolved in a large excess of ethylene glycol to obtain a glycolate which is further reacted with about 0.5 mols of chloroacetic acid per mole of sodium to yield the sodium salt of the hydroxy acid. Excess ethylene glycol and by-products of the reaction are removed by distillation and by washing with acetone. The sodium salt is converted to the free hydroxy acid by the addition of hydrochloric acid, and the resulting sodium chloride is removed by precipitation with ethanol followed by filtration.

The hydroxy acid filtrate is slowly heated up to about 200° C, preferably in the presence of $MgCO_3$, to remove alcohol and water by distillation. Upon further heating at atmospheric pressure the p-dioxanone is formed and distills over at a head temperature of between about 200°-220° C. The purity of the crude dioxanone product is generally about 60-70 percent as determined by gas chromatography and yields are in the order of 50 to 70 percent.

The crude p-dioxanone is further purified to about 98 percent by redistillation, and finally purified to 99+% by multiple crystallizations and/or distillation.

B. Polymerization of p-dioxanone

Highly purified p-dioxanone is polymerized in the presence of an organometallic catalyst such as diethyl zinc or zirconium acetylacetonate to obtain high molecular weight, fiber forming polymers according to the following typical procedure.

0.1 M (10.2 g) of dry, 99+% pure p-dioxanone monomer is weighed into a dry flask under an inert atmosphere of dry nitrogen and 0.36 ml of 0.138M diethyl zinc in heptane are added. The monomer to catalyst ratio is calculated as 2000 : 1. After completely mixing the catalyst and monomer, the flask is swirled at intervals over a period of about one hour or less at room temperature until initiation and polymerization is evident by the occurrence of gelation. The flask is then connected to a vacuum of about 14 inches of Hg. The sealed flask is maintained at 80° C in a constant temperature bath for about 72 hours to complete the polymerization. The resulting polymer is characterized by an inherent viscosity I.V. of 0.70 measured on a 0.1% solution of polymer in tetrachloroethane at 25° C, a glass transition temperature T_g of −16° C, a melting temperature T_m of 110° C, and a crystallinity of 37 percent.

In the polymerization procedure, the initial one hour hold time for polymerization initiation is required only when using volatile catalysts which would be lost if the polymerization mixture was immediately placed under vacuum. When nonvolatile catalysts such as zirconium acetyl acetonate are used, this hold time may be omitted and the polymerization reaction mixture placed under vacuum immediately following addition and mixing of catalyst. As a further alternative, the entire polymeriza-

tion reaction may be conducted under an inert atmosphere at atmospheric pressure.

C. Polymer Extrusion

The polymer obtained in the preceding step is thoroughly dried and melt extruded through a spinnerette using conventional textile fiber spinning procedures to obtain one or more continuous monofilament fibers suitable for use as synthetic absorbable sutures. The spun filaments are drawn about 5x at a temperature of about 43° C to increase molecular orientation and enhance physical properties, particularly tensile strength. The drawn monofilaments having a diameter of about 11 mils corresponding to a size 2-0 suture are characterized by an inherent viscosity of 0.64, a crystallinity of 30 percent, a straight tensile strength of 36,600 psi, an elongation of 99.4 percent, and a knot strength of 31,900 psi.

EXAMPLE II

The method of Example I was repeated using 0.13 ml of zirconium acetyl acetonate catalyst (7500 : 1 monomer to catalyst ratio) in the polymerization reaction. Properties of polymer and fiber were as follows:

Polymer

I.V.: 0.71
Tg: −16° C
Tm: 111° C
Crystallinity: 49%

Fiber

I.V.: 0.57
Tensile Strength: 38,600 psi
Elongation: 88.5 percent
Knot Strength: 32,300 psi

EXAMPLE III

Polydioxanone polymers were prepared in accordance with the polymerization method of Example I using 0.20 ml of zirconium acetyl acetonate catalyst (5000 : 1 monomer to catalyst ratio) and a polymerization temperature of 90° C. Polymer properties were as follows:

I.V.: 0.65
Tg: −19° C
Tm: 109° C
Crystallinity: 35%

EXAMPLE IV

The method of Example III was repeated using 0.50 ml of zirconium acetylacetonate catalyst. (2000 : 1 monomer to catalyst ratio). Polymer properties were as follows:

I.V.: 0.59
Tg: −17° C
Tm: 111° C
Crystallinity: 44%

EXAMPLE V

The method of Example I was repeated at a monomer to catalyst ratio of 4000 : 1 and with a polymerization reaction of three days at 80° C. The resulting polymer had an inherent viscosity of 0.86 and crystallinity of 30 percent. Fibers extruded from the polymer and drawn 6x at 87° C had a diameter of 9 mils, a straight tensile strength of 65,100 psi, elongation of 47.6%, and knot strength of 46,400 psi.

EXAMPLE VI

The method of Example I was repeated using tetraoctylene glycol titanate as the polymerization catalyst. The monomer to catalyst ratio was 12,300 : 1 based on titanium content, and the polymerization reaction was maintained at 80° C for six days. The resulting polymer had an inherent viscosity of 0.86 and a crystallinity of 33 percent. Extruded filaments drawn 6x at 83° C had a diameter of 11 mils, a tensile strength of 55,600 psi, a dry knot strength of 48,800 psi, and a Young's modulus of 167,000 psi.

EXAMPLE VII

Two lots of polydioxanone were prepared according to the method of Example VI using a monomer to catalyst ratio of 26,700 : 1 and with a polymerization reaction of six days and 12 days. The resulting polymers had inherent viscosities of 0.81 and 0.84 respectively. The polymers were combined and extruded into fiber which, after drawing 6x, had the following physical properties.

Fiber Diameter: 9 mils
Tensile Strength: 70,600 psi
Elongation: 46.3
Dry Knot Strength: 50,300 psi

The monofilament fibers had a high degree of softness and pliability.

EXAMPLE VIII

In Vivo Absorption

Two 2 cm segments of monofilament fiber from Example I having a diameter corresponding to size 2-0 suture were implanted aseptically into the left gluteal muscles of 24 female Long Evans rats. The implant sites were recovered after periods of 60, 90, 120 and 180 days and examined microscopically to determine the extent of absorption.

After 60 days the suture cross sections were still transparent and intact. The tissue reactions were slight and most sutures were encapsulated with fibrous tissue. The sutures at this period remained birefringent under polarized light.

At 90 days the sutures were becoming translucent and had lost some of their birefringent properties. A few of the suture cross sections stained pink (eosinophilic) around the periphery and the edges were indistinct, indicating the onset of absorption. The tissue reactions generally consisted of a fibrous capsule and a layer of macrophages interposed between it and the suture surface.

At 120 days the sutures were translucent, most cross sections had taken on an eosinophilic stain, and the sutures appeared to be in the process of active absorption. The tissue reactions consisted of an outer layer of fibroblasts with an interface of macrophages several cell layers thick. Absorption at 120 days was estimated to be approximately 70 percent complete.

At 180 days, absorption of the suture was substantially complete. The incision healed with minimal adverse tissue reaction.

EXAMPLE IX

In Vivo Strength Retention

Segments of the sutures of several Examples were implanted in the posterior dorsal subcutis of female Long Evans rats for periods of 14, 21 and 28 days. The

sutures were recovered at the designated periods and tested for straight tensile strength with the following results.

Test	Fiber	Implantation Time Days	Tensile Strength Pounds	Strength Retention %
a)	EX. I -	0	3.37	
		14	1.46	43.4
		21	1.14	33.8
		28	—	—
b)	EX. I - (Sterilized)[1]	0	3.08	
		14	1.16	37.6
		21	0.97	31.4
		28	0.70	22.9
c)	EX. VI - (Unannealed)	0	3.47	
		14	2.27	65.3
		21	1.62	46.7
		28	1.53	44.1
d)	EX. VI - (Annealed)[2]	0	6.47	
		14	5.39	83.3
		21	4.87	75.3
		28	4.30	66.5
e)	EX. VI - (Annealed)[2,3]	0	3.82	
		14	2.07	54.0
		21	1.36	35.5
		28	0.68	17.8
f)	EX. V - (Sterilized)[1]	0	4.05	
		14	2.77	68.4
		21	2.40	59.3
		28	2.15	53.2
g)	EX. V - (Sterilized)[3]	0	3.45	
		14	2.11	61.3
		21	1.36	39.3
		28	0.92	26.6

[1]Sterilzed with ethylene oxide at 30° C.
[2]Annealed under nitrogen 24 hours at 65° C.
[3]Sterilized with cobalt 60.

EXAMPLE X

Small quantities of polydioxanone polymer were prepared in accordance with the general method of Example I using chromatographically pure p-dioxanone monomer and diethyl zinc and tetraoctylene glycol titanate as catalysts. Polymer prepared with diethyl zinc catalyst at a monomer to catalyst ratio of 4,000 and with a polymerization reaction of three days at 80° C had an inherent viscosity of 1.18. Polymer prepared with tetraoctylene glycol titanate catalyst at a monomer to catalyst ratio of 12,250 and with a polymerization reaction of 6 days at 80° C had an inherent viscosity of 1.15. A second batch of high purity p-dioxanone monomer twice distilled in an annular still under a vacuum of 0.10–0.15 mm Hg was polymerized in the presence of tetraoctylene glycol titanate catalyst at a monomer to catalyst ratio of 13,300 and at 80° C for 6 days. The resulting polymer had an inherent viscosity of 2.26.

EXAMPLE XI

Preparation of Methyl-p-Dioxanone

Following the general procedure of Example I,, metallic sodium was dissolved in a large excess of 1,2-propane diol and chloroacetic acid was added at 110°–115° C. Excess diol was removed by distillation and the sodium salt of the hydroxy acid converted to free acid by the addition of water and hydrochloric acid. Sodium chloride was precipitated by the addition of ethanol and removed by filtration. The resulting product was distilled in the presence of M_gCO_3 to remove excess alcohol and water and to recover crude methyl dioxanone monomer as a distillate at 196° to 202° C. After purification, the monomer can be polymerized and extruded to form fibers suitable for use as absorbable sutures as described in Example I.

EXAMPLE XII

Preparation of Dimethyl-p-Dioxanone

The procedure of Example XI was repeated reacting metallic sodium with 2,3-butanediol and choroacetic acid at about 130° C. Crude dimethyl dioxanone monomer was recovered from the distillation at 190° to 213° C. After purification the monomer can be polymerized and extruded to form fibers suitable for use as absorbable sutures as described in Example I.

EXAMPLE XIII

Preparation of 1,4-dioxepan-2-one

The procedure of Example VI was repeated reacting metallic sodium with 1,3-propane diol and chloroacetic acid. Crude 1,4-dioxepan-2-one monomer was recovered from the distillation at 300° to 310° C. After purification, the monomer can be polymerized and extruded to form fibers suitable for use as absorbable sutures as described in Example I.

We have discovered that exceptionally high purity of p-dioxanone monomer is required to obtain polymers having a sufficiently high inherent viscosity to yield strong fibers upon extrusion. In general, the monomers are purified to 99+% by distillation and recrystallization prior to polymerization, and the resulting polymers have an inherent viscosity of at least about 0.50, and preferably 0.80 or higher measured as above described. As illustrated in Example X, polymers prepared from highly purified dioxanone have inherent viscosities well in excess of 1.10.

Drawn fibers of polydioxanone possess an unique combination of desirable properties. In particular, the monofilament fibers combine high tensile strength and knot strength with a pliability not to be found in any previous absorbable suture material, natural or synthetic. For example, the Young's modulus of the polydioxanone fiber of Example VI was 167,200 psi. In comparison, the Young's modulus for monofilament polyglycolide fibers and for 90/10 glycolide/lactide copolymer fibers is about 1 - 2 million psi, while that for moist catgut is about 350,000 psi. The low Young's modulus of polydioxanone makes this fiber particularly well suited for use as an absorbable monfilament suture, whereas prior synthetic absorbable sutures have largely been limited to braided, multifilament constructions which tend to be softer and more flexible than corresponding sizes of monofilament material. Monofilamented sutures are, of course, preferred for use in many surgical applications such as in ophthalmic procedures where smoothness of the suture surface is of particular importance.

The polymers of p-dioxanone of the present invention are also unique as compared with prior synthetic absorbable materials in that the sutures of these polymers can be sterilized by cobalt 60 radiation as well as by ethylene oxide. As illustrated in Example IX, while cobalt 60 sterilization results in some reduction in fiber strength and some increase in the in vivo rato of strength loss, the sterilized fiber nevertheless retains sufficient strength initially and for 28 days in vivo to make the fiber suitable for use in surgical procedures.

While the preceding examples have been directed to the preparation of homopolymers of p-dioxanone, methyl dioxanone, dimethyl dioxanone, and 1,4-dioxepan-2-one, these examples are for purposes of illustration only and are not limiting of the invention. Mixtures

of these polymers, copolymers of two or more of the above enumerated monomers, and copolymers of these monomers with up to about 50% by weight of other copolymerizable monomers which produce non-toxic and absorbable polymers are likewise included within the present invention. For example, such copolymers of dioxanone with lactide and/or glycolide are useful in the preparation of absorbable sutures, and the physical and chemical properties of such sutures such as strength, stiffness, and rate of absorption can be controlled by varying the relative propertions of the monomer constituents. In addition, the copolymers may be prepared by random, block or graft polymerization techniques in order to obtain particular combinations of compositions and physical and chemical properties. In certain applications where the rate of absorption of polydioxanone is less than desired, copolymers of dioxanone with from about 5 to 25 percent or more glycolide having a faster rate of absorption may be preferred.

It is to be understood that inert additives such as coloring materials and plasticizers can be incorporated in the sutures. Any of a variety of plasticizers such as, for instance, glyceryl triacetate, ethyl benzoate, diethyl phthalate, dibutyl phthalate and bis 2-methoxyethyl phthalate can be used if desired. The amount of plasticizer may vary from 1 to about 20 percent or more based on the weight of the polymer. Not only does the plasticizer render the filaments even more pliable, but it also helps in spinning. As used herein, the term "inert" means materials that are chemically inert to the polymer, and biologically inert to living tissue, i.e., do not cause any of the adverse effects previously discussed.

Filaments of the present invention are adversely affected by moisture and are accordingly preferably packaged in a substantially moisture free environment and in hermetically sealed packages, a preferred form of which is shown in FIG. 2. In FIG. 2, there is shown a suture package 14 having disposed therein a coil of suture 12, one end of which is attached to needle 13. The needle and suture are positioned within a cavity 16 that is evacuated or filled with a dry atmosphere such as air or nitrogen. The package is fabricated of two sheets of aluminum foil or an aluminum foil-plastic laminate and heat sealed or bonded with adhesive at the skirt 16 to hermetically seal the cavity and isolate the contents of the package from the external atmosphere.

Filaments of the present invention may be used as monofilament or multifilament sutures, or may be woven, braided, or knitted either alone or in combination with absorbable fibers such as polyglycolide or poly (lactide-co-glycolide), or with non-absorbable fibers such as nylon, polypropylene, polyethyleneterephthalate, or polytetrafluoroethylene to form multifilament sutures and tubular structures having use in the surgical repair of arteries, veins, ducts, esophagi and the like.

Multifilament yarns that contain polymer filaments of the present invention together with nonabsorbable filaments are illustrated in FIG. 4 wherein the nonabsorbable fiber is represented by the hatched fiber cross section 19. In FIG. 4, the fibers 20 are extruded from homopolymer or copolymer compositions of the present invention as described above. The relative proportions of absorbable filaments 20 and nonabsorbable filaments 19 may be varied to obtain the absorption characteristic desired in the woven fabric or tubular implants. Methods of weaving and crimping vascular prostheses are described in U.S. Pat. 3,096,560.

Composite fabrics of absorbable and nonabsorbable materials fashioned by textile processes including weaving, knitting, and fabricating by the nonwoven felting of fibers are described in U.S. Pat. No. 3,108,357 and U.S. Pat. No. 3,463,158. Similar techniques may be used in the manufacture of surgical aids wherein nonabsorbable fibers are combined with absorbable fibers composed of the polymers of this invention. The surgical utility of "bicomponent filaments" containing absorbable and nonabsorbable components is described in U.S. Pat. No. 3,463,158, the teaching of which is incorporated herein by reference. Monofilaments of the polymers of the present invention may be woven or knitted to form an absorbable fabric having the structure illustrated in FIG. 5, useful surgically in hernia repair and in supporting damaged liver, kidney, and other internal organs.

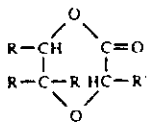
The products of the invention are useful in surgical applications where an absorbable aid or support is required, as for example, in the formation of surgical mesh, absorbable staples, artifical tendons, or cartilage material, and in other uses where a temporary aid during healing is needed. They may also be used to advantage in repairing hernias and in anchoring organs which have become loose.

The polymers of the present invention are also useful in the manufacture of cast films and other solid surgical aids such a scleral buckling prostheses. Thus, cylindrical pins, screws as illustrated in FIG. 3, reinforcing plates, etc., may be machined from the cast polymer having in vivo absorption characteristics depending upon the polymer composition and molecular weight.

Many different embodiments of this invention will be apparent to those skilled in the art and may be made without departing from the spirit and scope thereof. It is accordingly understood that this invention is not limited to the specific embodiments thereof except as defined in the appended claims.

We claim:

1. A sterile, synthetic absorbable suture comprising oriented fiber of a polymer of a monomer having the formula:



wherein R' and R are individually hydrogen, methyl or ethyl, said suture being dry to the extent of being substantially free of moisture, and characterized by a Young's modulus of less than about 600,000 psi with a correspondingly high degree of softness and flexibility, an initial straight tensile and knot strength of at least about 40,000 psi and 30,000 psi respectively, and substantially complete absorption in vivo within about 180 days.

2. A suture of claim 1 wherein R and R' are hydrogen and the monomer is p-dioxanone.

3. A suture of claim 2 wherein said polymer is characterized by an inherent viscosity greater than about 0.50 measured as 0.1% solution of polymer in tetrachloroethane at 25° C.

4. A suture of claim 3 comprising a homopolymer of p-dioxanone.

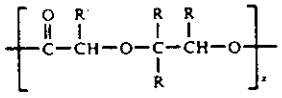
5. A suture of claim 1 comprising a polymer of methyl-p-dioxanone.

6. A suture of claim 1 comprising a polymer of dimethyl-p-dioxanone.

7. A suture of claim 1 comprising a copolymer of more than 50% by weight p-dioxanone and less than 50% by weight of at least one other monomer copolymerizable with p-dioxanone to an absorbable polymer.

8. A suture of claim 7 wherein said copolymer is of p-dioxanone and glycolide or lactide.

9. A sterile synthetic absorbable suture comprising oriented fiber of a polymer having units of the formula:



wherein R' and R are individually hydrogen, methyl, or ethyl and x is the degree of polymerization resulting in a fiber forming polymer, said suture being dry to the extent of being substantially free of moisture, and characterized by a Young's modulus of less than about 600,000 psi with a correspondingly high degree of softness and flexibility, an initial straight tensile and knot strenght of at least about 40,000 psi and 30,000 psi respectively, and substantially complete absorption in vivo within about 180 days.

10. A suture of claim 9 wherein said polymer is a homopolymer of p-dioxanone having an inherent viscosity of at least 0.50 in a 0.1% solution of tetrachloroethane at 25° C.

11. A suture of claim 10 wherein the inherent viscosity of said polymer is at least 0.80.

12. A suture of claim 9 wherein said polymer is a copolymer of more than 50% by weight p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

13. A suture of claim 12 wherein said polymer is a copolymer of p-dioxanone and lactide or glycolide.

14. A suture of claim 9 wherein said polymer is a homopolymer of methyl-p-dioxanone or copolymer of more than 50% by weight methyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

15. A suture of claim 9 wherein said polymer is a homopolymer of dimethyl-p-dioxanone or copolymer of more than 50% by weight dimethyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

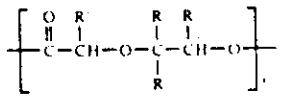
16. A suture of claim 1 having a surgical needle attached to at least one end thereof.

17. A needle and suture combination of claim 16 packaged in a sterile and dry environment within a hermetically sealed and substantially moisture impervious container.

18. A suture of claim 9 having a surgical needle attached to at least one end thereof.

19. A needle and suture combination of claim 18 packaged in a sterile and dry environment within a hermetically sealed and substantially moisture impervious container.

20. A surgical prosthesis comprising a fabric manufactured at least in part from synthetic absorbable fibers of a polymer having units of the formula:



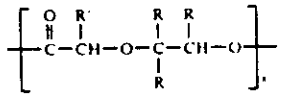
wherein R' and R are individually hydrogen, methyl, or ethyl and x is the degree of polymerization resulting in a fiber forming polymer, said fibers being dry to the extent of being substantially free of moisture, and characterized by a Young's modulus of less than about 600,000 psi with a correspondingly high degree of softness and flexibility, an initial straight tensile and knot strength of at least about 40,000 psi and 30,000 psi respectively, and substantially complete absorption in vivo within about 180 days.

21. A surgical prosthesis of claim 20 wherein said polymer is a homopolymer of p-dioxanone or a copolymer of more than 50% by weight p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

22. A surgical prosthesis of claim 20 wherein said polymer is a homopolymer of methyl-p-dioxanone or a copolymer of more than 50% by weight methyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

23. A surgical prosthesis of claim 20 wherein said polymer is a homopolymer of dimethyl-p-dioxanone or a copolymer of more than 50% by weight dimethyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

24. A surgical prosthesis comprising a solid surgical aid formed from an absorbable polymer having units of the formula:



wherein R' and R are individually hydrogen, methyl, or ethyl and x is the degree of polymerization resulting in a fiber forming polymer, said prosthesis being dry to the extent of being substantially free of moisture.

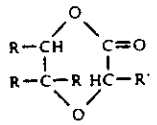
25. A surgical prosthesis of claim 24 wherein said polymer is a homopolymer of p-dioxanone having an inherent viscosity of at least 0.50 in a 0.1% solution of tetrachloroethane at 25° C.

26. A surgical prosthesis of claim 24 wherein said polymer is a copolymer of at least 50% by weight p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

27. A surgical prosthesis of claim 24 wherein said polymer is a homopolymer of methyl-p-dioxanone or acopolymer of more than 50% by weight methyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

28. A surgical prosthesis of claim 24 wherein said polymer is a homopolymer of dimethyl-p-dioxanone or a copolymer of more than 50% by weight dimethyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

29. A method of closing a wound in living tissue which comprises approximating the edges of the wound with a synthetic absorbable suture consisting of at least one filament of a polymer of a monomer having the formula:



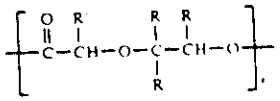
wherein R' and R are individually hydrogen, methyl or ethyl, said suture being at least partially embedded in the living tissue, and leaving said suture in said tissue until the embedded suture is absorbed during the healing process, said suture being characterized by a Young's modulus of less than about 600,000 psi with a correspondingly high degree of softness and flexibility, an initial straight tensile and knot strength of at least about 40,000 psi and 30,000 psi respectively, and substantially complete absorption in vivo within about 180 days.

30. A method of claim 29 wherein R and R' are hydrogen and the monomer is p-dioxanone.

31. A method of claim 29 wherein the monomer is methyl-p-dioxanone.

32. A method of claim 29 wherein the monomer is dimethyl-p-dioxanone.

33. A method of closing a wound in living tissue which comprises approximating the edge of the wound with a synthetic absorbable suture consisting of at least one filament of a polymer having units of the formula:



wherein R' and R are individually hydrogen, methyl or ethyl, and x is the degree of polymerization resulting in a fiber forming polymer, said suture being at least partially embedded in the living tissue, and leaving said suture in said tissue until the embedded suture is absorbed during the healing process, said suture being characterized by a Young's modulus of less than about 600,000 psi with a correspondingly high degree of softness and flexibility, an initial straight tensile and knot strength of at least about 40,000 psi and 30,000 psi respectively, and substantially complete absorption in vivo within about 180 days.

34. A method of claim 33 wherein said polymer is a homopolymer of p-dioxanone having an inherent viscosity of at least 0.50 in a 0.1 percent solution of tetrachloroethane at 25° C.

35. A method of claim 34 wherein the inherent viscosity of said polymer is at least 0.80.

36. A method of claim 33 wherein said polymer is a copolymer of more than 50% by weight p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

37. A method of claim 36 wherein said polymer is a copolymer of p-dioxanone and lactide or glycolide.

38. A method of claim 33 wherein said polymer is a homopolymer of methyl-p-dioxanone or a copolymer of more than 50% by weight methyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

39. A method of claim 33 wherein said polymer is a homopolymer of dimethyl-p-dioxanone or a copolymer of more than 50% by weight dimethyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

* * * * *

US005147400A

United States Patent [19]

Kaplan et al.

[11] Patent Number: 5,147,400

[45] Date of Patent: Sep. 15, 1992

[54] CONNECTIVE TISSUE PROSTHESIS

[75] Inventors: Donald S. Kaplan, Weston; John Kennedy, Stratford; Ross R. Muth, Brookfield, all of Conn.

[73] Assignee: United States Surgical Corporation, Norwalk, Conn.

[21] Appl. No.: 581,462

[22] Filed: Sep. 12, 1990

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 349,648, May 10, 1989, Pat. No. 4,990,158.

[51] Int. Cl.[5] A61F 2/08

[52] U.S. Cl. 623/13; 623/1; 623/11; 623/66

[58] Field of Search 623/1, 13, 11

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Primary Examiner—David Isabella
Assistant Examiner—Debra S. Brittingham
Attorney, Agent, or Firm—Thomas R. Bremer; Peter G. Dilworth; Rocco S. Barrese

[57] ABSTRACT

A semi-bioabsorbable connective tissue prosthesis, e.g., a replacement for the human anterior cruciate ligament, is provided whose stress-strain characteristics closely match those of the natural tissue.

58 Claims, 5 Drawing Sheets

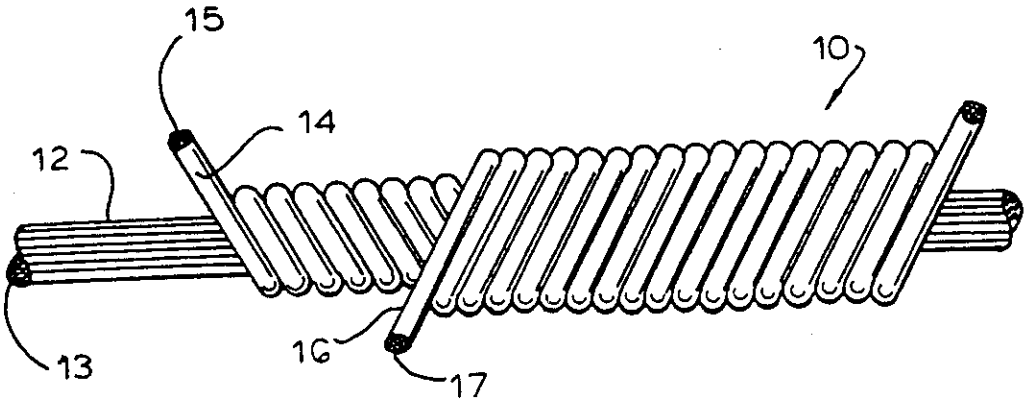
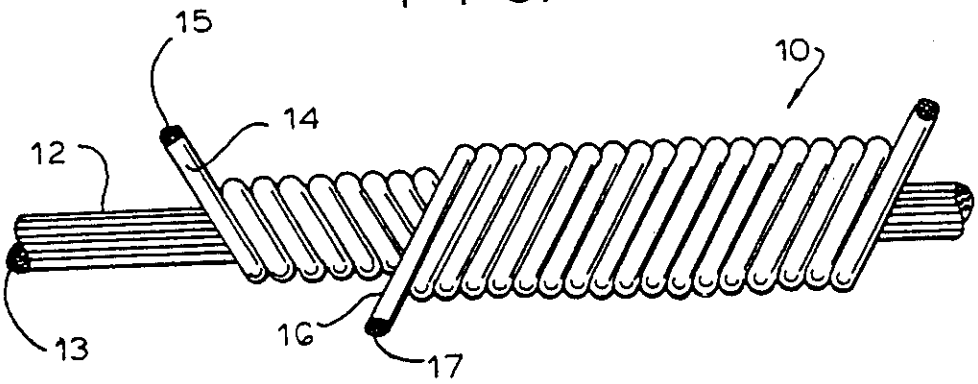


FIG. 1



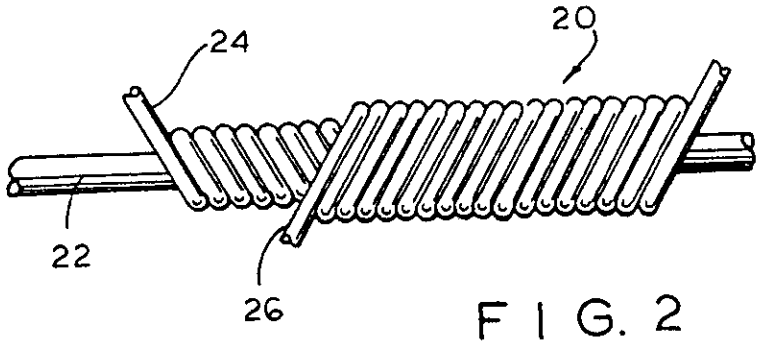


FIG. 2

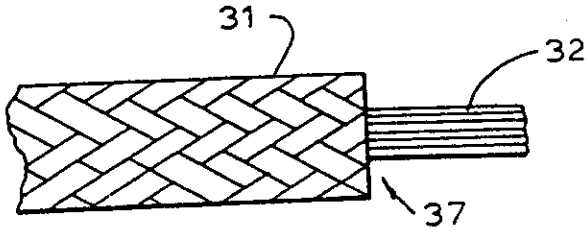
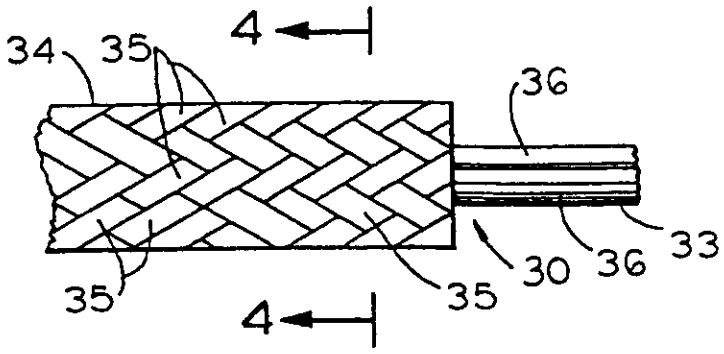


FIG. 5

FIG. 3



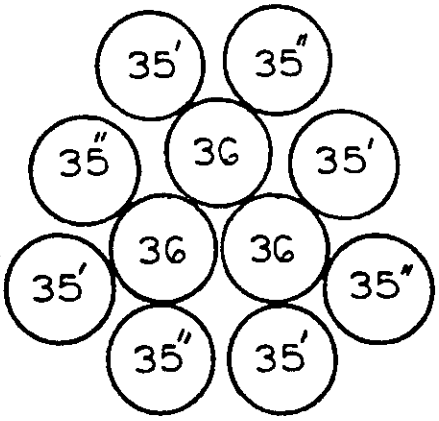
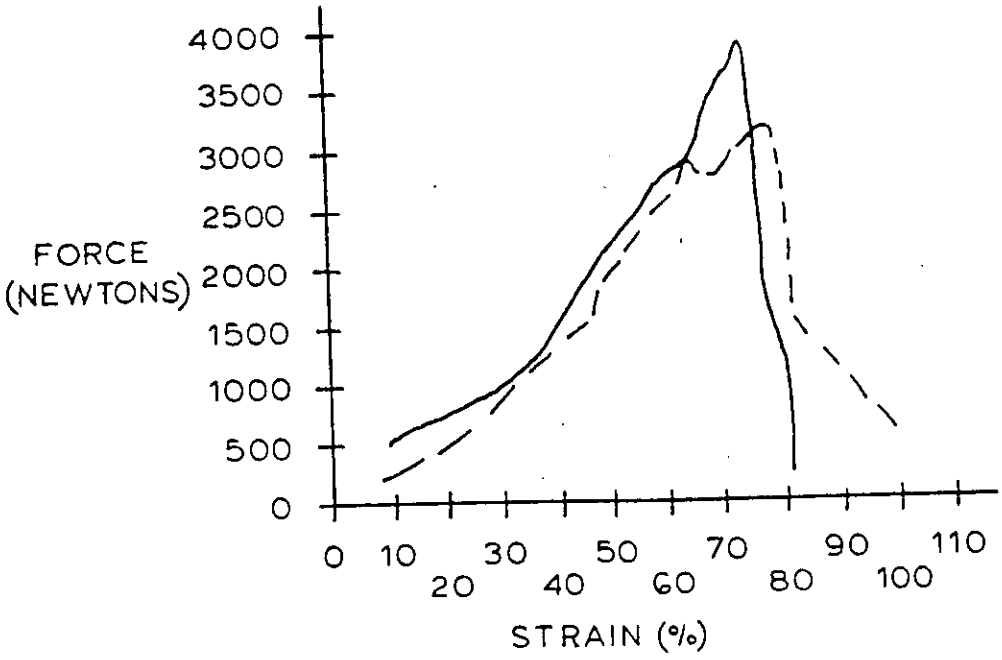


FIG. 4

FIG. 6



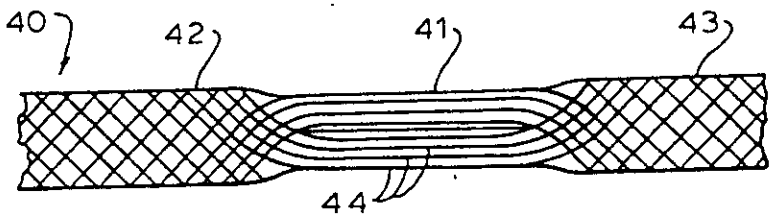


FIG. 7

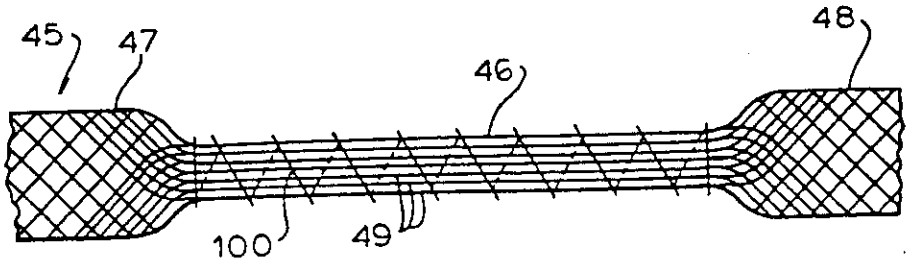


FIG. 8

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FIG. 9

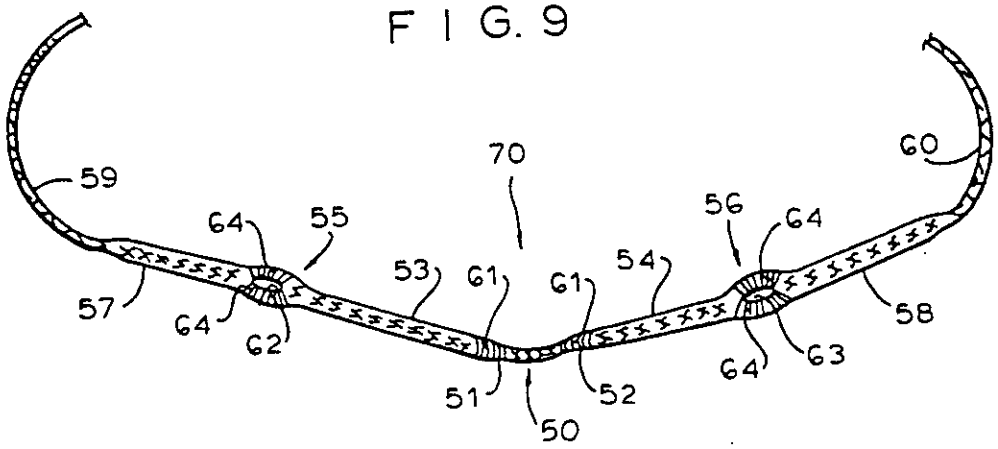


FIG. 10

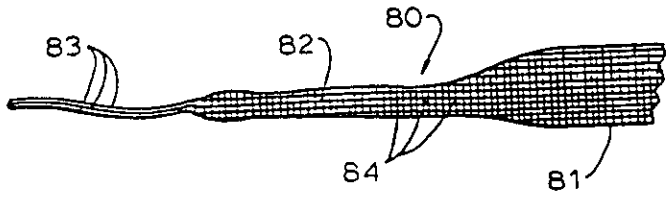
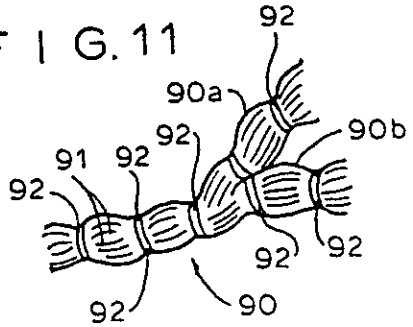
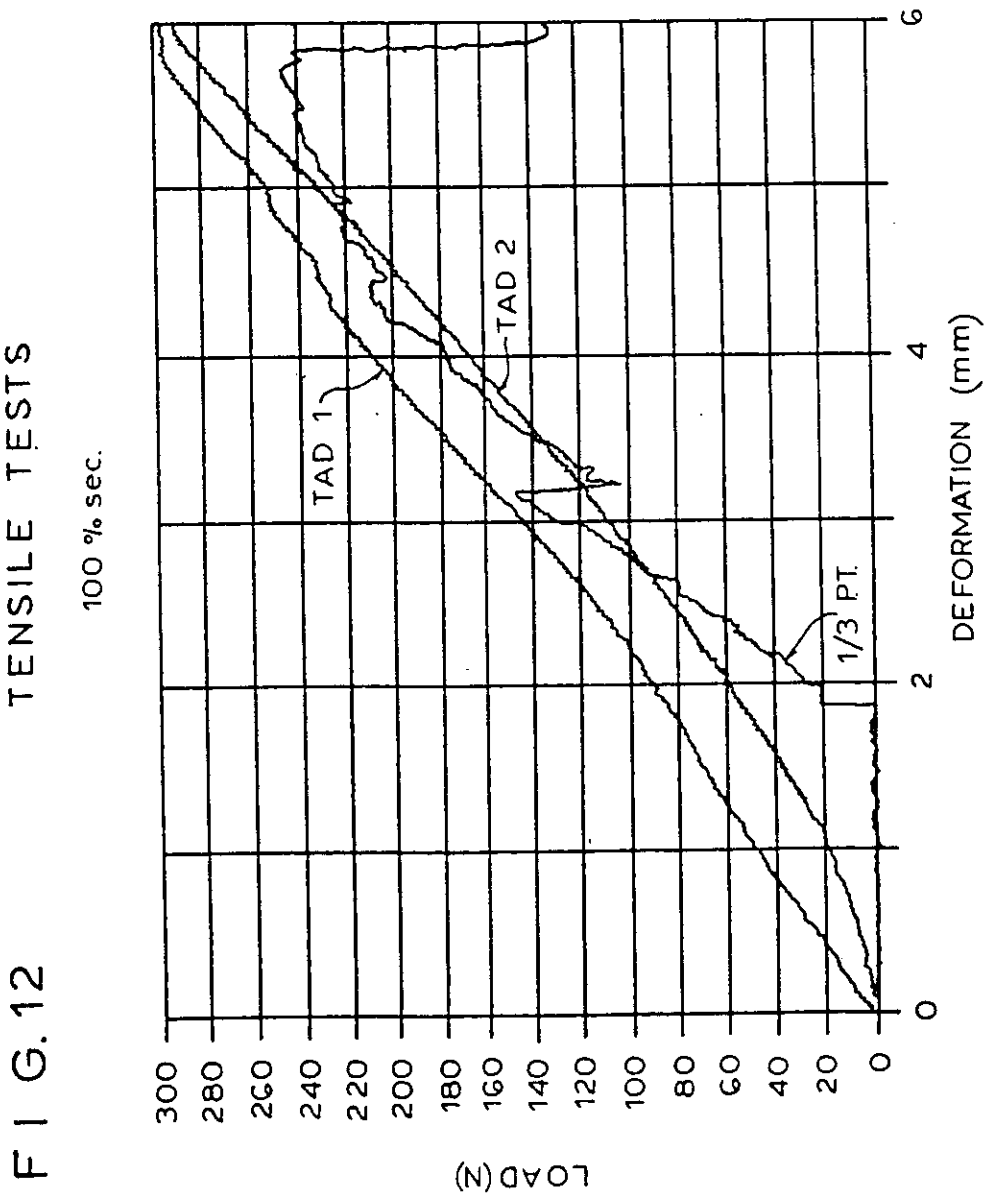


FIG. 11




TENSILE TESTS
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160
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200
220
240
260
280
300

FIG. 12

CONNECTIVE TISSUE PROSTHESIS

CROSS REFERENCE TO RELATED APPLICATION

The application is a continuation-in-part of commonly assigned, co-pending U.S. patent application Ser. No. 349,648, filed May 10, 1989, now U.S. Pat. No. 4,990,158.

BACKGROUND OF THE INVENTION

This invention relates to a connective tissue prosthesis and, in particular, to a biocompatible ligament or tendon prosthesis which closely approximates the biomechanical characteristics of the natural tissue to be replaced or augmented.

Numerous connective tissue materials and constructions have been proposed for use as temporary or permanent grafts in ligament and tendon repair. Feagin, Jr., Ed., *The Crucial Ligaments/Diagnosis and Treatment of Ligamentous Injuries About the Knee* (Churchhill Livingstone, N.Y., 1988) describes a number of partially bioabsorbable materials which have been investigated for use as ligament grafts. In Chapter 33 of this publication (Rodkey, "Laboratory Studies of Biodegradable materials for Cruciate Ligament Reconstruction"), it is reported that while a 100 percent biodegradable ligament fabricated from polyglycolic acid (PGA) was found to be safe, strong, well-tolerated and provided stability for the repaired anterior cruciate ligament in dogs, its complete resorption within five weeks makes it unsuitable for use in prostheses intended for humans since a human ligament prosthesis must provide support over a much longer period of time. It is further reported that a study in dogs of the intraarticular use of a partially biodegradable ligament prosthesis possessing a Dacron (i.e., DuPont's polyethylene terephthalate (PET)) and PGA core and a separate outer sleeve woven from PGA and Dacron of a different percentage of composition gave disappointing results.

U.S. Pat. Nos. 4,792,336 and 4,942,875 describe a surgical device for repairing or augmenting connective tissue and comprising a plurality of fibers, in which the majority of the fibers are in a direction essentially parallel to the length of the device and can be either 100 percent bioabsorbable or can contain a nonabsorbable component. Additionally, sleeve yarns consisting completely of absorbable material wrap around these axial or warp yarns.

Biomedical Business International Report No. 7041 (Second Revision, May 1986), "Orthopaedic and Diagnostic Devices", pages 5—5 to 5-12, identifies a variety of materials which have been used in the fabrication of prosthetic ligaments including carbon fiber, expanded Teflon (i.e., DuPont's polytetrafluoroethylene), a combination of silicone and PET, polypropylene, polyethylene, nickel-chromium alloy fibers individually enclosed in synthetic textile or natural silk, carbon material coated with gelatin, polyester combined with PET fibers, bovine tissues, and others.

Other disclosures of ligament and tendon repair devices are provided, inter alia, in U.S. Pat. Nos. 3,805,300; 4,187,558; 4,301,551; 4,483,023; 4,584,722; 4,610,688; 4,668,233; 4,775,380; 4,788,979; and PCT Patent Publication No. WO 89/01320.

Chapter 33 (page 540) of the Feagin, Jr. publication referred to above identifies the characteristics of an ideal ligament prosthesis as follows:

(1) it must be durable with adequate strength to withstand the extreme forces placed upon it, yet compliant enough to allow for repetitive motion without failure or excessive creep elongation;

(2) it must be tolerated by the host with no antigenic or carcinogenic reaction;

(3) if partially or completely biodegradable, the size of the individual fibers and the construction pattern must be appropriate to support and allow eventual reconstitution of the repaired structure with ingrowth of fibrous tissue that matures to normal or near normal collagen;

(4) it must tolerate sterilization and storage; and

(5) it should be easily implanted using surgical and potentially arthroscopic techniques.

The existence of so many different types of materials and devices for use in connective tissue repair, some of which have been identified above, bears testimony to the difficulty of meeting some, much less all, of the foregoing characteristics in a single prosthetic device.

SUMMARY OF THE INVENTION

It is a principal object of the invention to provide a semi-bioabsorbable or fully bioabsorbable connective tissue prosthesis, e.g., a ligament or tendon repair device, which exhibits the stress-strain properties of the natural tissue to be replaced or augmented.

It is a specific object of the invention to provide the foregoing connective tissue prosthesis as a structure formed from a composite yarn comprising a non-bioabsorbable core yarn surrounded by a bioabsorbable or semi-bioabsorbable cover or sheath yarn.

It is a further specific object of the invention to provide a connective tissue prosthesis formed from a composite yarn wherein an elastic core yarn is wrapped with a relatively inelastic, bioabsorbable or semi-bioabsorbable sheath yarn, so as to exhibit the stress-strain properties of natural tissue.

It is another specific object of the invention to provide a prosthetic replacement for a human anterior cruciate ligament which is based on the aforesaid structure, in particular, one fabricated from a yarn whose sheath yarn component is derived from a glycolide-lactide copolymer.

In keeping with these and other objects of the invention, there is provided a connective tissue prosthesis comprising:

(a) a core made up of a first biocompatible composite yarn extending in the lengthwise direction; and

(b) a sheath surrounding the core and fabricated from a second biocompatible yarn,

wherein the first composite yarn in the core (a) comprises a biocompatible, non-bioabsorbable core yarn component surrounded by a biocompatible, bioabsorbable or semi-bioabsorbable sheath yarn component.

The second biocompatible yarn forming the sheath (b) may be the same as, or different from, the first composite yarn which forms the core (a). More specifically, the second biocompatible yarn may also comprise a biocompatible, non-bioabsorbable core yarn component surrounded by a biocompatible, bioabsorbable or semibioabsorbable sheath yarn component.

Also in keeping with the above and other objects of the invention, a connective tissue prosthesis is provided which comprises a tubular component fabricated from

composite yarn, the yarn comprising a biocompatible, nonbioabsorbable core yarn component surrounded by a biocompatible, bioabsorbable or semi-bioabsorbable sheath yarn component.

The foregoing connective tissue prostheses meet the Feagin, Jr. criteria, identified sucra, to a surprising degree. Due to elasticity of the composite yarn core component and relative inelasticity of the composite yarn sheath component, the stress-strain characteristics of the connective tissue prostheses closely match those of the natural tissue which they replace and their resorption properties can be calibrated to maintain the functionality of the prostheses throughout the entire period of the tissue regeneration process. The prostheses of this invention are readily sterilizable, possess good storage stability when suitably protected from hydrolytic forces, and can be installed at a ligament, tendon, vascular, or tracheal repair site employing known surgical reconstruction techniques.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1 and 2 are enlarged isometric views of composite yarns which are utilized in the construction of the connective tissue prosthesis herein;

FIG. 3 is an enlarged isometric view of an alternative composite yarn utilized in the construction of the connective tissue prosthesis herein;

FIG. 4 is a schematic, cross-sectional view along line 4—4 of FIG. 3;

FIG. 5 represents a section of a ligament prosthesis manufactured from the composite yarn of FIG. 1 and suitable for use in the surgical reconstruction of the human anterior cruciate ligament;

FIG. 6 is a plot of experimental data showing the stress-strain characteristics of the prosthesis of FIG. 5 compared with the stress-strain characteristics of a natural ligament as reported in the literature;

FIG. 7 represents a section of a tubular ligament prosthesis manufactured from the composite yarn of the present invention and having an unbraided center section;

FIG. 8 represents a section of a tubular ligament prosthesis similar to FIG. 7 and additionally having the unbraided center section helically wrapped with a yarn;

FIG. 9 represents a section of a braided prosthesis manufactured from composite yarn of the present invention and modified in various fashion over the length thereof;

FIG. 10 represents a section of a tubular braided prosthesis manufactured from composite yarn of the present invention and provided with threading means;

FIG. 11 represents a section of a prosthesis manufactured from composite yarn of the present invention in which the prosthesis is branched; and

FIG. 12 is a plot of experimental data showing the stress-strain characteristics of the prosthesis of FIG. 7 compared with a canine patellar tendon.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in FIG. 1, composite yarn 10 comprises a core yarn component 12 made up of a multiplicity of individual biocompatible, essentially non-bioabsorbable and preferably elastic filaments 13, advantageously provided with a slight to moderate twist, and a sheath yarn component 14 made up of a multiplicity of individual biocompatible, bioabsorbable or semi-bioabsorbable and preferably relatively inelastic filaments 15 wound in a first direction around the core and an external multifilamentous sheath yarn component 16, also made up of individual biocompatible, bioabsorbable or semi-bioabsorbable and preferably relatively inelastic filaments 17, wound in a second and opposite direction around sheath yarn component 14. For example, multifilamentous sheath yarn component 16 may comprise both absorbable and non-absorbable filaments 17. Generally, the filaments 13 of core yarn component 12 are substantially parallel.

Non-bioabsorbable core yarn component 12 functions to impart elasticity to composite yarn 10 and acts as a scaffolding during and after absorption of the bioabsorbable sheath. Bioabsorbable sheath yarn components 14 and 16 function to provide the composite yarn with relative inelasticity, tensile strength, and absorption characteristics which allow for desirable tissue ingrowth and incorporation of the composite yarn into the body structure. Sheath yarn components 14 and 16 each have a lengthwise axis which is non-perpendicular to the lengthwise axis of core component 12. While core yarn component 12 can be wrapped with a single layer of sheath yarn component, the illustrated arrangement of two layers of sheath yarn components 14 and 16 is generally preferred as this construction helps to give composite yarn 10 a balanced structure which resists crimping or kinking when used in the manufacture of a prosthesis such as shown in FIGS. 5 and 7-11.

Where, as shown in the embodiment of FIG. 1, at least two sheath yarn components are employed in the construction of the composite yarn, the composition, number and denier of the individual filaments, and braiding (if any) of these yarn components as well as their relative rates of bioabsorption can differ. For example, non-absorbable filaments may be combined with absorbable filaments to provide one or more semi-absorbable sheath yarn components. This capability for differential absorption can be advantageously exploited in a connective tissue prosthetic device in which the outermost sheath yarn component is absorbed by the body at a faster rate than the underlying sheath yarn component, or vice versa. thus resulting in a staged absorption of the sheath components of the composite yarn.

Core yarn component 12 must be essentially non-bioabsorbable, i.e., it must resist degradation when, as part of the connective tissue prosthesis of this invention, it is implanted in a body. The term "non-bioabsorbable" as used herein applies to materials which permanently remain within the body or at least remain in the body for a relatively long period of time, e.g., at least about two years. It is preferred to employ a core yarn material which is also elastic, i.e, a polymeric material which in filamentous form exhibits a relatively high degree of reversible extensibility, e.g., an elongation at break of at least about 30 percent, preferably at least about 40 percent and more preferably at least about 50 percent. Fiber-forming polymers which are both non-bioabsorbable and elastic, and as such preferred for use as the core yarn component herein, include fiber-forming polyolefins such as polyethylene homopolymers, polypropylene homopolymers, ethylene propylene copolymers, ethylene propylene terpolymers, etc., fluorinated hydrocarbons, fluorosilicones, isobutylenes, isoprenes, polyacrylates, polybutadienes, polyurethanes, polyether-polyester copolymers, and the like. Hytrel (DuPont), a family of copolyester elastomers based on (soft) polyether segments and (hard) polyester segments, and span-

dex, an elastomeric segmented polyurethane, provide especially good results.

Hytrel is manufactured in various commercial grades by DuPont, such as Hytrel 4056, 5526, 5556 and 7246. Hytrel 5556 is especially suitable as the core component 12 of the composite yarn 10 when used to form a vascular graft, while Hytrel 7246 is well-suited for the core component 12 of the composite yarn 10 when used to form a ligament prosthesis or tendon augmentation device.

Several properties of the various Hytrel grades are presented in the table below:

	Hytrel Grade No. (Injection Molded at 23° C. for Testing)			
	4056	5526	5556	7246
Hardness in durometer points (ASTM Test No. D2240)	40	55	55	72
Flexural Modulus (ASTM Test No. D790)				
at −40° C. in MPa	155	930	930	2,410
at −40° F. in psi	22,500	135,000	135,000	350,000
at 23° C. in MPa	55	207	207	518
at 73° F. in psi	8,000	30,000	30,000	75,000
at 100° C. in MPa	27	110	110	207
at 212° F. in psi	3,900	16,000	16,000	30,000
ASTM Test No. D638				
[i]Tensile Strength at Break,				
MPa	28.0	40.0	40.0	45.8
psi	4050	5800	5800	6650
[i]Elongation at Break, %	550	500	500	350
[ii]Tensile Stress at 5% Strain,				
MPa	2.4	6.9	6.9	14.0
psi	350	1,000	1,000	2,025
[ii]Tensile Stress at 10% Strain,				
Mpa	3.6	10.3	10.3	20.0
psi	525	1,500	1,500	2,900
Izod Impact (Notched) (ASTM Test No. D256, Method A)				
at −40° C. in J/cm	No Break	No Break	No Break	0.4
at −40° F. in ft-lbf/in	No Break	No Break	No Break	0.8
at 23° C. in J/cm	No Break	No Break	No Break	2.1
at 73° F. in ft-lbf/in.	No Break	No Break	No Break	3.9
Resistance to Flex Cut Growth, Ross (Pierced), in Cycles to 100% cut growth (ASTM. Test No. D1052)	$>1 \times 10^6$	$>5 \times 10^5$	$>5 \times 10^5$	—
[iii]Initial Tear Resistance, Die C (ASTM Test No. D1004),				
in kN/m	101	158	158	200
in lbf/in	580	900	900	1,146
Melt Flow Rate in g/10 min. (ASTM Test No. D1238)	5.3	18	7.0	12.5
Test Conditions: Temperature, °C./Load, Kg	190/2.16	220/2.16	220/2.16	240/2.16
[iv]Melting Point (ASTM Test No. D3418)				
in °C.	148	202	202	219
in °F.	298	396	396	426
Vicat Softening Point (ASTM Test No. D1525)				
in °C.	108	180	180	207
in °F.	226	356	356	405
Specific Gravity (ASTM Test No. D792)	1.16	1.20	1.20	1.25
Water Absorption, 24 hr. in % (ASTM Test No. D570)	0.6	0.5	0.5	0.3

[i]head speed 50 mm/min. or 2 in/min
[ii]head speed 25 mm/min or 1 in/min.
[iii]specimens 1.9 mm or 0.075 in. thick.
[iv]differential scanning calorimeter (DSC), peak of endotherm

Corresponding properties of other grades of Hytrel are available from DuPont.

If desired, the core yarn component can be provided with a nonabsorbable hydrophilic coating to improve its wettability by body fluids, e.g., synovial fluid. Hydrophilic coatings which are suitable for this purpose include polymeric materials such as the sparingly cross-linked poly(hydroxyethyl methacrylate) hydrogels disclosed in U.S. Pat. Nos. 2,976,576 and 3,220,960; hydrogels based on cross-linked polymers of n-vinyl lactams and alkyl acrylates as disclosed in U.S. Pat. No. 3,532,679; graft copolymers of hydroxyalkyl methacrylate and polyvinylpyrrolidone disclosed in U.S. Pat. No. 3,621,079, and many others.

Fiber-forming materials which are relatively inelastic are suitable for providing the sheath yarn component of composite yarn 10 provided such materials are fairly rapidly bioabsorbed by the body, e.g., exhibiting a loss of tensile strength in from about 2 to about 26 weeks and total absorption within from about two to about fifty

two weeks. It is to be understood, however, that the expression "relatively inelastic" does not preclude the presence of some minor degree of elasticity in the sheath yarn component, merely that it excludes a degree of elastic behavior as described in connection with the preferred type of core yarn component.

The sheath yarn component can be woven, braided or knitted in whole or in part and will ordinarily possess a relatively high tensile strength, e.g., a straight tensile strength of at least about 30,000 p.s.i., preferably at least about 60,000 p.s.i. and more preferably at least about 90,000 p.s.i.

Bioabsorbable, relatively inelastic fiber-forming polymers and polymer blends from which the sheath yarn component herein can be formed include those derived at least in part from such monomers as glycolic acid, glycolide, lactic acid, lactide, p-dioxanone, trimethylene carbonate, e-caprolactone, hydroxycaproic acid, etc., and various combinations of these and related monomers as disclosed, e.g., in U.S. Pat. Nos. 2,668,162; 2,703,316; 2,758,987; 3,225,766; 3,297,033; 3,422,181; 3,531,561; 3,565,077; 3,565,869; 3,620,218; 3,626,948; 3,636,956; 3,736,646; 3,772,420; 3,773,919; 3,792,010; 3,797,499; 3,839,297; 3,867,190; 3,878,284; 3,982,543; 4,047,533; 4,052,988; 4,060,089; 4,137,921; 4,157,437; 4,234,775; 4,237,920; 4,300,565; 4,429,080; 4,441,496; 4,523,591; 4,546,152; 4,559,945; 4,643,191; 4,646,741; 4,653,497; and, 4,741,337; U.K. Patent No. 779,291; D. K. Gilding et al., "Biodegradable polymers for use in surgery—polyglycolide/poly(lactic acid) homo- and copolymers: 1", *Polymer*, Volume 20, pages 1459–1464 (1979), and D. F. Williams (ed.), *Biocompatibility of Clinical Implant Materials*, Vol. II, ch. 9: "Biodegradable Polymers" (1981).

Sheath yarn components manufactured from polymers of high lactide or glycolide content, e.g., those in which at least about 75 percent of the monomeric units are derived from either glycolide or lactide, are preferred for the construction of the composite yarn of this invention. Polymers of high glycolide content tend to be absorbed more quickly than those possessing a high lactide content. Accordingly, the glycolide-based polymers may be preferred for the manufacture of a sheath yarn component providing the outermost sheath yarn(s) in a multiple sheath yarn component construction, the underlying internal sheath yarn(s) being manufactured from the more slowly absorbable lactide-based polymers. An especially preferred lactide-glycolide copolymer for forming the sheath yarn component of the composite yarn contains from about 70 to about 90, and preferably from about 75 to about 85 mole percent lactide monomer with the balance being provided by the glycolide monomer. Thus, for example, a sheath yarn component formed from a lactide-glycolide copolymer based on 80 mole percent lactide-20 mole percent glycolide is especially advantageous for constructing the composite yarn, and ultimately, the connective tissue prosthesis, of the present invention. The sheath yarn component, which is preferably braided around the core yarn component, may comprise a plurality of bioabsorbable fibers in turn comprising at least two different chemical compositions.

The deniers of core yarn component **12** and sheath yarn components **14** and **16** are not especially critical and those of commercially available yarns such as Vicryl (a glycolide/lactide copolymer suture available from Ethicon) and Dexon (a polyglycolide suture available from American Cyanamid) are suitably employed. Preferably, the deniers are selected so as to provide a composite yarn having an overall denier of from about 40 to about 1200 and preferably from about 80 to about 500, the overall denier of the core and/or sheath yarn components being from about 20 to about 600 and preferably from about 40 to about 300. The deniers of individual filaments in the core and sheath yarn components of multifilamentous construction can vary widely, e.g., from about 0.2 to about 6.0 and preferably from about 0.4 to about 3.0. The base weight for a desired composite yarn will determine the size and weight of the component elements of the yarn. Composite yarn **10** possesses sufficient core material to impart, inter alia, a desired resiliency and sufficient sheath material to provide, inter alia. a desired tensile strength for a particular connective tissue prosthetic application. In general, the core component can represent from about 20 to about 80 percent, and preferably from about 30 to about 70 percent of the total weight of composite yarn **10**. Optimum core and sheath component weights will naturally vary depending on the specific application and can be readily determined in a given case based on the desired physical properties of the prosthetic device without undue experimentation.

Methods and apparatus for covering core yarn components with sheath yarn components are well known and need not be described here in detail. In general, the sheath yarn components are wrapped about the core yarn component on a covering machine which includes a hollow spindle with rotating yarn supply bobbins supported thereon. The elastic core yarn component is fed through the hollow spindle and the elastic sheath yarn components are withdrawn from the alternate direction rotating supply bobbins and wrapped about the core yarn component as it emerges from the hollow spindle. The core yarn component is preferably under a slight tension during the covering procedure and the sheath yarn components are laid down in a side-by-side array. The number of wraps per inch will depend on the denier of the sheath yarn components but should be sufficient to cause the sheath yarn components to lay close to the core yarn component when tension on the latter is relaxed.

As desired, the filaments which comprise a sheath yarn component can be provided with no twist or with varying degrees of twist. Where the yarns are twisted, it can be advantageous to balance or equalize the twist in the final composite yarn structure. Thus, for example, in the embodiment of composite yarn **10** in FIG. **1**, if sheath yarn component **14** has a given twist, sheath yarn component **16** should have an equivalent twist. Since sheath yarn components **14** and **16** are laid down in opposite directions, the twist in each of these yarn components will be neutralized in the final structure of the composite yarn. Similarly, sheath yarn components **14** and **16** are advantageously of about equal weight in order to provide further balance in the composite yarn.

The composite yarn **20** shown in FIG. **2** is similar to that of FIG. **1** except that core yarn component **22** constitutes a monofilament and internal and external sheath yarn components **24** and **26**, respectively, each constitutes a monofilament. In all other structural and compositional respects, composite yarn **20** can be like that of composite yarn **10**.

An alternative composite yarn **30** is illustrated in FIGS. **3** and **4**. Composite yarn **30** comprises a core yarn component **33** and a braided sheath yarn component **34**. As with core yarn components **12** and **22** of

FIGS. 1 and 2, core yarn component 33 is made up of one or more biocompatible, essentially non-bioabsorbable and preferably elastic filaments 36 which define the longitudinal axis of composite yarn 30. Braided sheath yarn component 34 comprises individual sheath yarn filaments or sheath yarn filament bundles 35 which traverse core yarn component 33 in a substantially conventional braided configuration to provide core yarn component 33 with a braided tubular external sheath 34. The individual sheath yarn filaments or sheath yarn filament bundles 35 are biocompatible, bioabsorbable or semi-bioabsorbable, and relatively inelastic. In a preferred embodiment of the present invention as illustrated in FIGS. 3 and 4, sheath yarn component 34 comprises sheath yarn filaments of different chemical composition. For example, a portion of the sheath yarn filaments 35', e.g., 30 to 70% by weight, may be formed of a bioabsorbable polymer exhibiting relatively slow bioabsorption, e.g., polylactide or a copolymer comprising a high lactide mole percentage, while the remainder of the sheath yarn filaments 35'' may be formed of a second bioabsorbable polymer which exhibits relatively fast bioabsorption, e.g., polyglycolide or a copolymer comprising a high glycolide mole percentage. Sheath yarn component 34 may also be fabricated from individual filaments having more than two different chemical compositions, one or more of which optionally being nonbioabsorbable.

In the embodiment illustrated in FIGS. 3 and 4, core yarn component 33 is preferably manufactured from Hytrel filaments 36 and has a denier of about 270, while sheath yarn component 34, which is braided on an eight carrier braider, has a denier of about 204, for a total denier of this composite yarn 30 of about 474.

FIG. 5 illustrates an anterior cruciate ligament prosthesis 37 manufactured from warp and filling composite yarns 10 of FIG. 1. Prosthesis 37 is constructed by constructing a sheath 31 about core 32 by weaving, braiding or knitting on a known or conventional loom. For example, the sheath may be braided about the core on a braiding machine which includes braider bobbins. Composite yarn forming the sheath may be wound onto an appropriate number of braider bobbins which are then loaded onto a carrier braider with the yarns on the bobbins then being braided and tied to form the sheath. The core (if one is required) can be pulled through the sheath, e.g. manually to form the prosthesis. In other words, the core will be at least partially surrounded by the sheath. Other prostheses illustrated herein can be manufactured in similar fashion. The sheath components of the individual composite yarns from which ligament prosthesis 30 is manufactured will erode over time due to their bioabsorption leaving only the nonabsorbable core component as a permanent or long term scaffold for new ligament tissue growth.

FIGS. 7-11 illustrate examples of other ligament prostheses which can be manufactured from the composite yarn of the present invention, e.g. as illustrated in FIGS. 1-3. More particularly, FIG. 7 illustrates a tubular ligament prosthesis or tendon augmentation device 40 having an unbraided center section 41 bounded by braided sections 42 and 43. The individual composite yarns 44 in the unbraided center section 41 can be drawn in generally parallel relationship, if required. The length of the unbraided center section 41 can vary, e.g., from about one or two inches up to about seven or eight inches. The unbraided center section 41 provides tensile strength and/or tissue ingrowth advantages.

Additionally, a tubular ligament prosthesis or tendon augmentation device 45 as illustrated in FIG. 8 can be manufactured from the composite yarn of the present invention. The prosthesis 45 is similar to the one illustrated in FIG. 7 and comprises an unbraided center section 46 bounded by braided sections 47 and 48. A helical wrap 100 is provided about the unbraided center section 46 to improve handling and manipulation of the unbraided section 46 during implantation, while absorption/degradation of the helical wrap 100 frees the individual yarns 49 of the center unbraided section 46 to provide the appropriate tensile strength and/or tissue ingrowth advantages. In this regard, the yarn forming the helical wrap 100 can be the composite yarn of FIGS. 1-3 or formed of a different kind of material, e.g. completely bioabsorbable or nonbioabsorbable material. The tubular ligament prostheses of FIGS. 7 and 8 are both constructed by braiding the end sections 42, 43 or 47, 48 in a known or conventional loom and, in the case of FIG. 8, additionally wrapping the helical yarn 100 about the center unbraided section 46, also with a known or conventional loom. The prostheses of FIGS. 7 and 8 are especially suitable as replacements for anterior cruciate ligaments.

FIG. 9 illustrates a braided prosthesis 70 which can be manufactured from the composite yarns of FIGS. 1-3 and which is also modified along the length thereof. More specifically, the prosthesis of FIG. 9 comprises a center region 50 bordered by first outer regions 51, 52, second outer regions 53, 54, third outer regions 55, 56, fourth outer regions 57, 58, and fifth outer regions 59, 60. The center region 50 comprises a sheath of braided composite yarn, e.g., as illustrated in FIGS. 1-3, about a core (not illustrated) also formed of composite yarn. First outer regions 51, 52 additionally comprise a wrapping 61 about the braided yarn, this wrapping 61 being formed of the same composite yarn as illustrated in FIGS. 1-3 or a different kind of material, e.g. a totally bioabsorbable or nonabsorbable material. This wrapping 61 serves to at least temporarily retain the sheath about the core.

The second outer regions 53, 54 also formed of tubular braided composite yarn as illustrated in FIGS. 1-3 with an appropriate core material (not illustrated) that forms a thicker core than any core present in center section 50 (the center section 50 can be coreless, if required). Third outer regions 55, 56 are divided as illustrated in FIG. 9 to form respective openings 62 and 63. This allows attachment means to be inserted through the respective openings to secure the ligament prosthesis 70 in place. As illustrated in FIG. 9, the sections 55, 56 around the openings 62 and 63 are also covered with wrapping 64 which is similar to the wrapping 61 covering regions 51 and 52.

Next, fourth outer regions 57 and 58 follow which are similar in structure and composition to second outer regions 53 and 54. Regions 57 and 58 narrow down into fifth outer regions 59 and 60 as illustrated in FIG. 9, which can be used, e.g. for threading the ligament prosthesis 70. All sections of prosthesis 70, including the various wrappings 61 and 64, can be fabricated together on a conventional known loom. Prosthesis 70 is especially suitable as a replacement for an anterior cruciate ligament.

FIG. 10 discloses a coreless prosthetic ligament 80 that can be prepared from the composite yarn illustrated in FIGS. 1-3. The coreless prosthetic ligament is braided with a wider central section 81, and a narrower

outer section from which unwoven yarns 83 extend to form a leading section to enhance threading of prosthetic ligament 80 upon implantation. Sheath yarns 84 of prosthetic ligament 80 can be woven, braided, or knitted on a conventional loom. Sheath sections 81 and 82 of ligament prostheses 80 are tubular, i.e. coreless. Prostheses 80 is also especially suitable as a replacement for an anterior cruciate ligament.

As illustrated in FIG. 11, a ligament prosthesis 90 can be prepared from composite yarns illustrated in Figs. 1-3 of the present invention which form a sheath about a supporting structure (not illustrated). This supporting structure can be a core formed from the composite yarns as described above, or it can be a single, integral member, formed of semi-bioabsorbable or non-bioabsorbable material forming a supporting base for yarns 91. This supporting structure, along with the bundle of yarns 91, can be divided into two branches 90*a* and 90*b*, with the yarns 91 of the prosthesis retained on the supporting structure or core at various points by fastening means 92 which can also be constituted by composite yarn of FIGS. 1-3 or by other kinds of material, e.g. totally bioabsorbable or nonabsorbable filaments. In this regard, the yarns 91 need just be bundled together without any interweaving, braiding or knitting, so long as the yarns 91 are securely held together on the core by the fastening means 92. Alternatively, yarns 92 can be woven, knitted, or braided about the core on a conventional loom to form branches 90*a* and 90*b*.

Other prosthetic structures which can be prepared with the composite yarn of the present invention are apparent to one of skill in the art in light of the disclosure herein.

It is within the scope of this invention to coat or impregnate the prosthesis with, or otherwise apply thereto, one or more materials which enhance its functionality, e.g., surgically useful substances, such as those which accelerate or beneficially modify the healing process when the prosthesis is applied to a graft site. So, for example, the prosthesis can be provided with a therapeutic agent which will be deposited at the grafted site. The therapeutic agent can be chosen for its antimicrobial properties, capability for promoting tissue repair or for specific indications such as thrombosis. Thus, for example, antimicrobial agents such as broad spectrum antibiotics (gentamicin sulphate, erythromycin or derivatized glycopeptides) which are slowly released into the tissue can be incorporated into the prosthesis to aid in combating clinical and sub-clinical infections in a surgical or trauma wound site.

To promote wound repair and/or tissue growth, one or several growth promoting factors can be introduced into the tubular prosthesis, e.g., fibroblast growth factor, platelet derived growth factor, macrophage derived growth factor, alveolar derived growth factor, monocyte derived growth factor, magainin, and so forth. To decrease abrasion, increase lubricity, etc., the prosthesis can be coated with copolymers of glycolide and lactide and polyethylene oxide, calcium salts such as calcium stearate, compounds of the Pluronic class, copolymers of caprolactone, caprolactone with PEO, polyHEMA, etc. Especially advantageous is a coating of hyaluronic acid with or without cross-linking.

Additionally, polypeptides such as Human Growth Factor (HGF) can also be coated upon or impregnated in the prosthesis to promote healing. The term "Human Growth Factor" or "HGF" embraces those materials, known in the literature, which are referred to as such and includes their biologically active, closely related derivatives. The HGFs can be derived from naturally occurring sources and are preferably produced by recombinant DNA techniques. Specifically, any of the HGFs which are mitogenically active and as such effective in stimulating, accelerating, potentiating or otherwise enhancing the wound healing process are useful herein, e.g., hEGF (urogastrone), TGF-beta, IGF, PDGD, FGF, etc. These and other useful HGFs and closely related HGF derivatives, methods by which they can be obtained and methods and compositions featuring the use of HGFs to enhance wound healing are variously disclosed, inter alia, in U.S. Pat. Nos. 3,883,497; 3,917,824; 3,948,875; 4,338,397; 4,418,691; 4,528,186, 4,621,052; 4,743,679 and 4,717,717; European Patent Applications 0 046 039; 0 128 733; 0 131 868; 0 136 490; 0 147 178; 0 150 572; 0 177 915 and 0 267 015; PCT International Applications WO 83/04030; WO 85/00369; WO 85/01284 and WO 86/02271 and UK Patent Applications GB 2 092 155 A; 2,162,851 A and GB 2 172 890 A, all of which are incorporated by reference herein. Of the known HGFs, hEGF, TGF-beta and IGF are preferred for use in the therapeutic composition of this invention.

The HGFs can be introduced with appropriate carrier such as carrier proteins disclosed, e.g., in "Carrier Protein-Based Delivery of Protein Pharmaceuticals", a paper of Biogrowth, Inc., Richmond, Calif., presented at a symposium held June 12-14, 1989 in Boston, Mass.

EXAMPLE 1

The following illustrates the manufacture of a ligament prosthesis as illustrated in FIG. 5.

A 420 denier composite yarn as illustrated in FIG. 1 was formed from a Hytrel 7246 yarn as the core component and a lactide (80 mole percent)-glycolide (20 mole percent) copolymer yarn providing the sheath component.

Six plies of the 420 denier composite yarn were wound onto 32 braider bobbins. The bobbins were loaded onto a 32 carrier braider to provide braided sheath 31. About one meter of the yarns from the 32 bobbins was pulled manually in parallel to provide a core 32 of 80,640 (420×6×32) overall denier. Application of braided sheath 31 also 420×6×32 or 80,640 overall denier resulted in ligament prosthesis 37 possessing an overall denier of 161,280. The stress (force in Newtons)-strain characteristics of prothesis 37 were measured and compared with the stress-strain characteristics of a human anterior cruciate ligament as reported in Noyes et al., *Journal of Bone and Joint Surgery*, Vol. 58-A, No. 8, p. 1074, et seq. (Dec. 1976). As shown in the plotted data of FIG. 6, the stress-strain characteristics of prosthesis 37 (continuous line) closely matched those of the natural tissue (broken line), an altogether remarkable achievement relative to known connective tissue prostheses.

EXAMPLE 2

The following illustrates manufacture of a tendon augmentation device 40 as illustrated in FIG. 7.

A 431 denier composite yarn as illustrated in FIG. 1 was formed from a Hytrel 7246 yarn to provide the core component 12, a lactide (80 mole percent)—glycolide (20 mole percent) copolymer yarn to provide the inner sheath component 14, and a lactide (10 mole percent)—glycolide (90 mole percent) copolymer yarn to provide the outer sheath component 16.

Six plies of the 431 denier composite yarn were wound onto 16 braider bobbins. The bobbins were loaded onto a 16 carrier braider to provide braided sections 42 and 43. About 70 mm of the yarn from the 16 braider bobbins was braided to form one of sections 42 and 43, and then the braiding was stopped. Then, about 35 mm. of the yarn from the 16 braider bobbins was pulled manually to form the unbraided center section 41, and then braiding was continued for another 70 mm of the yarn to form the other of sections 42 and 43. The resulting tendon augmentation device 40 had a total denier of 41,376 (431×6×16).

The tendon augmentation device 40 was implanted in a canine knee replacing the center third of the patellar tendon. Physical testing was carried out comparing two tendon augmentation devices 40 (TAD-1 and TAD-2) to the center third of the canine patellar tendon (½ P.T.) being replaced. More specifically, the stress (force in Newtons) —strain or load-deformation characteristics of devices 40 and the canine patellar tendon were measured and compared with one another.

As shown in the plotted data of FIG. 12, the responses of both tendon augmentation devices 40 (TAD 1 and TAD 2) were very similar to the one third canine patellar tendon. Moreover, tendon augmentation devices 40 (TAD 1 and TAD 2) were generally stronger than the replaced canine patellar tendon which failed when too great a load was applied thereto.

EXAMPLE 3

A composite yarn as illustrated in FIGS. 3 and 4 was fabricated using Hytrel 7246 fibers as the core component 33 and bioabsorbable sheath component fibers 35 of two different chemical compositions: first bioabsorbable fibers 35' fabricated from an 80 mole percent lactide/20 mole percent glycolide copolymer, and second bioabsorbable fibers 35" fabricated from a 10 mole percent lactide/90 mole percent glycolide copolymer. The first bioabsorbable fibers 35' were formed into yarn bundles, each yarn bundle comprising 12 filaments and having a total denier of 24. The second bioabsorbable fibers 35" were also formed into yarn bundles, each yarn bundle comprising 17 filaments and having a total denier of 27.

The composite yarn was formed using three Hytrel yarn bundles, each Hytrel yarn bundle comprising 70 filaments, to form a core component 33 of approximately 270 denier. The braided sheath component 34 was formed around the Hytrel core component 33 using an 8 carrier braider, 4 carriers each of the first and second bioabsorbable yarn bundles. The composite yarn thus formed exhibited a tensile strength of 3.19 grams/denier, and is suitable for use in fabricating a connective tissue prosthesis of the present invention.

What is claimed is:

1. A connective tissue prosthesis comprising:

a) a core made up of a first biocompatible composite yarn extending in a lengthwise direction; and

b) a sheath surrounding the core, said sheath being fabricated from a second biocompatible yarn;

the first composite yarn in said core (a) comprising a non-bioabsorbable core yarn component surrounded by an at least semi-bioabsorbable sheath yarn component.

2. The connective tissue prosthesis of claim 1, wherein the second biocompatible yarn in said sheath (b) comprises a non-bioabsorbable core yarn component surrounded by an at least semi-bioabsorbable sheath yarn component.

3. The connective tissue prosthesis of claim 2 wherein the sheath yarn component is bioabsorbable.

4. The connective tissue prosthesis of claim 1 exhibiting stress-strain characteristics approximately those of the natural connective tissue replaced or augmented by the prosthesis.

5. The connective tissue prosthesis of claim 1 wherein said connective tissue prosthesis is a ligament or tendon prosthesis.

6. The connective tissue prosthesis of claim 1 wherein said connective tissue prosthesis is a human anterior cruciate ligament prosthesis.

7. The connective tissue prosthesis of claim 1 in which the core component comprises at least one filament.

8. The connective tissue prosthesis of claim 7 in which the core (a) of the prosthesis comprises multiple composite yarns.

9. The connective tissue prosthesis of claim 7 wherein the core component comprises multiple filaments.

10. The connective tissue prosthesis of claim 1 in which the sheath component comprises at least one filament.

11. The connective tissue prosthesis of claim 10 wherein the sheath yarn component comprises multiple filaments.

12. The connective tissue prosthesis of claim 1 in which the core component is manufactured from at least one polymeric material selected from the group consisting of polyethylene homopolymers, polypropylene homopolymers, ethylene-propylene copolymers, ethylene propylene terpolymers, fluorinated hydrocarbons, fluorosilicones, isobutylenes, isoprenes, polyacrylates, polybutadienes, polyurethanes, and polyether-polyester copolymers.

13. The connective tissue prosthesis of claim 1 in which the core component possesses an elongation at break of at least about 30 percent.

14. The connective tissue prosthesis of claim 1 in which the sheath component is an absorbable, relatively inelastic polymeric material derived at least in part from a monomer selected from the group consisting of glycolic acid, glycolide, lactic acid, lactide, p-dioxanone, trimethylene carbonate, e-caprolactone and hydroxycaproic acid.

15. The connective tissue prosthesis of claim 1 in which the sheath component is a lactide-glycolide copolymer.

16. The connective tissue prosthesis of claim 12 in which the sheath component is a lactide-glycolide copolymer containing from about 70 to about 90 mole percent lactide units.

17. The connective tissue prosthesis of claim 16 in which the sheath component is a lactide-glycolide copolymer containing from about 75 to about 85 mole percent lactide units.

18. The connective tissue prosthesis of claim 1 wherein the sheath (b) covering the core (a) is at least partially woven.

19. The connective tissue prosthesis of claim 18 wherein the sheath (b) is entirely woven.

20. The connective tissue prosthesis of claim 1 further comprising at least one bioactive substance.

21. The connective tissue prosthesis of claim 1, wherein said sheath component is helically wound about said core component.

22. The connective tissue prosthesis of claim 21, additionally comprising

a second sheath component helically wound about said sheath component in a different direction.

23. The connective tissue prosthesis of claim 22, in which said second sheath component is a lactide-glycolide copolymer.

24. The connective tissue prosthesis of claim 22, wherein said first and second sheath components have different ratios of absorption.

25. The connective tissue prosthesis of claim 1, wherein said sheath component is braided around said core component.

26. The connective tissue prosthesis of claim 25, wherein said sheath component comprises a plurality of bioabsorbable fibers, said fibers comprising at least two different chemical compositions.

27. The connective tissue prosthesis of claim 1, wherein said core (a) and sheath (b) together are branched at discrete locations to form gaps between branches of said prosthesis.

28. The connective tissue prosthesis of claim 27, wherein a yarn is wrapped about said sheath (b) at discrete locations to at least temporarily retain said sheath (b) about said core (a).

29. The connective tissue prosthesis of claim 28, wherein said wrapping yarn comprises a biocompatible, non-bioabsorbable core yarn component surrounded by a at least semi-bioabsorbable sheath yarn component.

30. The connective tissue prosthesis of claim 29 wherein said sheath component of said wrapping yarn is bioabsorbable.

31. The connective tissue prosthesis of claim 1 wherein said sheath yarn component is bioabsorbable.

32. The connective tissue prosthesis of claim 1 wherein the sheath (b) covering the core (a) is at least partially braided.

33. The connective tissue prosthesis of claim 32 wherein the sheath (b) is entirely braided.

34. The connective tissue prosthesis of claim 1 wherein the sheath (b) covering the core (a) is at least partially knitted.

35. The connective tissue prosthesis of claim 34 wherein the sheath (b) is entirely knitted.

36. A connective tissue prosthesis comprising:

a tubular component fabricated from composite yarn, said yarn comprising a biocompatible, core yarn component surrounded by a biocompatible, at least semi-bioabsorbable sheath yarn component.

37. The connective tissue prosthesis of claim 36, comprising a center section where said yarn is unbraided and bordered by sections where said yarn is braided.

38. The connective tissue prosthesis of claim 37, additionally comprising

a helical wrap about said unbraided center section.

39. The connective tissue prosthesis of claim 38, wherein said helical wrap is fabricated from composite yarn comprising a biocompatible, non-bioabsorbable core yarn component surrounded by a biocompatible, at least semi-absorbable sheath yarn component.

40. The connective tissue prosthesis of claim 39, wherein said sheath component is bioabsorbable.

41. The connective tissue prosthesis of claim 36, additionally comprising

a threading member attached to an end thereof, said threading member comprising a composite yarn which comprises a biocompatible, non-bioabsorbable core yarn component surrounded by a biocompatible, at least semi-bioabsorbable sheath yarn component.

42. The connective tissue prosthesis of claim 41 wherein said sheath component is bioabsorbable.

43. The connective tissue prosthesis of claim 36 wherein said sheath component is bioabsorbable.

44. Methed for manufacturing a connective tissue prosthesis, comprising

forming said connective tissue prosthesis from a first biocompatible composite yarn comprisng a non-bioabsorbable core yarn component surrounded by an at least semibioabsorbable sheath yarn component.

45. The method of claim 44, wherein said connective tissue prosthesis comprises a core and a sheath, said core being at least partially surrounded by said sheath.

46. The method of claim 45, wherein said biocompatible composite yarn forms said core.

47. The method of claim 44, wherein said biocompatible composite yarn forms said sheath.

48. The method of claim 44, wherein the sheath is woven about the core.

49. The method of claim 48, wherein

the sheath is braided from braider bobbins loaded onto a carrier braider, and

the core is pulled through the thus-braided sheath.

50. The method of claim 48 wherein the sheath is braided about the core.

51. The method of claim 44 wherein said sheath component is bioabsorbable.

52. The method of claim 44 wherein the sheath is knitted about the core.

53. Method for manufacturing a tubular connective tissue prosthesis, comprising

forming a tubular component from composite yarn comprising a biocompatible, non-bioabsorbable core yarn component surrounded by a biocompatible, at least semi-absorbable sheath yarn component.

54. The method of claim 53 wherein the tubular component is formed by weaving.

55. The method of claim 53 wherein the tubular component is formed by braiding.

56. The method of claim 55, wherein the tubular component is braided from braider bobbins loaded onto a carrier braider.

57. The method of claim 53 wherein the tubular component is formed by knitting.

58. The method of claim 53 wherein the sheath component is bioabsorbable.

* * * * *

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000228

US005116360A

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[45] Date of Patent: May 26, 1992

[54] MESH COMPOSITE GRAFT

[75] Inventors: Leonard Pinchuk; John B. Martin, Jr., both of Miami; Bruce A. Weber, Pembroke Pines, all of Fla.

[73] Assignee: Corvita Corporation, Miami, Fla.

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[51] Int. Cl.[5] A61F 2/06

[52] U.S. Cl. 623/1; 623/11; 623/12

[58] Field of Search 623/12, 1

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Primary Examiner—David Isabella

Assistant Examiner—Debra S. Brittingham

Attorney, Agent, or Firm—Lockwood, Alex, FitzGibbon & Cummings

[57] ABSTRACT

A mesh composite graft including an inner component, an outer component formed from strands of durable material, such as polyethylene terephthalate, and an intermediate component made from strands of bicompatible synthetic material having a melting point less than that of the durable material from which the outer component is formed and less than that of the biocompatible synthetic material from which the inner component of the graft is formed. By heating the graft to a temperature grater than the melting point of the material from which the intermediate component is formed but less than the melting point of the outer component material and less than the melting point of the material from which the inner component is formed, the components are bound by the melted intermediate component to provide a totally porous, compliant composite graft reinforced by the outer component.

19 Claims, 1 Drawing Sheet

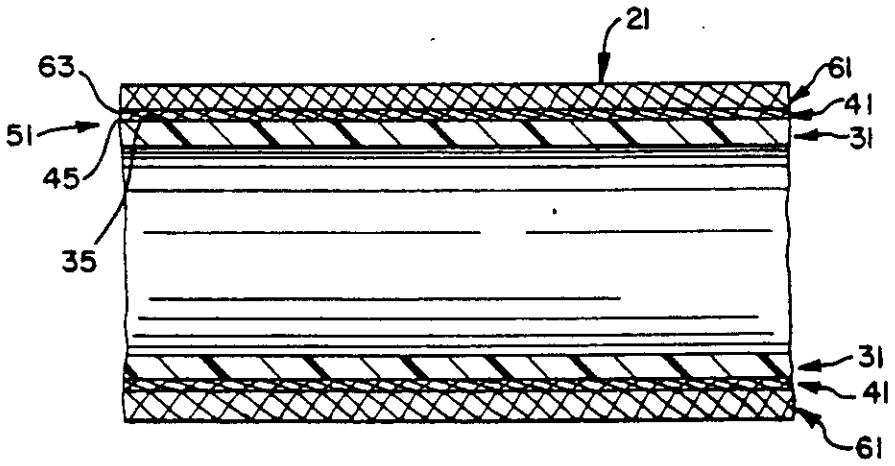


FIG. 1

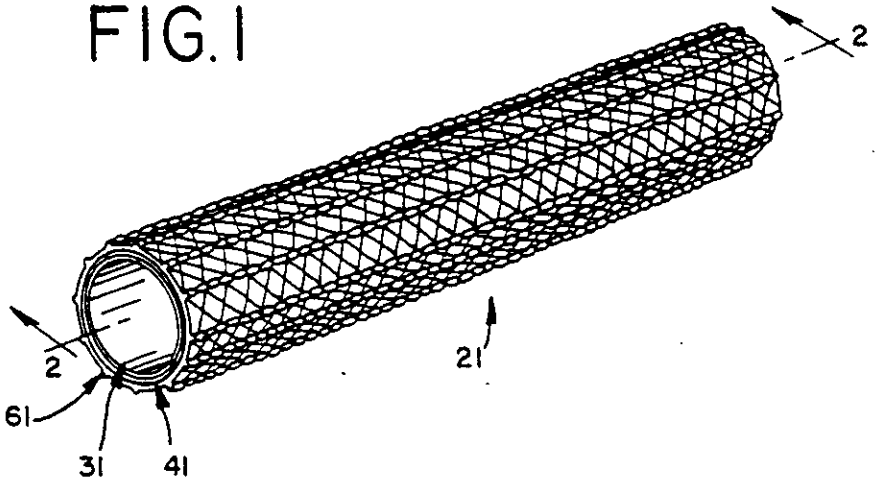
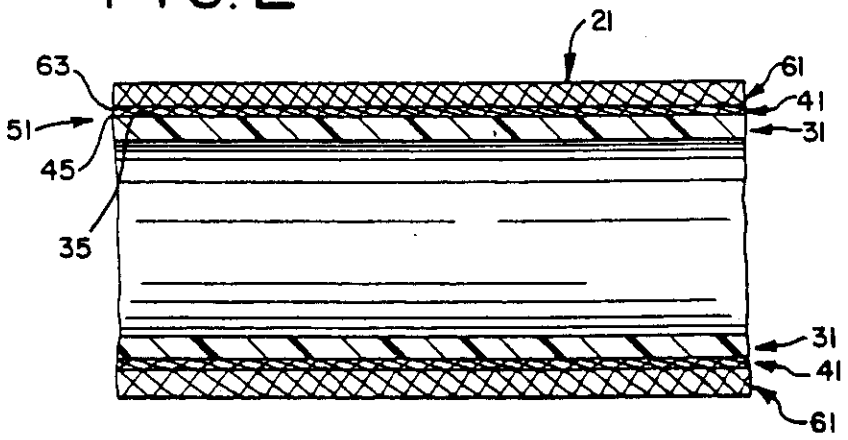


FIG. 2



MESH COMPOSITE GRAFT

BACKGROUND AND DESCRIPTION OF THE INVENTION

The present invention generally relates to implantable prostheses and the like and to methods for making same. More particularly, the invention relates to a graft, such as a vascular graft or AV-shunt, having a compliant porous inner component and a compliant porous load-bearing outer component, bound together by a porous intermediate component that is made of material having a melting point lower than that of the materials from which the inner and outer components are made. With the outer component bound by the intermediate component to the inner component, a porous, yet strengthened integral graft results.

Blood vessels are not straight, rigid tubes but elastic conduits made of a variety of materials and having a compliance that varies with functional considerations. For example, the venous system functions, in part, as the blood reservoir for the body. In order to be able to respond to a larger volume of blood sent into the system because of, for example, a change in arterial blood pressure, the vessels of the venous system must be sufficiently compliant so that they can distend. The arterial system functions as the body's pressure reservoir. In order to avoid the wide swings in the blood pressure and flow that are possible with every contraction and relaxation of the heart, yet be able to maintain sufficient blood pressure so that blood can be pushed into all regions of the body, including through the small-diameter arterioles and the microcirculatory bed, the arteries must have sufficient compliant strength to elastically expand and recoil without the marked distension of the venous system.

Conventional grafts, however, are generally made of materials and in shapes that provide a structure whose compliance is markedly different from that of the walls of the vessel to which they may be attached. Grafts having walls less compliant than that of the host vessel walls are problematic in that conditions, such as intimal hyperplasia and stenotic narrowing, may develop. Grafts with walls having greater compliance than that of the vessel to which the graft is attached are problematic in that a portion of the graft wall may balloon—that is, develop an aneurysm—after implantation.

Other known grafts, while they may be compliant, may not necessarily be made from biocompatible materials. The implantation of a graft made from such material may prompt a thrombogenic or immunological response with the resultant deleterious formation of microthrombi or microocclusions in and around the graft. Other grafts are made from generally non-porous materials, that, accordingly, do not facilitate the ingrowth of cells and tissue within the graft. The full incorporation of the graft into the surrounding host tissue is thereby frustrated. Still other conventional grafts are made from microporous textiles that require preclotting of the vessel wall with blood to prevent leakage of blood at implantation.

A demand therefore is present for an integral graft made from biocompatible materials and having a structure that has compliant strength similar to that of natural tissue but that is sufficiently porous so that the graft may become incorporated into the host tissue yet not leak blood. The present invention satisfies the demand.

The present invention includes a three component system, an inner component, an intermediate component, and an outer component. While the components may be made from materials having generally different melting points and different mechanical properties, at a minimum the inner component and outer component are made from a material or materials having a melting temperature higher than the material from which the intermediate component is made. More specifically, the inner component is porous and is made from a biocompatible synthetic material, preferably a polyurethane composition made with an aromatic polycarbonate intermediate, having a melting point that is, at a minimum, in excess of the melting point of the composition from which the intermediate component is formed (further discussed below).

There are many methods by which the inner component may be made, such as the many known methods used to produce porous compliant vascular prostheses. One such method is termed phase inversion or separation which involves dissolving a urethane in a solvent, such as dimethyl acetamide (DMA), forming a coat on a mandrel—such as by dipping the mandrel into the dissolved urethane—and then immersing the urethane coating in a solution such as water by which DMA may be dissolved, but not urethane, thereby causing the urethane to bead-up and form a porous matrix.

Another method by which the inner component may be formed is termed particle elution. The method utilizes water soluble particles such as salt (NaC1, MgC12, CaCo2, etc.) polymers, such as polyvinylpyrrolidone, sugars etc. The particles are mixed or blended into a urethane composition, and after forming a graft from the mixture such as by dip coating or extruding the particle filled plastic, the particle is eluted out with a suitable solvent.

Additional methods include replamineform, that involves the dissolution of a matrix, such as that of a sea urchin, out of the urethane with hydrochloric acid, spray techniques where filaments or beads of urethane are sprayed onto a mandrel to produce a porous vascular graft, and electrostatic deposition of urethane fibers from solution.

However, the porous vascular graft preferred in this invention is prepared according to the method detailed in U.S. Pat. No. 4,475,972 to Wong. This patent is incorporated hereinto by reference. An antioxidant may be added to further prevent degradation of the fibers drawn of the material from which the inner component is made.

Regardless of the nature and method of manufacturing the porous inner component, the intermediate component is comprised of one or more layers of a biocompatible synthetic material, preferably a polyurethane material, having a melting point lower than the melting point of the material from which the inner component is formed and lower than the melting point of the material from which the outer component is made.

The outer component comprises a mesh network made of strands, fibers, beads or expanded versions of a durable material such as a composition of fluorocarbons, such as expanded polytetrafluoroethylene ("ePTFE")—commonly termed Teflon—or stable polyesters, such as preferably polyethylene terephthalate ("PET")—commonly termed Dacron. This material is preferably warp-knitted in a tricot or double tricot pattern and shaped in a tubular configuration. It can also be appreciated that the outer component can be woven, braided,

weft-knitted and the like with loose fibers, textured fibers and the like to provide increased compliance. With the three components in place, a composite graft according to the present invention is formed by heating the structure to a temperature at or above the melting point of the material from which the intermediate component is formed but below the melting temperature or temperatures of the material from which the outer component is formed and of the material from which the inner component is formed. In this temperature range, the intermediate component may melt without the melting of either the inner component and the outer component, thereby mechanically bonding the inner component to the outer component.

The multi-component system of the present invention provides a number of advantages over conventional grafts. The use of a durable material, such as PET or ePTFE, from which the outer component may be formed is advantageous because of the known strength that such material has in the body. Devices made from PET or ePTFE when implanted in the body are known to maintain their integrity for some three decades. Further advantageously, it has been found that a graft—made according to the present invention and in which PET is used to form the outer component —has a burst strength and a tensile strength that is some two times greater than that of a conventional graft. Such strength prevents the dilation of the vessel in response to, for example, an increase in blood flow and/or pressure, creep relaxation of the urethane, biodegradation of the urethane, plasticization of the urethane, etc. Decreases in the strength of PET that may occur after implantation due, for example, to the absorption of water after implantation, are minimal as Dacron has a low water absorption ability.

The use of a knitted pattern according to which the durable strands of the outer component may be configured is advantageous due to the increased compliance such a pattern provides. As stated above, a durable material such as PET is recognized as a strong yet not necessarily compliant material. However, by knitting the strands from which the outer component is formed into a network, a compliant reinforcing outer component is formed. The use of such a material from which to form the outer component in the three component system of the present invention advantageously provides a strengthened, yet compliant graft.

The winding of strands of synthetic material, such as polyurethane over a mandrel to form an inner component is further advantageous because of the resultant porosity of the component. While the intermediate component may be made porous, for example, by painting synthetic material over the inner component and utilizing the phase inversion method or the particle elution method to form a porous matrix, preferably the intermediate component is formed by winding strands of synthetic material, such as polyurethane over the inner component, to provide a highly porous network. Utilizing strands of PET configured in a knitted pattern to form the outer reinforcement component further provides a porous network. Advantageously, by combining these individually porous components together in a composite graft, a totally porous integral graft results. Porosity is an advantage in medical devices, such as vascular grafts, because an open structure allows vascular fluid to infiltrate and communicate to and from the surrounding tissue and the interior of the graft and allows the ingrowth of tissue to occur within the graft. Accordingly, the device becomes better incorporated into the surrounding tissue, thereby further securing the device within the implantation site.

Uniting the three components into a single composite graft advantageously facilitates the use of the device. The graft may be implanted without the need for any assembly immediately prior to use. The graft may be also cut and/or sutured as a unit without the need for the separate cutting and/or suturing of each component. Methods for cutting the composite graft include scalpel, scissors, hot wires, shaped blades, and the like. The speed with which the graft may be implanted is a particularly distinct advantage since the device is implanted only when a patient is undergoing surgery.

The use of a polycarbonate intermediate rather than, for example, a polyether urethane to make the polyurethane material from which the inner component is preferably made is advantageous as the resultant inner component better resists degradation. The resistance to degradation is further aided by the addition of antioxidant to the material from which the inner component is formed.

It is, accordingly, a general object of the present invention to provide an improved graft.

Another object of the present invention is to provide an integral improved graft made from a composite of layers of synthetic materials.

It is also an object of the present invention to provide a graft that is totally porous thereby facilitating the incorporation of the graft into the site of implantation.

An additional object of the present invention is to provide an improved graft having an outer component which strengthens the device without significantly impairing the overall compliance of the graft.

These and other objects, features and advantages of this invention will be clearly understood and explained with reference to the accompanying drawings and through a consideration of the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

In the course of this description, reference will be made to the attached drawings, wherein:

FIG. 1 is a perspective view illustrating an embodiment of a composite vascular graft according to the present invention with an outer component of knitted durable material positioned over and bound by an intermediate component to an inner component; and

FIG. 2 is a cross sectional view of the composite vascular graft according to the present invention illustrated in FIG. 1.

DESCRIPTION OF THE PARTICULAR EMBODIMENTS

The present invention is a composite vascular graft—generally designated as 21 in FIGS. 1 and 2—comprised of an inner component 31, an intermediate component 41, and an outer component 61. The inner component will be described first.

Inner component 31 is fabricated from a biocompatible synthetic material, preferably polyurethane, having a melting temperature that is, at a minimum, greater than the melting temperature of the material from which the intermediate component is formed. Preferably, in those embodiments in which the inner component 31 is formed from polyurethane, it is made with an aromatic polycarbonate urethane. Polycarbonate urethanes are preferred over polyether urethanes due to

their superior biostability. The aromatic polycarbonate urethanes have melting points in the range of 150° C. to 230° C. This is in contrast to some aliphatic polycarbonate urethanes that have melting points between 90° C. and 130° C. It can also be appreciated that the inner member may be composed of non-urethane materials such as silicone rubber, polyolefins, fluoroelastomers, ePTFE, and the like. An antioxidant, such as Irganox 1010, may be added to the inner member to further prevent degradation of the strands from which the inner component is formed. The melting temperature of the material from which the inner component is preferably formed exceeds 150° C.

The methods by which the inner component **31** may be fabricated include those disclosed in U.S. Pat. No. 4,475,972 to Wong. According to a fabrication method taught in the Wong patent, termed "solution processing", the inner component material is dissolved in a solvent and forced out of one or more orifices to form one or more continuous fibers. The fibers are drawn directly onto a rotating mandrel. As the distributor or spinnerette reciprocates along the mandrel, non-woven strands are layered on top of each other to form porous, non-woven network of criss-crossing strands.

The intermediate layer **41** is formed of a biocompatible synthetic material, such as a polyolefin, a silicone thermoplastic material, etc., or preferably a polyurethane material having a melting temperature less than that of the materials from which the inner and outer components are formed. The intermediate layer can be drawn in the manner described in the Wong patent so that at least one fibrous layer is laid over the inner component **31** to form a porous intermediate layer. This intermediate layer can be spun from solution as described in the Wong patent or can be simply wound onto the inner layer from a spool of the biocompatible low melting point material. Alternatively, phase inversion or particle elution methods may be used to form a porous intermediate component. Examples of suitable low melting point biocompatible materials include the aliphatic polycarbonate or polyether urethanes with melting points of 90° C. to 130° C. The resultant porous, non-woven network of strands forming the intermediate component **41**, as drawn over the inner component **31** form a unit **51** which facilitates the transmission of fluid.

Mesh **61**, composed of strands of durable material, such as PET or ePFTE , knitted or woven in a generally elongated cylindrical shape and whose inner surface **63** is of a diameter equal to or slightly larger than the diameter of the outer surface **45** of the intermediate component **41**, is fitted over the intermediate component **41**. To provide compliance to the mesh network of strands from which the outer component is formed, the strands are configured preferably in a knitted pattern. Tricot or double tricot warp knit patterns are preferred. Double tricot patterns are further advantageous because they provide greater depth to the outer component **61** and thereby facilitate the acceptance of and retention of sutures and tissue ingrowth through the graft **21**. Tricot or double tricot warp patterns are further advantageous in that they are generally more interlocking than other patterns and therefore resist "running". Other acceptable patterns according to which the strands of the outer component **61** may be formed include jersey or double jersey patterns, woven or braided and multiple layers of the above. Also, the fibers comprising the outer structure may be textured or non-textured and be of a variety of deniers.

The outer component **61** as positioned over the inner component and intermediate component is heated to a temperature equal to or greater than the temperature at which the material from which the intermediate component **41** is formed melts but less than the temperature and/or temperatures at which the material or materials from which the outer component and from which the inner component **31** is formed melts. When the inner component **31** is formed from the preferred material described above, the components are heated to a temperature less than 150° C. but greater than the temperature at which the material from which the intermediate component **41** is formed melts, such as 110° C. By maintaining the three components at such a temperature for a period of time, such as ten minutes, the intermediate component melts thereby securing the outer component **61** and the inner component **31** to each other. To further ensure the secure full engagement of the outer component **61** by the melted intermediate component **41**, the outer component **61** may be forcefully pressed into the intermediate component **41** during the heating step such as mechanically and/or with or under pressure. After heating, the united three components are cooled thereby providing an integral mesh composite graft **21**.

A mesh composite graft **21** according to the present invention is totally porous and compliant, yet advantageously includes a load bearing component, the outer component **61**, which adds strength to the graft and prevents the failure of the graft even in response to greater fluid volume pressures from within, creep relaxation of the inner member and possible biodegradation effects of the inner member.

The advantageous compliance of the composite graft may be adjusted by varying the number of strands from which the inner component and the intermediate component **41** are formed. The compliance of the composite graft **21** may be adjusted also by varying the materials from which the inner component **31** and the intermediate component **41** are formed while maintaining the relationship that the intermediate component **41** must melt at a lower temperature than the materials from which the outer component and the material from which inner component **31** is formed. The compliance of the mesh composite graft **21** may be adjusted further by adjusting the angle at which the strands of the inner component **31** and/or the strands of the outer component **61** are laid down—a higher angle provides a less compliant component and thereby a less compliant graft.

The compliance may be adjusted even further by altering the knitting parameters, such as courses and wales per inch, the stitch density, the fiber denier, the number of strands per filament, the composition of the fibers and filaments such as a mixture of PET and Spandex compositions and whether the outer member is knitted, woven or braided.

The advantageous overall porosity of the graft **21** may be adjusted also in a number of ways. In addition to varying the size and number of the strands from which the inner component **31** and intermediate component **41** are formed, the strands of each component may be drawn at different angles to provide decreased pore size and resultant decreased porosity. Similarly, the porosity of the outer component **61**, and thereby the porosity of the composite graft **21** may be varied by varying the

size and/or number of the strands and stitch density used to make the outer component mesh.

It can also be appreciated that the outer component need not be a tube formed specifically for this purpose from materials as above but can also be made from a vascular graft preformed from a porous matrix material such as ePTFE. One such graft is manufactured by W. L. Gore and marketed as a Gore-Tex graft. The ePTFE graft may be sheathed over the previously described inner and intermediate components and heat fused into a similar composite graft described in this document. Similarly, the inner members may be a Gore-Tex graft, the intermediate component, a heat fusable thermoplastic, and the outer component, a Dacron knit.

Regardless of the configuration of the inner, intermediate and outer components of the graft, i.e. be it spun, salt eluted, phase inverted, wound with an outer PET mesh, or in which an ePTFE configuration is utilized, the resultant composite graft 21 as formed may be implanted in vascular locations and retained in place through conventional methods, such as suturing. The preferred use of PET, knitted in a preferred tricot or double tricot pattern, from which to make the outer component 61 of the graft 21 provides a graft having a greater thickness than grafts without such a load bearing component. The outer component 61 facilitates the greater retention of the sutures within the graft.

It will be understood that the embodiments of the present invention as described are illustrative of some of the applications of the principles of the present invention. Modifications may be made by those skilled in the art without departure from the spirit and scope of the invention.

We claim:

1. A composite graft for implantation within a host, comprising:

an inner component made from wound, criss-crossing layers of fibers of a first biocompatible synthetic material and shaped to form a porous generally elongated cylindrical shape having a lumen through which blood may flow, said inner component having an outer surface;

an intermediate compliant bonding component made from wound, criss-crossing layers of fiber of a second biocompatible synthetic material, said second material having a melting point lower than the melting point of said first material and lower than the melting point of polyethylene terephthalate, said intermediate component positioned generally over and substantially covering said outer surface of said inner component, said intermediate component being porous and having an outer surface;

said intermediate component as positioned over said outer surface of the inner component forming a fluid transmission unit;

an outer component made from a mesh formed from strands of matrices of durable material, said strands or matrices preformed in a generally elongated cylindrical shape having a lumen therethrough and a diameter which is approximately equal to the outside diameter of said intermediate component, said outer component is positioned over and substantially covering said outer surface of the intermediate component; wherein each said outer component and said inner component is bonded to said intermediate component when each of the components is heated to a temperature less than the melting temperature of said firs material and said durable material thereby securing said components to each other to form a totally porous mesh composition graft.

2. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said inner component is made is polyurethane

3. The mesh composite graft according to claim 2, wherein said polyurethane is made with a polycarbonate intermediate.

4. The mesh composite graft according to claim 2, wherein said polyurethane is made with an aromatic polycarbonate urethane.

5. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said inner component is made is silicone rubber.

6. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said inner component is made is a polyolefin.

7. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said inner component is made is a fluoroelastomer.

8. The mesh composite graft according to claim 3, wherein said polyurethane includes an antioxidant to prevent degradation of said inner component.

9. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said intermediate component is made is polyurethane.

10. The mesh composite graft according to claim 9, wherein said polyurethane is an aliphatic polycarbonate.

11. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said intermediate component is made is a polyolefin.

12. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said intermediate component is made is a silicon thermoplastic material.

13. The mesh composite graft according to claim 1, wherein said outer component is further secured to said fluid transmission unit by pressing said outer component into said intermediate component during heating.

14. The mesh composite graft according to claim 1, wherein said mesh is formed by knitting said strands of polyethylene terephthalate.

15. The mesh composite graft according to claim 1, wherein said mesh is formed by knitting said strands of polyethylene terephthalate in a tricot pattern.

16. The mesh composite graft according to claim 1, wherein said mesh is formed by knitting said strands of polyethylene terephthalate in a double tricot pattern.

17. The mesh composite graft according to claim 2, wherein said mesh is formed from strands of expanded polytetrafluoroethylene.

18. The mesh composite graft according to claim 2, wherein said mesh is preformed from strands of polytetrafluoroethylene.

19. The mesh composite graft according to claim 2, wherein said mesh is a preformed porous matrix of expanded polytetrafluoroethylene.

* * * * *

DEC 4 1992 PAT. & TRADEMARK OFF

ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

December 2, 1992
(Date of Deposit)

Matthew S. Goodwin
Name of applicant, assignee, or Registered Representative

(Signature)

DEC 10 1992

GROUP 1500

December 2, 1992
(Date of Signature)

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

AMENDMENT

Dear Sir:

Please reconsider the above-identified application in view of the following remarks. These remarks are subdivided into a discussion of the claimed invention, and an analysis of the rejection, to facilitate an understanding of the significant differences between the cited art and the claimed invention.

Discussion of the Invention

A proper understanding of the invention is critical for appreciating the dissimilarities between the invention and the teachings of the cited references.

In a broad sense, the invention is a braided suture which contains dissimilar filaments of first and second fiber-forming materials. However, the proper characterization of the claimed suture goes far beyond this simple description.

The braided suture is made up of multifilament yarns. A multifilament yarn is a bundle of individual filaments which are integrated to form a single unit, that is, an individual multifilament yarn. The braided suture has a first and second set of these multifilament yarns in a braided construction. Each of the filaments of the first set of yarns is composed of a first fiber-forming material. Similarly, each of the filaments of the second set of yarns is composed of a second fiber-forming material.

The importance of the construction of the first and second set of yarns cannot be diminished. The braided construction is not accurately characterized by simply referring to a suture with filaments of dissimilar fiber-forming materials in a braided construction. Rather, filaments of a first fiber-forming material must be bundled to prepare a first set of multifilament yarns, and filaments of the second fiber-forming material must also be bundled to prepared the second set of multifilament yarns.

Once an understanding of the composition and construction of each set of first and second yarns is achieved, the importance of a further characterization of the braid construction can now be understood and appreciated. One yarn from the first set of yarns is in direct intertwining contact with a yarn from the second set of yarns. This limitation does not simply mean that the dissimilar filaments are fabricated into a braided construction, that is, dissimilar filaments are in "intertwining contact". Rather it is a multifilament yarn which is in direct intertwining contact with another multifilament yarn. Again, it is important to emphasize here that the multifilament yarns are integrated bundles of individual filaments, and it is this integrated bundle of filaments of a first fiber-forming material which is in direct intertwining

contact with another integrated bundle of individual filaments of a second fiber-forming material.

One way to accurately characterize the braided suture of this invention is to refer to it as a structured mechanical blend of dissimilar fiber-forming materials. The fiber-forming materials are first arranged into integrated bundles to form multifilament yarns and then these multifilaments yarns are further arranged so that at least one yarn from the first set of yarns directly intertwines with a multifilament yarn from the second set of yarns. This can be contrasted with a random, braided construction where filaments of dissimilar fiber-forming materials are randomly braided with one another to form a braided suture.

The heterogeneous braids of this invention exhibit truly outstanding and surprising properties. The integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual multifilament yarns (see the specification at page 4, lines 30-33). In the preferred embodiment, each yarn from the first set of multifilament yarns is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar multifilament yarns (see the specification at page 6, lines 28-31, and claim 15). In this way, yarn compatibility can be further enhanced and the overall physical and biological properties of the heterogeneous braid can be further improved as well.

What is truly surprising with respect to the claimed heterogeneous braid construction is that certain bulk properties of the claimed braid are better than what one skilled in the art would expect. A skilled artisan would expect the properties of the braid to simply follow the "Rule of Mixtures", where the bulk property

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000237

measured would be estimated to be a weighted average of its component properties. Upon studying the Examples in the specification, it will be noted that the bending rigidity of the heterogeneous braids in Examples 1 and 2 do not follow the Rule of Mixtures, but surprisingly show an enhanced bending rigidity relative to the weighted average of their filament components. This behavior is not achieved when dissimilar individual filaments are randomly braided to form the braided suture.

In setting forth the claimed invention, the heterogeneous braid does not encompass braided sutures with randomly braided individual filaments, as described in detail above. Further, the claimed heterogeneous braid could not be construed to cover known braids which have a core of longitudinally extending yarns composed of filaments of a first fiber-forming material, and a sheath of braided yarns composed of a second set of filaments of a dissimilar fiber-forming material. This braid construction does not fall within the scope of the claimed braid because these sheath yarns are not in direct intertwining contact with any of the core yarns. In other words, none of the sheath yarns are braided about a core yarn, but simply shroud the core yarns to form the sheath construction.

Analysis of the Rejection

1. Claims 21 and 23 were rejected under 35 USC §102(b) as being clearly anticipated by Doddi et al. ("Doddi"). Doddi does not anticipate the claimed suture, and therefore this rejection should be withdrawn.

The Examiner has correctly pointed out that Doddi does indeed disclose a surgical suture comprising filaments of two different polymers in a braided configuration (column 9, lines 47-56).

However, as discussed in detail above, more is required to meet the limitations of the claimed suture than just a disclosure concerning filaments of two different polymers in a braided configuration. Doddi teaches nothing more than braiding individual filaments, and fails to provide any guidance as to how that braiding should be carried out. Therefore, one skilled in the art would be lead to believe that what Doddi had in mind was to simply braid individual filaments in a randomized fashion to fabricate a multifilament suture. It is important enough, however, to reemphasize again that the claimed braid requires the bundling of individual filaments into an integrated unit to form a multifilament yarn. It is this multifilament yarn which directly intertwines with another multifilament yarn to form Applicants' braid construction.

Since Doddi only teaches randomly braiding filaments of dissimilar fiber-forming materials, it does not anticipate the claimed braided suture. Doddi simply fails to enable one skilled in the art to construct a braided suture in the manner set forth by Applicants, and it is axiomatic that a reference which lacks enablement is deficient as a reference to anticipate a claimed invention. Accordingly, it is respectfully requested that the rejection of claims 21 and 23 under 35 USC §102(b) as being clearly anticipated by Doddi be withdrawn.

2. Claims 22 and 24 were rejected under 35 USC §103 as being unpatentable over Kaplan et al. ("Kaplan") taken with Doddi. The Examiner asserts it would have been obvious to substitute PET and PTFE fibers of Doddi for the filaments of Kaplan to arrive at Applicants' claimed suture. Applicants respectfully traverse this rejection for the reasons given below.

The Examiner correctly points out that Kaplan discloses a ligament prosthesis made from a core component and a braided sheath component as illustrated in Figures 3 and 4, and discussed at column 8, line 65, through column 9, line 34. However, Kaplan suffers from the same deficiencies as does Doddi, and therefore fails to teach or suggest the claimed braided suture.

Firstly, the Examiner has made specific reference to the Kaplan specification regarding the makeup of the core components and the sheath yarn component. The only component which has a braided construction is the sheath yarn component. It is clear from Figure 3 of Kaplan that none of the sheath yarn components are in direct intertwining contact with the core component. In other words, the sheath yarn component is a true "sheath" which shrouds the core but is not in any way integrally braided with the core. Therefore, since the core is not in a braided construction, its composition is irrelevant with respect to the claimed braided suture.

When the focus is shifted to the more relevant aspect of the Kaplan disclosure, specifically the sheath yarn component, the Examiner has correctly pointed out that the sheath yarn component may be "fabricated from individual filaments having more than two different chemical compositions, one or more of which optionally being non-absorbable". (Column 9, lines 25-28). However, Kaplan neither teaches nor suggests how his sheath yarn component is to be fabricated from these dissimilar individual filaments, nor is there any guidance to one skilled in the art as to how such dissimilar individual filaments are to be braided. Accordingly, just as was the case with the deficient Doddi reference, one skilled in the art could only be lead to randomly braid the dissimilar individual filaments into a braid construction.

The teaching of Kaplan once again lacks the essence of the claimed invention, which is: bundled filaments of a first fiber-forming material form a first set of a multifilament yarns, and at least one of these multifilament yarns is intertwined with a multifilament yarn composed of bundled filaments of a second fiber-forming material. To put it bluntly, Kaplan teaches randomized braiding, and the claimed suture sets forth a structured braid. This difference is not trivial, as pointed out with reference to the discussion of Applicant's specification, and particularly Examples 1 and 2.

It should also be pointed out here that even if Doddi and Kaplan were combined, their combined teachings would still fail to meet the limitations of the claimed braided suture. This is so because neither reference, taken singularly or in combination, discloses a structured braid set forth in the claims, but merely sets forth randomized braiding of individual filaments.

For all of the reasons given above, especially taken in light of the detailed discussion of the claimed braided suture and its surprising advantages, the rejection of claims 22 and 24 under 35 USC §103 as being unpatentable over Kaplan taken with Doddi is improper. Accordingly, it is respectfully requested that this rejection be withdrawn.

3. Applicants acknowledge with gratitude the withdrawal of the rejection of claims 21-24 under 35 USC §103 as being unpatentable over Burgess, expressed in the previous Office Action dated July 8, 1992. (Paper No. 3). It is presumed that Applicants' response to this rejection in their Amendment dated August 6, 1992, spelling out the distinctions between Burgess and the claimed

invention, clearly convinced the Examiner that the claimed surgical suture is patentable over this art.

4. The prior art made of record and not relied upon by the Examiner is duly noted, and does not affect the patentability of Applicants' claimed invention.

5. Since all formal requirements appear to have been met, and the claimed invention is patentable over the art of record or any other art of which Applicants are aware, Applicants respectfully solicit a Notice of Allowance at the Examiner's earliest convenience.

Respectfully submitted,



Matthew S. Goodwin
Attorney for Applicant
Reg. No. 32,839

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2794
December 2, 1992

Case Docket No.: ETH-782

In re application of Alastair W. Hunter et al.

Serial No. 838,511

Filed 4 February 19, 1992

For STERILIZED HETEROGENEOUS BRAIDS

MAIL ROOM DEC 21 1992 PAT & TRADEMARK OFF

RECEIVED DEC 1 0 1992 GROUP 1500

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Sir:

Transmitted herewith is an amendment in the above-identified application.

[ ] No additional fee is enclosed because this application was filed prior to October 25, 1965 (effective date of Public Law 89-83).

[X] No additional fee is required.

[X] One stamped, self-addressed postcard for the PTO Mail Room date stamp.

[ ] Petition For Extension of Time and charge to Deposit Account of Appropriate Fee.

The fee has been calculated as shown below.

CLAIMS AS AMENDED

(1)	(2)	(3)	(4)	(5)	(6)	(7)
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDITIONAL FEE
TOTAL CLAIMS	* 24	minus	** 24	= 0	x $22	= $ 000.00
INDEP. CLAIMS	* 1	minus	*** 3	= 0	x $74	= $ 000.00
			TOTAL ADDITIONAL FEE FOR THIS AMENDMENT			$ 000.00

* If the entry in Col.2 is less than the entry in Col.4, write "0" in Col.5
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

[X] Charge $ 000.00 to Deposit Account No. 10-750/ETH-782/MSG. Three copies of this sheet are enclosed.

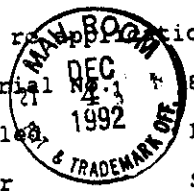
[X] Please charge any additional fees in connection with the filing of this communication, or credit overpayment, to Deposit Account No. 10-750/ETH-782/MSG. Three copies of this sheet are enclosed.

[ ] A check in the amount of $ _____ is attached.

Matthew S. Goodwin
Attorney of Record
Reg. No. 32,019

Matthew S. Goodwin
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933-7003
(908) 524-2791
December 2, 1992

Case Docket No.: ETH-782

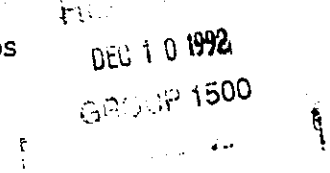


In re application of Alastair W. Hunter et al.

Serial No.: 838,511

Filed: February 19, 1992

For STERILIZED HETEROGENEOUS BRAIDS



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INDEP. CLAIMS	* 1	minus	*** 3	= 0	x $74	= $ 000.00
			TOTAL ADDITIONAL FEE FOR THIS AMENDMENT			$ 000.00

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*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

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Reg. No. 32,019

Matthew S. Goodwin
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933-7003
(908) 524-2791
December 2, 1992

Case Docket No.: ETH-782

In re application of Alastair W. Hunter et al.

Serial No. 838,511

Filed February 19, 1992

For STERILIZED HETEROGENEOUS BRAIDS

MAIL ROOM DEC 4 1 1992 U.S. PATENT & TRADEMARK OFFICE

DEC 1 0 1992
GROUP 1500

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

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			TOTAL ADDITIONAL FEE FOR THIS AMENDMENT			$ 000.00

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[ ] A check in the amount of $ _____ is attached.

Attorney of Record
Reg. No. 32,019

Matthew S. Goodwin
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933-7003
(908) 524-2791
December 2, 1992

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address : COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/838,511	02/19/92	HUNTER A	ETH-782

EXAMINER	
RAYMOND, C	
ART UNIT	PAPER NUMBER
1504	7

15N1

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

DATE MAILED: 03/18/93

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☑ Responsive to communication filed on Dec. 2, 1992 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☑ Claims 1 - 24 are pending in the application.
   Of the above, claims 1 - 20 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 21 - 24 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 9-89)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 21 is rejected under 35 U.S.C. § 102(e) as being anticipated by Kaplan et al.

Kaplan et al. discloses a connective tissue prosthesis comprising a braided sheath yarn component and a core yarn component. The braided sheath comprises braided filaments or braided filament bundles (column 9, lines 4-12). A sheath component containing filaments of different chemical compositions is specifically disclosed (column 9, lines 12-16). Claim 21 is therefore anticipated by Kaplan et al.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as

prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 21-24 are rejected under 35 U.S.C. § 103 as being unpatentable over Doddi et al. taken with Kaplan et al.

Doddi et al. disclose a surgical suture comprising filaments of two different polymers in a braided configuration (column 9, lines 47-56). Suitable biocompatible, non absorbable filaments include PET and PTFE (column 9, lines 51-53).

Kaplan et al. discloses a ligament prosthesis comprising a core component and a braided sheath component. The core component is "made up of one or more biocompatible, essentially non-bioabsorbable..." filaments (column 9, lines 1-3). The sheath yarn component may be fabricated from one or more non-bioabsorbable fibers (column 9, lines 25-28). It would have been obvious to form the sheath component of the device of Kaplan et al. from PTFE and PET. PTFE is known to inpart improved knot run down properties to sutures (see Block U.S. Pat. No. 3,527,650). PET is noted for its low cost and high strength. The core yarn component must be non-bioabsorbable (column 4, lines 45-46). Since PET is non-bioabsorbable, biocompatible and has the desirable properties noted above, its use as the core component would have been obvious. Claims 21 and 22 are therefore unpatentable over Doddi et al. taken

with Kaplan et al.

Kaplan et al. fail to disclose the prosthesis of their invention connected to a needle. Prosthesis are, however, implanted in the body using a needle. Claims 23 and 24 are therefore unpatentable over Doddi et al. taken with Kaplan et al.

Applicant's arguments with respect to claims 21-24 have been considered but are deemed to be moot in view of the new grounds of rejection.

Any inquiry concerning this communication should be directed to Chris Raimund at telephone number (703) 308-2374.

C. Raimund:pdw
February 25, 1993

GEORGE F. LESMES
SUPERVISORY PATENT EXAMINER
GROUP 150



ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

August 4, 1993
(Date of Deposit)

Hal Brent Woodrow
Name of applicant, assignee, or Registered Representative

Hal Brent Woodrow
(Signature)

August 3, 1993
(Date of Signature)

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SEP 1 1993

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Submitted herewith on Form PTO-1449, is a listing of documents known to the Applicants and/or their attorney in compliance with the requirements of 37 C.F.R. §1.56. Copies of these documents are also being submitted.

These documents are being submitted after the first Office Action. Accordingly, the Patent and Trademark Office is authorized to charge Account No. 10-750/ETH-782/HBW the appropriate fee under 37 C.F.R. §1.17(p) for the citation of these documents. Three copies of this statment are included.

CS14107 09/08/93 07838511 10-0750 140 126 200.00CH

Consideration of the cited documents and making the same of record in the prosecution of the above-noted application are respectfully requested.

Respectfully submitted,

Hal B. Woodrow
Reg. No. 32,501

JOHNSON & JOHNSON
One Johnson and Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976

ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

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Hal Brent Woodrow
(Signature)

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Consideration of the cited documents and making the same of record in the prosecution of the above-noted application are respectfully requested.

Respectfully submitted,

Hal B. Woodrow
Reg. No. 32,501

JOHNSON & JOHNSON
One Johnson and Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976

Sheet 1 of 1

Form PTO-1449

INFORMATION DISCLOSURE CITATION IN AN APPLICATION

Docket No.	Serial No
ETH-782	838,511
Applicant: Alastair W. Hunter, et al.	
Filing Date: Feb. 19, 1992	Group Art Unit: 1504

U.S. PATENT DOCUMENTS

Exam'r Init.	Document No.	Date	Name	Class	Sub Class	File Date
CWR	3,463,158	8/26/69	Edward Emil Schmitt, et al.	606	228	1/9/67
CWR	4,979,956	12/25/90	Thomas A. Silvestrini	623	13	7/10/89
CWR	3,636,956	1/25/72	Allan K. Schneider	128	335.5	5/13/70
CWR	4,141,087	2/27/79	Shalaby W. Shalaby, et al.	3	1	1/19/77
CWR	4,959,069	9/25/90	Karl W. Brennan, et al.	606	228	10/20/89

FOREIGN PATENT DOCUMENTS

Exam'r Init.	Document No.	Date	Country	Class	Sub Class	Translate Yes	Translate No
CWR	GB 2 082 213	8/16/80	Great Britian	—	—	✓	

OTHER REFERENCES (include author, title, date, pertinent pages, etc.)

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000254

Examiner: [signature] Date Considered: NOVEMBER 8, 1993

Examiner: Initial if citation considered, whether or not citation is in confirmance with MPEP §609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.



DOCKET NO. ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

ASSOCIATE POWER OF ATTORNEY

Sir:

In the matter of the above-identified application, I hereby appoint Hal Woodrow (Reg. No.32,501), whose postal address is One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933-7003, my associate attorney to prosecute said application, to make alterations and amendments therein, to file continuing applications claiming the benefit of said application, to receive the patent and to transact all business in the Patent Office connected with said application.

I request all communications with respect to said application be addressed to Audley A. Ciamporcero, Jr., One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933-7003. All telephone calls should be directed to Hal Woodrow at (908) 524-2976.

Signed at New Brunswick, in the County of Middlesex and State of New Jersey, this 3rd day of August, 1993.

Attorney for Applicant(s)
Jason Lipow Reg. No. 25509

One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
DATED: August 3, 1993

MAIL AUG 9 1993 PAT & TRADE MARK

CKET NO. ETH-782 Cp154

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

August 4, 1993
(Date of Deposit)

Hal B. Woodrow
Name of applicant, assignee, or Registered Representative

Hal Brent Woodrow
(Signature)

August 3, 1993
(Date of Signature)

SEP 1 1993

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

PETITION FOR EXTENSION OF TIME
AND AUTHORIZATION TO CHARGE
DEPOSIT ACCOUNT THEREFOR

Dear Sir:

Applicant(s) petition(s) the Commissioner of Patents and Trademarks to extend the time for response to the Office Action dated March 18, 1993 for two (2) month(s) from June 18, 1993 to August 18, 1993. An Amendment responding to the aforesaid Office Action is being filed concurrently herewith.

Please charge Deposit Account No. 10-750/ETH-782/HBW in the name of Johnson & Johnson for the cost of filing this Petition. Three copies of this Petition are enclosed.

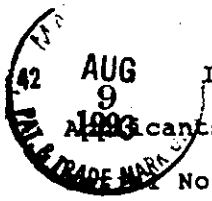
P 30003 08/30/93 07838511 10-0750 030 116 360.00CH

Respectfully submitted,

Hal Brent Woodrow

Hal B. Woodrow
Reg. No. 32051
Attorney for Applicant(s)

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
DATE: August 4, 1993



DOCKET NO. ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

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August 4, 1993
(Date of Deposit)

Hal B. Woodrow
Name of applicant, assignee, or Registered Representative

Hal Brent Woodrow
(Signature)

August 3, 1993
(Date of Signature)

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

SEP 1 1993

PETITION FOR EXTENSION OF TIME
AND AUTHORIZATION TO CHARGE
DEPOSIT ACCOUNT THEREFOR

Dear Sir:

Applicant(s) petition(s) the Commissioner of Patents and Trademarks to extend the time for response to the Office Action dated March 18, 1993 for two (2) month(s) from June 18, 1993 to August 18, 1993. An Amendment responding to the aforesaid Office Action is being filed concurrently herewith.

Please charge Deposit Account No. 10-750/ETH-782/HBW in the name of Johnson & Johnson for the cost of filing this Petition. Three copies of this Petition are enclosed.

SEP 1 1993

Respectfully submitted,

Hal Brent Woodrow
Hal B. Woodrow
Reg. No. 32051
Attorney for Applicant(s)

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
DATE: August 4, 1993

AUG 9 1993

ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

August 4, 1993
(Date of Deposit)

Hal B. Woodrow
Name of Applicant, Assignee, or Registered Representative

(Signature)

August 3, 1993
(Date of Signature)

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

AMENDMENT

Dear Sir:

This amendment is responsive to the Office Action of March 18, 1993.

SEP 1 1993

IN THE CLAIMS

Please amend claim 21 as follows:

(Once Amended)

~~21~~. A surgical suture [comprising] consisting essentially of a [the] heterogeneous braid [of claim 1] composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core.

26

CLAIM 2

REMARKS

Please note that the attorney prosecuting this application for the assignee, Johnson & Johnson, is now Hal Brent Woodrow (Reg. No. 32,501). This change has been authorized by the Associated Power Attorney submitted herewith. No change in the address for correspondence is necessary.

Claim 21 has been amend to place this claim in proper form for allowance. Claim 21 as amended claims a heterogeneous braid composed of a first and second set of yarns. The first set of yarns are made of a fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP, and PE materials. The second set of yarns are made of a fiber-forming material selected from the group consisting PET, nylon and aramid materials. Support for there amendments may be found in the specification on page 4, lines 12-22 and page 8, lines 3-23. Accordingly, applicants request entry of this amendment and reconsideration of claim 21.

The rejection of claim 21 under 35 U.S.C. §102(e) as being anticipated by Kaplan et al. has been reviewed. However, applicants respectfully submit that claim 21 as amended is not anticipated by Kaplan. Kaplan, as stated by the Examiner, describes a connective tissue prosthesis comprising a braided sheath yearn component and a core yarn component. The sheath yarn being a biocompatible yarn that is bioabsorbable or semi-bioabsorbable (column 9 lines 10-12). In one embodiment the sheath yarn could also contain a non-bioabsorbable yarn of one or more chemical composition (column 9 line 25-27). Claim 21 as amended does not claim a sheath yarn composed of a bioabsorbable yarn. Accordingly, Kaplan et al. does not anticipate claim 21 under 35 U.S.C. § 102(e). Therefore, applicants request reconsideration and withdrawal of the rejection of claim 21 as being anticipated by Kaplan et al.

Applicants have also reviewed the rejection of claims 21-24 under 35 U.S.C. § 103 as being unpatentable over Doddi et al. taken with Kaplan et al. However, applicants respectfully submit that claims 21-24 are patentable over these documents.

Doddi et al. describes (column 9, lines 46-56) multifilament sutures composed of p-dioxanone and/or 1,4 dioxepan-2-one and alkyl substituted derivatives that may be woven, braided or knitted, either alone or in combination with nonabsorbable fibers. Although Doddi is a significant contribution to the art, Doddi does not describe heterogeneous braids formed from a first set of yarn composed of a plurality of filaments formed from materials selected

from the group consisting of PTFE, FEP, PFA PVDF, PETFE, PP and PE; and a second set of yarn composed from a plurality of filaments formed from materials selected from the group consisting of PET, nylon and aramid. Accordingly, Doddi alone would not render the present invention obvious.

Kaplan et al. as discussed previously describes a prosthesis comprising a core component and a braided sheath component. The sheath component which is designed to "erode over time" (column 9, line 52) to leave only the nonabsorbable core component. The sheath, however, may optionally have, in addition to the bioabsorbable sheath yarn, one or more non-bioabsorbable filaments. Applicants, therefore, respectfully submit that Kaplan does not suggest or disclose combining a first set of nonabsorbable yarns (i.e. PTFE) and a second set of nonabsorbable yarn (i.e. PET). In fact, Kaplan teaches away from this combination.

In column 2, Kaplan describe one of the objects of their invention as being "a prosthesis being formed of a composite yarn wherein an elastic core yarn is wrapped with a relatively inelastic, bioabsorbable or semi-absorbable sheath yarn so as to exhibit the stress-strain properties of natural tissue" (column 2, lines 36-41). In column 4, Kaplan describes fluorinated hydrocarbons, polypropylene and polyethylene as elastic core polymers as opposed to the inelastic sheath polymers desired in the sheath. Thus, Kaplan appears to suggest that the sheath yarns listed by the applicant in claim 21 should not be used as in sheaths. Applicants respectfully submit that in view of Kaplan teaching away from the present invention that the combination of Kaplan with Doddi does not render the present invention obvious. Accordingly, Applicants request reconsideration and withdrawal of the rejection of claims 21-24.

The citation of Block (U.S. Patent No. 3,527,650) has also been considered, but is respectfully submitted to be non-analogous art. Block describes the use of PTFE particles on the external surface of a PET suture as a lubricant. Block, however, does not suggest or disclose PTFE fiber as having a lubricating effect. Therefore, Block's use of PTFE particles does not suggest or disclose the use of PTFE fibers in braids.

Applicants also wish to alert the Examiner to the applicants' intent to change the inventorship because of the reduced scope of the claims. Dennis D. Jamiolkowski will no longer appear as an inventor if the present claims are allowed. Papers to effectuate this changed inventorship will be submitted when one or more of the present claims are indicated to be allowable.

Respectfully requested,

Hal Brent Woodrow

Hal B. Woodrow
Reg. No. 32,501

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
Date: August 3, 1995

GP 1504

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84 NOV 12 1993
PAT. & TRADEMARK OFF.

ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

November 9, 1993
(Date of Deposit)
Hal Brent Woodrow
Name of applicant, assignee, or Registered Representative

Hal Brent Woodrow
(Signature)

November 9, 1993
(Date of Signature)

RECEIVED GROUP 150
NOV 10 1993

11-24-93
7560
Raimund

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

SUPPLEMENTAL AMENDMENT

Dear Sir:

This Supplemental Amendment is an amendment to the Amendment submitted on August 4, 1993.

REMARKS

Applicants have noticed that the Amendment of August 4, 1993 under the heading "In The Claims" states, "Please amend claim 2 as follows:", however, the claim designated as being amended is claim

Noted - corrected by Examiner -
M Lemer (SPE)
12-30-93

21. Applicants respectfully request this sentence be changed to read "Please amend claim 21 as follows:".

H. Brent Woodrow

Hal Brent Woodrow
Reg. No. 32,501
Attorney for Applicant(s)

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
November 9, 1993

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/518,511	05/03/90	HUNTER	MINIER.C

EXAMINER
15N1/11.3

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

ART UNIT	PAPER NUMBER
1203	11

DATE MAILED: 11/27/93

NOTICE OF ALLOWABILITY

PART I.

1. ☑ This communication is responsive to the Amendment filed August 9, 1993.
2. ☑ All the claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice Of Allowance And Issue Fee Due or other appropriate communication will be sent in due course.
3. ☑ The allowed claims are 21, 23, 24, 7, 8, 10-12, 14, 18-20.
4. ☐ The drawings filed on _____ are acceptable.
5. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has [_] been received. [_] not been received. [_] been filed in parent application Serial No. _____, filed on _____.
6. ☑ Note the attached Examiner's Amendment.
7. ☐ Note the attached Examiner Interview Summary Record, PTOL-413.
8. ☐ Note the attached Examiner's Statement of Reasons for Allowance.
9. ☐ Note the attached NOTICE OF REFERENCES CITED, PTO-892.
10. ☑ Note the attached INFORMATION DISCLOSURE CITATION, PTO-1449.

PART II.

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" indicated on this form. Failure to timely comply will result in the ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

1. ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
2. ☐ APPLICANT MUST MAKE THE DRAWING CHANGES INDICATED BELOW IN THE MANNER SET FORTH ON THE REVERSE SIDE OF THIS PAPER.
   a. ☐ Drawing informalities are indicated on the NOTICE RE PATENT DRAWINGS, PTO-948, attached hereto or to Paper No. _____. CORRECTION IS REQUIRED.
   b. ☐ The proposed drawing correction filed on _____ has been approved by the examiner. CORRECTION IS REQUIRED.
   c. ☐ Approved drawing corrections are described by the examiner in the attached EXAMINER'S AMENDMENT. CORRECTION IS REQUIRED.
   d. ☐ Formal drawings are now REQUIRED.

Any response to this letter should include in the upper right hand corner, the following information from the NOTICE OF ALLOWANCE AND ISSUE FEE DUE: ISSUE BATCH NUMBER, DATE OF THE NOTICE OF ALLOWANCE, AND SERIAL NUMBER.

Attachments:

- ✓ Examiner's Amendment
- _ Examiner Interview Summary Record, PTOL-413
- _ Reasons for Allowance
- _ Notice of References Cited, PTO-892
- ✓ Information Disclosure Citation, PTO-1449
- _ Notice of Informal Application, PTO-152
- _ Notice re Patent Drawings, PTO-948
- _ Listing of Bonded Draftsmen
- _ Other

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000264

PTOL-37 (REV. 4-89) *

USCOMM-DC 68-5788

Part III EXAMINER'S AMENDMENT

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Hal B. Woodrow on November 15, 1993.

Permission was given to amend the claims as follows:

Cancel claims 1 - 6, 9, 13, 15, 16, 17 and 22.

In claims 7, 8, 10, 11, 12, 14, 18, 19 and 20, line 1, change "heterogeneous braid" to "surgical suture".

In claim 7, line 1, change "6" to "21".

In claim 10, line 1, change "9" to "8".

In claim 14, line 1, change "13" to "12".

In claim 18, line 1, change "17" to "14".

In claim 20, line 1, change "1" to "21".

In claim 24, line 1, change "22" to "14".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Raimund whose telephone number is (703) 308-2374.

Chris Raimund/cwr
November 15, 1993

GEORGE F. LESMES
SUPERVISORY PATENT EXAMINER
GROUP 150

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: Box ISSUE FEE
COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

19N/111.

ROBERT J. KINSEN
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

☐ Note attached communication from the Examiner
☐ This notice is issued in view of applicant's communication filed _____

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
07/338,511	04/19/89	012	ROBINSON, J.	1911 11/15/91

First Named Applicant HUNTER, ALASTAIR G.

TITLE OF INVENTION: STERILIZED HETEROGENEOUS BRAID

	ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
	ETH-732	606/231.000	367	UTILITY	NO	$1170.00	02/10/92

THE FEE DUE IS THE AMOUNT IN EFFECT AT THIS TIME. IF THE AMOUNT OF THE ISSUE FEE INCREASES PRIOR TO PAYMENT, APPLICANT WILL BE NOTIFIED OF THE BALANCE OF ISSUE FEE DUE.

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT.

PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY Status shown above.
If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the patent and Trademark Office of the change in status, or
B. If the Status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:
A. Pay FEE DUE shown above, or
B. File verified statement of Small Entity Status before, or with, pay of 1/2 the FEE DUE shown above.

II. Part B of this notice should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B should be completed and returned. If you are charging the ISSUE FEE to your deposit account, Part C of this notice should also be completed and returned.

III. All communications regarding this application must give series code (or filing date) and serial number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to contrary.

IMPORTANT REMINDER: Patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (REV.7-92) (OMB Clearance is pending) PATENT AND TRADEMARK OFFICE COPY

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000266

PART B—ISSUE FEE TRANSMITTAL

MAILING INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE. Blocks 2 through 6 should be completed where appropriate. All further correspondence including the Issue Fee Receipt, the Patent, advances orders and notification of maintenance fees will be mailed to address entered in Block 1 unless you direct otherwise, by: (a) specifying a new correspondence address in Block below, or (b) providing the PTO with a separate "FEE ADDRESS" for maintenance fee notifications with the payment of Issue Fee or thereafter. **See reverse for Certificate of Mailing.**

MAIL ROOM FEB 18 1994 PAT. & TRADEMARK OFF.

1 CORRESPONDENCE ADDRESS	2 INVENTOR(S) ADDRESS CHANGE (Complete only if there is a change)
JOHNSON PLAZA	INVENTOR'S NAME Street Address City, State and ZIP Code CO-INVENTOR'S NAME Street Address City, State and ZIP Code ☐ Check if additional changes are on reverse side

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED

First Named Applicant

TITLE OF INVENTION

	ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
		606-231.000	56	UTILITY			

3. Correspondence address change (Complete only if there is a change)

30431 02/22/94 07838511
P. 30432 02/22/94 07838511

10-0750

4. For printing on the patent front page, list the names of not more than 3 registered patent attorneys or agents OR alternatively, the name of a firm having as a member a registered attorney or agent. If no name is listed, no name will be printed.

1 Hal Brent Woodrow
2
3

170.00CH
30.00CA

DO NOT USE THIS SPACE

5. ASSIGNMENT DATA TO BE PRINTED ON THE PATENT (print or type)

(1) NAME OF ASSIGNEE: Ethicon, Inc. Recorded- 2/19/92 Reel-6023 Frame-941

(2) ADDRESS: (CITY & STATE OR COUNTY) Somerville, N.J.

(3) STATE OF INCORPORATION, IF ASSIGNEE IS A CORPORATION: Ohio

A ☐ This application is NOT assigned.
☒ Assignment is being previously submitted to the Patent and Trademark Office.
☐ Assignment is being submitted under separate cover. Assignments should be directed to Box ASSIGNMENTS.

PLEASE NOTE: Unless an assignee is identified in Block 5, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the PTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

6a. The following fees are enclosed:
☐ Issue Fee ☐ Advanced Order - # of Copies _____ (Minimum of 10)

6b. The following fees should be changed to: DEPOSIT ACCOUNT NUMBER 10-0750 (ENCLOSED PART C)
☒ Issue Fee ☒ Advanced Order - # of Copies 10 (Minimum of 10)
☐ Any Deficiencies in Enclosed Fees

The COMMISSIONER OF PATENTS AND TRADEMARKS is requested to apply the Issue Fee to the application identified above.

(Signature of party in interest of record)	(Date)
32,501 Hal Brent Woodrow	2/16/94

NOTE: This Issue Fee will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the Patent and Trademark Office.

TRANSMIT THIS FORM WITH FEE-CERTIFICATE OF MAILING ON REVERSE

PTOL-85B (REV.7-92)(OMB Clearance is pending)

Certificate of Mailing

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

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Commissioner of Patents and Trademarks
Washington, D.C. 20231

on February 16, 1994
(Date)

Hal Brent Woodrow
(Signature)

Hal Brent Woodrow
(Typed or Printed Name)

February 16, 1994
(Date)

Note: If this certificate of mailing is used, it can only be used to transmit the Issue Fee. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing.

94 FEB 18 PM 8:55
PATENT & TRADEMARK OFC
IRSB DIVISION

This form is estimated to take 20 minutes to Complete. Time will vary depending upon the needs of the individual applicant. Any comments on the amount of time you require to complete this form should be sent to the Office of Management and Organization, Patent and Trademark Office, Washington, D.C. 20231 and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

PART B—ISSUE FEE TRANSMITTAL

MAILING INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE. Blocks 2 through 6 should be completed where appropriate. All further correspondence including the Issue Fee Receipt, the Patent, advances orders and notification of maintenance fees will be mailed to addressee entered in Block 1 unless you direct otherwise, by: (a) specifying a new correspondence address in Block below; or (b) providing the PTO with a separate "FEE ADDRESS" for maintenance fee notifications with the payment of Issue Fee or thereafter. **See reverse for Certificate of Mailing.**

MAIL ROOM 68 FEB 18 1994 PAT & TRADEMARK OFF.

1. CORRESPONDENCE ADDRESS	2. INVENTOR(S) ADDRESS CHANGE (Complete only if there is a change)
	INVENTOR'S NAME
	Street Address
	City, State and ZIP Code
	CO-INVENTOR'S NAME
	Street Address
	City, State and ZIP Code
	☐ Check if additional changes are on reverse side

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED

First Named Applicant

TITLE OF INVENTION

2/18/94

	ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
	ETH-			UTILITY	NO		02/18/94

Note: If this certificate of mailing is used, it can only be used to transmit the Issue Fee. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing must have its own certificate of mailing.

3. Correspondence address change (Complete only if there is a change)

4. For printing on the patent front page, list the names of not more than 3 registered patent attorneys or agents OR alternatively, the name of a firm having as a member a registered attorney or agent. If no name is listed, no name will be printed.

1 Hal Brent Woodrow

2

3

DO NOT USE THIS SPACE

5. ASSIGNMENT DATA TO BE PRINTED ON THE PATENT (print or type)

(1) NAME OF ASSIGNEE: Ethicon, Inc. Recorded- 2/19/92 Reel-6023 Frame-941

(2) ADDRESS: (CITY & STATE OR COUNTY) Somerville, N.J.

(3) STATE OF INCORPORATION, IF ASSIGNEE IS A CORPORATION: Ohio

A. ☐ This application is NOT assigned.

☒ Assignment is being previously submitted to the Patent and Trademark Office.

☐ Assignment is being submitted under separate cover. Assignments should be directed to Box ASSIGNMENTS.

PLEASE NOTE: Unless an assignee is identified in Block 5, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the PTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

6a. The following fees are enclosed:
☐ Issue Fee ☐ Advanced Order - # of Copies: (Minimum of 10)

6b. The following fees should be changed to:
DEPOSIT ACCOUNT NUMBER 10-0750
(ENCLOSED PART C)
XX Issue Fee XXX Advanced Order - # of Copies 10 (Minimum of 10)
☐ Any Deficiencies in Enclosed Fees

The COMMISSIONER OF PATENTS AND TRADEMARKS is requested to apply the Issue Fee to the application identified above.

(Signature of party in interest of record) 32,501 Hal Brent Woodrow (Date) 2/16/94

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PTOL-85B (REV.7-92)(OMB Clearance is pending)

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000269

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C.A. No.04-12457 PBS
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MAIL ROOM NOV 24 1993 PAT. & TRADEMARK OFF.

Gp 1504

ETH 782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Alastair W. Hunter, Dennis D. Jamiolkowski and Arthur Taylor, Jr.

Serial No. 07/838,511 Group No. 1504

Filed: February 19, 1992 Examiner: C. Raimund

For: STERILIZED HETEROGENOUS BRAIDS

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GROUP 1500

CERTIFICATE OF MAILING (37 CFR 1.8(a))

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Hal Brent Woodrow
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Date: November 22, 1993 Hal Brent Woodrow
Signature of Person Mailing Paper

12-6-93

Commissioner of Patents and Trademarks
Washington, D. C. 20231

7560
Raimund

AMENDMENT, PETITION AND FEE DELETING CORRECTLY NAMED ORIGINAL PERSON(S) WHO ARE NOT INVENTOR(S) OF INVENTION NOW BEING CLAIMED (37 CFR 1.48(b)

1. This amendment and petition under 37 CFR 1.48(b) is to delete the name(s) of the following person(s) originally named as inventor(s) of the invention now being claimed:

Dennis D. Jamiolkowski

2. Claims Now On File

The claims in this application are as follows:

[ ] originally filed claim(s) _____

[ ] originally filed claims _____ as amended on _____

[ ] claim(s) _____ filed on _____

[X] claim(s) 21-24 filed on February 19, 1992 as amended on August 4, 1993 and amended by the Examiner's Amendment of November 15, 1993

OK to enter
MR

P 30079 12/07/93 07:38:19 10-0758

[X] claims 25-33 added by the Examiner's Amendment of November 15, 1993

3. **DILIGENCE**

This amendment and petition is being filed

[X] diligently after discovery that any claim(s) for which the above-named inventor who is being deleted are now no longer the inventor of the subject matter being claimed.

4. **STATUS OF INVENTORSHIP AFTER AMENDMENT**

[ ] Attached is an explanation of the facts, including the ownership of all the claim(s) at the time the last claimed invention was made (Declaration of Inventorship and Common Ownership of Claims in Application).

5. **FEE (37 CFR 1.17(h)**

The fee required is paid as follow:

[X] charge Account No. 10-750/HBW/ETH-782 for any fee deficiency

[X] charge Account No. 10-750/HBW/ETH-782 the sum of $130.00

Hal Brent Woodrow
Reg. No. 32,501

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
November 22, 1993

PTO UTILITY GRANT
Paper Number 14

The United States of America

The Commissioner of Patents and Trademarks

Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this

United States Patent

Grants to the person or persons having title to this patent the right to exclude others from making, using or selling the invention throughout the United States of America for the term of seventeen years from the date of this patent, subject to the payment of maintenance fees as provided by law.

Bruce Lehman

Commissioner of Patents and Trademarks

Sandra L. Morton

Attest

PTO-1584

UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/838,911	02/19/92	HUNTER	[illegible]

15N1/0527

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER

ART UNIT	PAPER NUMBER
1504	

DATE MAILED 05/27/94

A. ☐ The petition filed _____ under 37 CFR 1.312(b) is granted.
The paper has been forwarded to the examiner for consideration on the merits.

B. ☒ The amendment filed 2/16/94 under 37 CFR 1.312 has been considered, and has been:

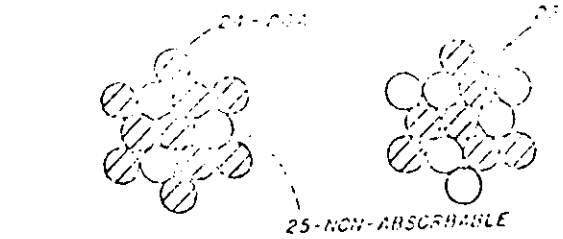
1. ☐ entered
2. ☒ entered as directed to matters of form not affecting the scope of the invention (0.3311).
3. ☐ disapproved. A report appears below.
4. ☐ entered in part. A report appears below.

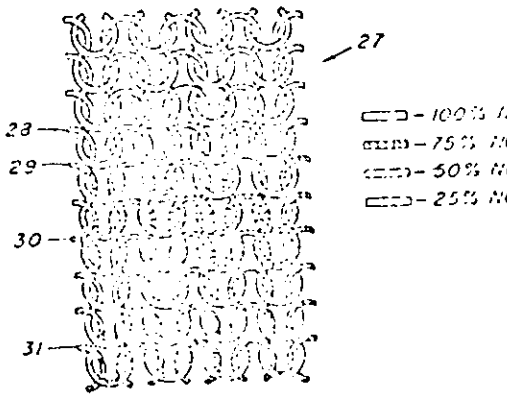
Report:

SUPERVISORY PATENT EXAMINER
GROUP 150

PLEASE FURNISH YOUR ZIP CODE IN ALL CORRESPONDENCE

FORM PTOL-271 (REV. 7/89)





INVENTORS.
EDWARD EMIL SCHMITT
ROCCO [illegible]LBERT POLISTINA
BY
[signature]
ATTORNEY

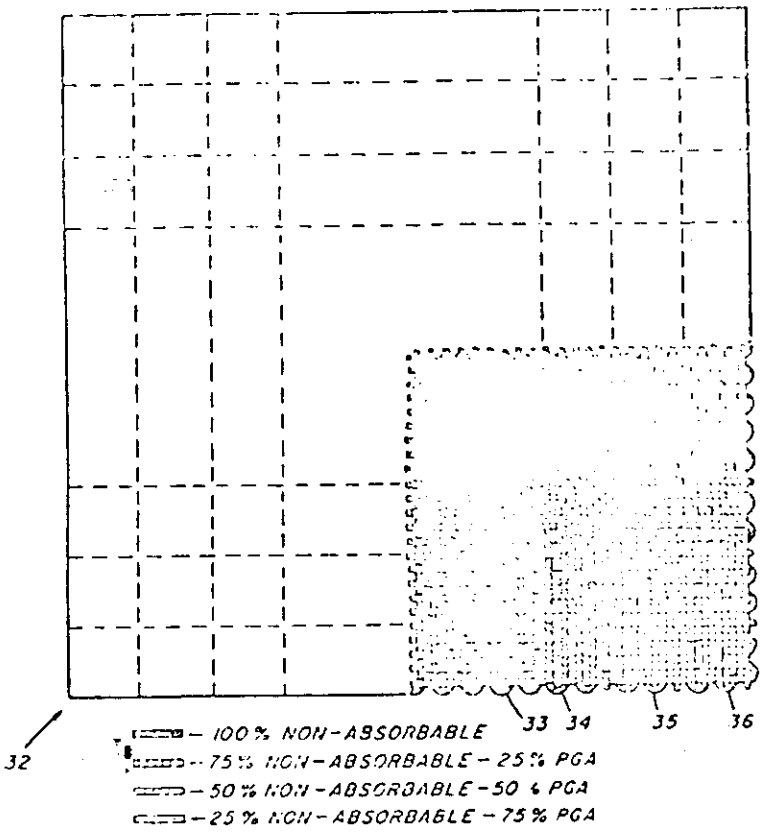


FIG - 3

INVENTORS
EDWARD EMIL SCHMITT
ROCCO ALBERT POLISTINA
BY
Samuel Brandstaft
ATTORNEY

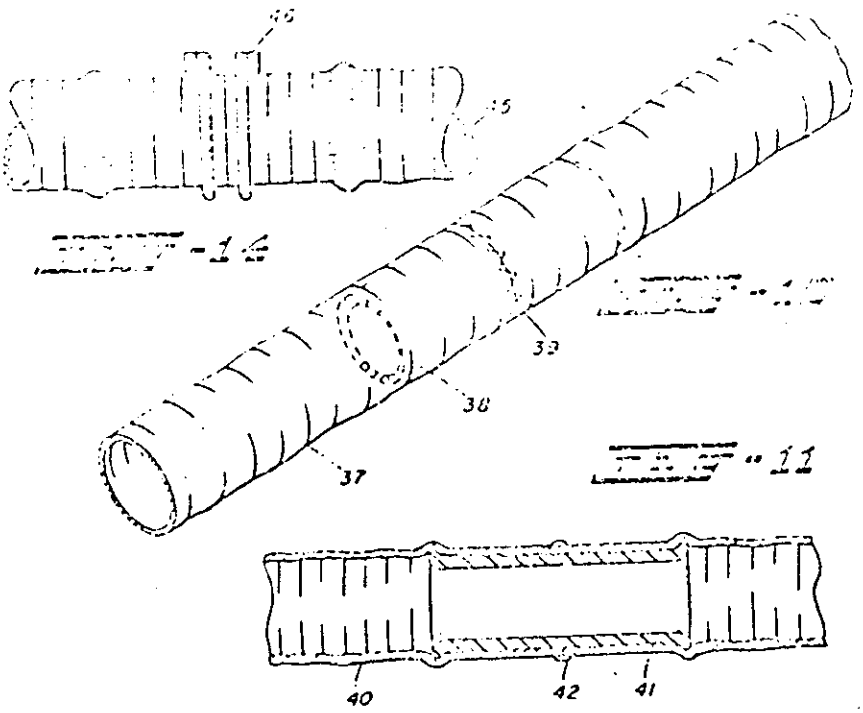


FIG -14

FIG -15

FIG -11

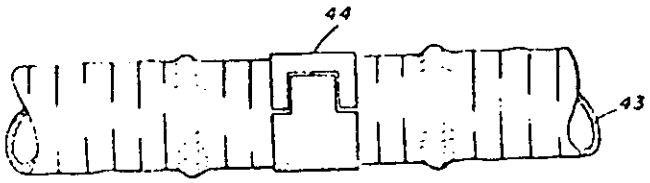


FIG -13

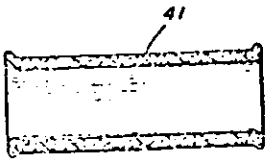


FIG -12

INVENTORS
EDWARD EMIL SCHMITT
ROCCO ALBERT POLISTINA
BY

ATTORNEY

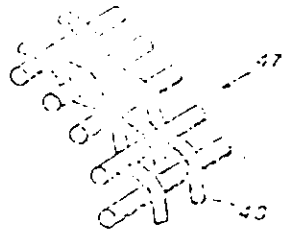


FIG - 15

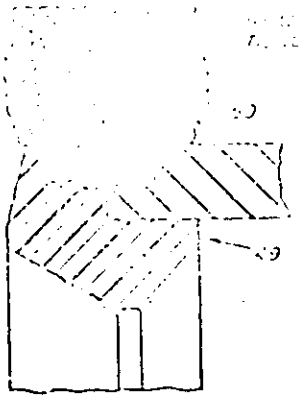


FIG - 16

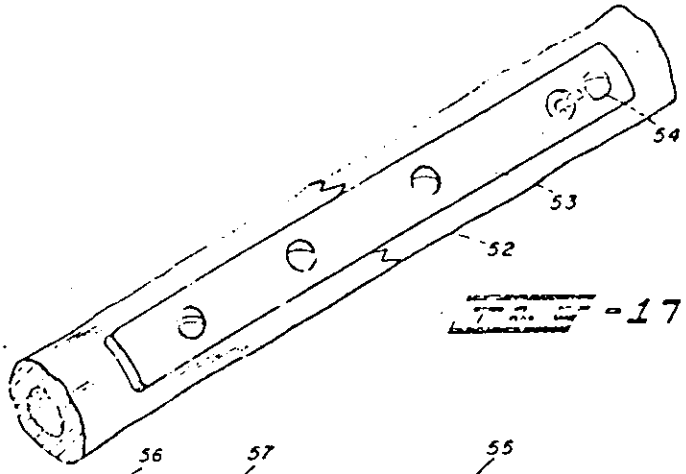


FIG - 17

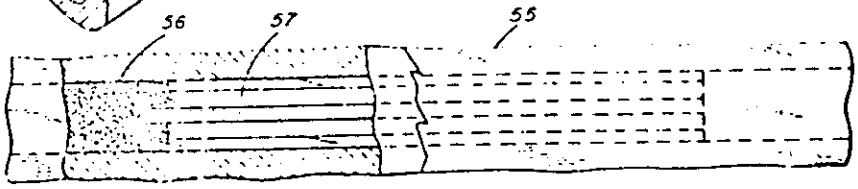


FIG - 18

INVENTORS,
EDWARD EMIL SCHMITT
ROCCO ALBERT POLISTINA
BY
ATTORNEY

U.S. Cl. 128—334

ABSTRACT OF THE DISCLOSURE

Polyglycolic ester, the acid polymer thereof (PGA), has a high tensile strength as well as a high degree of flexibility. Fabrics of the fibers of this polymer, when implanted in living tissue, are absorbed by the tissue at discrete areas where the body fluids contact the fabric. As each fiber is absorbed, it is replaced by living tissue. Fabric structures of an intermixture of PGA and non-absorbable material are particularly useful in tissue repair or replacement so that living tissue mechanically unites about the non-absorbable fiber structure, locking it into place.

CROSS REFERENCES

This application is a continuation-in-part of application Ser. No. 320,543, filed Oct. 31, 1963 now U.S. Patent 3,297,033, Jan. 10, 1967, "Surgical Sutures."

Field of invention

This invention relates to absorbable surgical elements of polyhydroxyacetic ester hereafter called polyglycolic acid (PGA).

Prior art

The use of submucosal tissue and ribbons therefrom internally is described in such patents as United States Patent 2,167,251, Rogers, "Surgical Tape of Submucosa Tissue," July 25, 1939, United States Patent 2,143,910, Didusch, "Ribbon Gut and Method of Using the Same," Jan. 17, 1939, and United States Patent 2,127,903, Bowen, "Tube for Surgical Purposes and Methods of Preparing and Using the Same," Aug. 23, 1938.

U.S.P. 2,836,181, J. S. Tapp, "Flexible Nylon Tube and Method for Preparing Same" shows a braided heat crimped formic acid treated nylon tube spliced into a blood vessel, with the crimp permitting a desired degree of flexibility.

U.S.P. 3,099,0[illegible], M. L. Edwards, "Heart Valve" shows a plastic cardiac valve, in which a fabric is emplaced in a ring around the valve, and sutured to the heart tissue, to permit the heart tissue to grow to such fabric, and hold the valve in position in the heart.

U.S.P. 3,054,406, F. C. Usher, "Surgical Mesh," Sept. 18, 1962, shows the use of a polyethylene woven mesh fabric implanted in the human abdominal wall for reinforcing and healing defects.

U.S.P. 3,108,357, W. J. Liebig, "Compound Absorbable Prosthetic Implants, Fabrics and Yarns Therefor" shows flexible fabrics of mixed absorbable and non-absorbable textile fibers for implantation, and reinforcement of tissue.

U.S.P. 3,123,135, F. C. Usher, "Method of Repairing Body Tissue," Mar. 10, 1964, shows the use of knitted linear polyethylene mesh attached to edges of tissue defect. The polyethylene is sewed to and permanently reinforces the tissue at the edges of the defect. Additional details appear in Usher, G[illegible] or Mersey Steel in the Repair of [illegible]" [illegible] American Surgeon 24, 316-[illegible]

[illegible]

U.S. Cl. 128—334

SUMMARY

[illegible]

A "filament" is a [illegible] a non-absorbable or absorbable material. It may be [illegible] linear or staple.

"Staple" is used to designate a group of shorter fibers which are usually twisted together to form a long, continuous thread.

Non-absorbable surgically acceptable filaments include filaments of polyalkylenes, such as polyethylene, preferably linear polyethylene with a density of about 0.94 or higher, or polypropylene, preferably [illegible] polypropylene; or a polyamide, such as nylon; or a polyester, such as Dacron; or a polyacrylonitrile, such as Orlon or Creslan; or a halogenated polyalkylene, such as polytetrafluoroethylene, such as Teflon, or other halogenated polyalkylene, such as Kel-F or FEP, or cotton, or silk, or linen; or a metal such as stainless steel, tantalum, silver, gold, or platinum. The above are illustrative. Any non-absorbable material which is essentially inert in living mammalian tissue, particularly human tissue, is suitable as a non-absorbable filament. Those materials having a comparatively high tensile strength and flexibility are preferred.

An absorbable filament is one which is absorbed, that is digested or dissolved, in living mammalian tissue.

A "thread" is a plurality of filaments, either continuous or staple, twisted together.

A "strand" is a plurality of filaments or threads twisted, plaited, braided, or laid parallel to form a unit for further construction into a fabric, or used per se, or a monofilament of such size as to be woven or used independently.

A "bicomponent filament" is a filament composed of two separate materials. As used herein, the term is limited to a filament having one non-absorbable component and one absorbable component. The components may be adjacent. The most easily formed and preferred bicomponent filament is a sheathed filament with an internal non-absorbable material coated, or sheathed, approximately concentrically, with an absorbable component.

A "bicomponent thread" includes a thread of bicomponent filaments or a blend of different separate monofilament components twisted together, or both.

A "bicomponent strand" is a strand of one or more bicomponent filaments, or two different filament materials, or both, at least one component of which is absorbable.

A "bicomponent fabric" is a woven, knitted, felted, adhesively united, or otherwise formed [illegible] of bicomponent [illegible] fabric [illegible] component [illegible] components, at least one component [illegible] absorbable.

A "[illegible] fabric" is a [illegible] with a [illegible] already [illegible] for example by [illegible] a [illegible] system of [illegible] may be [illegible]

surgical prostheses.

[illegible] a resistance to PGA is completely dissolved in the body leaves little or no residual scar tissue from the PGA.

A "braid" or "braided suture" is a portion of bicomponent fabric, or fiber equivalent, made by selection of strands for the fabric, or components for the strand or strands, in a manner such that, over a short distance, of 1 inch to 15 inch, or more, so that a fabric or strand changes in composition from a nonabsorbable material, or substantially non-absorbable material, to predominantly or completely absorbable material, whereby living tissue can replace the absorbable component and a gradual transition is provided between the nonabsorbable reinforcing prosthesis and the adjacent living tissue. With an arterial implant, for instance, a problem of trouble has been the line of juncture between the implant and the natural artery wall. With a gradual transition, no sharp line of demarkation exists, and, hence, failures between the prosthesis and tissue are minimized. With implants of the types shown by Usher, supra, the edges of the reinforcing element could cause difficulties. With a gradual transition, a line of potential risk is eliminated.

For different purposes and in different types of tissue the rate of absorption may vary but in general an absorbable prosthesis should have a high portion of its original strength as possible for at least three days, and sometimes as much as fifteen days or more, and preferably should be completely absorbed by muscular tissue within from forty-five to ninety days or more depending on the mass of the cross-section. The rate of absorption in other tissues may vary even more.

In common with many biological systems, the requirements are not absolute and the rate of absorption as well as the short-term strength requirement varies from patient to patient and at different locations within the body, as well as with the thickness of the section of PGA.

The PGA may be formed as tubes or sheets for surgical repair and may also be spun as thin filaments and woven or felted to form absorbable sponges or absorbable gauze, or used in conjunction with other structures as prosthetic devices, within the body of a human or animal where it is desirable that the structure have short-term strength, but be absorbable. The medical articles include tubes, including branched tubes for vessels, nerve or intestinal repair, nerve splicing, tendon splicing, sheets for tying up and supporting damaged bones, liver and other intestinal organs, protecting damaged surface areas such as abrasions, particularly major abrasions over areas where the skin and underlying tissues are damaged or surgically removed.

The synthetic character and hence predictable formability and [illegible] from a controlled [illegible]

[illegible]

[illegible]

[

an internal sleeve both expanded or [illegible].

FIGURE 12 shows a prosthetic sleeve formed of a helically coiled strip of solid polyglycolic acid with overlapping ends to aid in holding a blood vessel in the sleeve.

FIGURE 13 shows the sleeve of FIGURE 12 in use in which an external spring clip of solid polyglycolic acid holds the ends of the blood vessel in place.

FIGURE 14 shows the sleeve of FIGURE 12 having two expandable annular clips positioned to hold the ends of the blood vessel approximated.

FIGURE 15 is a portion of a woven tube of fabric of individual strands which are at least in part absorbable.

FIGURE 16 shows a portion of a heart valve prosthesis in heart tissue using a fabric in part composed of polyglycolic acid to aid in holding the valve in place.

FIGURE 17 shows a broken bone, the ends of which are held together by a solid bar of polyglycolic acid held to the bone by polyglycolic acid screws.

FIGURE 18 shows a broken bone, the ends of which are held in position by an internal dowel pin of polyglycolic acid.

PGA for the construction of the prostheses shown in the drawings can be produced as set forth in the following examples, in which parts are by weight, unless otherwise clearly indicated:

EXAMPLE 1

100 parts of recrystallized glycolide (melting point 85.0 to 85.5° C.) are intimately mixed with 0.02 part of methoxyacetic acid, 0.03 part of phenoldisulfide (Sun-o-Nox), and 0.01 part antimony trifluoride. Separate glass tubes are each charged with approximately 20 grams of the mixture, deoxygenated by repeated evacuation and argon purging, then sealed under vacuum and heated to 185 to 190° C. for 4½ hours. On cooling a white opaque tough PGA is produced in a 97.5% yield with a melt viscosity at 245° C. of 5,000 poises. The polymer is reheated and spun into filaments at a temperature of about 230° C. at a speed of about 150 feet per minute. The filaments produced are cooled, then drawn at about 55° C. When drawn to five times the original length a strong tough filament is produced. The drawn filaments are in condition for use.

EXAMPLE 2

The polymer of the preceding example is formed into a plurality of smaller filaments, which are then twisted into a polyfilamentary strand, which is heated and cold drawn following the techniques of Example 1.

Because it is a synthetic polymer the [illegible] forming are more versatile than at present [illegible] carrying materials.

[illegible] an inert atmosphere of CO_2 [illegible] H_2O.

[illegible] a base of about [illegible] with 3 parts of [illegible] for comparison, 0.01 part of a [illegible] H_2O (about 0.01% of [illegible] based on the weight of the polymerizable [illegible] parts of diethyl phthalate [illegible] parts of [illegible] The tube is evacuated and purged with argon. The tube is evacuated and [illegible] and the top is sealed. The [illegible] tube is placed in a vertical position in a closed glass chamber throughout which dibutyl phthalate is refluxed at 222° C. The boiling point of the dimethyl phthalate is controlled by decreasing the pressure of the system. At periodic intervals after melting, the viscosity of the reaction mixture is measured by raising the steel ball by means of a magnet and measuring the rate of the fall of the ball in seconds. Sixty minutes after the melt is first observed, the ball drop time is 550 sec./in. or about 720.0 poises, and after 120 minutes, the ball drop time is 50.0 seconds, or about 7500 poises.

The PGA thus produced is spun into .002 inch diameter fibers and used to form bicomponent strands.

Additional PGA, similarly produced is used to coat Dacron threads, in varying weight ratios to form bicomponent strands which are braided into tubular arterial implants to splice into sections of arteries.

Additional PGA, similarly produced is used to form sheets. These sheets are wrapped around nerves, traumatically severed, to protect such nerves from invasive scar tissue growth, while the nerve is regenerating.

Also the PGA so produced is fabricated into the prosthetic devices shown in the drawings.

As is shown in the drawings, a bicomponent filament 23 was formed by dipping a non-absorbable filament 21 of Dacron into a PGA melt forming a PGA coating 22 on the surface of the non-absorbable Dacron 21.

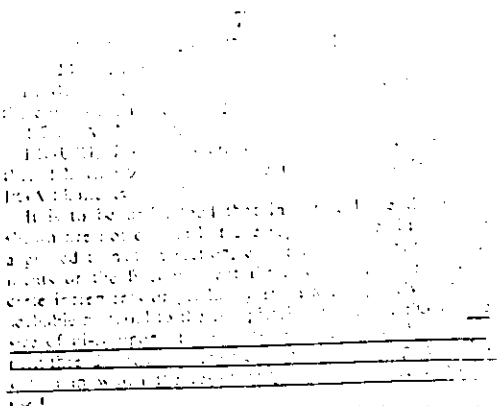
As shown in FIGURE 1 the dip was such that approximately 25% of the cross section was of Dacron and 75% of PGA.

In FIGURE 2 the structure is the same except that the relative proportions are changed to approximately 50% of each material.

In [illegible] the structure is the same except that the proportions are [illegible] such that approximately 75% of the cross section is of Dacron and about 25% on the surface is PGA.

[illegible] filament is shown.

[illegible] of a bicomponent filament [illegible] comprises of 3 non-





[illegible]

[illegible] Type 316 stainless steel pin of [illegible] to those made of PGA.

With both the experimental and control animals the course of healing was uneventful. The bones were essentially healed by the 6th week. After sacrifice, femurs were [illegible] and the effect of time on the implants were observed. As expected in the [illegible] short [illegible] and the stainless steel pin was [illegible] but since the internal spike was largely [illegible] where the metallic pin was present, there was no marrow tissue.

Where the medullary rod of polyglycolic acid had been used, at six weeks the overall structure of the rod was essentially unchanged but there were fissures developing on the surface and the cut ends which had been simply defined were somewhat rounded. The rod was somewhat softened on the surface. There was a progressive increase in the amount of erosion of the PGA rod with time but this erosion was never associated with inflammation or other adverse reaction. By the 24th week the rod of polyglycolic acid was essentially digested and the bone now showed normal tissue architecture.

EXAMPLE 5

An implantable bone plate affixed with absorbable pins

Femurs of the hind legs of rabbits were bisected as described in Example 4. The cut ends were [illegible] and immobilized by use of an internal support [illegible] from a sheet of polyglycolic acid approximately [illegible] inch thick 3/4" wide and 1 inch long, shaped to conform generally to the bone by softening the plastic with heat and premolding it about a metal rod of suitable diameter. The premolded plate was centrally located over the cut bone and while held in position, small holes were drilled through the plate and completely through the bone with a 1/16 inch drill, two holes on each side of the bone break. Small PGA nails about 3/4 inch long and slightly over 1/16 inch in diameter made by flattening rod of this diameter by pressing against a heated surface were driven through the holes in the PGA plate and completely through the bone to hold the plate in place. The soft tissue was approximated, the incised legs sutured and the animals were returned to their cages. Animals were then sacrificed and bone sections taken at 3, 6, 12, 18 and 24 week intervals. The bone sections were decalcified and were carefully examined to determine the fate of the PGA cells and plate and to observe the course of healing. At 3 weeks the bone was joined [illegible] PGA plate was essentially [illegible] PGA [illegible] fibrous tissue. There was [illegible] fibrous tissue. [illegible]

[illegible]

[illegible]

[

XR 3,636,956

[15] 3,636,956

[45] Jan. 25, 1972

Schneider

[54] POLYLACTIDE SUTURES

[72] Inventor Allan K. Schneider, Wilmington, Del

[73] Assignee Ethicon, Inc., Somerville, N.J.

[22] Filed May 13, 1970

[21] Appl. No.: 36,797

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 700,036, Jan. 24, 1968, abandoned, which is a continuation-in-part of Ser. No. 449,630, Apr. 20, 1965, abandoned, which is a continuation-in-part of Ser. No. 308,685, Sept. 13, 1963, abandoned, which is a continuation-in-part of Ser. No. 231,860, Oct. 19, 1962, abandoned.

[52] U.S. Cl. 128/335.5, 260/78.3

[51] Int. Cl. A61l 17/00

[58] Field of Search 128/334, 335.5; 260/78.3

[56] **References Cited**

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3,297,033	1/1967	Schmitt et al.	128/335.5

FOREIGN PATENTS OR APPLICATIONS

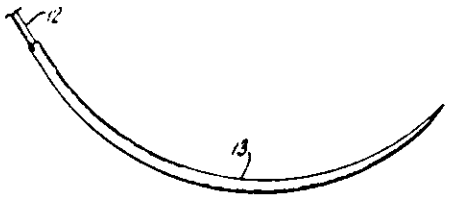
5,354	11/1964	Iran	128/335.5
779,291	7/1957	Great Britain	260/78.3

Primary Examiner—Dalton L. Truluck
Attorney—Robert W. Kell and Robert L. Minier

[57] **ABSTRACT**

Absorbable surgical sutures that are dimensionally stable within the body may be prepared by the extrusion of polylactide polymer, including copolymers of L(−) lactide with up to 35 mole percent of glycolide. Said polymers are characterized by an inherent viscosity of at least 1.0, and the extruded filaments are oriented by drawing at a temperature of about 50° to about 140° at a draw ratio of up to 11x, and annealed. Sutures so prepared have a tensile strength of from 25,000 p.s.i. to 100,000 p.s.i.

79 Claims, 5 Drawing Figures



PATENTED JAN 25 1972 3,636,956

Fig. 1.

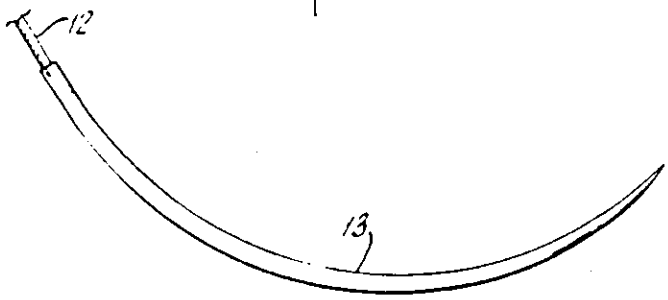


Fig. 2.

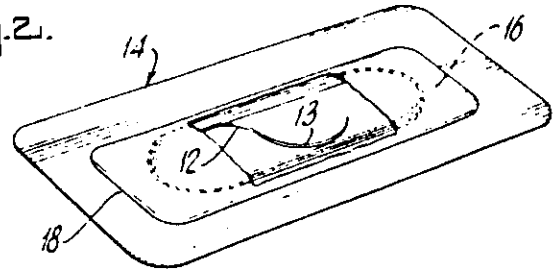


Fig. 3.

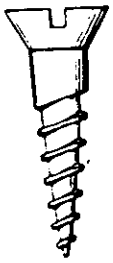


Fig. 4.

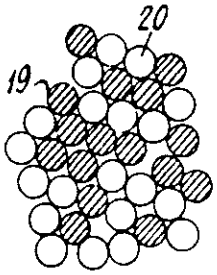
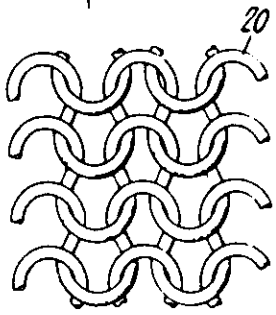


Fig. 5.



INVENTOR
ALLAN K. SCHNEIDER
BY Robert W. Kelly
ATTORNEY

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POLYLACTIDE SUTURES

This application is a continuation-in-part of my copending U.S. application Ser. No. 700,036, filed Jan. 24, 1968, now abandoned, which in turn was a continuation-in-part of my then copending U.S. application Ser. No. 449,630, filed Apr. 20, 1965, now abandoned, which in turn was a continuation-in-part of my then copending U.S. application Ser. No. 308,688, filed Sept. 13, 1963, now abandoned, which in turn was a continuation-in-part of my then copending U.S. application Ser. No. 231,860, filed Oct. 19, 1962, also now abandoned.

This invention relates to new articles of manufacture and to their use. More particularly, the invention is concerned with surgical aids prepared from synthetic polymers including copolymers of lactic acids and their use in surgical applications, e.g., sutures and ligatures and other prosthetic devices used in joining or supporting living tissues.

Catgut (actually from sheep or beef intestine) is the most commonly used absorbable suture now on the market. In many instances, however, it may cause adverse tissue reaction in the sutured flesh. This, together with the fact that it requires storage under moist conditions, makes it less than an ideal suture material. Nylon, stainless steel, cotton, linen, ramie, "Teflon" fluorocarbon resin, "Dacron" polyester fibers, silk, and other materials have been suggested and/or used as surgical sutures. Some of them have advantages over catgut in strength, uniformity, and storage characteristics, but they are not absorbed by living tissue.

Among the requirements of the ideal absorbable suture product are that it should handle properly, should approximate and hold tissue for proper healing with the least possible damage, should not tear tissue, should have adequate tensile strength, should be controllably uniform in properties, including dimensional stability within the body, should be sterilizable, should be absorbable by living tissue, preferably at a constant rate regardless of the place in the body and the condition of the patient, without causing such unfavorable tissue reactions as walling off, granuloma formation, excessive edema, etc., and finally should be capable of tying and holding surgical knots properly.

This invention fulfills the above requirements to a remarkable degree by providing highly oriented, high tenacity filaments of polymers and copolymers of lactic acid, the filaments having excellent dimensional stability in body tissue and preferably retracting less than 10 percent in an empirical test in which the filaments are immersed in water at 37° C. for a period of 24 hours.

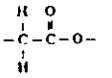
These filaments are prepared from lactic acid homopolymers and copolymers having an inherent viscosity of at least 1, preferably above 1.2, as determined at 0.1 percent concentration in benzene by weight at 25° C. prior to being oriented. Any polylactide composition containing up to about 15 percent by weight of repeating units of the formula:



(1)

wherein R is lower alkylene, preferably methylene ($-CH_2-$) or ethylene ($-CH_2CH_2-$), m is 0 or 1, R' is hydrogen or lower alkyl, R'' is hydrogen or alkyl of up to about 22 carbons when m is 0 and hydrogen or lower alkyl when m is 1, and can be the same as R' or different, can be employed to make the sutures of this invention. Preferred, because of availability of starting materials, are repeating units derived from alpha-hydroxycarboxylic acids, i.e., units of the above formula in which m is 0. Most preferred, because of the properties of the sutures made therefrom, are repeating or comonomer units derived from glycolide or DL-lactide, i.e., repeating units of formula (1) in which m is 0, R' is hydrogen or methyl, and R'' is hydrogen. In other words, the number of carbon atoms in the repeating unit is two to about 24, preferably two to about eight, and most preferably two to three. It will be understood

that when m is 0, R' is methyl, and R'' is hydrogen, the repeating unit in formula (1) could be derived from DL-lactide. This would result in a copolymer containing both antipodal species derived from alpha-hydroxypropionic acid. When the repeating unit in formula (1) is identical with the principal unit, the polylactide composition is a homopolymer. In the specific instance when m is 0 and both R' and R'' are hydrogen, (when glycolide is the comonomer), the polylactide composition may contain about 35 mole percent of repeating units of the formula



(2)

Such copolymers of L(−) lactide and glycolide may also be employed to make the sutures of this invention.

Illustrative of the comonomers which can be employed with the lactide to form copolymers useful in preparing the filaments of this invention, there can be name glycolide, beta-propiolactone, tetramethylglycolide, beta-butyrolactone, gamma-butyrolactone, pivalolactone, and intermolecular cyclic esters of alpha-hydroxybutyric acid, alpha-hydroxyisobutyric acid, alpha-hydroxyvaleric acid, alpha-hydroxyisovaleric acid, alpha-hydroxycaproic acid, alpha-hydroxy-alpha-ethylbutyric acid, alpha-hydroxyisocaproic acid, alpha-hydroxy-beta-methylvaleric acid, alpha-hydroxyheptanoic acid, alpha-hydroxyoctanoic acid, alpha-hydroxydecanoic acid, alpha-hydroxymyristic acid, alpha-hydroxystearic acid, and alpha-hydroxylignoceric acid.

The filaments prepared from the above-described lactide polymers and copolymers are conveniently formed by melt-extruding the polylactic acid through a spinneret and then drawing the filaments in one or more stages to about four times their original length to effect orientation and to improve their tensile strength. The resultant oriented filaments are strong and retain much of their strength on being tied into surgeon's knots.

To further improve their dimensional stability and particularly tensile strength retention, one may subject them to an annealing treatment. This optional annealing treatment is effected by heating the filament, while holding it essentially taut, at 60° to 150° C., and then allowing it to cool to room temperature (25° C.) while held taut. The annealing is preferably conducted for such a time that the filament shows less than 10 percent shrinkage on subsequent immersion, for 24 hours without tension, in water at 37° C. The heating step of annealing usually requires from 0.5–5 minutes, to as long as 1 week.

A filament which meets the foregoing shrinkage test (37° C.) undergoes substantially no shrinkage when used as a suture in contact with body tissues (see example II). The conditions of this test are designed to give a quick in vitro measure of the dimensional stability of the filaments that can be projected to their usefulness as suture materials. In this connection, it should be mentioned that the conditions of draw have an influence over the shrinkage. Further, it has been found that those filaments showing little shrinkage in 24 hours at 37° C. have relatively little shrinkage when implanted in an animal body.

Since the function of a suture is to join and hold severed tissue until healing is well along, and to prevent separation as a result of movement or exercise, the suture should have adequate strength. It is particularly important that strength be maintained when knots are tied and during the actual procedure of drawing tight a suitable knot. Filaments from lactic acid polymers in high molecular weight oriented form are exceptionally strong and most significantly retain a high proportion of their strength at the knot point, as shown in the following table.

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TABLE I

	Tensile strength (straight pull) p.s.i.	Percent elongation at break	Tensile strength (surgeon's knot) p.s.i.*	Percent loss in strength, knot vs. straight
Poly-L(−) lactide	[1] 130,000	17	83,000	29
Do	[2] 100,000	16	78,000	28
Catgut	[3] 80,000	20	29,000	64
	[4] 64,000	20	27,000	39
L(−) lactide/gamma-butyrolactone (95/5) copolymer	[5] 59,000	17	42,000	29

[1] Inherent viscosity = 2.8, 10X draw, 0.006 inch diameter.
[2] Inherent viscosity = 2.8, 10X draw, 0.008 inch diameter.
[3] Chromic gut (0.006–0.010 inch diameter).
[4] Chromic gut (0.010–0.013 inch diameter).
[5] After U.S. Pharmacopoeia
[6] Inherent viscosity (bulk polymer) = 3.0 (spun filament) = 1.6, 10X draw, 0.009 inch diameter.

As will be apparent from table I, the inherent viscosity of the spun filament, i.e., the oriented filament, may be somewhat less than that of the bulk polymer or copolymer, for during the extrusion operation some degradation of the polymer may occur depending on the extrusion conditions employed. If the sutures are sterilized by high energy radiation, there may be a further lowering of the molecular weight of the polymer, and a resulting decrease in tensile strength. However, by starting with lactide polymers and copolymers having inherent viscosities of at least 1, the sutures prepared therefrom are entirely satisfactory if one minimizes degradation during sterilization, even though there may be some loss in inherent viscosity due to extrusion and orientation.

The filaments of this invention are further characterized by their hydrolysis behavior and absorbability. On treatment with boiling water for 100 hours, they lose at least 20, and preferably at least about 50 percent, of their weight. On treatment with boiling water for a period of 50 hours, the copolymers lose at least about 8 percent of their weight, and preferably they lose at least about 35 percent of their weight.

By varying the type and amount of comonomer employed, the rate of hydrolysis (absorption) of the suture can be controlled. In contrast to the highly variable absorption rates of catgut, the absorption of polylactide polymers is relatively more independent of the place in the body where used and of the condition of the patient. Since the hydrolysis rate of a particular lactic acid polymer is constant at a fixed temperature, say, at 37° C., absorption can be speeded up, for instance, by using different copolymers. For example, poly-L-lactide was 15.3 percent absorbed in the back muscle of a rat after 270 days. Under comparable conditions, L(−)-lactide/DL-lactide (97/3) copolymer was 18.5 percent absorbed, L(−)-lactide/DL-lactide (95/5) copolymer was 29.0 percent absorbed, L(−)-lactide/glycolide (95/5) copolymer was 27.3 percent absorbed, and chromed catgut was 67 percent absorbed. The rate of absorption of a copolymer of L(−)-lactide and glycolide increase with increasing amounts of glycolide in the polymer chain.

As already indicated, high tensile strength is an exceedingly desirable characteristic for suture materials. The filaments of the present invention are characterized by having a tensile strength of at least 25,000 p.s.i., preferably above 40,000 p.s.i. Some have tensile strengths ranging up to 100,000 p.s.i. and higher. Their knot strengths, expressed in lbs. of pull, exceed the minimum limits set for absorbable sutures by the U.S. Pharmacopoeia, i.e., from 0.125 lb. for a 0.001–0.002 inch filament to 25 lbs. for a 0.036–0.040 inch filament.

In preparing the polymers and copolymers from which the filaments of this invention are made, the appropriate intermolecular cyclic ester or intramolecular cyclic ester (lactone) of the hydroxy acid is employed. These can be derived from pure D(−)- or L(+)-lactic acids, the optically inactive DL-lactic acid mixture, any desired mixtures of pure D(−)-lactic and L(+)-lactic acids, and other alpha, beta, or gamma-hydroxy acids, about which more will be said later. In general, it is preferred, for the preparation of lactic acid homopolymers and for the introduction of lactide repeating units into copolymers to use as a starting material a lactide derived from either the pure L(+)-acid or pure D(−)-acid because the polymers obtained therefrom have a higher melting point than those derived from the DL-acid mixtures, are much less water sensitive, are stronger, and have a greater degree of crystallinity. For example, the polylactides from the DL-acid melt at 130° to 140° C., whereas those from the L(+)-acid melt at 145° to 175° C. The polylactides from the L(+)-acid or D(−)-acid are less sensitive to alcohol, a commonly used disinfecting medium in surgery, than those from the DL-acid. The L(+)-form is more readily available than the D(−)-acid and hence is particularly preferred. It is to be understood that the various lactides can be made from the corresponding lactic acids by a variety of published methods including that described in Schneider U.S. Pat. No. 2,703,316.

Table II, below, summarizes data comparing the properties of polymers prepared from L(−) lactide with those prepared from DL-lactide.

TABLE II

	Polymer From	
	DL-lactide	L(−) lactide
inherent viscosity	0.7–2.0	0.7–3.5
melting point	130°–140° C	145°–175° C
optical activity	no	yes (−156°)
solubility	$CHCl_3$, benzene, acetone	$CHCl_3$, benzene, acetone
density	1.26	1.26
tensile strength at break (monofilament)	20,000–40,000 p.s.i.	70,000–100,000 p.s.i.
elongation at break (monofilament)	15–30 percent	15–30 percent
tensile strength at break (dry film)	26,000 p.s.i.*	29,000 p.s.i.*
inherent viscosity (film)	1.29*	1.27*
elongation at break (film)	48 percent*	23 percent*

*Taken from U.S. Pat. No. 2,758,987.

In general, the tensile modulus, melting point, and specific rotation of a lactic acid polymer is maximum for the homopolymer of a single-antipodal species and decreases with increasing amounts of the other antipodal species in the polymer chain. This characteristic of lactic acid copolymers is an advantage since it permits one to choose a copolymer composition that can be extruded to form filaments which have improved flexibility, without appreciable sacrifice in strength.

In preparing copolymers, the repeating units derived from comonomers discussed above are introduced by use of the appropriate cyclic esters. For repeating units derived from alpha-hydroxy acids, these are usually the intermolecular cyclic esters containing six-membered rings, e.g., glycolide. For repeating units derived from beta- or gamma-hydroxy acids, the monomeric lactones, e.g., beta-propiolactone and gamma-butyrolactone, are usually used.

The polymer filaments of the present invention may be woven, braided, or knitted either alone or in combination with nonabsorbable fibers such as nylon, polypropylene, ORLON, DACRON, or TEFLON to form tubular structures having use in the surgical repair of arteries, veins, ducts, esophagi and the like. The manufacture of such tubular structures wherein the wall of the tube is fabricated of absorbable and nonabsorbable threads is described in U.S. Pat. Nos. 3,304,557; 3,108,357, and 3,463,158, the teachings of which are incorporated herein by reference. Inasmuch as the polylactide filaments are thermoplastic such tubular grafts may be crimped on a mandrel at elevated temperature and upon cooling to room temperature, will retain the crimp.

Tubular structures of polylactide filaments may be prepared that are resistant to radial compression and expansion by applying a helical wrapping of polypropylene monofilament around the external surface of the tube and fusing the polypropylene to unite the helical wrapping with the polylactide filaments in the external surface of the tube as illustrated in U.S. Pat. No. 3,479,670.

The polymers of the present invention are also useful in the manufacture of cast films and other solid surgical aids such as scleral buckling prostheses. Thus, cylindrical pins, screws, reinforcing plates, etc., may be machined from the cast polymer having in vivo absorption characteristics depending upon the polymer composition and molecular weight.

The invention will appear more clearly from the following detailed description when taken in connection with the accompanying drawings which show by way of example preferred embodiments of the inventive idea. Referring now to the drawings

FIG. 1 is a perspective view of a needle-suture combination.

FIG. 2 is a perspective view of a suture-needle combination within a hermetically sealed container;

FIG. 3 illustrates a screw machined from the polymer of the present invention;

FIG. 4 is a cross-sectional view of a composite yarn containing filaments of different composition and,

FIG. 5 is a plan view of a knitted fabric.

In preparing the filaments of this invention, it is essential to use polymers made from highly-purified lactides. For example, for excellent results L(−) lactide should have a melting point of at least 96° C. and a specific rotation greater than −295°. The polymerization is effected by heating the lactide above its melting point, but below about 215° C. in the presence of a polyvalent metal oxide or compound thereof, under anhydrous conditions in an inert atmosphere.

Specially useful catalysts are zinc oxide, zinc carbonate, basic zinc carbonate, diethylzinc, titanium, magnesium or barium compounds, litharge, stannous octoate and the like.

The amount and type of catalyst used determine the particular temperature and time required to produce polymer useful for conversion to the filaments of this invention. Thus, the amount can be as low as 0.001 weight percent or as high as 2 weight percent. As a rule, the lower the amount of catalyst, the longer the time required to produce polymer of a given inherent viscosity and, conversely, the higher the catalyst concentration, the shorter the time. The best balance is usually obtained employing from 0.02 weight percent to 1 weight percent of catalyst.

In general, it is desirable to agitate the reaction mixture continuously during the polymerization in order to produce a homogeneous polymer at good conversions and to conduct the reaction in two steps, the first being carried out at a lower temperature than the second, or finishing step. Other methods, such as those disclosed in U.S. Pat. Nos. 2,703,316 and 2,758,987 can be used in making the polymers.

The following is a brief description of a method for preparing the polymer useful for conversion to the filaments of this invention: lactide, purified by several crystallizations from carbon tetrachloride, is placed with one or more solid comonomers in a thoroughly dried reactor equipped with a stirring bar, nitrogen inlet tube, and a drying tube filled conveniently with anhydrous magnesium sulfate or calcium chloride. Nitrogen, which has been dried by passage through anhydrous magnesium sulfate or calcium chloride, is introduced immediately above the reaction mixture and heating and stirring are started. When the temperature of the reaction mixture has reached about 100° C., the nitrogen inlet is replaced by a thermometer, and from about 0.001 to 2 weight percent of an oxide or salt, of group II metal of atomic number 12 through 56, or litharge is added. In the case of copolymerization with a liquid comonomer, the liquid comonomer is preferably added after the lactide has melted. Heating is continued until polymer having an inherent viscosity of at least 1 at 0.1 percent concentration in benzene at 25° C. is obtained. This may require from a few minutes up to 25 or more hours, depending upon the catalyst used.

Polymer, produced as above, may be suitably further treated by cutting it into small pieces, dissolving in a suitable solvent, for example, benzene, toluene, or xylene, and the polymer precipitated by pouring the solution into a large volume of a nonsolvent for the polymer, desirably hexane. The precipitated polymer is removed by filtration, transferred to a blender and a nonsolvent for the polymer is added. The blender is started and after a homogeneous mixture has been obtained, the mixture is filtered. The polymer is allowed to dry on the filter and is then transferred to a vacuum oven. After drying overnight at 100° C., the polymer is removed from the oven and allowed to cool to ambient temperature.

As already indicated, the polymer material can be converted to filaments by melt-extrusion and also by spinning from solution. The diameter of the resulting filaments may be as small as 0.001 inch or less for the individual strands making up the multifilament structures and as large as 0.045 inch for very heavy monofilament sutures. Generally, however, the filaments of this invention will not have a diameter greater than 0.020–0.025 inch. Preferred are monofilaments having diameters of about 0.001–0.020 inch and multifilament structures having individual filaments of from less than 0.00025 to 0.003 inch diameter.

It will be understood that spinning and drawing may be done singly or in multiples. To prepare multifilament braided sutures, one may take either monofilaments or groups of filaments to braid.

Spinnerets having orifice sizes of 0.005 inch or larger, say, up to 0.150 inch, are suitable for spinning monofils. In spinning from solution, the solution may be extruded either into an atmosphere heated up to or above the boiling point of the solvent or into a nonsolvent for the polymer, e.g., hexane.

After spinning, the polylactide polymer and copolymer filaments are drawn to effect orientation and to improve tensile strength. This is accomplished by drawing (permanently elongating) the filaments at a temperature between 50° C. and 140° C., preferably between 90° C. and 135° C. the preferred draw ratio being from 3:1 to 11:1. The drawing step may be conducted in one or more steps, in air or in a bath containing a liquid nonsolvent for the polymer, e.g., glycerol or water. This drawing brings about a marked increase in tensile strength and molecular orientation, as measured by the X-ray orientation angle.

Following the drawing, the filaments may be subjected to annealing. This may be carried out by running the oriented filaments from a feed roll to a takeup roll and heating the filaments between the rolls, with the takeup roll rotating at a speed ranging from the same speed of the feed roll to a speed 4 percent slower than that of the feed roll. At the first-mentioned speed ratio, essentially no shrinkage will take place, and at the second-mentioned speed ratio shrinkage will take place up to 4 percent of its length. As a consequence of this annealing, the filaments undergo essentially no shrinkage under the action of body fluids, when used as sutures.

Instead of spinning the polylactide polymers into filaments, it is possible to extrude or cast it into films, which are then drawn and annealed. The films thus treated can be cut into narrow strips for use as sutures. In the preferred embodiment the sutures are made from filaments.

As best illustrated in FIG. 1, if the polylactide filaments 12 are to be used for suturing, one end thereof may be inserted in a drilled needle 13 and securely fastened in place by swaging to form a needle and suture combination.

Polylactide filaments, unlike catgut, are adversely affected by moisture and tubing fluid. For this reason, polylactide prostheses are packaged dry in a hermetically sealed package a preferred form of which is shown in FIG. 2. Referring now to FIG. 2, there is shown a surgical package indicated generally as 14 having disposed therein a coil of polylactide suture 12 one end of which is attached to a needle 13. The needle and suture are positioned within a cavity 16 that is evacuated or

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filled with a dry atmosphere such as nitrogen. The package is fabricated of two sheets of aluminum foil or aluminum foil plastic laminate material and heat sealed or bonded with adhesive at the skirt 18 to hermetically seal the cavity and isolate the contents of the package from the external atmosphere.

It is to be understood that minor amounts of inert additives such as coloring materials and plasticizers can be incorporated in the sutures by being mixed with the copolymers by known techniques. Any of a variety of plasticizers such as, for instance, glyceryl triacetate, ethyl benzoate, and diethyl phthalate can be used to advantage, especially with poly-L lactide. Preferred plasticizers for the glycolide copolymers are dibutyl phthalate and bis 2-methoxyethyl phthalate. The amount of plasticizer may vary from 1–40 percent based on the weight of the polymer. Not only does the plasticizer render the filaments more pliable and more easy to handle, but it also helps in spinning. By the term "inert" is meant materials that are inert chemically to the polymer, and are inert to living tissue, i.e., do not cause any of the adverse effects discussed on page 2 of this specification.

The present invention may be further illustrated by the following examples:

EXAMPLE I

Filaments having a diameter of 11.5 to 12.5 mils, a modulus of 1.04×10^6, tensile strength of 47,000 lb./sq. in., a knot strength of 37,000 lb./sq. in., and an elongation at break of 21 percent, were prepared by spinning polymer from L(−) lactide, said polymer having an inherent viscosity of 2.44 (measured at 0.1 percent concentration in benzene at 25° C.), from melt at 190° C., and drawing to 6:1 ratio in glycerol at 95° C. Some of the filaments were annealed taut at 126° C. and others at 100° C. as shown in more detail in table III which follows:

TABLE III

Annealed Taut at 126° C. for 5 Min	Shrinkage
Placed relaxed in oven at 126° C. for 5 minutes	7.4 percent
Control (i.e., not annealed)	28.2 percent
Placed relaxed in water at 100° C. for 5 minutes	13.0 percent
Control	28.2 percent
Placed relaxed in water at 77° C. for 5 minutes	1.4 percent
Control	18.0 percent
Annealed Taut at 100° C. for 5 Min	
Placed relaxed in oven at 100° C. for 5 minutes	11.0 percent
Control	21.4 percent
Placed relaxed in water at 77° C. for 5 minutes	7.4 percent
Control	18.0 percent

Annealed filaments such as described above are particularly useful as sutures as evidenced from example II.

EXAMPLE II

A polymer of L(−) lactide, said polymer having an inherent viscosity of 1.4, was melt spun at 160° to 170° C. into a monofilament. The filament was then drawn to four times the undrawn length by passage over a metal plate heated to 90° C. The filament obtained measured 0.007 inch in diameter. To improve dimensional stability, the drawn monofilament was annealed for 3 minutes at 90°–95° C. while under tension. The drawn, annealed filament was cut to convenient length and sterilized by being placed in polyethylene bags, which were sealed and exposed to two passes under a Van de Graaff beam of 2 million electron volts (1 to 1.5 Mrads per pass). Some of the bags contained dry monofilament, some contained monofilament in water and some contained monofilaments in ethyl alcohol.

The effect of annealing can be seen by these observations. When the annealed monofilament was heated in a dry oven at 95° C. for 3 minutes in a relaxed state, it shrank less than 4 percent. By contrast, an identical monofilament that had not been annealed shrank 25 percent. The annealed monofilament at 77° C. in water for 5 minutes shrank 14 percent.

In another experiment, the annealed monofilament was implanted in the abdominal cavity of a young adult male rat. After 16 days the implantation was removed. It had undergone less than 2 percent shrinkage.

The monofilaments thus obtained were used to connect severed muscle tissue in rats and in dogs in accordance with the following procedure:

A midline incision was made in the rat's abdominal skin, the skin was peeled back, and two small slits were then made in the abdominal muscles, one on either side of the midline. Each rat was sutured with several loops of the sterilized monofils prepared as above in one incision. Each rat had, as a control, either plain or chromic catgut suture in the other incision (size 4–0, 0.006–0.008 inch diameter). The skin was then closed and clamped. The rats were observed at regular intervals.

The sterilized monofils were tested for suturing dogs as follows: a midline incision about 3 to 4 inches long was made in the skin over the abdomen of a 6-month old dog. The skin was separated from the abdominal musculature and retracted with conventional retractors. Three incisions about 1 inch long were made through the abdominal musculature. One incision was closed with polylactic acid suture material, the other incisions were sutured with commercial catgut sutures (U.S.P. type A plain, size 4–0, and type C medium chromic, size 4–0).

Rats were sacrificed at intervals of 2, 4, 7, 14, 28, 59, 91, and 140 days. Dogs were sacrificed at 14, 23, and 50 days. In these examinations it was observed that the polylactic acid monofilaments were more slowly absorbed than plain gut. Further, it was observed that there was less general tissue reaction with the polylactic acid, as shown by gross appearance and by examination of histological sections.

EXAMPLE III

Polymer from L(−) lactide having an inherent viscosity of 3.11 at 0.1 percent concentration in benzene at 25° C., prepared by previously described methods, was converted to sutures by melt spinning, drawing, and annealing as described in example I.

EXAMPLE IV

Monofils of poly-DL-lactic acid, having an inherent viscosity of 1.42 at 0.1 percent concentration in benzene at 25° C., were tested as sutures after having been sterilized by two passages under a 2 Mev. electron beam at 1 to 1.25 Mrads. per pass. The sterilized monofils (0.006–0.008 inch diameter) were tested in suturing rats as follows:

A midline incision was made in the rat's abdominal skin, the skin was peeled back, and two small slits were then made in the abdominal muscles, one on either side of the midlines. Each rat was sutured with several loops of the sterilized monofils prepared as above in one incision and with a catgut suture as control in the other incision (unchromed, size 4–0, 0.006–0.008 inch diameter). The skin was then closed and clamped. The rats were observed at regular intervals. After approximately one month, the poly-DL-lactic acid sutures were about 50 percent hydrolyzed; tissue reaction was minimal to absent with no evidence of granuloma formation and adhesions. In the rats sutured with catgut, the catgut absorbed to about 60 percent after about 1 month, but there was pronounced tissue reaction with evidence of adhesions and granulation.

After about 60 days, both the polylactic acid and catgut sutures were absorbed, but the rats sutured with the catgut showed more scar tissue than the rats sutured with the polylactic acid.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,636,956 Dated January 25, 1972

Inventor(s) Allan K. Schneider

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Col. 11, Table VI, under "Mole %", second occurrence, line 2 : -75- has been omitted.

Col. 11, Table VI, under "Grams", second occureence, line 2 : should read -71.4-.

Col. 12, line 8 : the degree sign should appear after "85".

Col. 12, line 59 : "Example 59" should read -Example XVIII-.

Col. 13, Table IX : the last number in the first line "Days post Implantation" should read -15-; the last number in second line should read -o.4-; the last number in last line should read -2.4-.

Col. 15, Claim 7 : "107" should read -1-.

Col. 15, Claim 15 : "114" should read -8-.

Signed and sealed this 28th day of November 1972.

(SEAL)
Attest:

EDWARD M.FLETCHER,JR.
Attesting Officer

ROBERT GOTTSCHALK
Commissioner of Patents

With rabbits, the suture material was found to be completely absorbed before about 38 days, irrespective of whether it was plain catgut or polylactic acid. However, the rabbits which were stitched with the polylactic acid sutures showed no adverse tissue reactions, with no tissue walling off or covering over of the suture material, in contrast to the behavior of catgut.

A midline incision of about 3 to 4 inches long was made in the skin over the abdomen of a 6-month old dog. The skin was separated from the abdominal musculature and retracted with conventional retractors. Two incisions about 1 inch long were made through the abdominal musculature. The right side incision was closed with polylactide suture material (size 4–0). The left incision was sutured with catgut (U.S.P. type A plain, size 4–0). After 4 days the polylactide was intact with no evidence of granulation or adhesion. At the end of 14 days, the dog was again examined and at the time the incision closed with the catgut showed intense inflammatory reaction. In contrast, the incision closed with the polylactic acid suture was free of granuloma formation, and the scar was clearly visible, i.e., no inflammation was evident. In both cases, however, the suture material had been absorbed by the tissue.

EXAMPLE V

A mixture of 95 parts by weight of L(−) lactide and 5 parts by weight of DL-lactide was fused under nitrogen, and there was added 0.125 part by weight of diethylzinc as a 25 percent solution in heptane. The mixture was heated at 105° C. for 1 hour at atmospheric pressure in an atmosphere of nitrogen. The solid L(−) lactide/DL-lactide (95/5) copolymer thus obtained had an inherent viscosity of 2.63 (0.1 percent solution in benzene at 34.5° C.). The copolymer was ground to a fine powder, which was in turn pressed to a plug suitable for use in an extrusion-spinning apparatus. Filaments of the copolymer were spun at about 200° C. through a 35 mil spinneret and were drawn to 6.4 times their original length in glycerol at about 120° C. The drawn filaments had the following properties:

Inherent viscosity	1.7
Diameter	12.5 mils
Tensile strength	58,500 p.s.i.
Elongation at break	20 percent
Modulus	1.08×10^6 p.s.i.
Knot strength	37,000 p.s.i.
Shrinkage after 5 minutes in water at 37° C	23 percent
Weight loss after 30 hours in boiling water	30 percent
After 90 Days in Distilled Water at 37° C	
Inherent viscosity	0.53
Tensile strength	19,000 p.s.i.
Weight loss	2.8 percent

After 90 Days in Distilled Water at 37° C

Inherent viscosity	0.38
Tensile strength	5,000 p.s.i.
Weight loss	3 percent

EXAMPLES VI–XIII

A number of other L(−) lactide copolymers were prepared and spun into filaments by the method of example V. When the comonomer was a liquid at ordinary temperature (beta-propiolactone, gamma-butyrolactone, or pivalolactone), it was added to the lactide only after the lactide had been fused. The bulk polymer properties, spinning conditions, and filament properties of these copolymers are summarized in the following table:

TABLE IV

	Examples							
	VI	VII	VIII	IX	X	XI	XII	XIII
Weight percent comonomer	7.5% DL-lactide	10% DL-lactide	15% DL-lactide	5% glycolide	10% glycolide	5% beta-propiolactone	5% gamma-butyrolactone	5% pivalolactone
Inh. visc. (bulk)	2.87	2.50	2.30	2.53	2.52	1.31	2.99	2.68
Spinning temp., °C.	190	200	200	210	190	.....	170	170
Draw ratio	8.6	8.1	7.5	6.8	8.0	.....	10	10
Drawing temp., °C.	128	125	100	125	100	.....	115	100
Inh. visc. (drawn fil.)	1.75	1.75	1.47	1.84	1.70	.....	1.73	1.61
Diameter (mils)	11.5	11.0	12.5	10.3	8.5	.....	9.4	8.5
Ten. strength (p.s.i.)	53,300	69,000	53,000	77,000	57,800	.....	59,000	58,000
Elong. at break, percent	20	20.7	15.5	14	32	.....	17	22
Modulus (p.s.i.)	1.4×10^6	1.1×10^6	1.1×10^6	1.1×10^6	0.46×10^6	.....	.....	1.2×10^6
Knot strength (p.s.i.)	37,800	37,100	30,000	43,000	37,000	.....	42,000	48,000
Shrinkage (H₂O/77° C./5 min.), percent	13	37.5–44	7.2	12	7.3	.....	11.5	11.5
Wt. loss (H₂O/100° C./30 hrs.), percent	64	66	65	45	.....	.....	.....	.....
After 30 days in water at 37° C.:								
Inh. visc. (drawn fil.)		0.54	.....	0.56	.....	.....	0.91	0.72
Ten. strength (p.s.i.)		29,600	.....	26,000	.....	.....	.....	.....
Wt. loss, percent		3.5	.....	7.4	.....	.....	5.6	9.3
After 90 days in water at 37° C.:								
Inh. visc. (drawn fil.)				0.34	.....	.....	0.54	0.35
Ten. strength (p.s.i.)				12,000	.....	.....	.....	.....
Wt. loss, percent				12.1	.....	.....	7.1	3.5

[1] About.

EXAMPLES XIV—XV

Copolymers of L-lactide with the intermolecular cyclic esters of alpha-hydroxybutyric acid and alpha-hydroxyheptanoic acid were made by essentially the method of example V.

A mixture of 44.2 parts of L-lactide and 5.8 parts of the cyclic ester of alpha-hydroxybutyric acid was fused under nitrogen, and there was added 0.08 part of 25 percent solution of diethylzinc in heptane. The mixture was heated at 105°–108° C. for 3 hours at atmospheric pressure in an atmosphere of nitrogen. The resulting copolymer of L-lactide and the intermolecular cyclic ester of alpha-hydroxybutyric acid (88.4/11.6) had an inherent viscosity of 2.15 (0.1 percent solution in benzene).

The copolymer of L-lactide and the intermolecular cyclic ester of alpha-hydroxyheptanoic acid (90/10) was prepared similarly from 45 parts of L-lactide, 5 parts of cyclic ester, and 0.08 part of 25 percent solution of diethylzinc in heptane. After the mixture was heated for 3 hours, the resulting polymer had an inherent viscosity of 2.28.

The spinning conditions and filament properties of these copolymers are summarized in table V.

The intermolecular cyclic esters of alpha-hydroxybutyric acid and alpha-hydroxyheptanoic acid were prepared essentially by the method of Bischoff and Walden, Ann. 279, 100 (1895). The sodium salts of the corresponding alpha-bromo acids were made from the acids and sodium methoxide in an ethyl ether/ethyl alcohol mixture. The cyclic esters were made by heating the sodium salts to 300°–315° C. under reduced pressure. The butyric acid derivative was purified by distillation at 78°–85° C./0.07 mm. and by crystallization from ethyl alcohol/petroleum ether, with cooling in solid carbon dioxide. The heptanoic acid derivative was purified by crystallization from pentane, with cooling in solid carbon dioxide, and from

ethyl alcohol. Both cyclic esters were characterized by elemental analyses and infrared absorption spectra

TABLE V

Example	XIV	XV
% Comonomer (by weight)	11.6% intermolecular cyclic ester of alpha-hydroxybutyric acid	10% intermolecular cyclic ester of alpha-hydroxyheptanoic acid
Inh. viscosity (bulk)	2.15	2.28
Spinning temperature	185° C	190° C
Draw ratio	10*	8
Drawing temperature	94° C., 122° C.*	98° C
Inherent viscosity	1.62**	1.63**
Tensile strength (p.s.i.)	66,300	59,100
Elongation at break	22.3%	18.3%
Modulus (p.s.i.)	1.04×10^5	0.95×10^5
Shrinkage (H_2O/77° C./5 min.)	20.6%	55.0%
Weight loss (H_2O/100° C./48 hrs.)	60.5%	63.6%

*The filament was drawn in two stages. In the first stage, it was drawn 7X (draw ratio) at 94° C., in the second, it was drawn at 122° C. to an extent sufficient to give an overall draw ratio of 10.

**Measured on undrawn filament. The inherent viscosities of the filaments of examples I - XIII were measured on drawn filaments.

EXAMPLE XVI

A mixture of 206 g. of powdered L-lactide/DL-lactide (90/10) copolymer and 0.6182 g. of the monosodium salt of 4-{4-(N-ethyl-p-sulfobenzylamino)diphenylmethylene}-{1-(N-ethyl-N-p-sulfoniumbenzyl)-$\Delta^{2,5}$-cyclohexadienimine}[F D & C (Food, Drug, and Cosmetic) Green No. 1] was rotated in a Fisher-Kendall mixer for 48 hours at room temperature. The resulting homogeneous mixture was pressed to a plug and spun into green monofilaments by essentially the method of example V.

EXAMPLE XVII

The weighed amounts of L(−) lactide melting at 98°–99° C. and having a specific rotation (sodium D-line, 25° C.) of −295 to −300, and glycolide (m.p. 82.8–84.5° C.) are mixed in the quantities indicated below and added to a cylindrical tube containing stannous octoate catalyst and a magnetic stir bar. After sealing under 110 mm. of mercury pressure, the vessel is heated at 105° C. for 96 hours with magnetic stirring to yield a cylinder of solid copolymer. In each case, 0.0039 mol (0.1580 g.) of stannous octoate is used as the catalyst. The monomer initiator ratio (A/I) is 1,500.

The reacting quantities and mol percent of the comonomers investigated in this example are summarized in the following table:

TABLE VI

GLYCOLIDE Mole %	GLYCOLIDE Grams	GLYCOLIDE Moles	LACTIDE Mole %	LACTIDE Grams	LACTIDE Moles
20	13.3	0.116	80	66.6	0.46
25*	19.1	0.163		77.8	0.69
30	20.2	0.17	70	58.6	0.41
35	23.6	0.20	65	54.7	0.38
40	26.7	0.23	60	50.4	0.35
45	30.2	0.26	55	46.1	0.32
50	33.4	0.29	50	41.8	0.29
55	39.2	0.34	45	40.1	0.28
60	47.1	0.41	30	25.1	0.17

A similar series is run using tetraphenyl tin as a catalyst at an A/I of 2,000 with similar results.

Each copolymer (from 20 mole percent glycolide to 70 mole percent glycolide) is extruded under pressure at a temperature of 10°–220° C. through a 35-mil orifice. The extruded fiber has a diameter of 33–36 mils and is drawn to five times its original length. The extruded fibers are heated to 70°–85° C. during this drawing step.

Strong resilient fibers having excellent tensile and dry knot strength are thus obtained, the physical characteristics of these fibers being summarized in the following table

*Used 0.1780 g. of catalyst

TABLE VII

Glycolide, mole percent	Diameter, mils	Straight, lbs.	Diameter, mils	Dry knot, lbs.	Initiator	K/S
20	15.9	8.87	15.4	6.96	Ph	0.82
20	12.4	6.00	13.1	6.82	O	0.66
25	14.7	9.14	15.2	6.61	O	0.73
25	14.8	8.66	15.2	6.17	Ph	0.66
30	15.1	9.28	15.1	6.80	O	0.80
30	15.1	10.2	14.8	6.77	O	0.84
34	14.6	8.38	14.2	6.34	Ph	0.76
40	14.3	10.2	14.3	6.63	O	0.84
40	14.2	11.4	14.1	6.7	O	0.80
46	14.1	10.0	14.7	7.12	Ph	0.73
50	14.8	11.2	13.8	6.78	O	0.84
60	14.1	8.26	14.0	6.58	Ph	0.76
60	14.2					

NOTE—Ph=tetraphenyl tin, monomer/initiator ratio=2,000. O=stannous octoate, monomer/initiator ratio=1,500. K/S=dry knot straight pull ratio.

The biological behavior of the L(−)-lactide glycolide copolymers prepared in accordance with the present example is summarized in table VIII. Sections of suture material are implanted subcutaneously in rats and removed at various intervals to determine changes in tensile strength and diameter. A large increase in the diameter of a suture following implantation is an indication of shrinkage (dimensional instability).

TABLE VIII

Glycolide, mole percent		Days post implantation 0	1	8	10	15
20	Tensile strength (lbs.)	10.1	8.8	6.7	4.2	4.0
	Diameter (mils)	14.8	15.4	16.6	16.4	16.4
25	Tensile strength (lbs.)	10.1	8.8	6.0	3.3	3.0
	Diameter (mils)	14.8	15.7	16.4	16.6	16.9
30	Tensile strength (lbs.)	10.3	9.2	6.4	3.0	1.6
	Diameter (mils)	14.1	15.4	22.7	23.8	24.2
35	Tensile strength (lbs.)	10.1	6.0	2.6	.....	.....
	Diameter (mils)	12.4	20.0	24.9	.....	.....
40	Tensile strength (lbs.)	8.6	3.4	2.2	0.0	.....
	Diameter (mils)	14.0	22.8	27.4	28.1	.....
50	Tensile strength (lbs.)	8.9	3.3	1.4	0.0	.....
	Diameter (mils)	16.0	26.6	29.4	41.0	.....
60	Tensile strength (lbs.)	8.6	2.8	0.2	.....	.....
	Diameter (mils)	14.1	30.2	36.4	.....	.....

EXAMPLE VIII

Fifty-four and seven-tenths parts by weight of L(−) lactide (0.38 mols) melting at 98°–99° C. and having a specific rotation (sodium D-line, 25° C.) of −295 to −300 is mixed with 23.6 parts by weight (0.20 mols) of glycolide (m.p. 82.8°–84.5° C.) and 0.0039 mol (0.158 parts by weight) of stannous octoate in a dry PYREX glass flask containing a stir bar under dry nitrogen. The monomer initiator ratio (A/I) is 1,500. The glass flask is sealed under 110 mm. of mercury pressure and the vessel is heated at 105° C. for 96 hours with magnetic stirring to yield a solid copolymer.

The 35 mole percent glycolide-lactide copolymer so obtained is extruded under pressure at an elevated temperature through a 35 mil orifice and drawn to five times the original length. The extruded fiber is heated to 70°–85° C. during this drawing step. The biological behavior of this 35 mole percent copolymer in rats is summarized in table IX

TABLE IX

Days post implantation	0	1	6	10	1
Tensile strength, lbs.	10.0	8.9	4.2	3.1	0
Tensile strength, p.s.i. X10³	60.0	53.3	25.2	18.6	2

A 35 mole percent copolymer, prepared as described above may be extruded to form a rod that can be oriented by drawing 3× at an elevated temperature. The rod so formed will have a tensile strength greater than 25,000 p.s.i.

Although this invention has been specifically illustrated with monofilaments, the products of the present invention may also be manufactured in the form of multifilaments, that may be braided to form sutures. Filaments suitable for braiding having a diameter in the range of 0.00025–0.003 inches may be conveniently obtained by dry spinning a L(−) lactide polymer dissolved in a suitable solvent. The manufacture of a braided size 2/0 suture from multifilament obtained by dry spinning a L(−) lactide copolymer is illustrated in the following example.

EXAMPLE XIX

A round-bottomed PYREX flask having a long neck is carefully cleaned, flame dried, evacuated and purged two times with dry nitrogen. To the flask is added under a dry nitrogen atmosphere:

231.42 parts glycolide (M.P. 82.8–84.5° C.) 30.19 wt. percent
533.52 parts L(−) lactide (M.P. 98°–99° C.) 69.61 wt. percent
1.5558 parts stannous octoate, 0.20 wt. percent

The flask is evacuated to 125 mm. pressure and heated at 105° C. for 66 hours. The polymer so obtained (inherent viscosity in 0.1 percent chloroform solution = 3.2–3.4) is dissolved in dry 1, 1,2-trichloroethane (distilled from phosphorous pentoxide) to give a clear 8 percent (W/W) solution (bulk viscosity 1,600 poise).

The spin dope (8 percent solution) is heated to 90° C. and extruded through a 10-hole 0.005 inch spinneret (capillary land/diameter = 2.4) at a rate of 3 milliliters per minute into a heated column 15 feet long and 6 inches in diameter. The temperature within the heated column varied from 128° C. at the bottom to 142° C. at the top and the column is swept with hot nitrogen (131–134° C.) at a rate of 5 cubic feet per minute. The extruded filaments are taken up on a reel at a linear speed of 150 feet per minute. The inherent viscosity of the filamentary material is 3.4 indicating no degradation during the spinning process. The copolymer filament is lustrous in appearance and has the following physical characteristics:

Tensile Strength	1.0 grams/denier
Elongation	330 percent
Young's Modulus	24 grams/denier

The filament contains about 1.5 percent residual solvent.

The yarn from the takeup spool is 6-plied to 60 filaments and drawn 4.5 times at 75° C. and 25 feet per minute input speed through a tubular furnace swept with nitrogen. The drawn yarns prepared as described above have the following physical characteristics:

Tensile Strength	2.8–3.3 grams/denier
Elongation	26 percent
Young's Modulus	50 grams/denier

The individual filaments have a tensile strength of about 4.5–5.0 grams/denier; an elongation of about 38 percent and a Young's Modulus of about 45 grams per denier. The yarn is braided to form a size 2/0 braided suture, packaged in a dry atmosphere in a hermetically sealed container and sterilized by Cobalt 60 gamma irradiation. The in vivo absorption characteristics of this braided suture material in rats are indicated in Table X.

TABLE X

	After days post implantation				
	0	1	6	10	15
Tensile strength (X10³ p.s.i.)	38	47	37	31	30

It will be noted from a comparison of table IX and table X that the braided structure obtained from yarn that has been dry spun from a suitable solvent (example XIX) retained in vivo tensile strength for a longer period of time than a melt extruded monofilament of similar composition (example XVIII). The improvement in in vivo tensile strength exhibited by the dry spun braided suture is such that the amount of glycolide in the lactide copolymer composition may be increased to 40 mole percent (34.8 weight percent glycolide, 65.2 weight percent L-lactide). A copolymer suture of this composition (40 mole percent glycolide 60 mole percent L-lactide) has tensile strength and absorption characteristics similar to catgut.

Multifilament yarns that contain polylactide filaments together with nonabsorbable filaments of DACRON, TEFLON, nylon, etc., are useful in the manufacture of vascular grafts. Such a multifilament yarn is illustrated in FIG. 4 wherein the nonabsorbable fiber is represented by the hatched fiber cross section 19. In FIG. 4, the fibers 20 are extruded from lactide polymer and copolymer compositions as described above. The relative proportions of absorbable filaments 20 and nonabsorbable filaments 19 may be varied to obtain the absorption characteristic desired in the woven fabric or tubular implants. Methods of weaving and crimping vascular prostheses are described in U.S. Pat. No. 3,096,560.

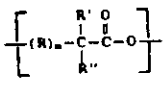
Composite fabrics of absorbable and nonabsorbable materials fashioned by textile processes including weaving, knitting, and fabricating by the nonwoven felting of fibers are described in U.S. Pat. No. 3,108,357 and U.S. Pat. No. 3,463,158. Similar techniques may be used in the manufacture of surgical aids wherein nonabsorbable fibers are combined with absorbable fibers composed of lactide polymers and copolymers. The surgical utility of "bicomponent filaments" containing absorbable and nonabsorbable components is described in U.S. Pat. No. 3,463,158, the teaching of which is incorporated herein by reference. Monofilaments of lactide polymers and copolymers may be woven or knitted to form an absorbable fabric having the structure illustrated in FIG. 5, useful surgically in hernia repair and in supporting damaged liver, kidney, and other internal organs.

The products of the invention are useful in surgical applications where an absorbable aid or support is required, for example, in the formation of surgical mesh, absorbable staple, artificial tendons, or cartilage material, and in other uses where a temporary aid during healing is needed. They may also be used to advantage in repairing hernias and in anchoring organs which have become loose.

As many apparently widely different embodiments of this invention may be made without departing from the spirit and scope thereof, it is to be understood that this invention is not limited to the specific embodiments thereof except as defined in the appended claims.

I claim:

1. A sterile surgical suture absorbable without causing unfavorable tissue reaction and essentially dimensionally stable within the body comprising an oriented synthetic polylactide polymer containing more than about 85 percent by weight of repeating units of one antipodal species of alpha-hydroxypropionic acid and no more than about 15 percent by weight of repeating units of the formula



where R is lower alkylene, m is an integer of 0 to 1, R' is selected from the class consisting of hydrogen and lower alkyl, and R'', which can be the same or different than R', is selected from the class consisting of hydrogen and alkyl of up to 22 car-

bons when m is 0 and, when m is 1, R'' is selected from the class consisting of hydrogen and lower alkyl, said polylactide before being oriented being characterized by having an inherent viscosity of at least 1.2 at 0.1 percent concentration in benzene at 25° C. and by losing at least about 20 percent of its weight on treatment with boiling water for a period of 100 hours, and being further characterized by exhibiting a tensile strength of from 40,000 to about 100,000 p.s.i. and by having a diameter of 0.0005–0.045 inches.

2. The suture of claim 1, packaged in a dry atmosphere within a hermetically sealed container.

3. The suture of claim 1, packaged within an evacuated hermetically sealed container.

4. The suture of claim 1, wherein the polylactide polymer is a poly L(−) lactide containing up to 15 percent by weight of repeating units derived from DL-lactide.

5. The suture of claim 1, containing a minor amount of inert coloring agent and plasticizer.

6. The suture of claim 1, containing bis 2-methoxyethyl phthalate as a plasticizer.

7. A method of retaining living tissue in a desired location and relationship during a healing process which comprises:

sewing living tissue with the suture of claim 107, whereby said suture becomes imbedded in the tissue;

and leaving the suture in said tissue until said suture is absorbed by the tissue during the healing process.

8. The suture of claim 1, having a sterile needle attached to one end thereof.

9. The needle and suture combination of claim 8, packaged in a dry atmosphere within a hermetically sealed container.

10. The needle and suture combination of claim 8, packaged within an evacuated hermetically sealed container.

11. The needle and suture combination of claim 8, wherein said monofilament is a poly-L-(−) lactide containing up to 15 percent by weight of repeating units derived from DL-lactide.

12. The needle and suture combination of claim 8, wherein said monofilament is a 95/5 weight percent copolymer of L(−) lactide and DL-lactide.

13. The needle and suture combination of claim 8, wherein said monofilament contains a minor amount of inert coloring agent and plasticizer.

14. The needle and suture combination of claim 8, wherein said monofilament contains bis 2-methoxyethyl phthalate as a plasticizer.

15. A method of retaining living tissue in a desired location and relationship during a healing process which comprises:

sewing living tissue with the suture of claim 114, whereby said suture becomes imbedded in the tissue;

and leaving the suture in said tissue until said suture is absorbed by the tissue during the healing process.

16. A sterile surgical suture absorbable without causing unfavorable tissue reaction and essentially dimensionally stable within the body comprising a synthetic polylactide copolymer containing at least about 65 mole percent of repeating units derived from one antipodal species of alpha-hydroxypropionic acid and not more than about 35 mole percent of repeating units derived from alpha-hydroxyacetic acid, said polylactide being characterized by having an inherent viscosity of at least 1.2 at 0.1 percent concentration in a suitable solvent at 25° C. and by losing at least about 20 percent of its weight on treatment with boiling water for a period of 100 hours, and being further characterized by exhibiting a tensile strength of from 40,000 p.s.i. to about 100,000 p.s.i. and by having a diameter of 0.0005–0.045 inches.

17. The suture of claim 16, packaged in a dry atmosphere within a hermetically sealed container.

18. The suture of claim 16, packaged within an evacuated hermetically sealed container.

19. The suture of claim 16, wherein the polylactide copolymer contains about 35 mole percent of repeating units derived from alpha-hydroxyacetic acid.

20. The suture of claim 16, wherein the polylactide copolymer contains about 30 mole percent of repeating units derived from alpha-hydroxyacetic acid.

21. The suture of claim 16, wherein the polylactide copolymer contains about 25 mole percent of repeating units derived from alpha-hydroxyacetic acid.

22. The suture of claim 16, wherein the polylactide copolymer contains about 20 mole percent of repeating units derived from alpha-hydroxyacetic acid.

23. The suture of claim 16, wherein the polylactide copolymer contains about 15 weight percent of repeating units derived from alpha-hydroxyacetic acid.

24. The suture of claim 16, wherein the polylactide copolymer contains about 5 weight percent of repeating units derived from alpha-hydroxyacetic acid.

25. The suture of claim 16, containing a minor amount of inert coloring agent and plasticizer.

26. The suture of claim 16, containing bis 2-methoxyethyl phthalate as a plasticizer.

27. A method of retaining living tissue in a desired location and relationship during a healing process which comprises:

sewing living tissue with the suture of claim 16, whereby said suture becomes imbedded in the tissue;

and leaving the suture in said tissue until said suture is absorbed by the tissue during the healing process.

28. The suture of claim 16, having a sterile needle attached to one end thereof.

29. The needle and suture combination of claim 28, packaged in a dry atmosphere within a hermetically sealed container.

30. The needle and suture combination of claim 28, packaged within an evacuated hermetically sealed container.

31. The needle and suture combination of claim 28, wherein the polylactide polymer contains about 35 mole percent of repeating units derived from alpha-hydroxyacetic acid.

32. The needle and suture combination of claim 28, wherein the polyactide polymer contains about 30 mole percent of repeating units derived from alpha-hydroxyacetic acid.

33. The needle and suture combination of claim 28, wherein the polylactide polymer contains about 25 mole percent of repeating units derived from alpha-hydroxyacetic acid.

34. The needle and suture combination of claim 28, wherein the polylactide polymer contains about 20 mole percent of repeating units derived from alpha hydroxyacetic acid.

35. The needle and suture combination of claim 28, wherein the polylactide polymer contains about 15 weight percent of repeating units derived from alpha-hydroxyacetic acid.

36. The needle and suture combinaton of claim 28, wherein the polylactide polymer contains about 5 weight percent of repeating units derived from alpha-hydroxyacetic acid.

37. The needle and suture combination of claim 28, wherein said monofilament contains a minor amount of inert coloring agent and plasticizer.

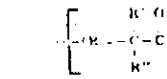
38. The needle and suture combination of claim 28, wherein said monofilament contains bis 2-methoxyethyl phthalate as a plasticizer.

39. A method of retaining living tissue in a desired location and relationship during a healing process which comprises:

sewing living tissue with the needle and suture combination of claim 28, whereby said suture becomes imbedded in the tissue;

and leaving the suture in said tissue until said suture is absorbed by the tissue during the healing process.

40. A sterile surgical suture absorbable without causing unfavorable tissue reaction and essentially dimensionally stable within the body in the form of a braided structure, comprising filaments of a synthetic polylactide polymer containing at least about 85 percent by weight of repeating units of one antipodal species of alpha-hydroxypropionic acid and no more than about 15 percent by weight of repeating units of the formula



where R is lower alkylene, m is an integer of 0 to 1, R' is selected from the class consisting of hydrogen and lower alkyl, and R'', which can be the same or different from R', is selected from the class consisting of hydrogen and alkyl group of up to 22 carbons when m is 0 and, when m is 1, R'' is selected from the class consisting of hydrogen and lower alkyl, said polylactide being characterized by having an inherent viscosity of at least 1.2 at 0.1 percent concentration in benzene at 25° C. and by losing at least about 20 percent of its weight on treatment with boiling water for a period of 100 hours, at least 50 percent of the filaments making up the braided structure being oriented and the diameter of the filaments ranging from 0.00025 to 0.003 inches; and the braided structure itself being characterized by exhibiting a tensile strength of from 40,000 p.s.i. to about 100,000 p.s.i.

41. The suture of claim 40, packaged in a dry atmosphere within a hermetically sealed container.

42. The suture of claim 40, packaged within an evacuated hermetically sealed container.

43. The suture of claim 40, wherein the polylactide copolymer filaments that make up said braided structure contain up to 15 percent by weight of repeating units derived from DL-lactide.

44. The suture of claim 40, wherein the polylactide copolymer filaments that make up said braided structure are a 95/5 weight percent copolymer of L(−) lactide and DL-lactide.

45. The suture of claim 40, wherein the filaments that make up said braided structure contain a minor amount of inert coloring agent and plasticizer.

46. The suture of claim 40, wherein the filaments that make up said braided structure contain bis 2-methoxyethyl phthalate as a plasticizer.

47. A method of retaining living tissue in a desired location and relationship during a healing process which comprises:

sewing living tissue with the suture of claim 40, whereby said suture becomes imbedded in the tissue;

and leaving the suture in said tissue until said suture is absorbed by the tissue during the healing process.

48. The suture of claim 40, having a sterile needle attached to one end thereof.

49. The needle and suture combination of claim 48, packaged in a dry atmosphere within a hermetically sealed container.

50. The needle and suture combination of claim 48, packaged within an evacuated hermetically sealed container.

51. The needle and suture combination of claim 48, wherein the polylactide copolymer filaments that make up said braided structure contain up to 15 percent by weight of repeating units derived from DL-lactide.

52. The needle and suture combination of claim 48, wherein the polylactide copolymer filaments that make up said braided suture are a 95.5 weight percent copolymer of L(−) lactide and DL-lactide.

53. The needle and suture combination of claim 48, wherein the filaments that make up said braided suture contain a minor amount of inert coloring agent and plasticizer.

54. The needle and suture combination of claim 48, wherein the filaments that make up said braided suture contain bis 2-methoxyethyl phthalate as a plasticizer.

55. A method of retaining living tissue in a desired location and relationship during a healing process which comprises

sewing living tissue with the suture and needle combination of claim 47, whereby said suture becomes imbedded in the tissue,

and leaving the suture in said tissue until said suture is absorbed by the tissue during the healing process

56. A sterile surgical suture absorbable without causing unfavorable tissue reaction and essentially dimensionally stable within the body in the form of a braided structure comprising filaments of a synthetic polylactide copolymer containing at least 60 mole percent of repeating units derived from one antipodal species of alpha-hydroxypropionic acid and no more than 40 mole percent of repeating units derived from alpha-hydroxyacetic acid, said polylactide being characterized by having an inherent viscosity of at least 1.2 at 0.1 percent concentration in a suitable solvent at 25° C. and by losing at least about 20 percent of its weight on treatment with boiling water for a period of 100 hours, at least 50 percent of the filaments making up the braided structure being oriented, and the braided structure itself being further characterized by exhibiting a tensile strength of at least 15,000 p.s.i. 10 days following implantation in an animal body

57. The suture of claim 56, packaged in a dry atmosphere within a hermetically sealed container

58. The suture of claim 56, packaged within an evacuated hermetically sealed container

59. The suture of claim 56, wherein the polylactide copolymer contains about 35 mole percent of repeating units derived from alpha-hydroxyacetic acid

60. The suture of claim 56, wherein the polylactide copolymer contains about 30 mole percent of repeating units derived from alpha-hydroxyacetic acid.

61. The suture of claim 56, wherein the polylactide copolymer contains about 25 mole percent of repeating units derived from alpha-hydroxyacetic acid.

62. The suture of claim 56, wherein the polylactide copolymer contains about 20 mole percent of repeating units derived from alpha-hydroxyacetic acid

63. The suture of claim 56, wherein the polylactide copolymer contains about 15 weight percent of repeating units derived from alpha-hydroxyacetic acid

64. The suture of claim 56, wherein the polylactide copolymer contains about 5 weight percent of repeating units derived from alpha-hydroxyacetic acid.

65. The suture of claim 56, wherein the filaments that make up said braided structure contain a minor amount of inert coloring agent and plasticizer.

66. The suture of claim 56, wherein the filaments that make up said braided structure contain bis 2-methoxyethyl phthalate as a plasticizer.

67. A method of retaining living tissue in a desired location and relationship during a healing process which comprises:

sewing living tissue with the suture of claim 56, whereby said suture becomes imbedded in the tissue;

and leaving the suture in said tissue until said suture is absorbed by the tissue during the healing process.

68. The suture of claim 56, having a sterile needle attached to one end thereof.

69. The needle and suture combination of claim 68, packaged in a dry atmosphere within a hermetically sealed container.

70. The needle and suture combination of claim 68, packaged within an evacuated hermetically sealed container.

71. The needle and suture combination of claim 68, wherein the polylactide copolymer filaments that make up said braided structure contain about 35 mole percent of repeating units derived from alpha-hydroxyacetic acid.

72. The needle and suture combination of claim 68, wherein the polylactide copolymer filaments that make up said braided structure contain about 30 mole percent of repeating units derived from alpha-hydroxyacetic acid.

73. The needle and suture combination of claim 68, wherein the polylactide copolymer filaments that make up said braided structure contain about 25 mole percent of repeating units derived from alpha-hydroxyacetic acid

74. The suture of claim 68, wherein the polylactide copolymer filaments that make up said braided structure contain about 20 mole percent of repeating units derived from alpha-hydroxyacetic acid

75. The needle and suture combination of claim 68, wherein the polylactide copolymer filaments that make up said braided structure contain about 15 weight percent of repeating units derived from alpha-hydroxyacetic acid

76. The needle and suture combination of claim 68, wherein the polylactide copolymer filaments that make up said braided

structure contain about 5 weight percent of repeating units derived from alpha-hydroxyacetic acid

77. The needle and suture combination of claim 68, wherein the filaments that make up said braided structure contain a minor amount of inert coloring agent and plasticizer

78. The needle and suture combination of claim 68, wherein the filaments that make up said braided structure contain bis 2-methoxyethyl phthalate as a plasticizer

79. A method of retaining living tissue in a desired location and relationship during a healing process which comprises

sewing living tissue with the needle and suture combination of claim 68, whereby said suture becomes imbedded in the tissue,

and leaving the suture in said tissue until said suture is absorbed by the tissue during the healing process

* * * * *

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C.A. No.04-12457 PBS
DMI000297

ited States Patent [19]

by et al.

[11] 4,141,087

[45] Feb. 27, 1979

ISOMORPHIC COPOLYOXALATES AND SUTURES THEREOF

Inventors: Shalaby W. Shalaby, Long Valley; Dennis D. Jamiolkowski, Paterson, both of N.J.

Assignee: Ethicon, Inc., Somerville, N.J.

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Int. Cl.[2] A61F 1/24; A61L 17/00; C08G 63/18; A61F 1/00

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Field of Search ..... 260/75 R, 860; 3/1, 3/1.4, 1.5; 128/92 B, 92 C, 334 R, 335.5

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Primary Examiner—Benjamin R. Padgett

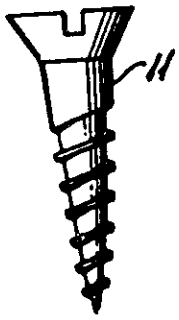
Assistant Examiner—T. S. Gron

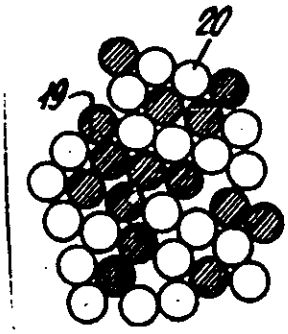
Attorney, Agent, or Firm—Wayne R. Eberhardt

[57] ABSTRACT

Synthetic absorbable sutures are prepared from copolyoxalate polymers having isomorphic sequences. The polymers are derived from mixtures of cyclic and linear diols, each having the same carbon chain length of 6 or 8 atoms. The cyclic diol may be aliphatic or aromatic. The diols are polymerized with dialkyl oxalate, preferably in the presence of an inorganic or organometallic catalyst, to obtain a highly crystalline isomorphic copolyoxalate polymer which is melt extruded and drawn to form oriented filaments. The filaments are characterized by good initial tensile and knot strength and a high order of softness and flexibility. When implanted in living animal tissue, the fibers have good strength retention over a period of at least 21 days and eventually absorb with a minimal degree of adverse tissue reaction.

21 Claims, 5 Drawing Figures





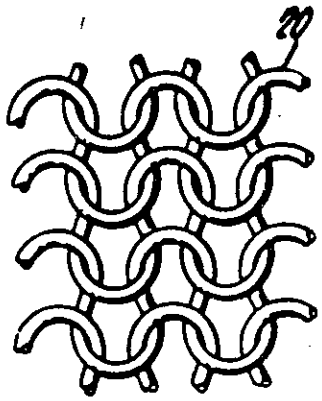


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Fig. 1.



Fig. 2.

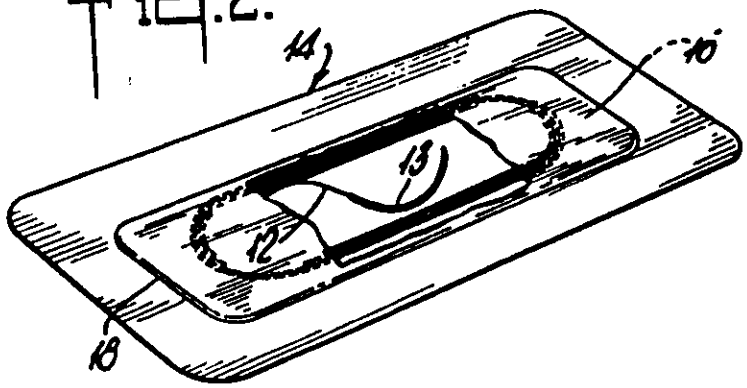


Fig. 3.

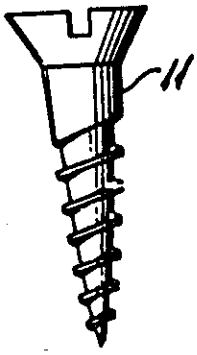


Fig. 4.

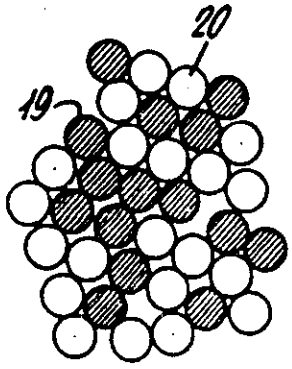
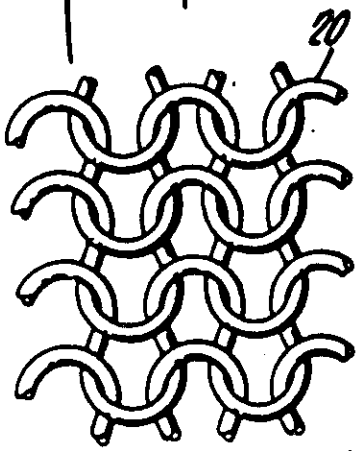


Fig. 5.



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ISOMORPHIC COPOLYOXALATES AND SUTURES THEREOF

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to synthetic absorbable sutures, and more particularly, to synthetic absorbable sutures comprising extruded and oriented filaments of copolymers of polyoxalates having isomorphic sequences.

2. Description of Prior Art

Absorbable suture materials have traditionally been natural collagenous materials obtained from sheep or beef intestine, commonly known as catgut. More recently, it has been proposed to manufacture synthetic absorbable sutures from polyesters of hydroxycarboxylic acids, notably polylactide, polyglycolide, and copolymers of lactide and glycolide. Such synthetic absorbable sutures are described in U.S. Pat. Nos. 3,636,956 3,297,033 and elsewhere in the literature. Polyesters of succinic acid have also been suggested for at least partially bioresorbable surgical articles as disclosed for example in U.S. Pat. No. 3,883,901.

Among the requirements of an ideal absorbable suture are that it should have good handling properties, should approximate and hold tissue for proper healing with minimal tearing and tissue damage, should have adequate straight tensile and knot strength, should be controllably uniform in properties including dimensional stability within the body, should be sterilizable, should be absorbable by living tissue, preferably at a constant rate regardless of the place in the body or the condition of the patient and without causing such unfavorable tissue reactions as walling off, granuloma formation or excessive edema, and finally should be capable of being properly and easily tied into surgical knots.

While multifilament sutures manufactured from polymers of lactide and glycolide fulfill the above requirements to a large degree, monofilament sutures of these materials are considerably less flexible than catgut and these synthetic sutures are accordingly generally limited to a multifilament, braided construction. Sutures of glycolide polymers are also not suitable for sterilization by radiation without suffering severe degradation of physical properties.

We have discovered that copolyoxalate copolymers having isomorphic sequences can be melt extruded into pliable, monofilament fibers which have good in vivo strength retention and are absorbed in animal tissue without significant adverse tissue reaction. The fibers have good tensile and knot strength, and can be sterilized by gamma radiation without serious loss of these properties. In addition, monofilament sutures of the polymers of the present invention have a high degree of softness and flexibility not found in many synthetic absorbable sutures of the prior art.

The preparation of polyoxalate polymers is described in the art. Carothers et al, J. Amer. Chem. Soc. 52, 3292 (1930) for example, describes the ester interchange reaction of diols such as ethylene glycol, 1,3-propanediol, or 1,4-butanediol with diethyl oxalate to yield a mixture of monomer, soluble polymer and insoluble polymer. The reaction of oxalic acid and an alkylene glycol to form polyester resins is described in U.S. Pat. No. 2,111,762, while the preparation of polyesters of fiber-forming quality from dicarboxylic acids and diols is described in U.S. Pat. Nos. 2,071,250-1 and 2,952,652. Isomorphic polymers including polyester copolymers have been discussed in the literature[1]. The particular isomorphic copolyoxalates of the present invention however, have not previously been known, nor has their preparation or use as synthetic absorbable sutures been suggested heretofore.

It is accordingly an object of the present invention to provide new and useful polymers of isomorphic copolyoxalates and articles made therefrom. A further object of this invention is to provide synthetic absorbable sutures of isomorphic copolyoxalates. It is a yet further object of this invention to provide surgical aids and prostheses fabricated of fibers or cast or machined from blocks of isomorphic copolyoxalate polymers.

SUMMARY

Highly crystalline isomorphic polyoxalate polymers are prepared by reacting mixtures of cyclic and linear diols with dialkyl oxalate, preferably in the presence of an inorganic or organometallic catalyst. The diols comprising the reaction mixture have the same carbon chain length separation between terminal OH groups of 6 or 8 carbon atoms. The cyclic diol may be trans 1,4-cyclohexane dialkanol or p-phenylene dialkanol and comprises

(1) Isomorphism in Synthetic Macromolecular Systems, G. Allegra and L. W. Bassi, Adv. Polymer Sci. 6, 549 (1969) from about 5 to 95 mol percent, and preferably from 40 to 75 r ol percent of the total diol reactant.

Copolymers prepared by the transesterification reaction of the two diols and diethyl oxalate are melt extruded into highly crystalline filaments suitable for use as synthetic absorbable sutures. Drawn and oriented filaments are characterized by high tensile and knot strength, a Young's modulus in most cases of less than about 600,000 psi providing a high order of filament softness and flexibility, and good strength retention and minimal tissue reaction in vivo.

DESCRIPTION OF DRAWINGS

FIG. 1 is a perspective view of a needle-suture combination;

FIG. 2 is a perspective view of a needle-suture combination within a hermetically sealed container;

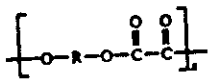
FIG. 3 illustrates a screw machined from the polymer of the present invention;

FIG. 4 is a cross-sectional view of a composite yarn containing filaments of different composition and;

FIG. 5 is a plan view of a surgical fabric knitted from fibers of the present invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

Polymers of the present invention are comprised of isomorphic units of cyclic and linear oxalates and have the general formula



wherein each R is

$$-(CH_2)_a-A-(CH_2)_a- \quad \text{I}$$

or

$-(CH_2)-_{a+2a}$ II

with from about 5 to 95 mol percent, and preferably from about 40 to 75 mol percent of R groups being I; A is trans 1,4-cyclohexylene or p-phenylene, a is 1 or 2 and is the same for I and II, and x is the degree of polymerization resulting in a fiber forming polymer having a molecular weight greater than about 10,000.

Polymers of the present invention are conveniently prepared by an ester interchange reaction between the afore-described mixture of diols and a lower ester of oxalic acid, preferably in the presence of an ester interchange catalyst. The preferred ester of oxalic acid is diethyl oxalate. The ester interchange is most preferably conducted in two stages wherein the reactants are first heated with stirring under a nitrogen atmosphere to form a prepolymer with the removal of ethanol, followed by postpolymerization under heat and reduced pressure to obtain a final polymer of the desired molecular weight and fiber forming quality. Polymers with low or moderate degrees of polymerization are postpolymerized in the liquid state or as finely-divided solid particles, depending on their melting temperature range.

The polymer is melt extruded through a spinnerette in a conventional manner to form one or more filaments which are subsequently drawn about 4X to 6X in order to achieve molecular orientation and improve tensile properties. The resulting oriented filaments have good tensile and dry knot strength and good in vivo strength retention.

It is well documented that the crystallinity and hence suitability for fiber-formation in both the AB and AA-BB type polyesters decreases significantly when the mol fraction of the major comonomer sequence decreases below about 80%. In some instances, if the comonomer sequences are isomorphic, chains composed of slightly less than 80% of the major sequences can pack into a crystalline form. However, randomly constructed copolyester chains based on almost equal amounts of the isomorphic comonomer sequences are generally found to be non-crystalline and poor fiber formers. Contrary to this general rule, the isomorphic copolyesters of the present invention display an unexpectedly high level of crystallinity of about 45% in a 50/50 copolyester. The polymers of the present invention are also unusual in that all copolymers through the entire composition range of from 5 to 95% of each isomorphic comonomer demonstrate levels of crystallinity comparable to those encountered in the parent homopolymers; namely between 30 and 50% depending on the thermal history. A similarly striking observation characteristic of these copolyesters is their display of melting endotherms, as shown by DSC, for the crystalline regions of all copolymers within the composition range of from about 5 and 95 mol % of each isomorphic comonomer. Constructed curves of the melting temperature versus composition did not reveal any positive eutectic composition in these systems. The X-ray and DSC data suggest strongly the uncommon presence of almost complete isomorphism in the copolyesters of the present invention.

Dimensional stability and tensile strength retention of the oriented filaments may be enhanced by subjecting the filaments to an annealing treatment. This optional treatment consists of heating the drawn filaments to a temperature of from about 40° to 130° C., most preferably from about 60° to 110° C. while restraining the filaments to prevent any substantial shrinkage. The filaments are held at the annealing temperature for a few seconds to several days or longer depending on the temperature and processing conditions. In general, annealing at 60° to 110° C. for up to about 24 hours is satisfactory for the polymers of the present invention. Optimum annealing time and temperature for maximum fiber in vivo strength retention and dimensional stability is readily determined by simple experimentation for each fiber composition.

Filaments of the present invention may be used as sutures in either a monofilament or a multifilament construction. Multifilament sutures are preferably braided but may also be twisted or covered in accordance with common practice. For use as sutures, it is necessary that the fibers be sterile, and sterilization may be accomplished by exposing the fibers to Cobalt 60 gamma radiation or to ethylene oxide. Such sterilization techniques are well known and commonly practiced in suture manufacture.

Since the function of a suture is to join and hold severed tissue until healing is well along, and to prevent wound separation as a result of movement or exercise, a suture must meet certain minimum standards of strength. It is particularly important that strength be maintained when knots are tied and during the actual procedure of drawing tight a suitable knot. Sutures prepared from oriented filaments of the present invention are characterized by a straight tensile strength of at least about 30,000 psi and a knot strength of at least about 20,000 psi, although significantly higher strengths may be obtained.

The preparation of high molecular weight oriented filaments of isomorphic polyoxalates is further illustrated by the following examples where all percentages are on a molar basis unless otherwise noted. The following analytical methods were used to obtain the data reported in the examples. Inherent viscosity (η_{inh}) was obtained on polymer solutions (1 gram/liter) in chloroform or hexafluoro-2-propanol (HFIP). The infrared spectra of polymer films (cast from $CHCl_3$ or HFIP) were recorded on a Beckman Acculab 1 spectrophotometer. The NMR spectra of the polymer solutions in $CHCl_3$ were recorded on an MH-100 or CFT-20 spectrophotometer. A DuPont 990 DSC apparatus was used to record the glass transition (T_g), crystallization (T_c) and melting (T_m) temperatures of the polymers under nitrogen, using about 5 mg samples and a heating rate of 10° C./min. or as otherwise specified. The thermogravimetric analysis (TGA) data of the polymers were recorded under nitrogen using a DuPont 950 TGA apparatus and a heating rate of 10° or 20° C./min. with about 10 mg samples. A Philips vertical goniometer with graphite crystal monochromatized copper K_α radiation was used to obtain the X-ray powder and fiber diffraction patterns of the polymers. Crystallinity was determined by the method of Hermans and Weidinger and the diffractometer patterns were resolved with a DuPont 310 curve analyzer.

In vitro hydrolysis of polymer discs (about 1.2 g, 2.2 cm diameter) and monofilaments (7–25 mil) was conducted at 37° C. in phosphate buffer comprising a solution of 27.6 g sodium dihydrogenphosphate monohydrate in 1000 ml. water adjusted to pH 7.25 with sodium hydroxide.

In vivo absorption (muscle) was determined by implanting two 2 cm segments of monofilament fiber into the left gluteal muscles of female Long Evans rats. The implant sites were recovered after periods of 60, 90, 120

180 days and examined microscopically to deter- the extent of absorption. In vivo absorption (sub- reous) is a non-histological technique in which nuous observation of the biological degradation of ents of suture is made by implanting two segments iture, 2 cm long, into the abdominal subcutis of g female rats. The implants are readily visible n the skin is wetted with propylene glycol and it of absorption can be determined by subjective l examination.

vivo strength retention was determined by im- ting segments of sutures in the posterior dorsal utis of female Long Evans rats for period of 5 to 30 . The sutures were recovered at the designated ds and pull-tested for straight tensile strength.

vitro strength retention was determined by placing ents of sutures in the afore-defined buffer at 50° C. periods of 2 to 4 days. The sutures were recovered he designated periods and pull-tested for straight ile strength.

EXAMPLES

General Polymerization Procedure

hethyl oxalate was heated with selected diols in a hanically-stirred reactor using a stannous alkanoate organic titanate catalyst. The reaction was con- ted under a nitrogen atmosphere at suitable temper- es until a substantial portion of the calculated ount of ethanol was obtained. Postpolymerization of resulting prepolymer was then continued under uced pressure using a suitable heating scheme. At end of the postpolymerization period, the molten ymer was allowed to cool slowly at room tempera- , isolated, ground and dried at 25° C. to 80° C. (de- ding on the polymer T_m) in vacuo for at least one . Alternatively, the prepolymer can be postpolymer- d partially in the liquid state, cooled, and then post- lymerized further in the solid state as finely divided ticles. Detailed experimental conditions for the prep- ation of representative samples of isomorphic polyox- tes and important properties of the resulting poly- rs are presented below.

EXAMPLE I

95/5 Poly (trans 1,4-Cyclohexylenedicarbinyl-co-hexamethylene Oxalate)

Distilled diethyl oxalate (19.0 g, 0.130 mol), recrystal- ed trans 1,4-cyclohexanedimethanol (19.8 g, 0.137 ol), 1,6-hexadiol (0.856 g, 0.00724 mol) and stannous toate (0.33 M in toluene; 0.080 ml, 0.026 mmol) were ded under dry and oxygen-free conditions to a glass actor equipped for magnetic stirring. The prepolymer as formed by heating the mixture at 120° C. for 3 ours under nitrogen at 1 atmosphere while allowing e formed ethanol to distill, followed by heating at 60° C. for 2 hours. The prepolymer was then heated in acuo (0.05 mm Hg) at 220° C. for 1 hour, and the ostpolymerization completed by heating at 215° C. for n additional 6 hours. The polymer was then allowed to ool to room temperature, isolated and ground, and inally dried in vacuo at room temperature.

Polymer Characterization:

ηinh in $CHCl_3$ = 0.50

DSC (20° C./min.): T_m = 210° C.

Polymer Melt-Spinning:

The polymer was spun using an Instron Rheometer with a 30 mil die at 207° C.

In Vitro Evaluation:

The undrawn fibers lost 21 and 66 percent of their initial mass after immersion in phosphate buffer at 37° C. for 42 and 127 days, respectively.

EXAMPLE II

85/15 Poly (1,4-Cyclohexylenedicarbinyl-co-hexamethylene Oxalate):

Distilled diethyl oxalate (58.4 g, 0.400 mols), recrystallized trans 1,4-cyclohexanedimethanol (less than 1% cis isomer; 53.9 g, 0.374 mols), 1,6-hexanediol (7.8 g, 0.066 mol), and stannous octoate (0.33M in toluene; 0.40 ml, 0.13 mmol) were added under dry and oxygen-free conditions to a glass reactor equipped for mechanical stirring. The mixture was heated at 120° and 150° C. for 2 and 3 hours, respectively, under nitrogen at one atmosphere while the formed ethanol distilled. The prepolymer was allowed to cool, then reheated to 200° C. under reduced pressure (0.1 mm Hg). Temperatures of 200°, 220° and 230° C. were maintained for 2, 3 and 4 hours while the collection of distillates continued. The resulting polymer (ηinh in $CHCl_3$ = 0.49) was cooled, isolated, ground (2 mm screen size), and then dried in vacuo at room temperature. Portions (30 g) of this ground polymer were postpolymerized in the solid state in glass reactors equipped for magnetic stirring by heating in vacuo (0.1 mm Hg) at 185° C. for 22 hours.

Polymer-Characterization:

ηinh in $CHCl_3$ = 1.14

DSC (20° C./min.): T_m = 187° C.

Polymer Melt-Spinning:

The polymer was spun at 230° C. using an Instron Rheometer with a 40 mil die. The fiber was quenched in ice water, wound, dried and subsequently drawn.

Fiber Properties:

Fibers drawn 5X in two stages, 4X at 62° C. followed by 1.25X at 119° C. exhibited the following properties: diameter = 8.5 mils, straight tensile strength = 8.39×10^4 psi; knot tensile strength = 5.06×10^4 psi; modulus = 6.61×10^5 psi; elongation = 15%.

In Vivo Evaluation:

Sterilized (via γ-radiation, 2.5 Mrads), drawn monofilament (8.5 mils) retained 89, 75, 10 and zero percent of its initial breaking strength (4.8 lbs.) after subcutaneous implantation in rat muscle for 3, 7, 14 and 21 days respectively. Drawn filaments implanted into the gluteal muscles of rats elicited median tissue responses in the slight range throughout a 180 day post-implantation period. Filaments drawn 4X at 60° C. followed by 1.25X at 110° C. and having a straight tensile of 6.76×10^4 psi showed indications of initial degradation 20 to 26 weeks after implantation.

In Vitro Evaluation:

Fibers drawn 4X at 60° C. (exhibiting a straight tensile of 4.33×10^4 psi) lost 40 percent of their initial mass after immersion in phosphate buffer at 37° C. for 84 days.

EXAMPLE III

80/20 Poly (1,4-Cyclohexylenedicarbinyl-co-hexamethylene Oxalate):

Distilled diethyl oxalate (43.8 g, 0.300 mol), recrystallized trans 1,4-cyclohexanedimethanol (cis isomer con-

tent = 1.0%, 36.3 g, 0.252 mol), 1,6-hexanediol (7.4 g, 0.063 mol), and stannous oxalate (12.4 mg., 0.060 mmol) were added under dry and oxygen-free conditions to a glass reactor equipped for mechanical stirring. The prepolymer was formed by heating the mixture at 120° C. for 2 hours under nitrogen at 1 atmosphere while allowing the formed ethanol to distill, followed by 160° C. for 2.5 hours. The mixture was allowed to cool, then reheated in vacuo (0.1 mm Hg) to 140° C. and maintained until the prepolymer melted. The temperature was then increased to 190° C., maintained for 30 minutes, then raised to 200° C. for 1.5 hours. The melt post-polymerization of the stirred polymer was completed by heating at 220° C. for 4.5 hours. The polymer was cooled, isolated, ground (screen size = 2 mm) and dried in vacuo at room temperature. To obtain the final product, the ground polymer was post-polymerized in the solid state in a glass reactor equipped for magnetic stirring by heating at 180° C. in vacuo (0.05 mm Hg) for 24 hours while allowing the formed diols to distill.

Polymer Characterization:

ηinh in $CHCl_3$ = 1.33

DSC (20° C./min.): T_m = 205° C.

Polymer Melt-Spinning:

The polymer was spun at 240° C. using an Instron Rheometer equipped with a 40 mil die. The extruded filaments were quenched in ice water, wound, then dried at room temperature in vacuo, and subsequently drawn 4X.

Fiber Properties:

Diameter = 9.0 mils; straight tensile strength = 7.31×10^4 psi; knot tensile strength = 3.46×10^4 psi; modulus = 7.7×10^5 psi; elongation = 15%.

In Vivo Evaluation:

Sterilized (by γ-radiation, 2.5 Mrads), fibers (9.0 mil) retained 85, 20 and zero percent of their initial breaking strength (4.2 lbs.) after subcutaneous implantation in rat muscles for 3, 7 and 14 days, respectively. These fibers were also implanted into the gluteal muscles of rats to determine tissue response and absorption characteristics. The median tissue response elicited by the samples was in the slight range after 5 days post implantation and in the minimal range after 42 days; absorption of the samples was first noted at 120 days and by 180 days approximately fifty percent of the material had been absorbed.

EXAMPLE IV

80/20 Poly (1,4-Cyclohexylenedicarbinyl-co-hexamethylene Oxalate):

Distilled diethyl oxalate (23.4 g, 0.160 mol), recrystallized trans 1,4-cyclohexanedimethanol (cis isomer content = 6.3%; 20.0 g, 0.139 mol), 1,6-hexandiol (4.1 g, 0.035 mol) and Tyzor OG* (0.117M in toluene, 0.28 ml, 0.033 mmols) were added under dry and oxygen-free conditions to a glass reactor equipped for magnetic stirring. A prepolymer was formed by heating the mixture at 120° C. for 19 hours under nitrogen at 1 atmosphere while allowing the formed ethanol to distill. The pressure was then reduced (0.05 mm Hg) and heating at 120° C. continued for 30 minutes longer. The temperature was then increased and maintained at 180° C., 190° C. and 200° C. for 2, 3 and 2 hours, respectively, while removing excess and formed diols. The polymer was allowed to cool, isolated, ground, and dried in vacuo at room temperature.

*Tyzor OG, a titanium glycolate catalyst manufactured by E. I. DuPont de Nemours and Co., Wilmington, Del., 19898

Polymer Characterization:

ηinh in $CHCl_3$ = 0.46

DSC (10° C./min.): T_m = 171° C.

TGA (10° C./min. under N_2): 0.25% weight lost at 275° C.

Polymer Melt-Spinning:

The polymer was spun using an Instron Rheometer with a 30 mil die at 172° C. The extruded filaments were quenched in ice water, dried in vacuo at room temperature, and finally drawn 5X at 43° C.

Fiber Properties:

ηinh in $CHCl_3$ = 0.42

X-ray: Major reflections correspond to 8.9 (W), 4.84 (M), 4.41 (S) and 3.42Å (W) d-spacings; 26% crystallinity. (Undrawn filaments were found to be 22% crystalline which increased to 31% by annealing at 70° C. for one hour).

Physical Properties:

Diameter = 11.1 mils; straight tensile strength = 2.07×10^4 psi; elongation = 35%.

In Vivo Evaluation:

The rate of absorption and tissue response of drawn filaments was determined by implantation into the ventral abdominal subcutis of Long-Evans rats. Some evidence of filament degradation was noted 11 to 14 weeks after implantation, with the bulk of the fiber being absorbed by 20 to 23 weeks. No tissue reaction to the implants was noted at any period.

In Vitro Evaluation:

The drawn fibers exhibited a 43% decrease in mass after immersion in the phosphate buffer at 37° C. for 28 days.

EXAMPLE V

67/33 Poly(trans 1,4-cyclohexylenedicarbinyl-co-hexamethylene Oxalate):

Distilled diethyl oxalate (40.0 g, 0.274 mol), recrystallized trans 1,4-cyclohexanedimethanol (25.9 g, 0.180 mol), 1,6-hexanediol (10.6 g, 0.0897 mol), and stannous octoate (0.33 M in toluene; 0.16 ml. 0.053 mmol) was added to a glass reactor equipped for mechanical stirring. The prepolymer was formed by heating the mixture under nitrogen at 120° C. for 9 hours, followed by 125° C. for 9 hours while collecting the distillates. The prepolymer was cooled, then reheated in vacuo (0.03 mm Hg) and maintained at 80, 120, 150, 170 and 180° C. for 1, 2, 2, 3 and 1.5 hours, respectively. The postpolymerization of the polymer melt was completed by heating at 195° C. for 6 hours while continuing to stir and remove distillates. The polymer was cooled, isolated, ground, and then dried at room temperature.

Polymer Characterization:

ηinh in $CHCl_3$ = 0.49

DSC (20° C./min.): T_m = 179° C.

Polymer Melt Spinning:

The polymer was spun at 175° C. using an Instron Rheometer with a 30 mil die. The resulting fibers were subsequently drawn 4X at 50° C.

Fiber Properties:

Diameter = 9.3 mils, straight tensile strength = 2.65×10^4 psi, knot tensile strength = 2.21×10^4 psi, modulus = 3.7×10^5 psi.

In Vivo Evaluation, Tissue Reaction:

Two centimeter long samples of sterilized (by γ-radiation, 2.5 Mrads) drawn fiber were implanted sub-

cutaneously in the abdominal wall of young female Long Evans strain rats. At intervals of 3, 14, 28, 56 and 90 days, two rats were sacrificed for examination of implants. The skin containing the fibers was excised and affixed to plastic sheets for preservation in formalin. Two tissue blocks were cut transversely from each site and embedded in paraffin for histologic preparation. Eight stained samples were examined at each interval for tissue reaction to the fibers. Only mild foreign body reactions were detected.

In Vivo Evaluation, Absorption:

Fiber segments sterilized by γ-radiation (2.5 Mrads) approximately 2 cm in length were inserted into the ventral abdominal subcutis of Long Evans rats (100 g, female) to determine the rate of absorption of the drawn fibers. One to two rats were sacrificed after various periods after implantation. The skin containing the implant sites was removed and dried. These preparations were examined and evaluated using both dissecting and transmission microscopes. Estimates of the amount of implant remaining were based on the length of the segment or fragments remaining and the decrease in the surface area made by palpating the implant in the dried hide and comparing it with a one week old preparation. Implants were fragmented at one week; migration and clumping of fragments was noted at subsequent kill periods. Evidence of degradation was first seen 16 weeks after implantation. Palpable fragments, in diminishing amounts, were present until 30 weeks. Quantitatively, about 100, 75, 45, 40, 20, 15 and 5 or less percent of the suture remained after 14, 16, 20, 23, 26, 30 and 36 weeks.

EXAMPLE VI

50/50 Poly (trans 1,4-cyclohexyldicarbinyl-co-hexamethylene Oxalate):

Distilled diethyl oxalate (38.0 g, 0.260 mol), recrystallized trans 1,4-cyclohexanedimethanol (20.2 g, 0.140 mol), 1,6-hexanediol (16.5 g, 0.140 mol), and stannous octoate (0.33 M in toluene, 0.16 ml, 0.053 mmol) were added under dry and oxygen-free conditions to a mechanically stirred glass reactor. Under nitrogen at one atmosphere, the mixture was heated to and maintained at 120° C. for 20 hours, while allowing the formed ethanol to distill. The prepolymer was cooled and then reheated in vacuo (0.05 mm Hg) to and maintained at 80°, 120°, 140°, 165°, 175°, 185°, and 195° C. for 1, 1, 3, 3.5, 2, 1 and 1 hour respectively. The removal of the diols was continued by heating at 200° C. for 8 hours to complete the postpolymerization. The polymer was cooled, isolated, ground, and then dried in vacuo at room temperature.

Polymer Characterization:

η_{inh} in $CHCl_3$ = 0.36

DSC (20° C./min.): T_m = 138° C.

Polymer Melt Spinning:

The polymer was spun at 136° C. using an Instron Rheometer (40 mil die) and was immediately drawn 5X at 53° C.

Fiber Properties:

X-ray Data: Major reflections correspond to 8.9 (W), 4.84 (M), 4.41 (S), and 5.40 Å (W) d-spacings; 36% crystallinity.

Physical Properties: Diameter = 10.6 mils, straight tensile strength = 1.36×10^4 psi, knot tensile strength = 1.13×10^4 psi, modulus = 1.33×10^5 psi, elongation = 27%.

In Vivo Evaluation:

Sterilized (by γ-radiation) drawn fiber segments (2 centimeters in length) were implanted into the ventral abdominal subcutis for study of the rate of absorption and tissue reaction.

At one week the implants were fragmented, clumping, and migrating, with the bulk of the suture being absorbed between 6 to 11 weeks. Thereafter, fragments with scattered birefringent particles or birefringent particles in a shell-like outline were observed. The birefringent particles decreased in amount until at 36 weeks only a few widely scattered particles were noted.

Only mild foreign body reactions were observed to be elicited by the sterilized drawn fiber segments during the test intervals of 3, 14, 28, 48, 90 and 180 day post implantation.

In Vitro Evaluation:

Undrawn fibers exhibited a 57 percent decrease in their initial mass after immersion in phosphate buffer at 37° C. for 28 days.

EXAMPLE VII

50/50 Poly (trans 1,4-cyclohexyldicarbinyl-co-hexamethylene Oxalate):

Distilled diethyl oxalate (58.5 g, 0.400 mol), recrystallized trans 1,4-cyclohexanedimethanol (cis isomer content = 0.7%; 29.7 g, 0.206 mol), 1,6-hexanediol (24.3 g, 0.206 mol), and stannous oxalate (16.5 mg, 0.080 mmols), were added under dry and oxygen-free conditions to a mechanically stirred glass reactor. The mixture was heated under nitrogen at one atmosphere to and maintained at 120° and 160° C. for 3 and 2 hours respectively while allowing the formed ethanol to distill. The propolymer was cooled and then reheated in vacuo (0.05 mm Hg) and maintained at 170°, 190° and 205° C. for 3, 2.5 and 3 hours respectively while continuing to remove excess and formed diol to complete the postpolymerization. The polymer was cooled, isolated, ground, and then dried in vacuo at room temperature.

Polymer Characterization:

η_{inh} in HFIP = 1.07

DSC (20° C./min.) T_m = 132° C.

Polymer Melt Spinning:

The polymer was spun at 150° C. using an Instron Rheometer (40 mil die) and was drawn 4X at 50° C. followed by 1.5X at 72° C.

Fiber Properties:

X-ray Data: Major reflections correspond to 9.11 (MS), 4.82 (S), 4.60 (W), 4.37 (S) and 3.45 Å (W) d-spacings; 46% crystallinity.

Physical Properties: Diameter = 7.6 straight-tensile strength = 51,300 psi, knot tensile strength = 36,400 psi, elongation = 31%.

EXAMPLE VIII

30/70 Poly (trans 1,4-cyclohexylenedicarbinyl-co-hexamethylene Oxalate):

Distilled diethyl oxalate (36.5 g, 0.250 mol), recrystallized trans 1,4-cyclohexanedimethanol (11.5 g, 0.0797 mol), 1,6 hexanediol (22.4 g, 0.190 mol), and stannous octoate (0.33 M in toluene; 0.16 ml, 0.053 mmol) were added under dry and oxygen-free conditions to a mechanically stirred reactor. The mixture was heated to and maintained at 125°, 140° and 160° C. for 2, 2 and 1 hour, respectively, under nitrogen at one atmosphere

while allowing the formed ethanol to distill. The prepolymer was cooled and then reheated in vacuo (0.1 mm Hg) and maintained at 150° and 185° C. for 16 and 3 hours, respectively. The postpolymerization was completed by maintaining the polymer at 200° C. for 5.5 hours while continuing to remove the diols under vacuum. The polymer was then cooled, isolated, ground and dried in vacuo at room temperature.

Polymer Characterization:

ηinh in $CHCl_3$ = 0.82

DSC (20° C./min): T_m = 85° C.

Polymer Melt Spinning:

The polymer was spun at 125° C. using an Instron Rheometer with a 40 mil die. The fiber was quenched in ice water, wound, dried in vacuo at room temprature, and subsequently drawn 5.6X at room temperature, followed by annealing at 55° C.

Fiber Properties:

Diameter 8.3 mils, straight tensile strength 5.18 × 10^4 psi, knot tensile strength 3.51 × 10^4 psi, modulus 2.11 × 10^5 and elongation 50%.

In Vivo Evaluation:

Sterilized (by γ-radiation, 2.5 Mrads), drawn fibers (9.8 mil diameter; 3.64 × 10^4 psi straight tensile strength; 2.34 × 10^4 psi knot tensile strength; 1.47 × 10^5 psi modulus; and an elongation of 45%) were implanted into the gluteal muscles of rats to determine their absorption and tissue response characteristics at 5, 21, 42 and 150 days post implantation.

At the 42 day period, there was no evidence of any morphologic changes of the implant sites indicating absorption. At the 150 day period, the fibers had a median value of 2 percent suture cross sectional area remaining (with a range of 0 to 20 percent).

Foreign body tissue responses to the samples were in the slight range at 5, 21 and 42 day periods and in the minimal range at the 150 day period.

In Vitro Evaluation:

Drawn fibers possessing physical properties similar to those of fibers used in the in vivo testing exhibited a 100% decrease in their initial mass after 141 days of immersion in phosphate buffer at 37° C.

EXAMPLE IX

5/95 Poly (trans 1,4-cyclohexylenedicarbinyl-co-hexamethylene Oxalate):

Distilled diethyl oxalate (19.0 g, 0.130 mol), recrystallized trans 1,4-cyclohexanedimethanol (1.0 g, 0.0069 mol), 1,6-hexanediol (16.3 g, 0.138 mol), and stannous octoate (0.33 M in toluene; 0.08 ml, 0.026 mmol) were added under dry and oxygen-free conditions to a glass reactor equipped for magnetic stirring. The prepolymer was formed by heating the mixture at 120° C. for 3 hours under nitrogen at one atmosphere while allowing the formed ethanol to distill, followed by 160° C. for 2 hours. The prepolymer was heated and maintained at 205° C. for 8 hours in vacuo (0.05 mm Hg). The polymer was then cooled, isolated, ground, and dried at room temperature.

Polymer Characterization:

ηinh in $CHCl_3$ = 0.88

DSC (20° C./min): T_m = 69° C.

TGA (20° C./min. under N_2): Less than 0.5% weight loss at 275° C. was recorded.

Polymer Melt Spinning:

The polymer was spun in an Instron Rheometer using 30 mil die at 85° C. The fibers were quenched in ice water and subsequently drawn 5X at room temperature.

Fiber Properties:

Diameter = 14.7 mils, straight tensile strength = 1.36 × 10^4 psi, knot tensile strength = 1.41 × 10^4 psi, modulus = 4.8 × 10^4 psi, elongation = 90%.

In Vitro Evaluation:

The drawn fibers exhibited a 93 percent decrease in their initial mass after immersion in phosphate buffer at 37° C. for 42 days.

EXAMPLE X

58/42 Poly (1,4-phenylenedicarbinyl-co-hexamethylene Oxalate):

Diethyl oxalate (14.6 g, 0.100 mols), recrystallized 1,4-benzenedimethanol (6.9 g, 0.050 mols), 1,6-hexanediol (8.3 g, 0.070 mols), and Tyzor TOT* catalyst (0.4 ml of a 1% solution) were added under dry and oxygen-free conditions to a glass reactor equipped for stirring. The prepolymer was formed by heating under nitrogen at one atmosphere at 140° C. for 4 hours while allowing the formed ethanol to distill. The mixture was then heated in vacuo (0.1 mm Hg) at 165° C. for 22 hours while continuing to remove distillates. A postpolymerization was conducted at 180°, 190°, and 200° C. for 2, 1 and 4 hours respectively. The polymer was cooled, ground and dried.

*Tyzor TOT, a tetraalkyl titanate catalyst manufactured by E. I. DuPont de Nemours and Co., Wilmington, Delaware, 19898.

Polymer Characterization:

ηinh in HFIP = 0.48

DSC (10° C./min): T_m = 170° C.

TGA (10° C./min in N_2): Less than 1% cummulative weight loss experienced at 250° C.

Polymer Melt Spinning:

The polymer was spun at 166° C. using an Instron Rheometer equipped with a 30 mil die.

In Vitro Evaluation:

Immersion of a molded disc, 2.2 cm in diameter, for 8 and 78 days in phosphate buffer at 37° C. resulted in a loss of 3 and 99 percent of the initial mass, respectively.

EXAMPLE XI

56/44 Poly (1,4-phenylenedicarbinyl-co-hexamethylene Oxalate):

Dibutyl oxalate (20.2 g, 0.100 mols), 1,4-benzenedimethanol (8.3 g, 0.060 mols), 1,6-hexanediol (5.6 g, 0.047 mols), and tetraisopropylorthotitanate catalyst (0.3 ml, of a 0.01M solution) were added under dry and oxygen-free conditions to a glass reactor equipped for magnetic stirring. The prepolymer was formed by heating at 140°, and 160° C. for 1, and 17 hours respectively under nitrogen at one atmosphere while allowing the formed butanol to distill. The pressure was reduced (0.2 mm Hg) while continuing to heat at 160° C. for an additional hour. The postpolymerization of the polymer melt was completed by heating at 180° C. and 200° C. for 2, and 3.5 hours, respectively, while continuing to remove distillates. The polymer was cooled, and isolated.

Polymer Characterization:

ηinh in HFIP = 0.42

DSC (10° C./min): T_m = 165° C.

TGA (10° C./min in N_2): Less than 1% cummulative weight loss experienced at 250° C.

In Vitro Evaluation:

Immersion of a molded disc, 2.2 cm in diameter, for 7 and 77 days, in phosphate buffer at 37° C. resulted in a loss of 3 and 56 percent of the initial mass, respectively.

EXAMPLE XII

50/50 Poly (1,4-phenylenedicarbinyl-co-hexamethylene Oxalate):

In a manner similar to that employed in Examples X and XI, the above identified copolymer having the following characteristics was produced:

DSC (10° C./min): T_m = 175° C.

TGA (10° C./min, in N_2): Less than 1% cummulative weight loss experienced at 250° C.

In Vitro Evaluation:

Immersion of a molded disc, 2.2 cm in diameter, for 8 and 78 days in phosphate buffer at 37° C. resulted in a loss of 6 and 54 percent of the initial mass, respectively.

While the preceding examples have been directed to the preparation of specific copolymers of polyoxalates, these examples are for purposes of illustration only and are not limiting of the invention. Mixtures of these polymers and combinations of these polymers with up to about 50 percent by weight of poly (alkylene oxalates) and other compatible polymers which produce non-toxic and absorbable polymers are likewise included within the present invention.

It is to be understood that inert additives such as coloring materials and plasticizers can be incorporated in the sutures. As used herein, the term "inert" means materials that are chemically inert to the polymer and biologically inert to living tissue, i.e., do not cause any of the adverse effects previously discussed. Any of a variety of plasticizers such as, for instance, glyceryl triacetate, ethyl benzoate, diethyl phthalate, dibutyl phthalate and bis-2-methoxyehtyl phthalate can be used if desired. The amount of plasticizer may vary from 1 to about 20 percent or more based on the weight of the polymer. Not only does the plasticizer render the filaments of the present invention even more pliable, it also serves as a processing aid in extrusion and thread preparation.

Filaments of the present invention are adversely affected by moisture and are accordingly preferably stored in hermetically sealed and substantially moisture-free packages, a preferred form of which is shown in FIG. 4. In FIG. 2, there is shown a suture package 14 having disposed therein a coil of suture 12, one end of which is attached to needle 13. The needle and suture are positioned within a cavity 16 that is evacuated or filled with a dry atmosphere of air or nitrogen. The illustrated package is fabricated of two sheets of aluminum foil or an aluminum foil-plastic laminate and heat sealed or bonded with adhesive at the skirt 16 to hermetically seal the cavity and isolate the contents of the package from the external atmosphere.

Filaments of the present invention may be used as monofilament or multifilament sutures, or may be woven, braided, or knitted either alone or in combination with other absorbable fibers such as poly (alkylene oxalate), polyglycolide or poly (lactide-co-glycolide), or with nonabsorbable fibers such as nylon, polypropylene, polyethylene-terephthalate, or polytetrafluoroethylene to form multifilament sutures and tubular structures having use in the surgical repair of arteries, veins, ducts, esophagi and the like.

Multifilament yarns that contain isomorphic copolyoxalate filaments of the present invention together with nonabsorbable filaments are illustrated in FIG. 4 wherein the nonabsorbable fiber is represented by the hatched fiber cross-section 19. In FIG. 4, the fibers 20 are extruded from polymer compositions of the present invention as described above. The relative proportions of absorbable filaments 20 and nonabsorbable filaments 19 may be varied to obtain the absorption characteristic desired in the woven fabric or tubular implants.

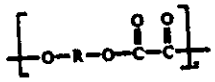
Composite fabrics of absorbable and nonabsorbable materials fashioned by textile processes including weaving, knitting and nonwoven felting are described in U.S. Pat. Nos. 3,108,357 and 3,463,158. Methods of weaving and crimping tubular vascular prostheses are described in U.S. Pat. No. 3,096,560. Similar techniques may be used in the manufacture of surgical aids wherein nonabsorbable fibers are combined with absorbable fibers composed of the polymers of this invention. The surgical utility of "bi-component filaments" containing absorbable and nonabsorbable components is described in U.S. Pat. No. 3,463,158 the teaching of which is incorporated herein by reference. Monofilaments of the polymers of the present invention may be woven or knitted to form an absorbable fabric having the structure illustrated in FIG. 5, useful surgically in hernia repair and in supporting damaged liver, kidney and other internal organs.

The polymers of the present invention are also useful in the manufacture of cast films and other solid surgical aids such as scleral buckling prostheses. Thus, cylindrical pins, screws as illustrated in FIG. 3, reinforcing plates, etc., may be machined from solid polymer having in vivo absorption characteristics depending upon the polymer composition and molecular weight.

Many different embodiments of this invention will be apparent to those skilled in the art and may be made without departing from the spirit and scope thereof. It is accordingly understood that this invention is not limited to the specific embodiments thereof except as defined in the appended claims.

We claim:

1. A synthetic absorbable suture of oriented fiber comprising an isomorphic polyoxalate polymer consisting essentially of units of cyclic and linear oxalates and having the general formula



wherein each R is

$$-(CH_2)_n - A - (CH_2)_n- \quad \text{I}$$

or

$$-(CH_2)_{n+x}- \quad \text{II}$$

and from about 5 to 95 mol percent of the R units are I; A is trans 1,4-cyclohexylene or p-phenylene, n is 1 or 2 and is the same for I and II, and x is the degree of polymerization resulting in a fiber forming polymer having a molecular weight greater than about 10,000.

2. A suture of claim 1 wherein said fiber is a monofilament.

3. A suture of claim 1 wherein said fiber is a multifilament.

4. A suture of claim 3 wherein said multifilament fiber is a braid.

5. A suture of claim 1 wherein n is 1 and A is trans 1,4-cyclohexylene.

6. A suture of claim 1 wherein n is 2 and A is trans 1,4-cyclohexylene.

7. A suture of claim 5 wherein from about 40 to 75 mol percent of the R units are of formula I.

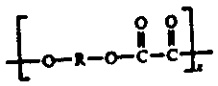
8. A suture of claim 1 wherein n is 1 and A is p-phenylene.

9. A suture of claim 1 wherein n is 2 and A is p-phenylene.

10. A suture of claim 1 having a surgical needle attached to at least one end thereof.

11. A suture of claim 10 packaged in a sterile and dry environment within a hermetically sealed and substantially moisture impervious container.

12. The method of closing a wound in living tissue which comprises approximating the wound tissue with an absorbable suture comprising of sterile, oriented fiber comprising an isomorphic copolyoxalate polymer consisting essentially of units of cyclic and linear oxalates and having the general formula



wherein each R is

$$-(CH_2)_n-A-(CH_2)_n- \quad \text{I}$$

or

$$-(CH_2)_{4+2n}- \quad \text{II}$$

with from about 5 to 95 mol percent of the R units being I; A is trans 1,4-cyclohexylene or p-phenylene, n is 1 or 2 and is the same for I and II, and x is the degree of polymerization resulting in a fiber forming polymer having a molecular weight greater than about 10,000.

13. The method of claim 12 wherein said fiber is a monofilament.

14. The method of claim 12 wherein said fiber is a multifilament.

15. The method of claim 14 wherein said multifilament fiber is a braid.

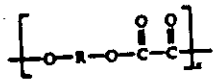
16. The method of claim 12 wherein n is 1 and A is trans 1,4-cyclohexylene.

17. The method of claim 12 wherein n is 2 and A is trans 1,4-cyclohexylene.

18. The method of claim 16 wherein units of formula I comprise from 40 to 75 mol percent of the R groups.

19. The method of claim 12 wherein A is p-phenylene.

20. A surgical prosthesis of a fabric manufactured at least in part from synthetic absorbable fibers comprising an isomorphic polyoxalate polymer consisting essentially of units of cyclic and linear oxalates and having the general formula:



wherein each R is

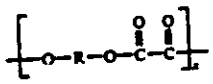
$$-(CH_2)_n-A-(CH_2)_n- \quad \text{I}$$

or

$$-(CH_2)_{4+2n}- \quad \text{II}$$

with from about 5 to 95 mol percent of the R units being I; A is trans 1,4-cyclohexylene or p-phenylene, n is 1 or 2 and is the same for I and II, and x is the degree of polymerization resulting in a fiber forming polymer having a molecular weight greater than about 10,000.

21. A surgical prosthesis of a solid surgical aid cast or machined from an absorbable polymer comprising an isomorphic polyoxalate polymer consisting essentially of units of cyclic and linear oxalates and having the general formula



wherein each R is

$$-(CH_2)_n-A-(CH_2)_n- \quad \text{I}$$

or

$$-(CH_2)_{4+2n}- \quad \text{II}$$

with from about 5 to 95 mol percent of the R units being I; A is trans 1,4-cyclohexylene or p-phenylene, n is 1 or 2, and is the same for I and II, and x is the degree of polymerization resulting in a fiber forming polymer having a molecular weight greater than about 10,000.

* * * * *

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000307

United States Patent [19]

Brennan et al.

[11] **Patent Number: 4,959,069**

[45] **Date of Patent: Sep. 25, 1990**

[54] **BRAIDED SURGICAL SUTURES**

[75] Inventors: **Karl W. Brennan**, Somerset; **Alison M. Skinner**, Long Valley, both of N.J.; **Gregory Weaver**, New Hope, Pa.

[73] Assignee: **Ethicon, Inc.**, Somerville, N.J.

[21] Appl. No.: **424,622**

[22] Filed: **Oct. 20, 1989**

[51] **Int. Cl.**[5] **A61B 17/00**

[52] **U.S. Cl.** **606/228**; 428/224; 87/7

[58] **Field of Search** 606/228, 229, 230, 231, 606/151; 138/123, 129; 139/317; 428/224

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Primary Examiner—Randall L. Green
Assistant Examiner—Gary Jackson

[57] **ABSTRACT**

A braided surgical suture is provided which in a first embodiment is woven in a spiral braid. The suture is braided by moving thread carriers from position to position around a circular path. As each carrier moves it moves from its present position to a succeeding position which is at least two positions removed from its present position. Such spiral braided sutures are advantageously produced without core filaments, providing benefits in strength, smoothness, pliability and cylindrical uniformity without the discontinuity of properties characteristic of conventionally braided cored sutures. In a second embodiment the suture is woven in a lattice braid, providing a plurality of distributed core passageways for individual core fibers.

17 Claims, 4 Drawing Sheets

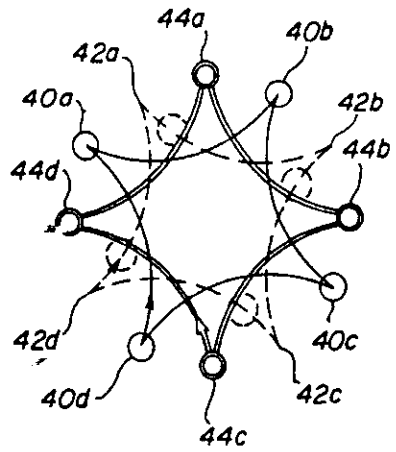


FIG-1a

PRIOR ART

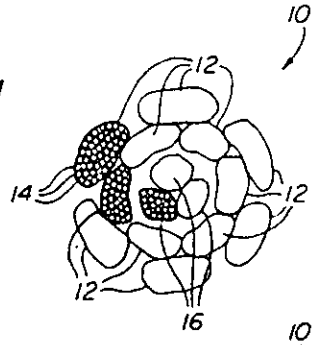


FIG-1b

PRIOR ART

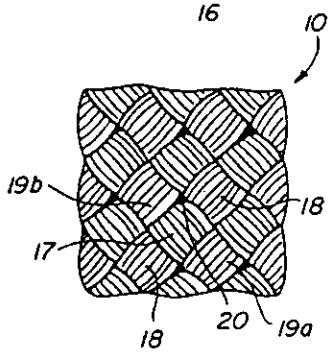


FIG-3

PRIOR ART

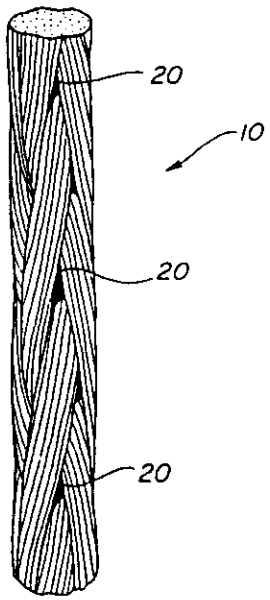


FIG-2 PRIOR ART

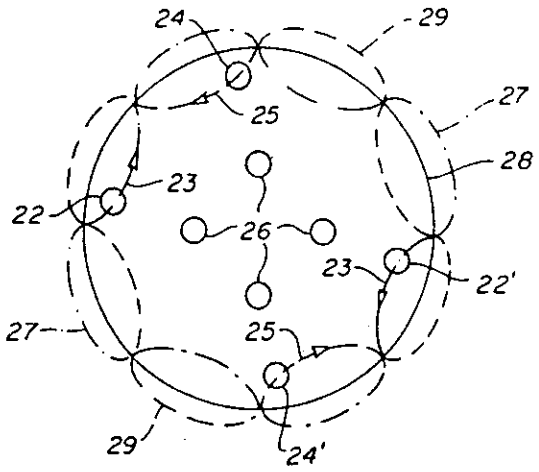


FIG-4a

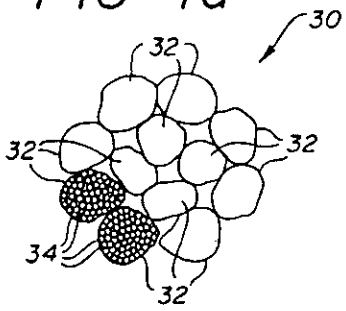


FIG-4b

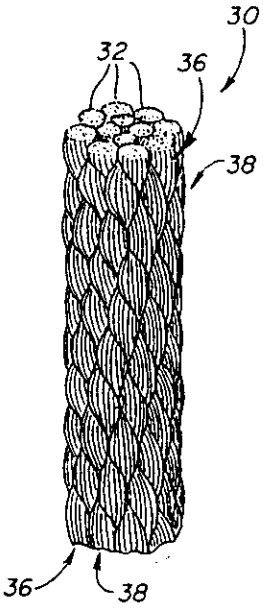


FIG-5a

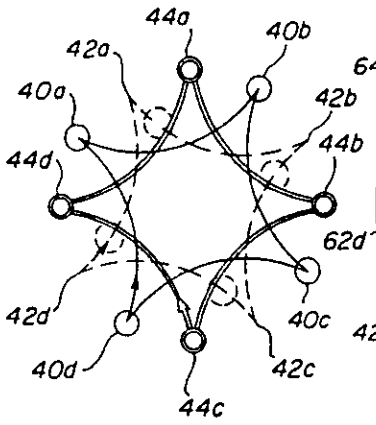


FIG-5b

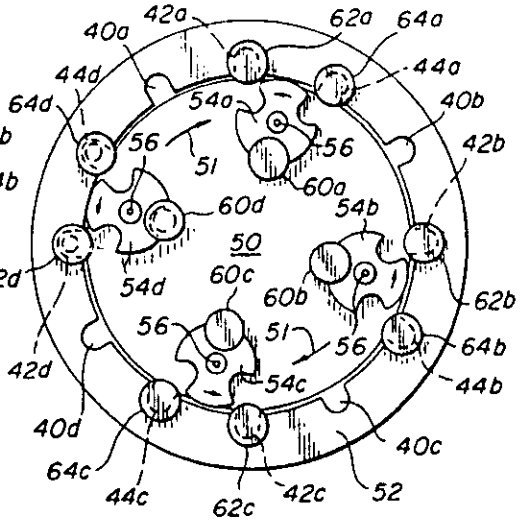


FIG-6a

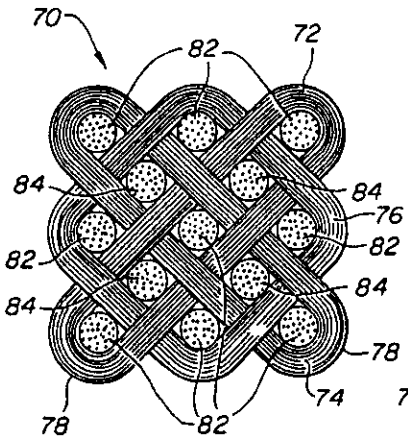


FIG-6b

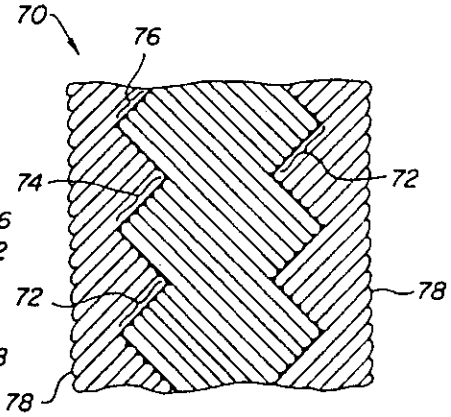
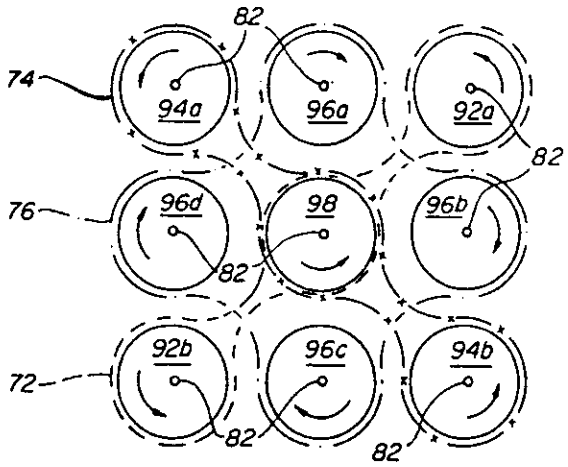


FIG-7



DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000312

BRAIDED SURGICAL SUTURES

This invention relates to surgical sutures and, in particular, to braided surgical sutures which obviate the need for a central fiber core.

Surgical sutures may be manufactured in two general forms: monofilaments and multifilaments. Monofilament sutures are generally made of natural materials such as gut, or of extruded polymeric materials such as Nylon, polypropylene, or poly (p-dioxanone), and are highly regarded for their uniform, smooth construction and uniformly distributed tensile strength. However, monofilament sutures generally have the drawback of being fairly rigid and lacking pliability. Multifilament sutures consisting of a plurality of braided filaments of a fine gauge have been found to provide the characteristic of pliability which is often desired by surgeons Such braided sutures may be made of poly(lactide-co-glycolide), polyglycolide, polyester, or silk, for example. But since braided sutures often lack substantial tensile strength, the braided filaments are conventionally braided in a tubular sheath around a core of longitudinally extending threads. Such braided sheath sutures with central cores are shown in U.S. Pat. No. 3,187,752; 4,043,344; and 4,047,533, for example.

Braided sutures with central core threads have been found to exhibit certain disadvantages, however. One is that the tensile strength of the suture is not evenly distributed between the braided sheath and the central core threads. As a consequence, when these sutures are stretched, the sheath and the core will respond differently to the application of the tensile forces. The sheath will respond to the forces independently of the central core threads, causing the central threads to move longitudinally relative to the surrounding sheath. The core threads can also flatten and redistribute themselves within the sheath instead of maintaining the desired rounded cross-sectional shape of the suture. It would be desirable for such tensile forces to be more uniformly distributed throughout the suture, so that all of the fibers of the suture will respond in unison to the tensile forces without distortion of the normal shape of the suture.

Conventionally braided sutures can also feel rough to the touch, due to the changing crossing pattern of the braided filaments, and the interstices formed where the braided fibers overlap and cross each other. To minimize this tactile characteristic it is often necessary to further process the braided suture by heating and stretching the suture. Furthermore, such interstices can trap and retain moisture in a wicking fashion. Retained moisture has been found to be a source of undesired deterioration of sutures made of certain materials, such as absorbable sutures made of poly(lactide-co-glycolide) or polyglycolide, and can also lead to retention of sources of infection within the braid. It would be desirable to form braided sutures which are smoother to the touch, and which do not exhibit interstices or passageways which can trap and retain moisture prior to use of the sutures.

It would further be desirable for braided sutures to match or exceed the breaking strength characteristics of presently available braided sutures with central core threads.

In accordance with the principles of the present invention, a braided suture is provided in which the filaments or threads are braided in a spiral pattern. Sutures

braided in a spiral pattern have been found to be capable of maintaining a uniformly rounded cross-sectional shape, and to distribute tensile forces uniformly throughout the braided fibers. Spiral braided sutures also do not form the tube-like structure of the conventional braiding pattern, which eliminates the need for a central fiber core. Since spiral braiding results in an outer sheath pattern in which the braided threads are all flowing in the same direction, the suture is much smoother to the touch than the conventionally braided suture. The smoothly flowing braided configuration also does not provide interstices which can trap undesired moisture in the suture. Furthermore, the spiral braided suture has been found to be stronger, smoother to the touch, and much more pliable than the conventionally braided suture.

In accordance with a further aspect of the present invention a suture is provided which is formed by lattice braiding. The lattice braided suture exhibits a plurality of interwoven threads in a generally rectangular cross-sectional configuration. The lattice braid may be woven around a plurality of core threads distributed in the internal interstices of the lattice network and interlocked into position, unlike the central bundle of core threads of the conventionally braided suture. The lattice braided suture has been found to be superior to the conventionally braided core suture in that it does not exhibit "core pop", the tendency of the core filaments to break through the braided sheath as the suture is bent.

In the drawings:

FIGS. 1*a* and 1*b* illustrate diagrammatic cross-sectional and side views of a conventionally braided suture;

FIG. 2 illustrates the braiding pattern of a conventionally braided suture;

FIG. 3 is a drawing of an enlarged view of the outer sheath of a conventionally braided suture;

FIGS. 4*a* and 4*b* illustrate diagrammatic cross-sectional and side views of a spiral braided suture of the present invention;

FIG. 5*a* illustrates the braiding pattern of a spiral braided suture of the present invention;

FIG. 5*b* is a diagrammatic plan view of a mechanism used to braid a spiral braided suture of the present invention;

FIGS. 6*a* and 6*b* illustrate the braiding pattern and outside sheath of a lattice braided suture of the present invention; and

FIG. 7 is a diagrammatic plan view of a mechanism used to braid a lattice braided suture of the present invention.

Referring first to FIGURE 1*a*, a conventionally braided suture 10 is shown in diagrammatic cross-section. The suture 10 comprises a plurality of threads or carriers 12 which are interwoven to form the braided sheath. Each thread generally comprises a number of individual fibers 14. The braided threads 12 form a tubular sheath around the central core threads 16, which extend longitudinally through the tubular sheath. The sheath is braided using at least three threads, or a greater even number of threads, such as 4, 6, 8, etc. The core may comprise one or any greater number of threads. The suture 10 is shown in FIG. 1*a* to exhibit its desired cylindrical uniformity. However, it has been found that during handling, heating and stretching of the suture during manufacture the tubular sheath can distort to an oval or oblong shape, with the core threads

16 redistributed in the sheath in an irregular or linear configuration.

As a consequence of the structural independence of the braided sheath and the core threads, the sheath and core will unevenly distribute tensile forces among these two substructures when the suture is stretched, causing the two to move relative to each other. The relative movement of the two can result in the formation of spaces or pockets inside the sheath, between threads 16 of the core and the surrounding sheath. These spaces can entrap moisture through the mechanism of wicking, resulting in premature deterioration and weakening of the suture in in vivo use of the suture.

The conventionally braided suture is woven as indicated by the braiding pattern of FIG. 2, shown in a plan view. The individual threads of the braided sheath feed from spools mounted on carriers 22, 22' and 24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction. In the illustrated embodiment carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. Disposed within the center of the loop 28 are carriers 26 which dispense the core threads of the suture. Thus, the moving carriers 22, 22', 24, and 24' dispense threads which intertwine to form the braided sheath, and the sheath is formed around the centrally located core threads dispensed from carriers 26. The threads from all of the carriers in a constructed embodiment of FIG. 2 are dispensed upward with respect to the plane of the drawing, and the braided suture is taken up on a reel located above the plane of the drawing.

FIG. 1*b* is an illustration of the outside of the braided sheath of the suture 10 of FIG. 1*a*, showing the crossing pattern of the braided threads 12. Each thread is composed a number of individual fibers as indicated by the lines on each thread. Where each thread appears on the outside of the sheath it is seen to be orthogonally directed with respect to the thread it crosses over, the thread from beneath which it appears, and the thread it next crosses under. For instance, thread 17 is orthogonally directed with respect to thread 18 on either side of thread 17 where thread 17 crosses over thread 18. The thread 17 is also orthogonally directed with respect to thread 19*a* from beneath which it appears, and with respect to thread 19*b* which it next crosses under.

This orthogonal crossing relationship of the braided threads results in the formation of small interstices or voids 20 where the threads cross one another, as shown in FIG. 3, which shows a drawing reproduction of an enlarged photograph of a conventionally braided suture. These voids 20 can entrap moisture which can lead to premature deterioration of the suture, and can also entrap bacteria and other sources of infection causing complication of wound healing.

Referring now to FIG. 4*a*, a spiral braided suture 30 of the present invention is shown in diagrammatic cross-section. The braided suture 30 comprises a plurality of interwoven and interlocked threads 32, each of which may comprise a number of individual fibers 34. Due to the interlocking of the threads 32, no central passageway is formed in which moisture can become entrapped. The interlocking of the threads also causes the threads to move in unison as a continuous structure, thereby uniformly distributing tensile forces when the suture 30 is pulled or stretched.

The spiral pattern of the suture 30 is clearly shown in the outside view of the suture of FIG. 4*b*. The threads on the outside are seen to be aligned in a spiral pattern which ascends from the lower left to the upper right in the drawing as the outer threads precess around the outer surface of the suture. One spiraling set of threads is indicated between arrows 36, and another set is indicated between arrows 38. As the pattern spirals, individual threads on the outer surface are in a parallel orientation with respect to each other and with respect to the longitudinal length of the suture as they continually reappear in the spiral pattern.

With all threads aligned in the parallel, offset spiral pattern of FIG. 4*b*, it may be seen that there are no voids or interstices formed on the outside surface of the suture. This is due to the parallel orientation of the threads, as opposed to the orthogonally directed crossing pattern of the threads of the conventionally braided suture of FIGS. 1*b* and 3. The parallel orientation of the outer appearing threads also provides a smoother feel to the suture, since the hand will sense the continuous, longitudinal orientation of the parallel threads as it is run along the suture.

A spiral braided suture of the present invention is formed of four or more interwoven threads. Preferably at least nine threads are braided in groups of three, and a braiding pattern for a spiral braided suture of twelve threads, arranged in groups of four, is shown in FIG. 5*a*. In the illustrated pattern the carriers move sequentially in the same direction around the circular loop of carriers. As they move, each carrier moves from its present position to a succeeding position which is at least two positions removed from its present position. In the illustration of FIG. 5*a*, each carrier moves to the third succeeding position around the loop. The twelve carriers are grouped into three groups of four carriers each. In the first group, carriers move in unison between positions 42*a*, 42*b*, 42*c*, and 42*d*. The carrier at position 42*a* moves to position 42*b*, passing by positions 44*a* and 40*b* as it does so. As it moves, the carrier at position 42*b* is moving to position 42*c*, bypassing positions 44*b* and 40*c*. At the same time the carrier at position 42*c* is moving to position 42*d*, and the carrier at position 42*d* is moving to position 40*a*.

After these four carriers have moved to their new positions in unison, the carriers at positions 44*a*, 44*b*, 44*c*, and 44*b* move to their succeeding positions. Then the carriers at positions 40*b*, 40*c*, 40*d*, and 40*a* move to their succeeding positions. The sequence then repeats in the same fashion.

Apparatus for executing the spiral braiding pattern of FIG. 5*a* is diagrammatically shown in FIG. 5*b*. The apparatus comprises a rotating central platform 50 which is surrounded by an annular plate 52. The platform 50 rotates as indicated by arrows 51. Pivotally mounted on the platform 50 are four rotating carrier pickups 54*a*, 54*b*, 54*c*, and 54*d* which rotate about pivot points 56. Each pickup has a number of apertures which engage the carriers to move them to their succeeding positions, the number being chosen in correspondence with the number of positions to be bypassed as the carriers move in their braiding pattern. In the illustrated embodiment the number of apertures is three, enabling the carriers to bypass two positions each time they are

moved. The twelve carrier positions are delineated by rounded openings in the annular plate 52, four of which are indicated at 40*a*, 40*b*, 40*c*, and 40*d*. The carriers which carry spools of thread are indicated at 60, 62, and 64.

In operation pickup 54*a* will engage the carrier 60*a* at position 40*a*. As the central platform 50 rotates the pickup 54*a* simultaneously rotates to transfer the carrier 60*a* from position 40*a* to position 40*b*, which has just been vacated by carrier 60*b*. The carrier 60*a* is seen to bypass carriers 62*a* and 64*a* as it travels to its succeeding position 40*b*. As carrier 60*a* is transferred by pickup 54*a*, pickups 54*b*, 54*c*, and 54*d* simultaneously are transferring carriers 60*b*, 60*c*, and 60*d* to their succeeding positions.

As the pickup 54*a* is about to deposit the carrier 60*a* at position 40*b*, the pickup engages carrier 64*a* to begin transferring that carrier to its succeeding position. The carriers 64*b*, 64*c*, and 64*d* are similarly engaged simultaneously by the other three pickuPs. After the carriers 60*a*, 60*b*, 60*c*, and 60*d* have been deposited at their new positions and the carriers 64*a*, 64*b*, 64*c*, and 64*d* are enroute to their succeeding positions, the pickups engage the carriers 62*a*, 62*b*, 62*c*, and 62*d* for transfer. As this sequence of carrier transfer continues, threads from the spools on the carriers are dispensed upward with respect to the plane of the drawing and the braided suture is taken up on a reel located above the apparatus.

A lattice braided suture 70 of the present invention is shown in FIG. 6*a*, which schematically illustrates the structure of the lattice braid. In FIG. 6*a*, three or more threads are braided in a lattice pattern. One thread or group of threads traverses the path 72, a loop extending from the upper right to the lower left of the drawing. As the carrier or carriers dispensing thread on path 72 move around this path, they alternately cross over and under the paths of the other threads that they encounter, the crossing pattern being determined by the times and locations of travel of the respective carriers. In a similar fashion a second carrier or carriers dispensing thread traverse a path 74 from the lower right to the upper left of the pattern. Like the first path, the thread dispensed from carriers travelling this path alternately crosses over and under the other paths it encounters. A third path 76 travels around the intersection of the first path 72 and the second path 74. Like the first two paths, the thread dispensed from the carrier or carriers traversing path 76 alternately crosses over and under the threads of the other paths it encounters.

The lattice braid of FIG. 6*a* is seen to exhibit a generally square shape in cross-section with rounded corners. While the lattice braided suture has been found to provide less tensile strength than the spiral braided suture, the lattice braided suture can be strengthened by the inclusion of individual core threads running longitudinally through the interlocking lattice. A number of core threads may be located at the positions indicated at 82 in the lattice, at the positions indicated at 84, or both. This uniform distribution of core threads throughout the lattice, which results in secure capture of the individual threads within the loops of the lattice, has been found to provide a uniform distribution of tensile forces throughout the suture.

The outside of the lattice braided suture 70 is illustratively shown in FIG. 6*b*. The outer threads of the lattice are seen to be distributed in an angularly offset, generally parallel configuration. The drawing shows the generally parallel alignment of threads 72, 74, and 76 on the outside of the suture, forming a substantially smooth, longitudinally extending outer thread surface on each side of the square configuration. The rounded corners 78, shown on each side of the drawing, are also seen to smoothly extend along the length of the suture.

Apparatus for braiding the lattice braided suture of FIG. 6*a* is schematically shown in FIG. 7. The apparatus includes a plurality of rotating discs which transfer the carriers around and along their intended paths of travel. In a preferred embodiment there are three carriers traversing each path. Extending through the center of each rotating disc is a core thread 82, each of which becomes engaged in the lattice loops formed around its respective disc. The path 72 is traversed by carriers which rotate around disc 92*a* and are then transferred to the central disc 98. Each carrier travels halfway around disc 98 and is then transferred to disc 92*b*. The carriers travel around disc 92*b* and back to the central disc 98. After travelling around the other side of disc 98 each carrier is transferred back to rotating disc 92*a* and its starting point.

In a similar manner a second group of carriers on the path 74 travel around disc 94*a* and are transferred to the central disc 98. After travelling halfway around disc 98 each carrier is transferred to disc 94*b*. Each carrier travels around the rotating disc 94*b*, back to the other side of the central disc 98, and is returned to disc 94*a* and its starting point.

The third path 76 passes around rotating discs 96*a*, 96*b*, 96*c*, and 96*d*. The carriers which travel this path 76 pass around three-quarters of each disc before being transferred to the succeeding disc in the loop. As each carrier traverses the path 76 it is seen to pass inside the end discs of the other two paths 72 and 74, thereby enclosing the intersection of these two paths at the central disc 98.

The apparatus of FIG. 7 may be operated with a plurality of carriers travelling each path simultaneously. For instance, the apparatus may be operated with three carriers on each path to form a lattice braid of 9 threads. Alternatively each path may include 4 carriers for a total of 12 braided threads. As a third example, the apparatus may operate with 6 carriers on each path for a total of 18 threads in the braided suture.

Spiral braided sutures of the present invention can be expected to provide a 20% improvement in smoothness over conventionally braided sutures, a 20% improvement in pliability, and a 50% improvement in cylindrical uniformity. The improvement in smoothness is due to the parallel alignment of the suture threads on the outside of the spiral braided suture. The improvement is pliability is due to the thread crossovers of the spiral braid, which enhances fiber mobility; the individual threads in the spiral braided suture will easily move relative to each other as the suture is bent. And since there is no core to become misaligned or misshapen, cylindrical uniformity is improved.

Improvements in breaking strength can also be expected for the spiral braided suture. In a test of breaking strength remaining (BSR) after 21 days of in vivo use of an absorbable suture of conventional braid, typically 40-50% of the breaking strength remains. A 15-20% improvement in BSR can be expected in use of a spiral braided suture of the present invention under the same conditions.

The lattice braided suture provides the capability of producing a high quality composite suture, in which advantage is taken of the different characteristics of one

type of material for the braid and another type of material for the core threads. As discussed above, the lattice braided suture is substantially more immune to the problem of core pop than the conventionally braided suture, since the core threads are distributed throughout the structure of the braid and are not positioned in a single central location. Both the spiral and lattice braided sutures have been found to exhibit less surface area exposed to ambient conditions, and hence less exposure to moisture, than conventionally braided sutures.

What is claimed is:

1. A braided surgical suture in which a plurality of surgically compatible filaments are woven in a spiral braid by moving filament dispensers to different positions around a closed loop, wherein an individual dispenser in the loop is moved from its current position to a succeeding position which is at least two positions removed from said current position.

2. The braided surgical suture of claim 1, wherein the number of filaments is at least nine.

3. The braided surgical suture of claim 2, wherein said filament dispensers move around said loop in the same direction.

4. The braided surgical suture of claim 3, wherein said filament dispensers are organized in three uniformly distributed groups around said loop and the dispensers in each group move around said loop in unison.

5. The braided surgical suture of claim 3, wherein the number of filaments is twelve and wherein an individual dispenser in the loop is moved from its current position to a succeeding position which is three positions removed from said current position.

6. The braided surgical suture of claim 1, wherein the portions of said filaments which are visible on the outside of said braided suture are oriented substantially parallel to each other and are distributed in patterns which spiral around the outside of said suture.

7. The braided surgical suture of claim 1, wherein said surgically compatible filaments are woven in a spiral braid without any central, longitudinally extending core filaments.

8. A braided surgical suture in which a plurality of surgically compatible filaments are woven in a lattice braid by moving filament dispensers in three closed loop paths, a first and second of said paths being generally oblong and crossing over each other at a central intersection, and the third of said paths passing through the ends of said first and second paths outside said central intersection.

9. The braided surgical suture of claim 8, wherein said suture in cross-section exhibits a generally rectangular shape, with filaments traversing said ends of said first and second paths being located at the corners of said rectangular shape.

10. The braided surgical suture of claim 8, wherein each moving filament dispenser alternately passes over then under the filaments dispensed on the paths it intersects.

11. The braided surgical suture of claim 10, wherein there are at least three filament dispensers traversing each of said paths.

12. The braided surgical suture of claim 8, wherein there are formed a plurality of core fillament passageways located adjacent to the points of intersection of two or more of said paths.

13. The braided surgical suture of claim 12, further comprising at least four core filaments located in ones of said passageways.

14. The braided surgical suture of claim 13, wherein said core filaments are symmetrically distributed with respect to said point of intersection.

15. The braided surgical suture of claim 13, wherein said core filaments are made of a different surgically compatible material than that of said woven filaments.

16. The braided surgical suture of claim 12, further comprising at least nine core filaments located in ones of said passageways.

17. The braided surgical suture of claim 12, further comprising at least thirteen core filaments located in ones of said passageways.

* * * * *

United States Patent [19]

Silvestrini

[11] Patent Number: 4,979,956

[45] Date of Patent: Dec. 25, 1990

[54] DEVICE AND METHOD FOR TENDON AND LIGAMENT REPAIR

[75] Inventor: Thomas A. Silvestrini, East Lyme, Conn.

[73] Assignee: Pfizer Hospital Products Group, Inc., New York, N.Y.

[21] Appl. No.: 378,437

[22] Filed: Jul. 10, 1989

Related U.S. Application Data

[63] Continuation of Ser. No. 115,087, Oct. 30, 1987, abandoned.

[51] Int. Cl.[5] A61F 2/06

[52] U.S. Cl. 623/13

[58] Field of Search 623/11, 12, 16, 13, 623/18

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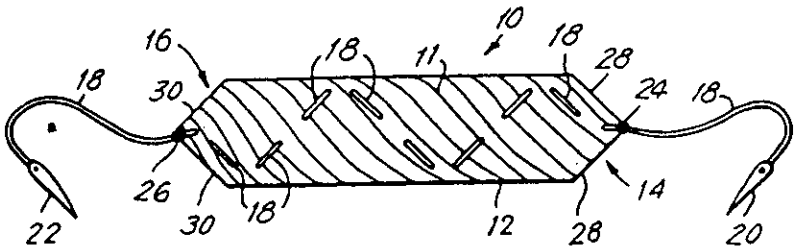
Primary Examiner—David J. Isabella

Attorney, Agent, or Firm—Peter C. Richardson; Lawrence C. Akers; John L. LaPierre

[57] ABSTRACT

A device, suitable for use in repairing a lacerated or severed tendon, particularly a hand flexor tendon, having a flat band body with opposite ends of the body designed to anchor connecting sutures. The device also finds applicability in the repair of lacerated or severed ligaments. Also disclosed is a method of repairing a severed tendon by implanting a flat band device suturing together the device and the tendon to effect an anastomosis along approximated ends of the severed tendon. Further disclosed is a method of repairing a lacerated or severed ligament.

28 Claims, 2 Drawing Sheets



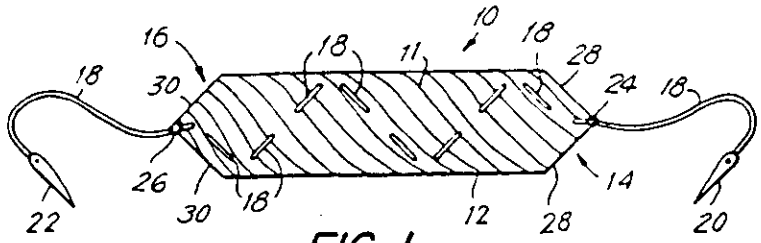


FIG. 1

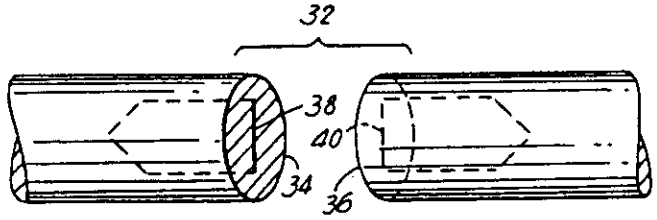


FIG. 2

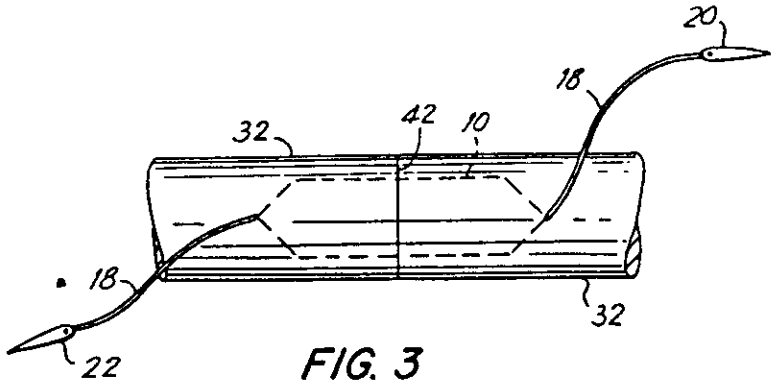


FIG. 3

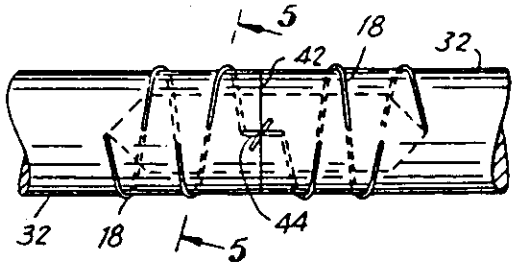


FIG. 4

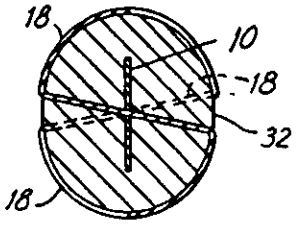


FIG. 5

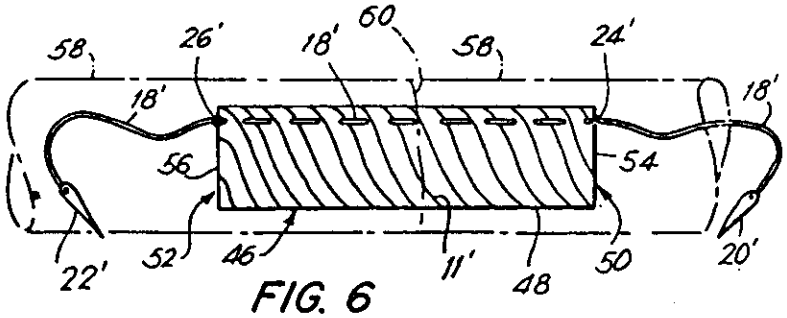


FIG. 6

DEVICE AND METHOD FOR TENDON AND LIGAMENT REPAIR

This is a continuation, of application Ser. No. 115,087, filed on Oct. 30, 1987, now abandoned.

BACKGROUND OF THE INVENTION

The present invention relates to a device for repairing severed or lacerated tendons and ligaments and, more particularly, the invention relates to a device having a flat band body constructed of resilient synthetic textile fiber and capable of receiving a suture element secured thereto at opposite ends of the body. Also contemplated by the invention are methods of anastomosing ends of severed or lacerated tendons and ligaments along an interface of approximated ends, by placing a device intratendonously, in the case of a tendon, or in juxtaposition, in the case of a ligament, bridging or spanning approximated ends, and suturing together either the tendon and the device or the ligament and the device. The objective is to provide a device and method for restoring tendons and ligaments, as nearly as possible, to their pre-damaged condition.

The successful repair of tendons, particularly hand flexor tendons, has been a problem for surgeons for many years. The past and current approach most commonly used by surgeons to achieve tendon repair is to anastomose severed tendons by using one of a variety of suturing techniques. A number of such techniques are commonly known and referred to as Bunnell, Kessler, Klienert, Tsuge and Becker, to name but a few. These techniques, while useful, are not entirely satisfactory because they allow surgeons to achieve successful repairs in only about 70% of the patients treated. Therefore, in view of the history of suture techniques which have been proposed and implemented from time to time by surgeons without any real improvement in repair strength or surgical result, the need for an improved device and method of anastomosis were clearly evident.

In addition to the foregoing suturing techniques most often used in tendon repair, in an effort to overcome the deficiencies encountered in the straight suturing approach, other devices and approaches have recently been tried to effect tendon repair. A typical device encountered might be one like that disclosed in U.S. Pat. No. 4,469,101. The teaching embodied in this patent specifies a structure having an open network or mesh of helically formed members to define a hollow tubular device wherein opposing ends of a lacerated tendon are introduced and brought into contact within the tube. The opposite ends of the tube are then sutured to the outer tendon wall and the contacting tendon ends are allowed to heal. Another device typically encountered in tendon repair might be one like that disclosed in U.S. Pat No. 4,501,029. This patent provides a continuous solid wall tubular device having in communication therewith a number of transversely extending passages. The tube is inserted between a replacement tendon and the tendon sheath. After blood supply from the sheath to the replacement tendon is established through the tubular passages, free movement of the tendon is established within the sheath. A third device encountered might be the plastic prosthetic tendon disclosed in U.S. Pat. No. 3,176,316. This patent provides a prosthesis having a solid central segment and hollow tubular ends comprising a mesh network wherein ends of a tendon are introduced and the prosthesis is sutured to the tendon.

There are certain disadvantages associated with each of the aforementioned tendon repair techniques and devices which the present inventive device and method either overcome or substantially lessen. Specifically, through the use of suturing techniques alone, irritations are minimized since sutures are buried inside the endotendon, but the strength of the anastomosis is not strong enough to allow aggressive mobility during healing. Consequently, there often occurs dehiscence of the suture leading to separation of approximated tendon ends, tissue ingrowth and slow or incomplete tendon healing. Inherent in the tubular mesh devices which are sutured to the tendon at ends of the devices is the exposure of a large amount of synthetic material on the outside of the epitenon which can cause excessive irritations. These irritations frequenty lead to adhesions between the injured tendon and the tendon surrounding which leads to retarded healing. The inventive device offers a minimum of irritation since it is substantially buried inside the endotendon, yet it offers higher strength of the anastomosed tendon compared to repairs using sutures. Lastly, the present device is one of structural simplicity which avoids both the complex geometry presented in the solid wall tubular device having a series of selectively positioned blood conveying passageways and the need to precisely locate such a prosthesis in the body to assure an adequate blood supply to the replacement tendon.

It should be understood that, while much of the foregoing discussion is directed toward tendon repair, the teachings encountered are also generally applicable to the repair of damaged ligaments. Clearly, there exists a need for a repair device which fosters superior mechanical repair properties and better healing characteristics than is currently found in the relevant surgical field. The present inventive device and method satisfies the need and, hence, advances the art field of tendon and ligament repair.

SUMMARY OF THE INVENTION

The present invention relates to a device used for repairing severed connective tissue of tendons and ligaments by approximating ends of the severed tissue and comprises an elongated body portion having a flat band structure with the body portion at opposite ends adapted to be connected to at least one needle bearing suture. The body structure may be a non-woven fabric, a composite reinforced with chopped fiber, a polymer sheet or a fabric which can be selected from a class of warp knits, weaves, nets and braids. The preferred braided fabric would be a triaxial braid or a flat band triaxial tube having either a monocomponent or bicomponent fiber element selected from a polymeric grouping and may include an elastomeric component. The preferred polymer for a monocomponent device body would be polyethylene terepthalate while for a bicomponent device the preferred polymers for the device body would be polyethylene terepthalate and polyester/polyether block copolymer. A suture or sutures may be lock stitched to opposite ends of the device body and may be incorporated into the body structure axially in either a longitudinal direction or in a bias direction. Additionally, a suture or sutures may be sewn into the body. The device body and associated suture or sutures may be covered with one or more gel coatings selected from a class of hydrogels with a preferred

coating being crosslinked calcium alginate. The body portion may assume a number of shapes but either a rectangle or a polygon, having ends tapered substantially to a point, is preferred. The ends of the body portion are preferably sealed to maintain edge integrity.

Also contemplated within the scope of the present invention are methods for repairing severed connective tissue of tendons and ligaments utilizing the inventive device heretofore described. Specifically, one method comprises the steps of creating a slot in the tissue of each opposing end of a severed tendon, where severance occured, inserting a first end of the device into one of the incised slots, inserting a second end of the device into the other of the incised slots, approximating opposing ends of the severed tissue, enclosing the device and therewithin bridging the ends, and suturing the tendon and the device together, passing sutures through the tendon and the implanted device along at least a portion of the length of the device, to anastomose the tendon along approximated ends of the severed connective tissue. A second method, relating to the repair of severed connective tissue of a ligament, comprises the steps of providing at least one inventive device, approximating opposing ends of the severed tissue, juxtaposing the ligament and the device with the device spanning approximated ends, and suturing the ligament and the device together, passing sutures through the ligament and the juxtaposed device along at least a portion of the length of the device, to anastomose the ligament along approximated ends of the severed connective tissue. In each of the methods, suturing will span at least the approximated ends and, preferably, suturing will be performed along substantially the entire length of the device.

The various features of novelty which characterize the invention are pointed out with particularity in the claims annexed to and forming a part of this disclosure. For a better understanding of the invention, its operating advantages and specific results obtained by its use, reference should be made to the corresponding drawings and descriptive matter in which there is illustrated and described typical embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an enlarged schematic representation of a tendon and ligament repair device, in accordance with the principles of the present invention, illustrating a flat band triaxial braid fabric structure having a single bias suture incorporated into the fabric body with the suture lock stitched to the body at opposite ends of the body.

FIG. 2 schematically illustrates a severed tendon, drawn at reduced scale, with slots incised in the tendon ends, before implantation of the repair device.

FIG. 3 is similar to FIG. 2, but with tendon ends approximated, and schematically illustrates the tendon repair device of FIG. 1 located within the endotendon prior to suturing.

FIG. 4 is similar to FIG. 3 and illustrates a completed repair showing suture penetration of both tendon and fabric body uniting tendon and device.

FIG. 5 is a cross-sectional view taken along line 5—5 of FIG. 4.

FIG. 6 is an enlarged schematic alternate embodiment of the invention showing in phantom a ligament with approximated ends and a flat band triaxial braid fabric structure, in place but prior to suturing, with a single axial suture incorporated into the fabric body with the suture lock stitched to the body at opposite ends thereof.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The description herein presented refers to the accompanying drawings in which like reference numerals refer to like parts throughout the several views, and in which, referring to FIG. 1, there is illustrated a repair device 10 of the present invention. The device has an elongated body portion 12 of flat band structural configuration, preferably a triaxial braid with the braid schematically designated as 11, and at a first end 14 and at a second end 16 a suture 18, having needles 20 and 22 at opposite ends, is connected or anchored to the body ends by a locking stitches 24 and 26. It should be understood that many types of knots or locking stitches, such as a double throw suture locking stitch, would be suitable to anchor the suture to the body portion. Locking the suture to the body could be accomplished at any time, as desired. The device shown in FIG. 1, it should be remembered, is a schematic representation and, therein depicted, the device has a flat band triaxial braid fabric structure with a single bias suture braided into the fabric body. It should also be understood that more than one suture could be attached to or incorporated into the fabric body and locked to the body ends. Furthermore, a suture or sutures could be sewn or stitched to the body along the body length instead of being braided into the body. In the preferred form of the device, the lock stitching of the suture to the ends of the braid body prevents the braid structure from bunching during insertion into tissue. The stitching also serves to center the suture pull of the device, thereby easing the insertion of the device into connective tissue. Also contemplated within the scope of the invention is a suture or sutures not incorporated into the fabric body per se but merely locked to one or both of the body ends. The ends 14 and 16 may be sealed along edges 28 and 30 to maintain edge integrity. Edge sealing may be accomplished using an ultrasonic sealing process or other means of heat treatment to keep edges from unraveling or separating.

The device body portion may be structurally configured as a non-woven fabric, a polymer reinforced with chopped fiber, a polymer sheet, a warp knit, a weave, a net or a braid. The construction of the desired flat band fabric into any one of these body portion structural configurations would be within the skill of those who manufacture textile products. A preferred structure would be a braid, preferably a triaxial braid. A flat band or flattened triaxial tube is within the scope of the invention. A triaxially-braided fabric, such as the ones schematically depicted in FIG. 1 and FIG. 6, and the methods of manufacturing them in different configurations, namely, flat bands, flat tubes, tubes, patches and strips, to name but a few, are well known to those skilled in the art of manufacturing braided polymeric articles. The triaxial braid may consist of a monocomponent fiber selected from a group of polymers consisting of polyethylene terepthalate, polyethylene, polypropylene, polyaramid, polyamide, polyetheretherketone, polyester/polyether block copolymer, liquid crystal polymeric fiber, nylon and carbon. The preferred polymer would be polyethylene terepthalate. The triaxial braid may also have a bicomponent fiber makeup with its components selected from the same polymer grouping. One of the components of the bicomponent

braid should be elastomeric with the preferred elastomer being polyester/polyether block copolymer. The preferred bicomponent braid comprises a first component of polyethylene terepthalate and a second component of polyester/polyether block copolymer.

The device may be coated to improve the ease of surgical installation and to minimize irritation to tissue during healing. The suture or sutures could also be coated to minimize adhesions formed during healing. The coating could be a gel, specifically a hydrogel, selected from the group consisting of sodium alginate, hyaluronic acid, crosslinked hyaluronic acid, crosslinked calcium alginate and a calcium alginate crosslinked hyaluronic acid mixture. The preferred lubricious coating for the device and sutures is crosslinked calcium alginate.

The device body as shown in FIG. 1 defines a polygon having opposed longitudinal ends each tapering to a point with the points, preferably, lying along the central longitudinal axis. The body may, however, as is shown in FIG. 6, take a rectangular shape. Other flat band structural shapes would be suitable and are within the scope of the present invention.

Turning to FIG. 2 through FIG. 5, in FIG. 2 there is shown severed connective tissue of a tendon 32 having separated ends 34 and 36. In each end 34 and 36, slots 38 and 40 have been incised within the endotendon using a suitable blade or cutting device (not shown). Each slot 38 and 40 will preferably be configured to conform substantially to one half the size of the repair device 10. FIG. 3 shows device 10 located within slots 38 and 40, suture 18 at opposite ends 14 and 16 of device 10 passing through tendon 32, and separated tissue ends 34 and 36 approximated as shown at 42. Device 10 is closed within the approximated tissue, bridging ends 34 and 36 which are in contact along joint 42. FIG. 4 and FIG. 5 depict a completed repair wherein the tendon and the device have been sutured together and the suture ends tied at 44. Suturing of the device into the tendon can be accomplished in many different ways. Thus, the device does not restrict the personal suturing preference of different surgeons. Anastomosis of the tendon will occur along approximated ends at 42. Suturing should span at least the approximated ends and, preferably suturing should be performed along substantially the entire length of the implanted device 10.

Turning to FIG. 6, there is schematically shown an alternate embodiment of the invention. Here depicted is a rectangular flat band repair device 46 having a triaxially braided fabric structure 11' and a suture 18', bearing needles 20' and 22', incorporated into elongated body portion 48 and axially oriented in a longitudinal direction. At first and second ends 50 and 52, suture 18' is affixed to the body ends by locking stitches 24' and 26'. As aforementioned in respect to the device 10, many types of knots or locking stitches would be suitable to affix the suture to the body portion and stitching could be accomplished when desired, namely, at time of manufacture or by a surgeon prior to device use. Lock stitching would be particularly useful, in addition to ease in installation, that is, prevention of fabric bunching, to keep the suture from being pulled through the fabric. More than one suture could be used and attached to or incorporated into the body fabric. Additionally, a suture might be sewn to the body along the length of the body rather than being braided into the body. The ends 50 and 52 may be sealed along edges 54 and 56 to maintain edge integrity, as in the case of device 10. All of the other structural features associated with device 10 are equally suitable for device 46.

In FIG. 6, device 46 is shown to be particularly useful in the repair of severed connective tissue of a ligament, illustrated in phantom and designated as 58. It should be understood, however, that a device of rectangular configuration would be equally useful in tendon repair and slots 38 and 40, as shown in FIG. 2, could assume a rectangular shape. Likewise, device 10 would be equally suitable in the repair of a ligament. Device 46, as provided in FIG. 6, is shown positioned alongside ligament 58 having severed ends approximated at 60. The device spans the approximated ends. It should be understood that more than one device could be used for the repair. While a completed repair is not shown in FIG. 6, a suturing technique like that shown in FIG. 4, and other techniques described in respect thereto, could be used to suture together ligament 58 and device 46. Anastomosis of the ligament will occur along approximated tissue ends at 60. Suturing should span at least the approximated ends and, preferably, suturing should be performed along substantially the entire length of device 46. In each of the repair techniques, namely, tendon and ligament, devices 10 and 46 are biocompatible and can be made from permanent, non-body absorbable materials, or from resorbable materials.

As heretofore mentioned, braiding can be accomplished using known technology and the inventive device can be manufactured using existing braiding machines modified to incorporate longitudinal fibers into the braided structures. By way of example, and not to be construed as limiting the invention, a 0.07 inch wide monocomponent polyethylene terepthalate device 10 can be braided on a 32-carrier triaxial braider using 70 denier white polyethylene terepthalate type 52 multifilament yarns and a single green 4-0 polyethylene terepthalate suture. The finished product is composed of 31 polyethylene terepthalate yarns and one 4-0 polyethylene terepthalate suture on the bias and 16 polyethylene terepthalate yarns on the longitudinal axis. In another example, a 0.07 inch wide bicomponent device 10 can be braided on a 24-carrier triaxial braider using 220 denier polyester/polyether block copolymer monofilaments, 70 denier white polyethylene terepthalate type 52 multifilament yarns, and a single green 4-0 polyethylene terepthalate suture. The finished construction is composed of 23 polyethylene terepthalate yarns and one 4-0 polyethylene terepthalate suture on the bias, and 12 polyester/polyether block copolymer fibers on the longitudinal axis. It should be understood that wider or narrower devices could be manufactured. The device is made from safe materials that surgeons are comfortable implanting and the device can easily be made in a variety of sizes to address different soft tissue repair situations. Device needles could be swaged onto the suture ends of affixed by other suitable means. Laboratory testing of a repair device used to anastomose explanted canine and bovine tendon has demonstrated that the initial strength of the repair junction is approximately twice the strength of tendon repairs made using conventional suturing techniques.

While in accordance with provisions of the statutes there is described herein specific embodiments of the invention, those skilled in the art will understand that changes may be made in the form of the invention covered by the claims appended hereto without departing from the scope and spirit thereof, and that certain features of the invention may sometimes be used to an

advantage without corresponding use of the other features.

I claim:

1. A device for use in repairing severed connective tissue of tendons and ligaments by approximating severed ends of said tissue bringing said tissue ends into abutment comprising an elongated body having a flat band structure, said body being sized and configured for enclosure within said abutting tissue ends, and with said body at first and second opposed non-bifurcated ends adapted to be connected to at least one needle bearing suture, with said suture being incorporated into said body substantially the length thereof, said suture being oriented in a bias direction.

2. The device according to claim 1 wherein said structure is a non-woven fabric.

3. The device according to claim 1 wherein said structure is a polymer reinforced with chopped fiber.

4. The device according to claim 1 wherein said structure is a polymer sheet.

5. The device according to claim 1 wherein said structure is a fabric selected from the group consisting of warp knits, weaves, nets and braids.

6. The device according to claim 5 wherein said fabric is a braid.

7. The device according to claim 6 wherein said braid is a triaxial braid.

8. The device according to claim 7, wherein said braid comprises a monocomponent fiber forming element.

9. The device according to claim 8 wherein said element is a polymer selected from the group consisting of polyethylene terepthalate, polyethylene, polypropylene, polyaramid, polyamide, polyetherether ketone, polyester/polyether block copolymer, liquid crystal polymeric fibers, nylon and carbon.

10. The device according to claim 9 wherein said polymer is preferably polyethylene terepthalate.

11. The device according to claim 7 wherein said braid comprises a bicomponent fiber forming element.

12. The device according to claim 11 wherein said element is a plurality of polymers selected from the group consisting of polyethylene terepthalate, polyethylene, polypropylene, polyaramid, polyamide, polyetherether ketone, polyester/polyether block copolymer, liquid crystal polymeric fibers, nylon and carbon.

13. The device according to claim 12 wherein at least one of said polymers is elastomeric.

14. The device according to claim 13 wherein said elastomeric polymer is preferably polyester/polyether block copolymer.

15. The device according to claim 12 wherein said polymers are preferably polyethylene terepthalate and polyester/polyether block copolymer.

16. The device according to claim 1 wherein said suture is lock stitched to said ends.

17. The device according to claim 1 wherein said suture is sewn into said body.

18. The device according to claim 17 wherein said suture is axially oriented in a longitudinal direction.

19. The device according to claim 1 wherein said body is covered with a gel coating.

20. The device according to claim 19 wherein said body and said suture are covered with a gel coating.

21. The device according to claim 20 wherein said coating is a hydrogel selected from the group consisting of sodium alginate, hyaluronic acid, crosslinked hyaluronic acid, crosslinked calcium alginate and a calcium alginate crosslinked hyaluronic acid mixture.

22. The device according to claim 21 wherein said hydrogel is preferably crosslinked calcium alginate.

23. The device according to claim 1 wherein said body defines a polygon.

24. The device according to claim 23 wherein said polygon is a rectangle.

25. The device according to claim 23 wherein at least one of said ends of said body terminates substantially in a point.

26. The device according to claim 25 wherein said point lies along a central axis of said body.

27. The device according to claim 1 wherein said ends are sealed proximate end edges to maintain edge integrity.

28. The device according to claim 1 wherein said body is a flat band triaxial tube.

* * * * *

As Originally Filed

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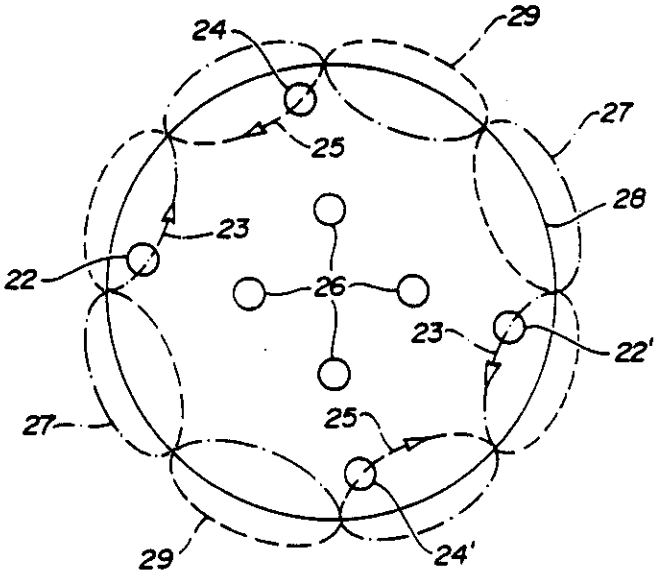
FIG-1



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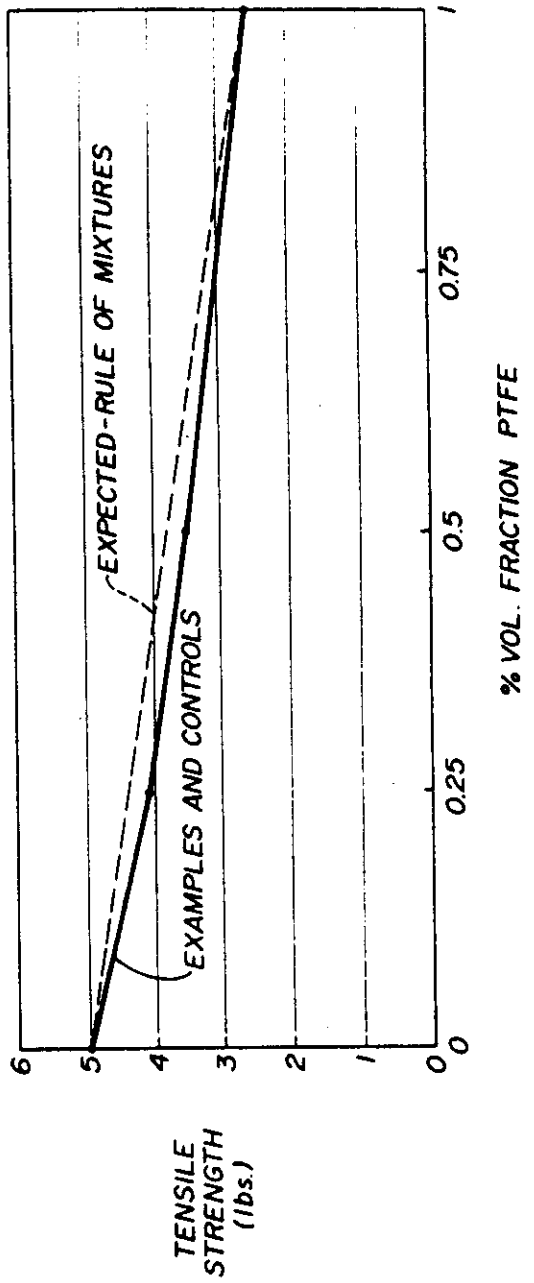

FIG-2

As Originally Filed

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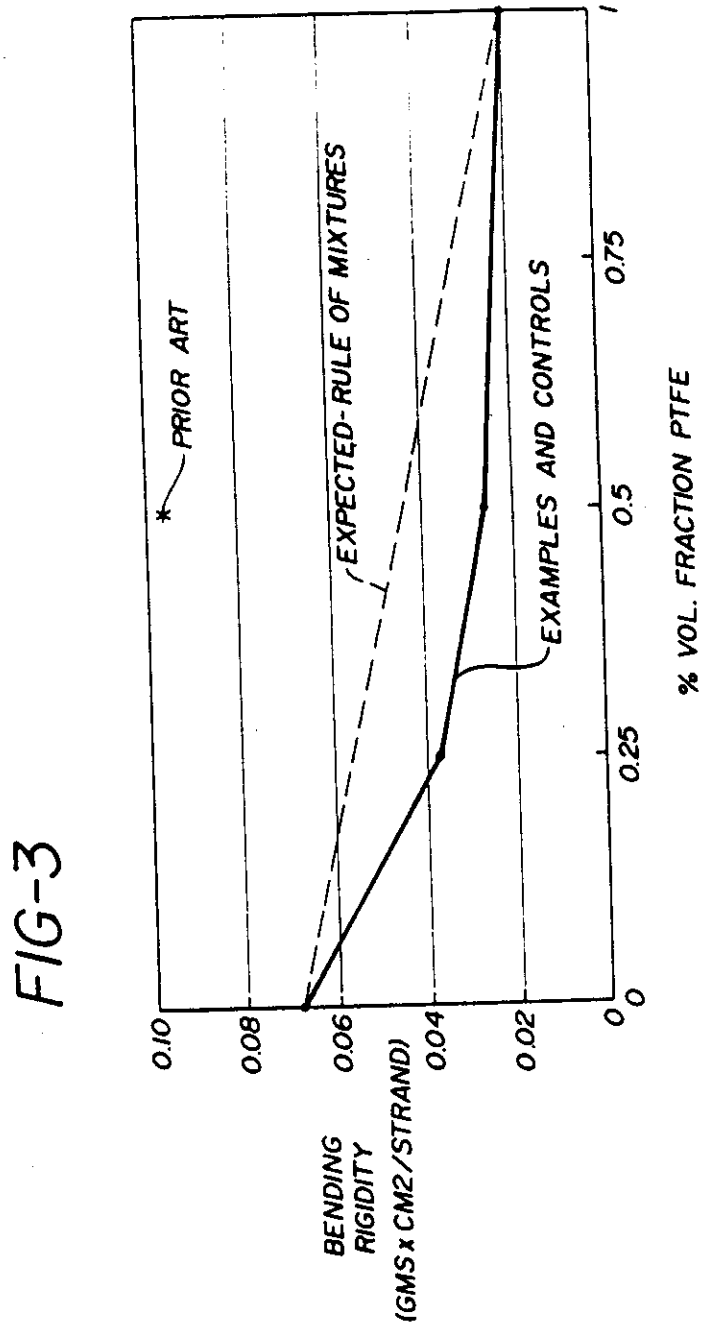

FIG-3

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   d 11 16

11.  4,959,069, Sep. 25, 1990, Braided surgical sutures; Karl W. Brennan,
et al., 606/228; 87/7; 428/224 [IMAGE AVAILABLE]

16.  4,470,941, Sep. 11, 1984, Preparation of composite surgical
sutures ; Leonard D. Kurtz, 264/136, 108, 134, 171, 174, 288.8, 290.5,
345; 606/230

=> d his

     (FILE 'USPAT' ENTERED AT 12:54:30 ON 25 JUN 92)
L1          5156 S SUTURE#
L2          8197 S BRAID?
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L5            18 S L3 AND L4
L6        103608 S COMPOSITE
L7   (   1043648)S S
L8             3 S L5 AND L6
L9            20 S L6(3A)L1

=> d 13 37 57 188

37.  5,059,213, Oct. 22, 1991, Spiroid braided suture ; Michael P.
Chesterfield, et al., 606/228 [IMAGE AVAILABLE]

57.  5,019,093, May 28, 1991, Braided suture ; Donald S. Kaplan,
et al., 606/228, 230 [IMAGE AVAILABLE]

188.  4,470,941, Sep. 11, 1984, Preparation of composite surgical
sutures ; Leonard D. Kurtz, 264/136, 108, 134, 171, 174, 288.8, 290.5,
345; 606/230

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d his

     (FILE 'USPAT' ENTERED AT 08:07:48 ON 22 OCT 92)
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L2          8447 S BRAID?
L3           230 S L1(5A)L2
L4        117600 S COMPOSITE OR HETEROGENEOUS
L5            40 S L4 AND L3
L6          9257 S PET OR POLYETHYLENETEREPHTHALATE
L7         49419 S PTFE OR TEFLON OR POLYTETRAFLUOROETHYLENE OR FLUOROPOLYM
ER
L8           735 S L6 AND L7
L9             5 S L8 AND L5
L10           35 S L5 NOT L9
L11            1 S L10 AND L6
L12            6 S L10 AND L7
L13           13 S L2 AND L4 AND L6 AND L7

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d 19 1 2 3 4 5

1. 4,470,941, Sep. 11, 1984, Preparation of composite surgical sutures; Leonard D. Kurtz, 264/136, 108, 134, 171, 174, 288.8, 290.5, 345; 606/230

2. 4,461,298, Jul. 24, 1984, Composite sutures of silk and hydrophobic thermoplastic elastomers; Shalaby W. Shalaby, et al., 606/231; 528/296

3. 4,441,496, Apr. 10, 1984, Copolymers of p-dioxanone and 2,5-morpholinediones and surgical devices formed therefrom having accelerated absorption characteristics; Shalaby W. Shalaby, et al., 606/230; 528/354; 606/231

4. 4,137,921, Feb. 6, 1979, Addition copolymers of lactide and glycolide and method of preparation; Yuzi Okuzumi, et al., 606/230; 525/411, 420; 528/354; 606/231; 623/1

5. 4,052,988, Oct. 11, 1977, Synthetic absorbable surgical devices of poly-dioxanone; Namassivaya Doddi, et al., 606/231; 528/354; 623/66

=> d 1 2 4 8 13

1. 5,147,400, Sep. 15, 1992, Connective tissue prosthesis; Donald S. Kaplan, et al., 623/13, 1, 11, 66 [IMAGE AVAILABLE]

2. 5,116,360, May 26, 1992, Mesh composite graft; Leonard Pinchuk, et al., 623/1, 11, 12 [IMAGE AVAILABLE]

4. 4,990,158, Feb. 5, 1991, Synthetic semiabsorbable tubular prosthesis; Donald S. Kaplan, et al., 623/1; 57/225 [IMAGE AVAILABLE]

8. 4,470,941, Sep. 11, 1984, Preparation of composite surgical sutures; Leonard D. Kurtz, 264/136, 108, 134, 171, 174, 288.8, 290.5, 345; 606/230

13. 3,748,828, Jul. 31, 1973, PROCESS AND APPARATUS FOR FLUID-LIQUID CONTACTING; Simon Lefebvre, 55/2, 29, 70, 73, 90, 93, 122, 233, 240, 300, 481, 527; 261/95, 103

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623 4-4C04

57 4-5D10

606 4-4C04

PATENT APPLICATION FEE DETERMINATION RECORD

Effective December 16, 1991

Application or Docket Number: 838511

CLAIMS AS FILED - PART I

	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE	SMALL ENTITY FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY FEE
FOR							
BASIC FEE				$ 345.00	OR		$ 690.00
TOTAL CLAIMS	24 minus 20 =	* 4	x $10=		OR	x $20 = 80	
INDEPENDENT CLAIMS	1 minus 3 =	* 0	x 36 =		OR	x 72 =	
MULTIPLE DEPENDENT CLAIM PRESENT			+ 110 =		OR	+ 220 =	
			TOTAL		OR	TOTAL	770

* If the difference in column 1 is less than zero, enter "0" in column 2

CLAIMS AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
AMENDMENT A	Total	* 24	Minus	** 24	=
	Independent	* 2	Minus	*** 3	=
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY ADDITIONAL FEE
x $10=		OR	x $20 =	
x 36 =		OR	x 72=	
+ 110 =		OR	+ 220 =	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
AMENDMENT B	Total	*	Minus	**	=
	Independent	*	Minus	***	=
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY ADDITIONAL FEE
x $10 =		OR	x $20 =	
x 36 =		OR	x 72 =	
+ 110 =		OR	+ 220 =	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
AMENDMENT C	Total	*	Minus	**	=
	Independent	*	Minus	***	=
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY ADDITIONAL FEE
x $10 =		OR	x $20 =	-
x 36 =		OR	x 72 =	
+ 110 =		OR	+ 220 =	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Form PTO-875
(Rev. 12-91)

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000330

STAPLE AREA

* U.S. GOVERNMENT PRINTING OFFICE: 1991-294-566

PATENT NUMBER

ORIGINAL CLASSIFICATION

CLASS	SUBCLASS
606	231

APPLICATION SERIAL NUMBER
07/838,511

APPLICANT'S NAME (PLEASE PRINT)
Hunter et al.

IF REISSUE, ORIGINAL PATENT NUMBER

CROSS REFERENCE(S)

CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)			
606	228			
87	7	9		
428	[illegible]	370		

INTERNATIONAL CLASSIFICATION

D	01	H	C	1/00

GROUP ART UNIT: 1504

ASSISTANT EXAMINER (PLEASE STAMP OR PRINT FULL NAME)
CHRISTOPHER W. RAIMUND

PRIMARY EXAMINER (PLEASE STAMP OR PRINT FULL NAME)
GEORGE F. LESMES

PTO 270
(REV. 5-91)

ISSUE CLASSIFICATION SLIP

U S DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000331

PTO 1130 (REV 11-91)

U.S. DEPARTMENT OF COMMERCE– PATENT & TRADEMARK OFFICE

PACE DATA ENTRY CODING SHEET

1ST EXAMINER	ESTEY	DATE	3-4-92
2ND EXAMINER		DATE	

APPLICATION NUMBER	TYPE APPL	FILING DATE MONTH	DAY	YEAR	SPECIAL HANDLING	GROUP ART UNIT	CLASS	SHEETS OF DRAWING
07 838511	1	02	19	92		1304	264	3

TOTAL CLAIMS	INDEPENDENT CLAIMS	SMALL ENTITY?	FILING FEE	FOREIGN LICENSE	ATTORNEY DOCKET NUMBER
24	1	0	770	Y	ETH-782

CONTINUITY DATA

CONTINUITY CODE	STATUS CODE	PARENT APPPLICATION SERIAL NUMBER	PARENT PATENT NUMBER	PARENT FILING DATE MONTH	DAY	YEAR
		0				
		0				
		0				
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		0				

PCT/FOREIGN APPLICATION DATA

FOREIGN PRIORITY CLAIMED	COUNTRY CODE	PCT/FOREIGN APPLICATION SERIAL NUMBER	FOREIGN FILING DATE MONTH	DAY	YEAR

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DM1000332

Case 1:04-cv-12457-PBS Document 85-11 Filed 08/11/2006 Page 48 of 53

SEARCHED

Class	Sub.	Date	Exmr.
606	228	6/25/92	CWR
606	230	6/25/92	CWR
606	231	6/25/92	CWR
606	update 228	8/26/92	CWR
	230	↓	↓
↓	231		
606	228	11/9/93	CWR
↓	231	↓	↓
87	7		
↓	8		
	9		
428	225		

INTERFERENCE SEARCHED

Class	Sub.	Date	Exmr.
606	231	11/15/93	CWR

SEARCH NOTES

	Date	Exmr.
APS SEARCH	6/25/92	CWR
APS SEARCH	10/22/92	CWR

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000333

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POSITION	INIT.	DATE
CLASSIFIER	[illegible]	3-4-92
EXAMINER	379	3-4-92
SUPERVIZER	391	3-5-96
CLERICAL		
CORPS CORR.		
SPEC. HAND.		
FILE MAINT.		

INDEX OF CLAIMS

Claim Final	Claim Original	Date 3/4/92	Date 11/2/92	Date 2/18/93	Date 8/15/95
1	①	+	—	—	+
2	2	+			+
3	3	+			+
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SYMBOLS

-	Rejected
=	Allowed
(Through cancel)	Canceled
+	Restricted
N	Non-elected
I	Interference
A	Appeal
O	Objected

Claim Final	Claim Original	Date
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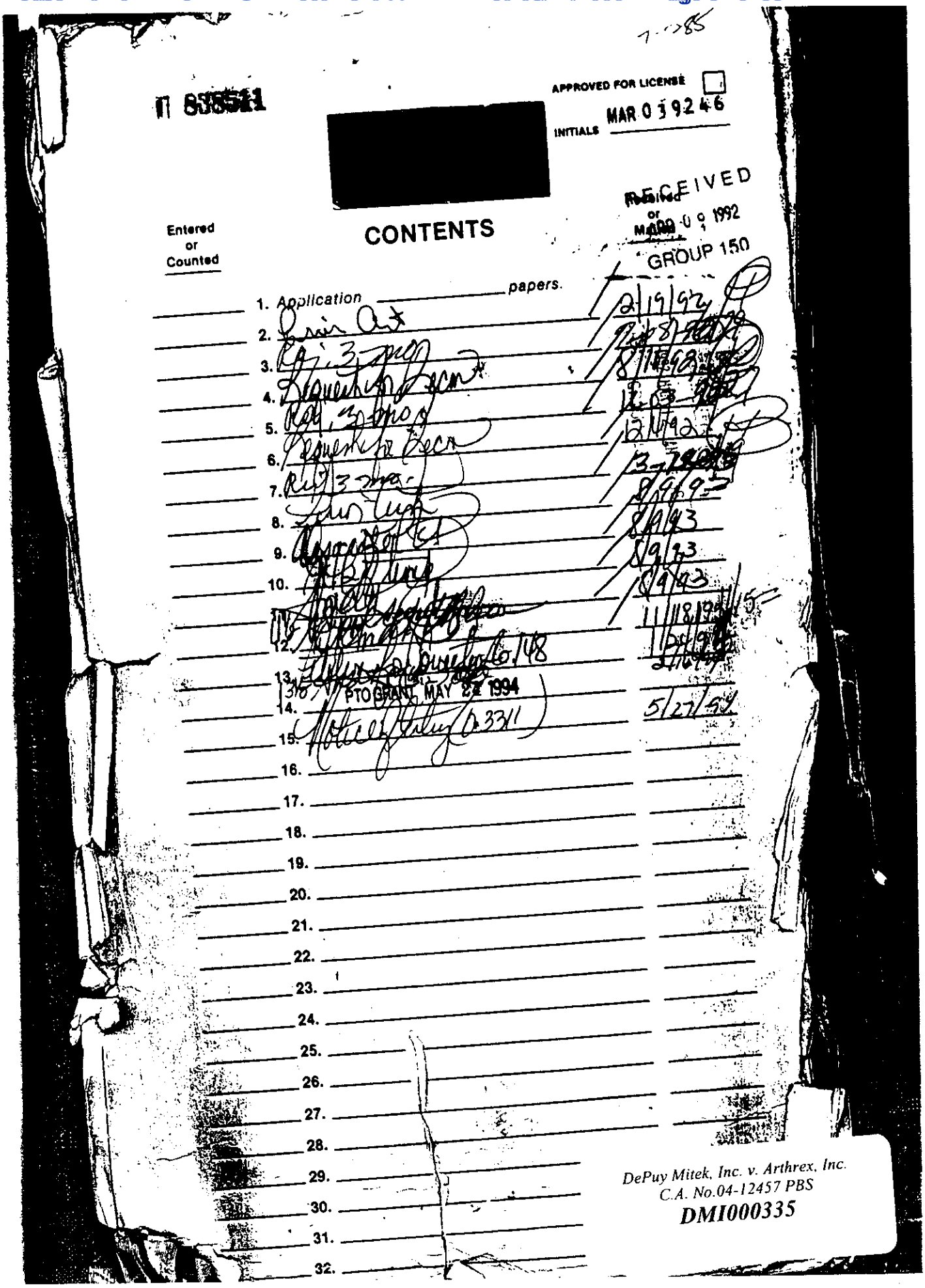

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Entered or Counted

CONTENTS

1. Application papers.
2. Power of Att
3. Cover Sheet
4. Request for Recn
5. Rec. Trans Memo
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7. Rec'd Trans Memo
8. Issue Fee
9. Appeal Brief
10. Notice of Allowance
11. Notice of Allowability
12. Petition to Revive
13. Letter Requesting Withdrawal of Attorney
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5/27/94

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000335

A COVERING COVER 1-800-366-6060
5/8" Classic DTC 16834 for 22 1/2" fibers

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

C.A. No. 04-12457 PBS

----------x

DePUY MITEK, INC.,

a Massachusetts corporation,

Plaintiffs,

v.

ARTHREX, INC.

a Delaware Corporation,

Defendant.

----------x

READ & SIGN COPY

DEPOSITION OF HAL BRENT WOODROW

New Brunswick, New Jersey

November 2, 2005

Reported by:

MARY F. BOWMAN, RPR, CRR

JOB NO. 97

WOODROW
AFTERNOON SESSION
2:06 p.m.
BY MR. TAMBURO:
Q. Back on the record. Mr. Woodrow, during the break, did you have a chance to speak with Mr. Goodwin regarding some of the issues we talked about earlier?
A. I had an opportunity to get information from Mr. Goodwin but not speak directly to him.
Q. And what did you learn?
A. As to the primary contact of the drafting of the patent, that was Mark Steckel. As to contributions to the invention, Mr. Goodwin had no specific recollections, although I don't know all the contributions of all the inventors, I do know what Mr. Jamiolkowski contributed because I -- I spoke with him about the bioabsorbable aspects of the invention and that was his contribution and that's why he was taken off and those materials were removed from the application.
Q. OK.
A. And then as to the IDS, there is apparently no -- we don't have any knowledge of

WOODROW
where the references came from or if the inventors did a search or what.
Q. Mr. Goodwin doesn't know?
A. Doesn't know.
MS. MALINOSKI: As to the other question, as to other questions, I did not get any further response yet.
MR. TAMBURO: OK, thank you.
Q. Mr. Woodrow, you said that Mr. Jamiolkowski was removed from the application as an inventor because there was no longer any bioabsorbable aspect to the invention?
A. Um-hm.
Q. Is that because of the claim amendment?
A. Yes, the claims were amended to remove bioabsorbable materials.
Q. We were talking earlier about the response to the office action, response dated August 6, 1992, and if you could just open up to that again, it is in Exhibit 3, starts on DMI 194.
A. Yes.
Q. OK. OK, Mr. Woodrow, can you look at the paragraph that begins with "In contrast" on

WOODROW
the page that's labeled 195.
A. Yes.
Q. There is a sentence, the last sentence of that paragraph says, "In fact, the fishing line of Burgess would have poor knot strength properties because of its braided construction as set forth in more detail below." Do you see that?
A. Yes.
Q. The next sentence or the first sentence of the next paragraph says, "Some of the braid filaments of the Burgess fishing line are composed of high tensile polythene thread." Do you see that?
A. Um-hm.
Q. Did Ethicon mean when it wrote this that the high tensile polythene thread used in Burgess would result in poor knot strength properties?
A. It appears the discussion was about the Burgess construction and that the strength imparted by the polythene thread would give low elongation and it says, in turn, poor strength properties and I think -- it says poor knot strength properties and I think this is, this goes

WOODROW
on with the issues as to what Burgess was teaching. But the issue that's being I think expounded upon in this amendment is following up or trying to bring forth an unanalogous art argument because what's being discussed is the differences between fishing line and suture and the fact that it is not -- it is not directly analogous art that one would use or look to create new sutures and this discussion is part of a discussion about the nature of the Burgess fishing line and its, in fact, I think a discussion that the fishing line has a different set of requirements than sutures and that this -- the way this was put together was viewed as a perhaps not an appropriate construct for a suture per se, and I think that goes on with Burgess' coating and a couple other things like that.
But I think the crux of this entire discussion really goes on analogous art. Sutures and fishing line are two different things and what's being discussed is that as prior art, Burgess really shouldn't apply because it is really nonanalogous art. And that's the concluding paragraph's discussion.

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS
C.A. No. 04-12457 PBS

- - -

TRAVEL TRANSCRIPT

DePUY MITEK, INC.,
a Massachusetts corporation,
Plaintiff,

v.

ARTHREX, INC.,
a Delaware corporation,
Defendant.

- - -

WEDNESDAY NOVEMBER 30, 2005

- - -

Oral deposition of DENNIS D. JAMIOLKOWSKI, taken pursuant to Notice, before Jeanne Cahill, RMR, CRR, at the offices of Woodcock Washburn, LLP, One Liberty Place, 33th Floor, 1650 Market Street, Philadelphia, Pennsylvania, commencing at 9:10 a.m.

Q. So there was no set process within J&J/Ethicon at that period of time; it was done on an individual basis?

A. I believe that to be the case, and, again, I'm speaking as to what I know as an R&D person.

MR. SABER: I appreciate that.

Why don't we take a break.

(A recess was taken.)

BY MR. SABER:

Q. Mr. Jamiolkowski, I want to move to discuss with you the project that led to the Hunter patent. Okay?

A. Okay.

Q. When did that project start from a research and development point of view at Ethicon?

A. I don't know.

Q. Do you have any best understanding?

A. If I had to guess, I'd say maybe 1987.

Q. What is that based on, that statement?

A. That I recall seeing a document dated I believe June 1988, in which some of the ideas are laid out there. So before things get recorded, people generally don't put down every single thought that they have.

Q. So you think that there was some thoughts or something going on prior to –

A. Prior to that.

Q. – June of '88?

A. Yeah.

Q. Have you seen any documentation of any of those thoughts prior to June of 1988?

A. I have not personally witnessed any, no, seen any.

Q. Do you know, does Ethicon have any documentation of this project prior to June of 1988?

A. I don't know if they do or don't.

Q. To the best of your knowledge, does Ethicon have any documentation of this project prior to June of 1988 for this project?

A. I don't know if they do or they don't.

Q. What have you done to find out if they had any documentation prior to June of 1988?

A. I personally have done none.

Q. Is there anything in specific related to this project that you can tell me about prior to June of 1988?

A. I can tell you about my own personal experience, and I don't know what those dates are, and what they – this would be relevant to my being named an inventor on the initial application.

Q. Okay.

A. One of the people in R&D management, I believe

she was a director at the time, had asked or was concerned about competition for our synthetic absorbable materials, and had asked a number of us to attempt to anticipate what our competition could possibly come out with.

We marketed at that time a material known as Vicryl, V-I-C-R-Y-L, which was and still is the leading synthetic absorbable suture, that has some characteristics with it in terms of strength retention and absorption characteristics, that is, when does it leave the body.

I felt that if I was a competitor, what I would love to have is to be able to have a suture that absorbed in about the same time frame as Vicryl, but held onto its strength much longer than did Vicryl.

So I had proposed what turned out to be a suture which was composite in nature; that is, it would use filaments based on Vicryl and filaments based on a polymer that would last much longer, a homopolymer or copolymer rich in lactide, L-A-C-T-I-D-E.

In discussing this idea with some colleagues, they thought it had some merit. I wound up documenting the idea, or to the best of my recollection, I recall documenting it in an idea memo that went through the Idea Review Board.

And it was their decision ultimately to combine that with the heterogeneous braid ideas of Steckel, Hunter, and Taylor, and J&J moved forward with the patent application that was meant to encompass all these ideas.

Q. So if I understand your testimony, you had one kind of idea –

A. Yes, sir.

Q. – at work, and Messrs. Hunter, Steckel and Taylor had another kind of idea at work, and at least initially, for purposes of a patent application, they got combined?

A. That's correct.

Q. With respect to – and you were a named inventor?

A. That is correct.

Q. As the application was originally filed, is that correct?

A. That is correct.

Q. And your work involved Vicryl, and what was the second material?

A. It was a polymer which was based entirely on lactide. That would be a homopolymer of lactide known as polylactide, or at the very least, a copolymer that was very rich in lactide, an example of which might be 90 parts lactide, 10 parts glycolide.

Q. And why -- you were dropped as an inventor at some point during the prosecution of the patent?
A. That's correct.
Q. Why was that?
A. It is my understanding, and it's what I believe, is that in the course of the prosecution, the scope of the claims was going to be narrowed, and those ideas or those claims in which I had provided a contribution were not going to be considered in the case going forward, in which case I provided no inventive contributions to the claims that were moving forward, so, consequently, I was not an inventor, a contributing inventor to those claims that went forward.
Q. That description that you just gave me, does that comport with your understanding of the facts?
A. Absolutely.
Q. So I take it that your work with the Vicryl or polylactide or a copolymer that was rich in the lactide did not get reflected in the claims of the patent as issued?
A. That's correct.
Q. And you had no role in the conception of the inventions that led to the claims that issued in the Hunter patent. Is that correct?
A. Yes, that is correct.

Q. What is Vicryl?
A. Vicryl is a random copolymer. Actually, I take that back. Vicryl is a suture material based on a random copolymer of glycolide and lactide, in which the major component is glycolide.
Q. What is glycolide?
A. Glycolide is a six-member lactone. Lactone is a cyclic ester.
I can certainly draw its structure.
Q. That's not necessary.
A. But think of it as a ring.
Q. What is lactide?
A. Lactide is also a cyclic ester that is a lactone, very similar to glycolide, except that it has two methyl groups present, two extra methyl groups.
Q. What is the -- just for the record, what is the chemical makeup of Vicryl?
A. Vicryl is polyester. It's an aliphatic polyester. In other words, it does not contain any benzene rings.
Q. And is there anything else in the chemical makeup?
A. You're going to have to give me an example of what you're looking for.
Q. Well, I'm trying to understand what Vicryl is made of.

A. Okay. Let me say this about that. An ester group is a chemical entity in which there is an arrangement of carbon and oxygen atoms. If I have a molecule that contains many of these ester groups in a row, I wind up producing a chain.
This material, because of having many, we can use the Greek word, poly, meaning many, and they're esters, so polyesters.
Q. You said there was a memo for the work that you did?
A. For the work that I conceived of. In terms of actual redaction to practice, I think this was more constructive reduction to practice.
Q. With respect to the work that Messrs. Hunter, Taylor and Steckel did, was there an idea memo for that?
A. I don't know if -- I don't know.
Q. Have you ever seen --
A. I have not seen one. If I had seen one, I would be able to answer that yes, there is.
Q. To the best of your knowledge, does an idea memo exist?
A. I have no knowledge of whether there is or there isn't. I would suspect that there is, but that's only speculation.

Q. You haven't seen it?
A. I haven't seen it.
Q. It wasn't in the materials that you reviewed?
A. If it was in there, I don't recall seeing it. I'm sure that if I came across it, I would have paid attention to it. So you know, if it was there, I missed it.
MR. SABER: Mr. Bonella, we haven't been provided with any idea memo in connection with this project. If one exists, we'd ask that it be produced?
MR. BONELLA: Okay. I'll take a look.
BY MR. SABER:
Q. Did Messrs. Hunter, Taylor and Steckel's idea go to an Idea Review Board?
A. I don't know. I would suspect that it did, but I don't know for sure.
Q. Okay. What is your basis of the testimony that you suspect that it did?
A. Well, because there was a significant experimental work being conducted, and towards that, I suspect that there had to be some knowledge of this project -- and I use the term "project" loosely -- some knowledge of this work by upper management, and that it got a certain amount of focus.
Q. Have you done anything to confirm or not

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. a Massachusetts Corporation Plaintiff, v. Arthrex, Inc. a Delaware Corporation Defendant.	)	Civil Action No. 04-12457 PBS

ARTHREX, INC.'S SECOND SUPPLEMENTAL OBJECTIONS AND RESPONSES TO DEPUY MITEK, INC.'S INTERROGATORY NOS. 3, 5, AND 7 AND ARTHREX'S SUPPLEMENTAL OBJECTIONS AND RESPONSE TO DEPUY MITEK, INC.'S INTERROGATORY NO. 6

Pursuant to Rule 33 of the Federal Rules of Civil Procedure and Rule 33.1 of the Local Rules of the United States District Court for the District of Massachusetts, Defendant Arthrex, Inc., ("Arthrex") hereby provides second supplemental responses to Defendant DePuy Mitek, Inc.'s ("DePuy Mitek's") Interrogatory Nos. 3, 5, and 7 of DePuy Mitek's First Set of Interrogatories and supplemental response to Defendant DePuy Mitek, Inc.'s ("DePuy Mitek's") Interrogatory No. 6 of DePuy Mitek's First Set of Interrogatories. These supplemental responses are based on information reasonably available to Arthrex at the present time. Arthrex reserves the right to further supplement these responses when, and if, additional information becomes available, or known, to Arthrex. These interrogatories also remain premature to the extent that they

seek expert information. Such information will be provided in accordance with the Federal Rules of Civil Procedure and the Joint Case Management Statement filed by the parties and Scheduling Order entered by the Court. Arthrex also reserves the right to object on any ground at any time to these Interrogatories. Arthrex further reserves the right to object on any ground to such other or supplemental Interrogatories DePuy Mitek may propound involving or relating to the subject matter of these Interrogatories.

GENERAL OBJECTIONS

Arthrex incorporates herein the General Objections included in its Objections and Answers to DePuy Mitek's First Set of Interrogatories as if fully set forth herein.

DEFINITIONS

Arthrex incorporates herein the Definitions included in its Objections and Answers to DePuy Mitek's First Set of Interrogatories as if fully set forth herein.

ANSWERS AND SPECIFIC OBJECTIONS

The following Second Supplemental Responses to DePuy Mitek's Interrogatory Nos. 3, 5, and 7 and Supplemental Response to DePuy Mitek's Interrogatory No. 6 are made subject to and without waiver of the foregoing General Objections, and such General Objections are incorporated into each Response as though fully set forth therein. To the extent particular General Objections are restated in a Response, they are provided because they are particularly applicable to the specific Interrogatory and such inclusion is not to be construed as a waiver of any other General Objections.

INTERROGATORY NO. 3.

Describe all facts that support Arthrex's contentions that it has not infringed any claim of the Patent-in-Suit as set forth in ¶¶ 12-13 of Arthrex's Answer including, but not limited to,

(a) identifying each element of each claim of the Patent-in-Suit that Arthrex contends is literally absent from each Arthrex Braided Suture Product;

(b) explain (i) what Arthrex contends the basic and novel characteristics of the invention claimed in the Patent-in-Suit are; (ii) each contention that Arthrex does not infringe the Patent-in-Suit because its Braided Suture Products have a material that materially affects the claims' basic and novel characteristics; and (iii) what the material effect on the claims' basic and novel characteristics are by an alleged material in Arthrex's Braided Suture Products.

(c) explain any Arthrex contention that any alleged absent claim element is not satisfied under the doctrine of equivalents by describing all alleged substantial differences between the claim and Arthrex's Braided Suture Products and any reason why the function/way/result test is not satisfied for each Arthrex Braided Suture Product; and

(d) explain all facts that support any prosecution history estoppel contention with respect to the Patent-in-Suit including but not limited to the specific pages and lines of the prosecution history that Arthrex contends evidence prosecution history estoppel; and

(e) identify the tensile strength and bending strength and rigidity of each Arthrex Braided Suture Product with and without a coating and how those properties were determined and what samples were used in any such determination.

RESPONSE

Arthrex objects to this Interrogatory as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The terms "Braided Suture Product" and "Arthrex Braided Suture Product" as defined by DePuy Mitek, are overly broad and include products not relevant to the present lawsuit. Arthrex also objects to this Interrogatory as premature since DePuy Mitek has not yet identified which claim(s) of the '446 patent it is asserting, the basis for its infringement allegations, or whether and how there is infringement under the doctrine of equivalents. Arthrex will supplement this answer once DePuy Mitek provides this further information. Arthrex further objects to this Interrogatory as premature to the extent that it seeks expert information. Any such information to which DePuy Mitek is entitled will be provided in accordance with the Federal Rules of Civil Procedure and the Joint Case Management Statement filed by the parties and Scheduling Order issued by the Court. Subject to and without waiving its general and specific objections, Arthrex answers:

Arthrex's FiberWire® suture products do not contain any of the "first fiber-forming materials" recited in the claims of the '446 patent, as properly construed. Arthrex further answers that the '446 patent does not have any basic and novel characteristics. See, for example, Arthrex's Response to Interrogatory No. 5, which is

incorporated herein by reference. The '446 patent, however, purports to have at least one basic and novel characteristic of the alleged invention in that it claims to achieve certain results with only a combination of one of a listed first fiber-forming material and one of a listed second fiber-forming material. Even if the claims of the '446 patent were improperly construed to support a contention that the Arthrex FiberWire® suture products contain both such fiber-forming materials, Arthrex's FiberWire® suture products have a coating that affects the alleged basic and novel characteristics of the '446 patent and Arthrex's FiberWire® suture products do not achieve the desired results without the coating. Arthrex also answers that at least for these reasons, its FiberWire® suture products do not infringe the claims of the '446 patent under the reverse doctrine of equivalents even if the claims could be construed to cover Arthrex's products.

Arthrex further answers that the function/way/result test is not met since Arthrex's FiberWire® suture products do not perform the same function or achieve the same results as claimed in the '446 patent. Moreover, even if the same function and result were achieved, Arthrex's FiberWire® suture products operate in a manner substantially different than that of the alleged invention defined by the claims of the '446 patent, as properly construed. Moreover, DePuy Mitek would be estopped from contending that there is infringement by the doctrine of equivalents for any limitation that was amended for reasons of patentability. *See e.g.*, Amendment dated August 4, 1993 in which claim 21 was amended from reciting "comprising" to "consisting essentially of." *See id.* in which specific fiber-forming materials for each set of yarns were added to claim 21.

Arthrex further answers that non-privileged document(s) from which information responsive to this Interrogatory may be derived or ascertained will be produced pursuant to Rule 33(d) of the Federal Rules of Civil Procedure and Rule 33.1 of the Court. Such document(s) will include Arthrex's 510(k) submission to the U.S. Food and Drug Administration as well as various test reports.

SUPPLEMENTAL RESPONSE

In addition to the above, Arthrex further responds that its FiberWire® suture products contain ultra high molecular weight polyethylene ("UHMWPE"), a material that is neither disclosed nor claimed as a first fiber-forming material in the '446 patent.

The fact that any mention of UHMWPE is absent from the '446 patent is also consistent with statements made by the applicants and their attorneys during prosecution of U.S. Application No. 838,511 ("the '511 application"), which eventually issued as the '446 patent. For example, in distinguishing the alleged invention over Burgess (U.K. Patent Application No. 2,218,312A), the applicants and their attorneys stated that one would not be motivated to use UHMWPE, as disclosed in Burgess for suture applications. The applicants and their attorneys further stated that if one were to employ the teachings of references such as Burgess "to modify a suture, then he would inevitably design an unacceptable suture." Amendment dated August 6, 1992 at pages 2-4. DePuy Mitek cannot now recapture this subject matter that was so clearly disclaimed during prosecution of the '511 application. Accordingly, for this additional reason, the asserted claims of the '446 patent cannot be properly construed to include UHMWPE. Similarly, these actions constitute prosecution history estoppel.

The '446 patent describes the purported basic and novel characteristics of the invention. The purported basic and novel characteristics of the '446 patent appear to be enhanced characteristics of the braid, such as pliability or handleability of the suture, without significantly sacrificing its physical properties.

Even if claims of the '446 patent were somehow construed to support a contention that Arthrex's FiberWire® suture products contain both such fiber-forming materials, Arthrex's FiberWire® suture products have a coating that affects the alleged basic and novel characteristics of the '446 patent, as described above. That is, Arthrex's FiberWire® suture products, without coating, do not achieve the desired results –

enhanced characteristics of the braid, such as pliability or handleability of the suture, without significantly sacrificing its physical properties.

Arthrex further responds that its FiberWire® suture products do not include first and second sets of continuous and discrete yarns where each of the discrete yarns is in a sterilized, braided construction, as required by the asserted claims because UHMWPE and PET are not braided before being combined with one another.

Arthrex also responds that its FiberWire® suture products do not include yarns from a first set and yarns from a second set, as required by the asserted claims because its FiberWire® suture products do not contain a yarn from the first set of yarns to provide pliability or a yarn from the second set of yarns to provide strength.

Arthrex further responds that the function/way/result test is not met since Arthrex's FiberWire® suture products do not perform the same function or achieve the same results as the alleged invention of the asserted claims of the '446 patent. Moreover, even if the same function and result were achieved, Arthrex's FiberWire® suture products operate in a manner substantially different than that of the alleged inventions of the asserted claims of the '446 patent. For example, Arthrex's FiberWire® suture products employ UHMWPE, a material not even considered viable for use in sutures by the applicants of the '446 patent and their attorneys – for strength. To the contrary, for improved strength, the '446 patent discloses the use of, among other materials, PET -- a material which Arthrex's FiberWire® suture products employ for improving handling properties.

SECOND SUPPLEMENTAL RESPONSE

In addition to the above, Arthrex further responds that its FiberWire® suture products contain ultra high molecular weight polyethylene ("UHMWPE"), a material that is neither disclosed nor claimed as a first fiber-forming material in the '446 patent.

Rather, the '446 patent discloses polyethylene ("PE") for use with its claimed suture. Had the inventors intended to include UHMWPE in its disclosure, it would have been specifically identified. Many other prior art patents to the '446 patent also disclosed PE for use with sutures – each of them meaning commodity PE and not UHMWPE. Some examples of such patents include U.S. Patent Nos. 3,939,969; 4,060,885; 4,142,628; 4,950,285; 5,080,667; 5,123,913; and 5,662,682. Likewise, prior art materials intending to disclose UHMWPE make a specific reference to UHMWPE and not PE. *See. e.g.*, U.K. Patent Application No. 2,218,312A, to Burgess ("Burgess"), the '575 patent, the DSM brochure entitled *Dyneema SK60, High strength/ high modulus fiber, Properties & Applications* ("the DSM brochure") (Bates range PR 8420 to 8429), and Cohan, et al., *An Evaluation of Ultrastrong Polyethylene Fiber as an Ophthalmic Suture,* Arch Ophthalmol – Vol. 103, December 1985 ("the Cohan article") (Bates range ARM 25132 to 25137).

Furthermore, the specification of the '446 patent makes clear that the relatively weak commodity PE, rather than the ultra strong UHMWPE was intended by the inventors. For example, the specification explains that the relatively weak fibers of the first fiber-forming group are too weak to be used alone as sutures and warns that using greater than 80% of such fibers will adversely affect the overall strength of the braid. PE is included in the group of relatively weak materials.

Arthrex further responds that the '446 patent describes the purported basic and novel characteristics of the invention as improved handleability and pliability performance of the suture without significantly sacrificing its physical properties. It is well known that suture handleability includes, but is not limited to, any of the following suture characteristics: knot sliding, knot tie-down, feel, tissue sliding, knot security, ease of cutting, pliability, coefficient of friction, lubricity, stiffness, softness, smoothness, lack of chatter, and lie-down of the knot, many of which are specifically mentioned or implied in the specification and would be understood by one of ordinary

skill in the art. The specification explained that strength (e.g., tensile and knot strength) and knot security are the physical properties of a suture that should not be appreciably sacrificed. The '446 patent achieves these results without the use of coating. In fact, the specification of the '446 patent denigrates the use of coating.

Even if claims of the '446 patent were somehow construed to support a contention that Arthrex's FiberWire® suture products contain both fiber-forming materials, as previously mentioned, Arthrex's FiberWire® suture products have a coating that affects the alleged basic and novel characteristics of the '446 patent. Arthrex's FiberWire® suture products use coating to improve the handleability of the suture without significantly sacrificing its physical properties. Such effects of coating on suture are well known in the art, are documented in U.S. patents, various materials produced by Arthrex and DePuy Mitek and in tests conducted by Arthrex. In addition, the coating affects the basic and novel characteristics of the '446 patent because the coating improves the knot strength of FiberWire suture.

Arthrex further responds that FiberWire sutures are sold with their ends tipped (*i.e.*, stiffened) to approximately 1 inch. The tipped ends are achieved by adding an adhesive material to the suture during processing. Tipping the ends of the suture make it easier for surgeons to thread the suture through surgical instruments, prevents fraying of the ends, and serves to restrict the fiber mobility of the first and second fiber forming materials and restricts the bendability of the tipped portion of the suture. Thus, the handleability is greatly improved over untipped suture.

Arthrex's FiberStick suture is a product that makes greater use of this adhesive material which affects the basic and novel characteristics of the '446 patent. FiberStick is stiffened to approximately 12-inches. The stiffened portion of FiberStick greatly improves handleability by easing passage of the suture through cannulated instruments and/or spinal needles and provides even greater restrictions of fiber mobility and bendability. The use of FiberStick also alleviates the need for monofilament or wire

suture shuttles. FiberStick also does not infringe the '446 patent for all the reasons discussed in connection with FiberWire in this answer and its supplements.

In addition to the non-infringement reasons discussed in connection with FiberWire in this answer and its supplements, Arthrex further states that its TigerWire suture includes UHMWPE, PET and nylon. Among other things, adding nylon to the suture increases stiffness (*i.e.*, less pliable) and improves the strength of the suture. Thus, the nylon added to the suture affects the alleged basic and novel characteristics of the '446 patent.

INTERROGATORY NO. 5.

To the extent that Arthrex contends that any claim of the Hunter patent is invalid under 35 U.S.C. § 102 or 103 (Answer at ¶¶ 9, 10):

(a) identify each item of prior art upon which Arthrex relies, and make an element-by-element application (providing specific citation to the relevant portions of the prior art) of each allegedly invalid claim to each item of prior art, explaining in detail the grounds for any allegation of invalidity under 35 U.S.C. § 102; and

(b) state the factual basis for any contention that any claim of the Patent-in-Suit is invalid under 35 U.S.C. § 103, including specifically, Arthrex's contentions of the level of ordinary skill in the art, the similarities and differences between each item of prior art and each claim, the scope and content of the prior art, and any secondary considerations.

RESPONSE

Arthrex objects to this Interrogatory as being vague and ambiguous to the extent it refers to "the Hunter patent," which is an undefined term. To the extent "the Hunter patent" refers to the '446 patent, Arthrex also objects to this Interrogatory as premature since DePuy Mitek has not yet identified which claim(s) of the '446 patent it is asserting,

the basis for its infringement allegations, or whether and how there is infringement under the doctrine of equivalents. Arthrex will supplement this answer once DePuy Mitek provides this further information. Arthrex further objects to this Interrogatory as premature to the extent that it seeks expert information. Any such information to which DePuy Mitek is entitled will be provided in accordance with the Federal Rules of Civil Procedure and the Joint Case Management Statement and the Scheduling Order entered by the Court. Subject to and without waiving its general and specific objections, Arthrex answers:

Non-privileged document(s) from which information responsive to this Interrogatory may be derived or ascertained will be produced pursuant to Rule 33(d) of the Federal Rules of Civil Procedure and Rule 33.1 of the Court. Moreover, U.S. Patents Nos. 5,318,575; 4,610,688; 3,942,532; 5,147,400, as well as others, taken individually and/or when their teachings are combined together or with other known prior art, disclose every limitation of claims of the '446 patent.

SUPPLEMENTAL RESPONSE

In addition to the above, Arthrex also responds that the currently asserted claims of the '446 patent (*i.e.*, claims 1, 2, 8 and 12) are invalid under 35 U.S.C. § 102/103 at least for the reasons stated below. Although Arthrex supplements its response to this interrogatory, this supplemental response is not a substitute for an expert report on invalidity which will be provided by Arthrex in accordance with the Case Management Statement adopted by the Court. Accordingly, this supplemental response is in no way limiting or restricting to any opinion or opinions which may be rendered by any Arthrex expert(s) in this case. Further, Arthrex's supplemental response is based on the claims currently being asserted by DePuy Mitek. Moreover, no claim interpretation has yet been rendered by the Court. Arthrex reserves the right to further supplement this response upon receiving and/or becoming aware of additional information, and/or

upon DePuy Mitek's assertion of additional and/or different claims, and/or upon a claim interpretation issued by the Court.

Arthrex further states that claim 1 of the '446 patent is invalid under 35 U.S.C. § 103 as being unpatentable over, for example, U.S. Patent No. 4,610,688 ("the '688 patent") in view of U.S. Patent No. 3,359,983 ("the '983 patent"), and optionally, in view of U.S. Patent No. 5,147,400 ("the '400 patent").

The '688 patent, for example, discloses a triaxially braided fabric containing interwoven first, second and third sets of fibers. '688 Patent at column 2, lines 26-30. The '688 patent also discloses that the first set of fibers is formed of polypropylene (PP) and that the second and third sets of fibers are formed of either nylon or PET. '688 Patent at column 6, lines 3-32. While the '688 patent does not specifically disclose a surgical suture, the '983 patent does. '983 Patent at Title.

It would have been obvious for a person of ordinary skill in the art at the time of the alleged invention to combine the teachings of the '688 patent with those of the '983 patent, and arrive at the alleged invention of claim 1 of the '446 patent. For example, such a person of ordinary skill in the art would realize from reading the '688 patent that braiding two different but complementary materials together would enable one to manufacture a prosthesis having desirable properties of both materials (*e.g.*, strength and pliability), where those materials are either PP and nylon, or PP and PET. Such a person also reading the '983 patent would realize that while many materials had, up to that time, been successfully used for surgical sutures, if one were to combine different materials in a braided form, one could arrive at a surgical suture having the desirable properties of both materials (*e.g.*, strength and pliability). Thus, a person of ordinary skill in the art would have been motivated to combine the teachings of the '688 patent and the '983 patent and arrive at the alleged invention of claim 1 of the '446 patent.

The '400 patent discloses a connective tissue prosthesis having a core yarn component and a braided sheath yarn component comprising individual sheath yarn

filament bundles which traverse the core yarn component in a substantially conventional braided configuration to provide the core yarn component with a braided tubular external sheath. '400 patent at column 9, lines 1-9. It would have been obvious for a person of ordinary skill in the art to combine the teachings of the '400 patent with those of the '688 and '983 patents and arrive at the alleged inventions of claim 1 of the '446 patent, including the optional core.

Claim 2 of the '446 patent depends from claim 1 and further recites that the suture is attached to a needle. Claim 2 is also invalid under 35 U.S.C. § 103 as being unpatentable in view of the '688 patent, the '983 patent and also in view of the state of the art at the time of the alleged invention, as demonstrated by, for example, U.S. Patent No. 3,454,011 ("the '011 patent"). *See e.g.*, '011 patent at FIG. 1.

Claim 8 of the '446 patent depends from claim 1 and further recites that the second set of yarns is PET. At least for the reasons described above, claim 8 is also invalid under § 103 since, for example, the '688 patent discloses the use of PET.

Claim 12 of the '446 patent depends from claim 8 and further recites that the suture is attached to a needle. Claim 12 is also invalid under § 103 at least for the same reasons as above.

Arthrex further responds that to the extent claims of the '446 patent were somehow construed to cover Arthrex's FiberWire® suture products, claims 1 and 8 of the '446 patent would be invalid under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,318,575 at least for the reasons described below in the claim chart.

'446 Patent Claim 1	U.S. Patent No.5,318,575
1. A surgical suture consisting essentially of	The '575 patent discloses a surgical suture. '575 Patent at Title; column 1, line 7.
a heterogeneous braid composed of a first	The '575 patent discloses that the fibers

and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and	can be multifilament fibers that are braided. '575 patent at column 3, lines 49-51. The '575 patent discloses that first fibers are braided with second fibers to form an elongated member. '575 Patent at claim 1.
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The '575 patent discloses that the first fibers are high molecular weight polyethylene fibers, preferably, SPECTRA®. '575 Patent at column 3, lines 61-67.
b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and	The '575 patent discloses that the second fibers are nylon or polyester. '575 Patent at column 3, lines 61-67; claims 11 and 12.
c) optionally a core.	The '575 patent discloses a core, although one is not necessary for purposes of this claim. '575 Patent at claim 7.

The '575 patent also discloses the use of a needle as recited in claims 2 and 12 of the '446 patent. '575 patent at column 5, lines 41-42. Accordingly, even if claims 1 and 8 were somehow construed to cover Arthrex's FiberWire® suture products, claims 2 and 12 would also be invalid under § 102 as anticipated by the '575 patent.

Arthrex further states that to the extent claim 1 of the '446 patent is somehow construed to cover any of Arthrex's FiberWire® suture products, claims 1 and 8 would

be invalid under 35 U.S.C. § 103 as being unpatentable over, for example, U.K. Patent Application No. 2,218,312A, to Burgess ("Burgess") in view of the state of the art at the time of the alleged invention, as disclosed, for example, in the '983 patent. For example, Burgess discloses a fishing line of braided construction, some braid filaments being of high molecular weight polyethylene and the other filaments being of polyester and/or nylon. Burgess at page 1. While Burgess does not specifically disclose a surgical suture, the '983 patent does. '983 Patent at Title.

It would have been obvious for a person of ordinary skill in the art at the time of the alleged invention to combine the teachings of Burgess with those of the '983 patent, and arrive at the alleged inventions of claims 1 and 8 of the '446 patent. For example, such a person of ordinary skill in the art would realize from reading Burgess that braiding two different but complementary materials together would enable one to manufacture a fishing line having desirable properties of both materials (e.g., strength and stiffness and/or low coefficient of friction), where those materials are UHMWPE, polyester and/or nylon. Such a person also reading the '983 patent would realize that while many materials had, up to that time, been successfully used for surgical sutures, if one were to combine different materials in a braided form, one could arrive at a surgical suture having the desirable properties of both materials (e.g., strength and stiffness and/or low coefficient of friction). Thus a person of ordinary skill in the art would be motivated to combine the teachings of Burgess and the '983 patent and arrive at the alleged inventions of claims 1 and 8 of the '446 patent.

Claims 2 and 12 would also be invalid under § 103 as being unpatentable over Burgess in view of the state of the art at the time of the alleged invention as disclosed in, for example, the '011 patent. '011 patent at FIG. 1.

Arthrex further states that to the extent claim 1 of the '446 patent is somehow construed to cover any of Arthrex's FiberWire® suture products, claim 1 would be

invalid under 35 U.S.C. § 103 as being unpatentable over, for example, the '688 patent in view of U.S. Patent No. 3,942,532 ("the '532 patent").

While the '688 patent, as described above, does not specifically disclose a braided suture, the '532 patent does. '532 Patent at Title.

It would have been obvious for a person of ordinary skill in the art at the time of the alleged invention to combine the teachings of the '688 patent with those of the '532 patent, and arrive at the alleged inventions of claims 1 and 8 of the '446 patent. For example, such a person of ordinary skill in the art would realize from reading the '688 patent that braiding two different but complementary materials together would enable one to manufacture a prosthesis having desirable properties of both materials (*e.g.*, strength and pliability), where those materials are either PP and nylon, or PP and PET. Such a person also reading the '532 patent would realize that while certain materials had, up to that time, been successfully used for surgical sutures, if one were to combine different materials in a braided form, one could arrive at a surgical suture having the desirable properties of both materials (*e.g.*, strength and pliability). Thus a person of ordinary skill in the art would be motivated to combine the teachings of the '688 patent and the '532 patent and arrive at the alleged inventions of claims 1 and 8 of the '446 patent.

Claims 2 and 12 of the '446 patent would also be invalid under § 103 at least for the same reasons mentioned above.

The above is not intended to be an exhaustive list of reasons why the '446 patent is invalid under 35 U.S.C. §§ 102, 103, but rather, it is intended to be only an exemplary list of such reasons.

SECOND SUPPLEMENTAL RESPONSE

In addition to the above, Arthrex further responds that to the extent claims of the '446 patent were somehow construed to cover Arthrex's FiberWire® suture products,

claims 1 and 8 of the '446 patent would be invalid under 35 U.S.C. § 103 as being unpatentable over, for example, U.K. Patent Application No. 2,218,312A, to Burgess ("Burgess") in view of Cohan, et al., *An Evaluation of Ultrastrong Polyethylene Fiber as an Ophthalmic Suture*, Arch Ophthalmol – Vol. 103, December 1985 ("the Cohan article") (Bates range ARM 25132 to 25137), which explains that UHMWPE had been used as a surgical suture. Had the Examiner known of the Cohan article in August 1992, he would have maintained the rejection of claims 1 and 8 on § 103 grounds.

Claims 2 and 12 of the '446 patent would also be invalid under § 103 as being unpatentable over Burgess and the Cohan article in view of the state of the art at the time of the alleged invention as disclosed in, for example, the '011 patent. '011 patent at FIG. 1.

In addition to the above, Arthrex further responds that to the extent claims of the '446 patent were somehow construed to cover Arthrex's FiberWire® suture products, claims 1 and 8 of the '446 patent would be invalid under 35 U.S.C. § 103 as being unpatentable over, for example, Burgess in view of the DSM brochure entitled *Dyneema SK60, High strength/ high modulus fiber, Properties & Applications* ("the DSM brochure") (Bates range PR 8420 to 8429). The DSM brochure, dated 1987, suggests using Dyneema UHMWPE in suture applications. *See* DSM brochure at p. 4. Had the Examiner known of the DSM brochure in August 1992, he would have maintained the rejection of claims 1 and 8 on § 103 grounds.

Claims 2 and 12 of the '446 patent would also be invalid under § 103 as being unpatentable over Burgess and the DSM brochure in view of the state of the art at the time of the alleged invention as disclosed in, for example, the '011 patent. '011 patent at FIG. 1.

Arthrex further responds that to the extent claims of the '446 patent were somehow construed to cover Arthrex's FiberWire® suture products, claims 1 and 8 of the '446 patent would be invalid under 35 U.S.C. § 103 as being unpatentable over, for

example, Burgess in view of either one of U.S. Patent Nos. 4,563,392 or 4,543,286, both to Harpell et al. ("the Harpell patents"). Both of the Harpell patents disclose the use of UHMWPE in surgical suture applications. Had the Examiner known of the Harpell patents in August 1992, he would have maintained the rejection of claims 1 and 8 on § 103 grounds.

Claims 2 and 12 of the '446 patent would also be invalid under § 103 as being unpatentable over Burgess and the Harpell patents in view of the state of the art at the time of the alleged invention as disclosed in, for example, the '011 patent. '011 patent at FIG. 1.

The above is not intended to be an exhaustive list of reasons why the '446 patent is invalid under 35 U.S.C. §§ 102, 103, but rather, it is intended to be only an exemplary list of such reasons.

INTERROGATORY NO. 6.

With respect to Arthrex's inequitable conduct defense and counterclaim:

(a) identify all persons who allegedly committed inequitable conduct;

(b) state all facts supporting Arthrex's contention that the such persons committed inequitable conduct; and

(c) identify each piece of information that was allegedly withheld and each alleged misrepresentation and why the alleged withheld information or misrepresentation is material.

RESPONSE

Arthrex objects to this Interrogatory to the extent that it seeks information not yet in Arthrex's possession. Most of the facts surrounding the alleged inequitable conduct are known to the applicants of U.S. Application No. 838,511 ("the '511 application"), which eventually issued as the '446 patent, and their attorneys; and since discovery has

only just begun in this case, Arthrex has not yet had an opportunity to obtain all information responsive to this Interrogatory. Subject to and without waiving its general and specific objections, Arthrex answers:

(a) At least the applicants of the '511 application and their attorneys, including Hal Brent Woodrow, committed the alleged inequitable conduct.

(b) During prosecution of the '511 application, the applicants and their attorneys mischaracterized and misrepresented the disclosure of U.S. Patent No. 5,147,400 to Kaplan et al. ("Kaplan") in distinguishing Kaplan from claim 21 of the '511 application. For example, in response to rejections on anticipation and obviousness grounds under 35 U.S.C. §§ 102, 103, on August 4, 1993, the applicants and their attorneys falsely represented that the sheath yarn component of Kaplan always contains at least in part, a bio-absorbable portion and that Kaplan teaches away from a combination of non-bioabsorbable yarns.

The applicants and their attorneys misrepresented Kaplan as stating "in one embodiment, the sheath yarn could also contain a non-bioabsorbable yarn of one or more chemical composition." *See* Amendment filed August 4, 1993 at page 2. The applicants and their attorneys then immediately went on to state that claim 21 does not claim a sheath yarn composed of a bio-absorbable yarn. *Id.*

Their statements regarding Kaplan's teachings were entirely misleading, however. Kaplan actually states that "sheath component 34 may also be fabricated from individual filaments *having more than two different chemical compositions, one or more of which optionally being non-bioabsorbable.*" [Emphasis added.] Kaplan at column 9, lines 25-28. In other words, Kaplan discloses that the sheath component may be fabricated from individual filaments, all of which may be non-bioabsorbable.

The applicants and their attorney again misrepresented the teachings of Kaplan when they stated that "the sheath, however, may optionally have, in addition to the bioabsorbable sheath yarn, one or more non-bioabsorbable filaments." *See* Amendment

filed August 4, 1993 at page 3. As described above, Kaplan does, in fact, disclose a sheath containing all non-bioabsorbable yarns.

(c) The mischaracterizations and misrepresentations made by the applicants and their attorneys were material since the Examiner ostensibly relied on them in deciding that the rejections based on Kaplan had been overcome and in allowing the '511 application after the Amendment was filed on August 4, 1993.

SUPPLEMENTAL RESPONSE

In addition to the above, Arthrex further responds that during the prosecution of the '511 application, applicants and their attorney, Matthew S. Goodwin, responded to a rejection based on U.K. Patent Application No. 2,218,312A to Burgess ("Burgess") by stating in a response, filed on August 6, 1992, that the use of a high tensile polythene thread in a braided construction, with polyester and/or nylon, would have poor qualities for a suture (*e.g.*, poor knot strength, poor knot security, low elongation and poor knot sliding) and that a designer using such materials for a suture would inevitably design an unacceptable suture. If applicants and their attorneys truly believed that high tensile polythene was included within their claimed invention, then they could not have honestly made these statements and representations to the examiner. Accordingly, in such circumstances, the applicants and their attorney made a material misstatement with intent to deceive the PTO.

INTERROGATORY NO. 7.

With respect to Arthrex's contentions that the asserted claims are invalid under 35 U.S.C. § 112 (Answer at Affirmative defenses ¶11):

(a) identify each claim of the Patent-in-Suit that is allegedly invalid under 35 U.S.C. § 112; and

(b) explain the factual basis for each such contention, and identify the specific section and statutory requirement of 35 U.S.C. § 112 that allegedly has not been met.

RESPONSE

Arthrex objects to this Interrogatory as premature since DePuy Mitek has not yet identified which claim(s) of the '446 patent it is asserting, the basis for its infringement allegations or whether and how there is infringement under the doctrine of equivalents. Arthrex will supplement this answer once DePuy Mitek provides this further information. Arthrex also objects to this Interrogatory to the extent it seeks information within the possession of DePuy Mitek. Subject to and without waiving its general and specific objections, Arthrex answers:

The claims of the '446 patent, if construed to cover Arthrex's FiberWire® suture products, are not enabled by the specification of the '446 patent (§ 112, first paragraph). For example, the '446 patent does not enable one skilled in the art to make and use a surgical suture that requires coating in order to achieve the desired results. The '446 patent also does not enable one skilled in the art to make and use a surgical suture containing ultra high molecular weight polyethylene (UHMWPE) as one of the fiber-forming materials. The claims of the '446 patent also do not particularly point out and distinctly claim the subject matter which the applicants regard as their invention (§ 112, second paragraph). For example, the terms "consisting essentially of," "direct intertwining contact" and each of the polymers recited in the claims are indefinite if attempted to be construed in a manner that covers Arthrex's products.

SUPPLEMENTAL RESPONSE

In addition to the above, Arthrex also responds that the currently asserted claims of the '446 patent (*i.e.*, claims 1, 2, 8 and 12) are invalid under 35 U.S.C. § 112 at least for the reasons stated below. Although Arthrex supplements its response to this

interrogatory, this supplemental response is not a substitute for an expert report on invalidity which will be provided by Arthrex in accordance with the Case Management Statement adopted by the Court. Accordingly, this supplemental response is in no way limiting or restricting to any opinion or opinions which may be rendered by any Arthrex expert(s) in this case. Further, Arthrex's supplemental response is based on the claims currently being asserted by DePuy Mitek. Moreover, no claim interpretation has yet been rendered by the Court. Arthrex reserves the right to further supplement this response upon receiving and/or becoming aware of additional information, and/or upon DePuy Mitek's assertion of additional and/or different claims, and/or upon a claim interpretation issued by the Court.

Arthrex further responds that if the claims of the '446 patent are somehow construed to cover Arthrex's FiberWire® suture products, the claims of the '446 patent are invalid under 35 U.S.C. § 112, first paragraph since the '446 patent does not enable one skilled in the art to make and use a surgical suture that requires coating in order to achieve enhanced characteristics of the braid, such as pliability or handleability of the suture, without significantly sacrificing its physical properties (such as suture strength, knot strength and security, etc.).

Arthrex further responds that if the claims of the '446 patent are somehow construed to cover Arthrex's FiberWire® suture products, the claims of the '446 patent are invalid under 35 U.S.C. § 112, first paragraph since the '446 patent does not enable one skilled in the art to make and use a yarn from the first set of disclosed yarns to provide strength or a yarn from the second set of disclosed yarns to provide pliability.

Arthrex further states that if the transitional phrase "consisting essentially of" of claim 1 of the '446 patent is properly construed, then claim 1 does not cover any accused product containing an unrecited material that affects the basic and novel characteristics of the alleged invention of claim 1, as described above in connection with Arthrex's supplemental response to Interrogatory No. 3. To the extent claim 1 is interpreted to

cover any of Arthrex's FiberWire® suture products, which do contain a coating that affects the basic and novel characteristics, as described in connection with Arthrex's supplemental response to Interrogatory No. 3, then claim 1 is invalid as indefinite under 35 U.S.C. § 112, second paragraph.

Arthrex further responds that neither the limitation "direct intertwining contact," as recited in claim 1, nor the limitation "plied together" are sufficiently defined in the specification. Further, any distinction between the two limitations, if any, is unclear. Thus, claims 1, 2, 8 and 12 are invalid as being indefinite under 35 U.S.C. § 112, second paragraph.

Arthrex also responds that the limitation "optionally a core," as recited in claim 1 of the '446 patent is an improper attempt to claim subject matter in the alternative, thereby rendering claims 1, 2, 8 and 12 invalid as indefinite under 35 U.S.C. § 112, second paragraph.

The above is not intended to be an exhaustive list of reasons why the '446 patent is invalid under 35 U.S.C. § 112, but rather, it is intended to be only an exemplary list of such reasons.

SECOND SUPPLEMENTAL RESPONSE

In addition to the above, Arthrex further responds that if the claims of the '446 patent are somehow construed to cover Arthrex's FiberWire® suture products, the claims of the '446 patent are invalid under 35 U.S.C. § 112, first paragraph, as not satisfying the written description requirement.

For example, there is no mention of UHMWPE in the specification. The disclosure in the specification of the characteristics of the first fiber-forming materials is consistent with that of PE and inconsistent with that of UHMWPE. Thus, a person of ordinary skill in the art at the time the '511 application was filed would not recognize

from the application that the inventors actually invented a suture containing UHMWPE as one of the first fiber-forming materials.

Dated: January 27, 2006

By: s/Charles W. Saber

Charles W. Saber
Stephen A. Soffen
Salvatore P. Tamburo
DICKSTEIN SHAPIRO MORIN
& OSHINSKY LLP
2101 L Street NW
Washington, D.C. 20037-1526
Telephone: (202) 861-9116
Facsimile: (202) 887-0689

Christopher Weld, Jr. (BBO # 522230)
Raymond P. Ausrotas (BBO # 640315)
TODD & WELD LLP
28 State Street, 31st Floor
Boston, MA 02109
Telephone: (617) 720-2626
Facsimile: (617) 227-5777

Counsel for Defendants Arthrex, Inc.
and Pearsalls, Limited

CERTIFICATE OF SERVICE

It is hereby certified that a true and correct copy of the foregoing Arthrex, Inc.'s Second Supplemental Objections and Responses to DePuy Mitek, Inc.'s Interrogatory Nos. 3, 5 and 7 and Supplemental Objections and Response to DePuy Mitek, Inc.'s Interrogatory No. 6 has been served by facsimile on the following counsel for DePuy Mitek, Inc. on this 27th day of January 2006:

Lynn A. Malinoski
Woodcock Washburn, LLP
One Liberty Place, 46th Floor
Philadelphia, PA. 19103
Phone: (215) 568-3100
Facsimile: (215) 568-3439

Daniel J. Gleason
Nutter McClennan & Fish LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA 02210-2604
Phone: (617) 439-2000
Facsimile: (617) 310-9000

s/Salvatore P. Tamburo
Salvatore P. Tamburo

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.,** **a Private Limited Company** **of the United Kingdom,** **Defendants.**	)	**Civil No. 04-12457 PBS**

Declaration of Dr. Matthew Hermes In Support of
DePuy Mitek's Claim Interpretation of the Hunter Patent

I. Background Information

A. Professional Experience

1. From 1983-95, I was employed with U. S. Surgical Corp. In 1983, I started as Senior Research Scientist. My duties from 1983-1986 included developing products based on bio-absorbable materials for use as medical devices. From 1986-1992, I initiated and led the first suture development program at U.S. Surgical. That program led to the commercialization of the Syneture™ suture product line. My responsibilities included all phases of surgical suture development from concept to commercialization. My suture group included seventeen team members directly involved in the design and development of commercial surgical suture products, including design and manufacture, fiber extrusion and processing, fiber design, yarn design, braiding specifications, selection of materials, braid design, prototype braiding, braid

post treatment, stretching, annealing, coating, packaging design, sterilization, testing, cooperating with regulatory department concerning 510(k) approval, and quality control.

2. In 1996, I authored the book "Enough for One Lifetime," the biography of Wallace Carothers, the inventor of Nylon. While writing this book from 1989-1996, I researched and studied the origins of synthetic fiber science including the history and development of nylon and polyester.

3. Before I worked at U.S. Surgical Corporation, I was a Research Director at Virginia Chemicals, at Celanese Co. from 1979-1983. Prior to being a Research Director, I was a Research Chemist, Supervisor, at E. I. DuPont from 1959-1979. At DuPont, I work with triaxial support systems and supervised a group that worked on elastomer coated fabrics.

From 1992-1994, I was an Adjunct Professor of Chemistry at the University of Wyoming.

From 1995-1997, I was a Consultant at Colorado Advanced Technology Institute.

In 2001 and 2006 I received two Small Business grants from the NIH for the development of unique all plastic manual wheelchairs and worked with Turbo Wheelchair company to develop, manufacture, and sell these unique devices.

B. Education

4. I have a Bachelor of Science in Chemistry from St. John's University, Brooklyn, NY, 1955. I have a Ph. D. in Chemistry from the University of Maryland, 1959. My mentor was Professor William Bailey who developed one of the earliest polymer science research groups in the country. My doctoral thesis related to polymers made using the Diels-Alder reaction. I also have a Masters of Arts in Liberal Studies from Wesleyan University, 1992.

5. A copy of my CV is attached under Tab A. A list of my publications and patents are set forth in my CV.

II. PERSONS OF ORDINARY SKILL IN THE ART WOULD UNDERSTAND THE CLAIMED PE TO INCLUDE ULTRA HIGH MOLECULAR WEIGHT PE

6. The Hunter Patent reasonably conveys to one of skill in the art and would convey to anyone with any familiarity with polymers that the inventors had possession of a claimed suture with ultra high molecular weight polyethylene (PE) as the first-fiber forming material. The first fiber-forming materials recited in Claim 1 – PTFE, FEP, PFA, PVDF, PETFE, PP and PE – are all polymeric materials. In other words, they are molecules formed of repeating chemical units, called "monomers." Polyethylene (PE), for example, is formed from repeating units of the monomer ethylene, (CH_2=CH_2). The polyethyelene (PE) may be referred to as $(CH_2\text{-}CH_2)_n$, where n = a whole number and indicates the number of repeating monomeric units of ethylene in the polymer.

7. The length of the chain of repeating units in a polymer (i.e., how high a number "n" is) determines the "molecular weight" of the polymer. The longer the chain (the higher "n" is), the higher the molecular weight of the polymer. Polymers are frequently referred to as having "low," "high," or, in some situations, "ultra high" molecular weights. Ultra high molecular weight PE has the same monomer as any other polyethylene, ethylene, (CH_2=CH_2). "High molecular weight" or "ultra high molecular weight" PE is just a longer chain of the repeating ethylene monomer (*i.e.*, *n* is a higher number) than "low molecular weight" or "medium molecular weight" PE.

8. In 1987, the Encyclopedia of Polymer Science and Engineering 2nd edition volume 10 recognized polyethylene as the "common (source-based)" name for all polymers made from ethylene (Tab B). The International Union of Pure Applied Chemistry (IUPAC), which has long been recognized as the world authority on chemical nomenclature, officially recognized that PE is the accepted abbreviations for all types of PE (Tabs B & C). Thus, one of

skill in the art would have known that "PE" or "polyethylene" as used in the Hunter Patent means all polymers from ethylene including ultra high molecular weight PE.

9. The Hunter Patent specifically claims "PE." Further, the Hunter Patent expressly describes "polyethylene (PE)" (Tab D, Hunter Patent at 4:27-30). One of skill in the art would have known that "PE" means "polyethylene" and means all polymers made from ethylene. PE is the generic name for all types of PE, including ultra high molecular weight PE.

10. A person of skill in the art would likely be a scientist in chemistry or a chemical, mechanical, or biomedical, biomechanical, or textile engineer (or other similar technical field) practicing in the field of suture design or development and having about 2 to 3 years of experience in the suture design field or person without such a degree but having about eight years experience in suture design or development. I am a person of skill in the art.

11. The Hunter Patent's description of PE is consistent with all types of PE. The Hunter Patent states that in a preferred embodiment the first set of yarns acts as lubricating yarns (Tab D, Hunter Patent at 4:11-12). PE including ultra high molecular weight PE is a lubricious yarn (Tab E at 52:24-53:2).

12. The Hunter Patent states that the first set of yarns may be derived from "non-absorbable polymers." PE including ultra high molecular weight PE is a non-absorbable polymer. The Hunter Patent also describes the first set of yarns as being made from fiber forming materials (Tab D, Hunter Patent at 4:30-32). PE including ultra high molecular weight PE is a fiber forming material. Therefore, the Hunter Patent's description of PE is consistent with the meaning of PE and includes ultra high molecular weight PE.

I declare under penalty of perjury that the foregoing is true and correct.

Date Executed: August 11, 2006 _/s/ Matthew E. Hermes, Ph.D.____

TAB A



Curriculum Vitae

Matthew E. Hermes, Ph. D.
76 Meridian Rd.
Beaufort, SC 29907

404-729-0758
hayden@islc.net

Profile:

Dr. Hermes is a scientist, inventor, fundraiser, biographer, educator and public servant with 50 years successful scientific research experience. He evaluates patterns of relationships - whether scientific, cultural or technical - and synthesizes novel and practical solutions to tough, real-world problems. Now he serves as Secretary/Treasurer of Turbo Wheelchair, Co., Inc., (Dr. Jane Hermes startup Company) and also:

- Actively consults in chemistry of biomedical devices and on intellectual property matters for small and FORTUNE 50 companies.
- Writes and initiates business plans for startup enterprises including advising and writing SBIR grant proposals.
- Maintains and publishes new systems of chemical education for university students through the award winning ChemCases.com web site and the ALSOS digital library.
- Consults on the processes affecting public education boards from his experience as an elected Public School Board member.

Recent Accomplishments

- As entrepreneur, Principal Investigator, applied for and received $750,000 (2001) and $100,000 (2006) NIH Small Business Innovative Research grants for design, development, prototype manufacture of durable, solid seat, folding engineering resin adult and children's manual wheelchairs (Merlexi Craft, see Merlexi.com).
- In wheelchair development made 20 design changes from first prototype, designed and built steel molds, manufactured 200 prototype wheelchairs for domestic demonstration, obtained FDA approval and manufactures commercial product. Chair most durable ever tested at University of Pittsburgh Human Engineering Research Laboratory. US Patent has been allowed. (US Application 20050098970).
- Project Director, ChemCases.Com, National Science Foundation-funded University General Chemistry curriculum development project. Written and published two ChemCases. More than 4.3 million pages delivered. Cited for excellence by SCIENCE, Scientific American and the WASHINGTON TIMES.

Earlier Accomplishments:

- At US Surgical Corp. through 1995, initiated and led research and development leading to introduction of absorbable polyester fiber sutures among 1,000+ suture products for the Company. Conceptualized, created and protoyped products. Designed, built and operated manufacturing.
- Discovered and patented and introduced practical methods for stabilizing moisture sensitive polyester fibers against hydrolysis. Invention reduced time to market introduction by five years.
- Envisioned and patented non-protein polymer systems incorporating unique features of predetermined length, composition and sequence. These distinctive properties in proteins drive all living systems.
- Obtained 27 patents in the surgical device/absorbable resin/suture field including seven dealing with polyester hydrolysis and its control.
- As Adjunct Professor of Chemistry at Wyoming, developed synthetic methods for structural assembly of polyesters with predetermined sequence. Monodisperse oligomers show protein-like configuration.
- Completed biography "Enough for One Lifetime, Wallace Carothers, Inventor of Nylon", published by the American Chemical Society March 1996.
- As Contract Consultant to Colorado Advanced Technology Institute, taught Applied Telecommunications to twelve rural Colorado governments and entities. Actively developing and maintaining four World-Wide-Web Internet sites with over 150 documents. AeRie presentation of Rural telecommunications chosen "Pick of the Week", May 1, 1995 by NCSA. Developed and managed web communications for Dept. of Commerce TIIAP GIS development grant.
- Marketing resort lodging through Internet connectivity, developing electronic marketing data and plans, 1995-1998. Commercial internet marketing resulted in $2.25M new business for Yampa Valley, Colorado.
- Elected to Steamboat Springs, Colorado RE-2 Board of Education, 1997-2000.
- Completed digitizing the 1881 "Atlas of Colorado". Produced CDROM of maps and western art as educational and recreational resource for the US Forest Service.
- Consultant in public board of education "policy governance" with Aspen Group International.
- At Virginia Chemicals, unraveled mystery of large industrial explosion and rationalized thermochemistry of the inorganic paper chemical, sodium hydrosulfite. Directed design engineering research for diallylamine plant.
- At DuPont solved the thirty-year problem of hydrolytic moisture degradation of abrasion resistant coatings for transparent acrylic sheet. Obtained 4 US patents on hydrolysis-resistant coatings as result of this work.
- At DuPont Central Research, discovered the chemistry of the treacherously explosive cyanogen azide. Developed safe handling methods and described mechanism of ring-chain tautomerisms and skeletal rearrangements.
- With Prof. William Bailey at Maryland, produced monomers and polymers demonstrating polymerization through Diels-Alder polymerization.

United States Patents: (31)

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3,714,214(1973) Alkoxy Silyl Alkyl Compounds
3,775,171(1973) Article Coated with Polysilicic Acid
3,781,251(1973) Alkoxy Silyl Alkyl Compounds and Polymers
4,744,365(1988) Compositions for Absorbable Surgical Devices
4,839,130(1989) Process of Absorbable Surgical Device

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
MH000277

4,844,854(1989) Process for Making a Surgical Device Using Two-Phase Compositions
5,019,093(1991) Braided Suture
5,037,429(1991) Improving the Stability of Braided Sutures
5,051,272(1991) Improving the Stability of a Polymeric Article
5,124,103(1992) Two Phase Compositions for Absorbable Surgical Devices
5,222,978(1993) Packaged Synthetic Absorbable Surgical Elements
5,226,912(1993) Combined Surgical Needle-Braided Suture Device
5,248,761(1993) Amino Acid Polyesters of Predetermined Sequence
5,256,762(1993) Polyesters of Predetermined Monomeric Sequence
5,261,886(1994) Cabled Core and Braided Suture Made Therefrom
5,282,829(1994) Hollow Body Implants
5,306,289(1994) Braided Suture of Improved Characteristics
5,312,437(1994) Absorbable Coating Compositions
5,320,624(1994) Blends of Glycolide and/or Lactide Copolymers
5,349,047(1994) Polyesters Having Predetermined Sequence
5,366,081(1994) Packaged Synthetic Surgical Suture Elements
5,424,136(1995) Polymers of 1,3 Dioxolane-4-ones
5,447,966(1995) Coating Surgical Articles
5,456,697(1995) Cabled Core and Braided Suture Made Therefrom
5,462,162(1995) Packaged Synthetic Absorbable Surgical Elements
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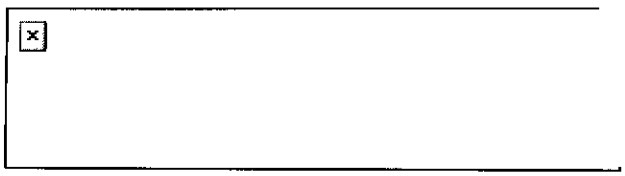
5,472,702(1995) Sterilization of Growth Factors
5,475,063(1995) Polymer Blends
6,228,954(2001) Blends of glycolide and/or lactide polymers and caprolactone and/or trimethylene carbonate polymers and absorabable surgical devices made therefrom
6,260,699(2001) Packaged, Synthetic Absorbable Suture Elements

Publications:

- ChemCases.com in the Classroom, American Chemical Society meeting, San Francisco, CA, March 30, 2000
- ChemCases Modular Curriculum as Distance Learning Tool, American Chemical Society Meeting, Anaheim, CA, March 23, 1999
- Gatorade as Case Study Curriculum Supplement, American Chemical Society Meeting, Dallas, TX, April 2, 1998.
- Gatorade, Why We Drink that Pale Yellow Stuff, Presentation at Kennesaw State University, Sept. 30, 1997.
- Carothers, A Man Clinging to His Craft, Presentations to the Delaware Section, American Chemical Society, April 17, 1996, the Middle Atlantic Regional Meeting, American Chemical Society, May 23, 1996 and the Delaware Section, American Institute of Chemical Engineering, Jan. 23, 1997.
- TV presentation, Science Odyssey, WGBH, Boston (January 14, 1998)
- TV Presentation, City University of New York's *Science and the Written Word* (Jan. 24, 1997).
- The Ineluctable Fate of Carothers, Chemistry and Industry, April 15, 1996
- "Enough for One Lifetime, Wallace Carothers, Inventor of Nylon", biography of the inventor Wallace H. Carothers, American Chemical Society, March 1996.
- DuPont Hires Carothers, Presentation at the Atlanta meeting of the American Chemical Society, Spring 1992.
- Synthetic Fibers from "Pure Science": DuPont Hires Carothers, Manmade Fibers, Their Origin and Development, ed. R. Seymour and R. Porter, Elsevier Applied Science, London, 1993, p. 227-243.
- Wallace Carothers, Inventor of Nylon, Presentation to the San Francisco Psychobiography Group, Jan. 14, 1993.
- Wallace Carothers, Inventor of Nylon, Presentation to the Wyoming Section of the American Chemical Society, April 27, 1993.
- Polyesters of Predetermined Sequence, with Dr. Bin Huang, Journal of Polymer Science, Vol. 33, p.1419(1995).



- W. J. Bailey, M. E. Hermes et al., Journal of Organic Chemistry, 27,1975(1962), 27,2732(1962), 27,3295(1962), 28,1724(1963), 29,1254(1964).
- F. D. Marsh and M. E. Hermes, Journal of the American Chemical Society, 86,4506(1964)
- F. D. Marsh and M. E. Hermes, Journal of the American Chemical Society, 87,1819(1965)
- M. E. Hermes and R. A. Braun, Journal of Organic Chemistry, 31,2568(1966)
- M. E. Hermes and F. D. Marsh, Journal of the American Chemical Society, 89,4760(1967)
- M. E. Hermes and F. D. Marsh, Journal of Organic Chemistry, 37,2969(1972)

Education:

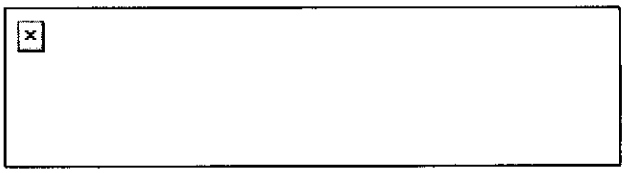
- B. S. Chemistry, St. John's University, Brooklyn, NY, 1955.
- Ph. D., Chemistry, University of Maryland, 1959.
- M. A., Liberal Studies, Wesleyan University, 1992.

Employment History:

- Research Chemist, Supervisor, E. I. DuPont, 1959-79.
- Research Director, Virginia Chemicals, Celanese Co., 1979-83.
- Corporate Research Scientist, U. S. Surgical Corp., 1983-94.
- Adjunct Professor, University of Wyoming, 1992-1994
- Consultant, Colorado Advanced Technology Institute, 1995-7
- President, F. V. Hayden Institute, 1996-present
- Adjunct Professor, Kennesaw State University, 1997-2002
- Turbo Wheelchair, Principal Investigator, 2001-2003
- Turbo Wheelchair, Secretary-Treasurer, 2003-Present

Personal

Married, Excellent Health.
Member Beaufort Rotary, American Chemistry Society, American Association for the Advancement of Science
4/07/2006



TAB B

US005314446A

United States Patent [19]

Hunter et al.

[11] Patent Number: 5,314,446

[45] Date of Patent: May 24, 1994

[54] STERILIZED HETEROGENEOUS BRAIDS

[75] Inventors: Alastair W. Hunter, Bridgewater; Arthur Taylor, Jr., Plainfield, both of N.J.; Mark Steckel, Maineville, Ohio

[73] Assignee: Ethicon, Inc., Somerville, N.J.

[21] Appl. No.: 838,511

[22] Filed: Feb. 19, 1992

[51] Int. Cl.[5] D04C 1/00

[52] U.S. Cl. 606/231; 606/228; 87/7; 87/9; 428/370

[58] Field of Search 606/228, 230, 231; 87/7, 8, 9; 428/225

[56] References Cited

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3,187,752	6/1965	Glick	128/335.5
3,463,158	8/1969	Schmitt et al.	606/228
3,527,650	9/1970	Block	117/7
3,636,956	1/1972	Schneider	128/335.5
3,942,532	3/1976	Hunter et al.	128/335.5
4,043,344	8/1977	Landi et al.	128/335.5
4,047,533	8/1977	Perciaccante et al.	128/335.5
4,052,988	10/1977	Doddi et al.	128/335.5
4,141,087	2/1979	Shalaby et al.	3/1
4,470,941	9/1984	Kurtz	264/136
4,624,256	11/1986	Messier et al.	128/335.5
4,946,467	8/1990	Ohi et al.	606/228
4,959,069	9/1990	Brennan et al.	606/228
4,979,956	12/1990	Silverstrini	623/13
5,116,360	5/1992	Pinchuk et al.	623/1
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2949920	3/1981	Fed. Rep. of Germany	A61F 1/00
WO86/00020	1/1986	PCT Int'l Appl.	A61L 17/00
2082213	8/1980	United Kingdom .	
2218312A	11/1989	United Kingdom	A01K 91/00

Primary Examiner—George F. Lesmes
Assistant Examiner—Chris Raimund
Attorney, Agent, or Firm—Hal Brent Woodrow

[57] ABSTRACT

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

12 Claims, 3 Drawing Sheets

FIG-1

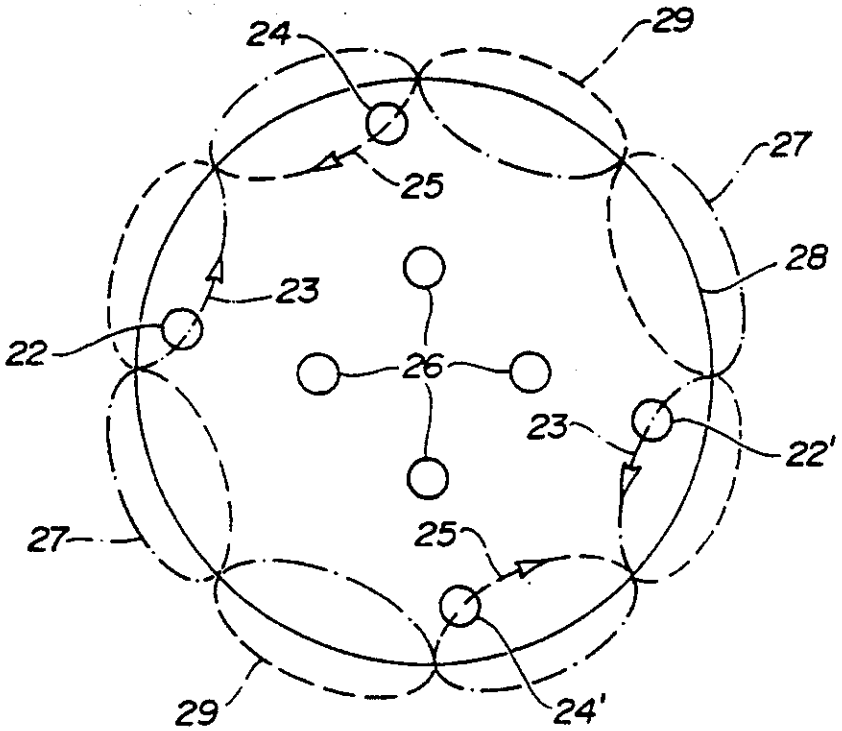


FIG-2

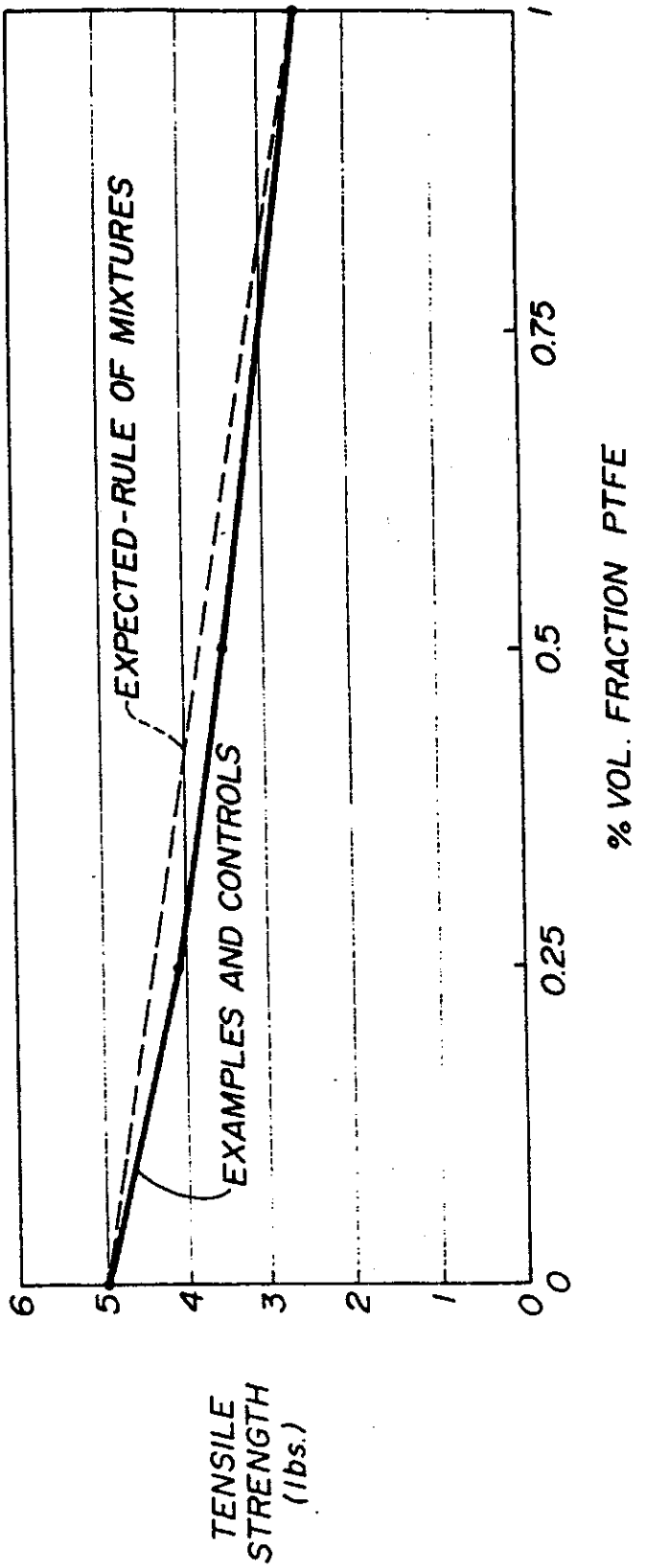
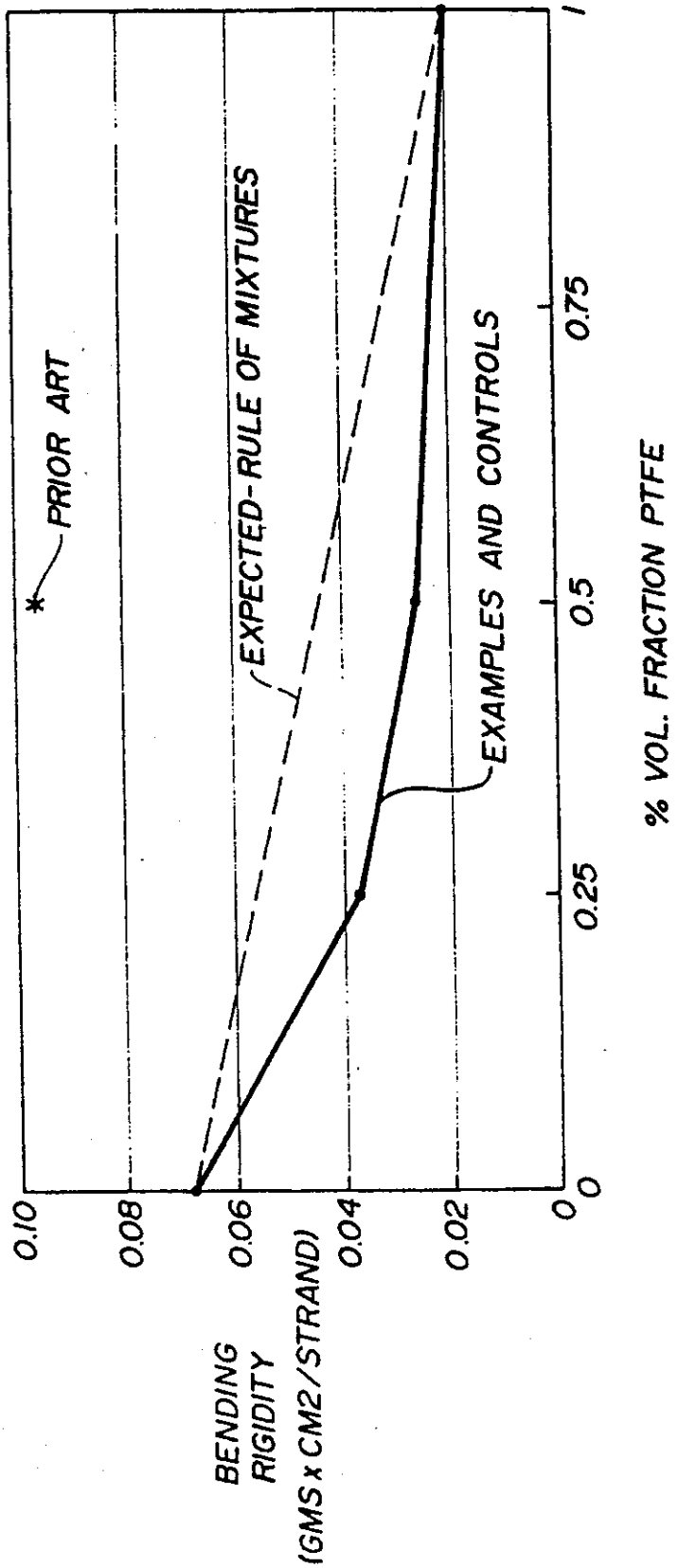

EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
TENSILE STRENGTH (lbs.)
6
5
4
3
2
1
0
0
0.25
0.5
0.75
1
% VOL. FRACTION PTFE

FIG-3


PRIOR ART
EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
0.10
0.08
0.06
0.04
0.02
0
0.25
0.5
0.75
1
BENDING RIGIDITY (GMS x CM2/STRAND)
% VOL. FRACTION PTFE

STERILIZED HETEROGENEOUS BRAIDS

BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid,. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutilate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ-caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Pat. 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Pat. No. 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by FIG. 3 which is described in detail below), apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for

the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

FIG. 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

FIG. 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Pat. Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Pat. Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns, respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone, ϵ-caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluorethylene copolymers (PETFE), the polycholorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of FIG. 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and

24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of FIG. 1 are dispensed upward with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in FIG. 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g. the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, than the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tieing a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tieing knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Pat. No. 4,470,941.

CONTROL I

FIBER MATERIALS: An 8×0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225° C.

CONTROL II

FIBER MATERIALS: An 8×0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

FIBER MATERIALS: An 8×0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300° C. and for a longer residence time to facilitate melting of the PET fibers.

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gm × cm²)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.81			0.0966	

As may be expected, the tensile strengths of the heterogenous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c=(Vf_a)(P_a)+(Vf_b)(P_b)$$

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and Vf_a and Vf_b are the volume fractions of components a and b. This behavior is clearly observed in FIG. 2, which shows a plot of tensile strength versus volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in FIG. 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the *bending moment-radius of curvature* plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Pat. No. 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and FIG. 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

What is claimed is:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core.

2. The surgical suture of claim 1 wherein the suture is attached to a needle.

3. The surgical suture of claim 1 wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.

4. The surgical suture of claim 3 wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.

5. The surgical suture of claim 4 wherein the first set of yarns is PTFE.

6. The surgical suture of claim 5 wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

7. The surgical suture of claim 6 wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

8. The surgical suture of claim 1 wherein the second set of yarns is PET.

9. The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

10. The surgical suture of claim 9 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

11. The surgical suture of claim 1 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

12. The surgical suture of claim 8 wherein the suture is attached to a needle.

* * * * *

TAB C

ENCYCLOPEDIA OF POLYMER SCIENCE AND ENGINEERING

VOLUME 10

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D. K. DANDGE
New Mexico Institute of Mining and Technology

L. G. DONARUMA
University of Alabama in Huntsville

NOMENCLATURE

Nomenclature, as used in this article, refers to the naming of polymeric materials. The nomenclature of scientific communication is emphasized, although there is generally little reason for differences between scientific and other, eg, commercial, usage.

Since the publication of the first edition of this Encyclopedia, the International Union of Pure and Applied Chemistry (IUPAC) has established the Commission on Macromolecular Nomenclature, which is now the leading nomenclature body in the polymer field. The Commission is promulgating a series of rules and definitions that are placing polymer nomenclature on a much more systematic basis than had previously been the case (Table 1) (1–21). The International Standardization Organization (ISO), primarily through its Technical Committee TC/61 Plastics, and various national nomenclature bodies (such as that of the American Chemical Society) are also helping to shape the field. Recent issues of *Chemical Abstracts* are additional authoritative sources of polymer nomenclature.

At the present time, the IUPAC Commission on Macromolecular Nomenclature is developing a set of definitions for many of the basic terms dealing with polymer molecules, assemblies of polymer molecules, polymer solutions, polymer crystals, polymer melts and solids, polymerization reactions, etc. It is also extending existing nomenclature to more complicated cases, such as cross-linked polymers. When this phase of the work is completed by the late 1980s, the naming of polymers and polymer terminology will have become largely systematized and, following the IUPAC practice in other fields of chemistry, a compendium of polymer nomenclature rules will be published.

Table 1. IUPAC Publications on Polymer Nomenclature

Title	Comment	Refs.
Report on Nomenclature in the Field of Macromolecules	obsolete	1
Report on Nomenclature Dealing with Steric Regularity in High Polymers	superseded by Ref. 2	3
Revised Report on Nomenclature Dealing with Steric Regularity in High Polymers	superseded by Ref. 4	2,5
Report of the Committee on Nomenclature of the International Commission on Macromolecules	obsolete	6
Basic Definitions of Terms Relating to Polymers		7,8
List of Standard Abbreviations (Symbols) for Synthetic Polymers and Polymer Materials (1974)	superseded by Ref. 9	10
Use of Abbreviations for Names of Polymeric Substances	Recommendations 1986	9
Nomenclature of Regular Single-Strand Organic Polymers		11
Stereochemical Definitions and Notations Relating to Polymers	Provisional Recommendations 1980	12 4
Nomenclature for Regular Single-Strand and Quasi Single-Strand Inorganic and Coordination Polymers	Provisional Recommendations 1984	13 14
Note on the Terminology for Molar Masses in Polymer Science		15–17
Source-Based Nomenclature for Copolymers		18
Definitions of Terms Relating to Individual Macromolecules, Their Assemblies, and Dilute Polymer Solutions		19
Definitions of Terms Relating to Crystalline Polymers		20
A Classification of Linear Single-Strand Polymers		21

Basic Definitions

No nomenclature document is more fundamental to a given science than the definitions of basic terms used in that area. The IUPAC Commission on Macromolecular Nomenclature published a document in 1974 (8) that offers definitions of 52 terms, including polymer, constitutional unit, monomer, polymerization, regular polymer, tactic polymer, block polymer, graft polymer, monomeric unit, degree of polymerization, addition polymerization, condensation polymerization, homopolymer, copolymer, bipolymer, terpolymer, copolymerization, and many others. Both structure-based and process-based definitions are given.

Source-based Nomenclature

Traditionally, polymers have been named by attaching the prefix poly to the name of the real or assumed monomer (the "source") from which it is derived.

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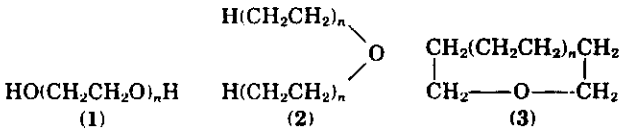
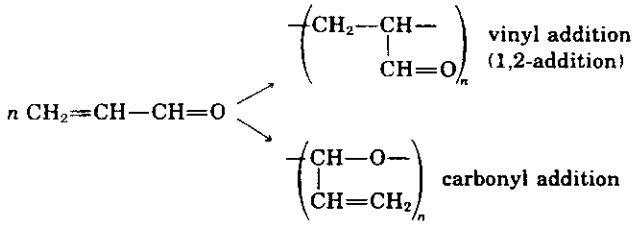
Thus polystyrene is the polymer made from styrene and will often be found in an index under "styrene, polymer of." When the name of the monomer consists of two or more words, parentheses should be used (1), as in poly(vinyl acetate), poly(methyl methacrylate), poly(sodium styrenesulfonate), etc. Failure to use parentheses can lead to ambiguity: polychlorostyrene can be the name of either a polychlorinated (monomeric) styrene molecule or a polymer derived from chlorostyrene; polyethylene oxide can refer to polymer (1), polymer (2), or the macrocycle (3).



These problems are easily overcome with parentheses; names such as poly(chloro)styrene, poly(chlorostyrene), and poly(ethylene oxide) clearly indicate the part of the name to which the prefix poly refers. The omission of parentheses is, unfortunately, quite common.

The principal deficiency of source-based nomenclature is that the chemical structure of the monomeric unit in a polymer is not identical with that of the monomer, eg, —CH_2—CHX— vs CH_2=CHX; thus the name polymonomer is actually a misnomer. The structure of the repeating unit is also not specified in this scheme; for example, polyacrolein does not indicate whether the vinyl or the aldehyde group has polymerized (see ACROLEIN POLYMERS).



Different types of polymerization can take place with many other monomers, depending on the polymerization conditions. Furthermore, a name such as poly(vinyl alcohol) refers to a hypothetical source, since this polymer is obtained by hydrolysis of poly(vinyl acetate). In spite of these serious deficiencies, source-based nomenclature is still firmly entrenched in industrial literature and, to a lesser extent, in scientific communication. It originated at a time when polymer science was less developed and the structure of most polymers ill-defined. The rapid advances now being made in structural determination of polymers will gradually shift the emphasis of polymer nomenclature away from starting materials and toward the structure of the macromolecules.

Copolymers. Copolymers are polymers that are derived from more than one species of monomer (8). Because this is a process-based definition, source-based nomenclature can be easily adapted to the naming of copolymers (18). However, the arrangement of the various types of monomeric units must be specified. Seven types of arrangements have been defined and are shown in Table 2, where A, B, and C represent the names of monomers. The monomer names are linked through a connective (infix), such as *-co-*, to form the name of the copolymer, as in poly(styrene-*co*-acrylonitrile). The order of citation of the mono-

mers is arbitrary, except for graft copolymers where the backbone monomer is named first.

An equally acceptable alternative scheme utilizes the prefix copoly followed by citation of the names of the monomers used, separated from each other by an oblique stroke. Parentheses are also needed. For example, copoly(styrene/butadiene) denotes an unspecified copolymer of styrene and butadiene. The other connectives of Table 2 are placed before such names to provide additional structural information, as in

stat-copoly(styrene/butadiene)
ran-copoly(ethylene/vinyl acetate)
alt-copoly(styrene/maleic anhydride)
per-copoly(ethylene phenylphosphonite/methyl acrylate/carbon dioxide)
block-copoly(styrene/butadiene/methyl methacrylate)
graft-copoly(styrene/butadiene)

It is not necessary to use parentheses to enclose vinyl acetate, maleic anhydride, methyl acrylate, etc, even though the name of each of these monomers consists of two words; the names of the polymers, as written here, are unambiguous.

The names of copolymers, derived either from the main scheme or the alternative, can be further modified to indicate various structural features. For example, the chemical nature of end groups can be specified as follows:

α-X-ω-Y-poly(A-*alt*-B)
α-butyl-ω-carboxy-*block*-copoly(styrene/butadiene)

Whereas subscripts placed immediately after the name of the monomer or the block designate the degree of polymerization or repetition, mass and mole fractions and molar masses, which in most cases are average quantities, are expressed by placing corresponding figures after the complete name of the copolymer. The order of citation is as for the monomeric species in the name. Unknown quantities are designated by *a*, *b*, etc. Some examples follow.

A block copolymer containing 75 mass % of polybutadiene and 25 mass % of polystyrene is

polybutadiene-*block*-polystyrene (0.75:0.25 *w*) or
block-copoly(butadiene/styrene) (75:25 mass %)

A graft copolymer, consisting of a polyisoprene backbone grafted with isoprene and acrylonitrile units in an unspecified arrangement, containing 85 mol % of isoprene units and 15 mol % of acrylonitrile units is

polyisoprene-*graft*-poly(isoprene-*co*-acrylonitrile) (0.85:0.15 *x*) or
graft-copoly[isoprene/(isoprene;acrylonitrile)] (85:15 mol %)

A graft copolymer consisting of 75 mass % of polybutadiene with a relative molecular mass of 90,000 as the backbone and 25 mass % of polystyrene in grafted chains with a relative molecular mass of 30,000 would be

polybutadiene-*graft*-polystyrene (75:25 mass %; 90,000:30,000 M_r)

Table 2. IUPAC Nomenclature of Copolymers[a]

Type	Arrangement of monomeric units	Structure	Connective	Example
unspecified	unknown or unspecified	(A-*co*-B)	*-co-*	poly[styrene-*co*-(methyl methacrylate)]
statistical	obeys known statistical laws	(A-*stat*-B)	*-stat-*	poly(styrene-*stat*-acrylonitrile-*stat*-butadiene)
random	obeys Bernoullian statistics	(A-*ran*-B)	*-ran-*	poly[ethylene-*ran*-(vinyl acetate)]
alternating	alternating sequence	$(AB)_n$	*-alt-*	poly[(ethylene glycol)-*alt*-(terephthalic acid)]
periodic	periodic with respect to at least three monomeric units	$(ABC)_n$ $(ABB)_n$ $(AABB)_n$ $(ABAC)_n$	*-per-*	poly[formaldehyde-*per*-(ethylene oxide)-*per*-(ethylene oxide)]
block	linear arrangement of blocks	—AAAAA—BBBBBB—	*-block-*[b]	polystyrene-*block*-polybutadiene
graft	polymeric side chain different from main chain[c]	—AAAAAAAAAAAA— B B B B B	*-graft-*[d]	polybutadiene-*graft*-polystyrene

[a] Main system of the IUPAC document (18); an alternative scheme is described in the text.
[b] The connective *-b-* has also been used.
[c] Main chain (or backbone) is specified first in the name.
[d] The connective *-g-* has also been used.

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A graft copolymer in which the polybutadiene backbone has a DP of 1700 and the polystyrene grafts have an unknown DP is named

graft-copoly(butadiene/styrene) (1700:*a* DP)

The published IUPAC copolymer document (18) should be consulted for the names of more complex copolymers, eg, those having a multiplicity of grafts or having chains radiating from a central atom (see also BLOCK COPOLYMERS; COPOLYMERS, ALTERNATING; COPOLYMERIZATION; GRAFT COPOLYMERS).

Structure-based Nomenclature

For organic polymers that are regular, ie, have only one species of constitutional unit in a single sequential arrangement, and consist only of single strands, the IUPAC has promulgated a structure-based system of naming polymers (11). As originally devised by the Polymer Nomenclature Committee of the American Chemical Society (22), it consists of naming a polymer as poly(constitutional repeating unit), wherein the repeating unit is named as a bivalent organic radical according to the usual nomenclature rules for organic chemistry. It is important to note that in structure-based nomenclature the name of the constitutional repeating unit has no relationship to the source from which the unit was prepared. The name is simply that of the largest identifiable unit in the polymer, and locants for unsaturation, substituents, etc are dictated by the structure of the unit.

The steps involved in naming the constitutional repeating unit are (*1*) identification of the unit, taking into account the kinds of atoms in the main chain and the location of substituents; (2) orientation of the unit; and (*3*) naming of the unit. Examples of names for some common polymers are given in Table 3. Note that in this system parentheses are always used to enclose the repeating unit.

Structure-based nomenclature can be utilized to name polymers with great complexity, provided only that they be regular and single-stranded. Among these are polymers with constitutional repeating units which consist, themselves, of a series of smaller subunits; polymers with heteroatoms or heterocyclic ring systems in the main chain; and polymers with substituents on acyclic or cyclic subunits of constitutional repeating units. Structure-based nomenclature is also applicable to copolymers having a regular structure, regardless of the starting materials used, eg, poly(oxyethyleneoxyterephthaloyl). In principle, it should be possible to extend the existing structure-based nomenclature beyond regular, single-strand polymers to polymers that have reacted, cross-linked polymers, ladder polymers, and other more complicated systems.

Structure-based nomenclature has gained acceptance in the scientific literature, eg, *Chemical Abstracts,* because it overcomes many of the deficiencies of source-based nomenclature.

Inorganic and Coordination Polymers. The nomenclature of regular single-strand inorganic and coordination polymers (qv) is governed by the same

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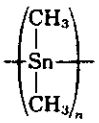
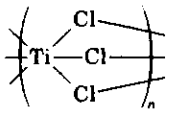
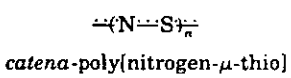
ındamental principles as that for single-strand organic polymers (14). The name such a polymer is that of the smallest structural repeating unit prefixed by ıe terms poly, *catena* (for linear chains) or other structural indicator, and des- nations for end groups. The structural units are named by the nomenclature ıles for inorganic and coordination chemistry. Some examples are



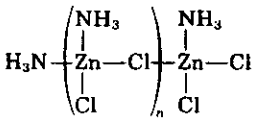
catena-poly[dimethyltin]



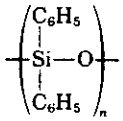
catena-poly[titanium-tri-μ-chloro]



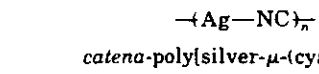
catena-poly[nitrogen-μ-thio]



α-ammine-ω-(amminedichlorozinc)-*catena*-poly[(amminechlorozinc)-μ-chloro]



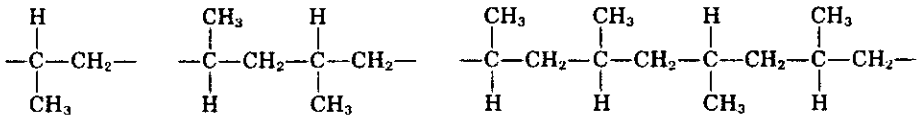
catena-poly[(diphenylsilicon)-μ-oxo]



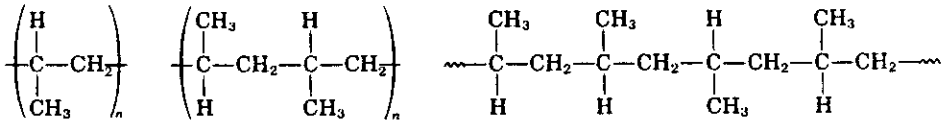
catena-poly[silver-μ-(cyano-*N*:*C*)]

Stereochemical Definitions and Notations. Structure-based nomenclature regular polymers (4) can denote stereochemical features if the repeating unit ;ed is the configurational unit, ie, a constitutional unit having one or more sites defined stereoisomerism (8). Structure-based names are then derived in the ;ual fashion. The various stereochemical features that are possible in a polymer ust be defined.

Natta and co-workers introduced the concept of tacticity, ie, the orderliness the succession of configurational repeating units in the main chain of a polymer. or example, in poly(propylene), possible steric arrangements are shown in Fischer ojections displayed horizontally:



ıd the corresponding polymers have the following structures:

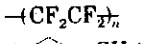
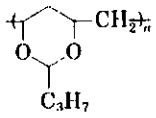
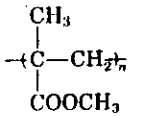
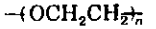
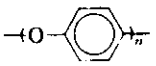
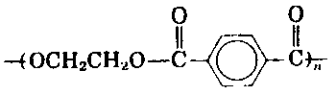
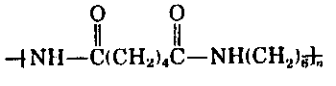
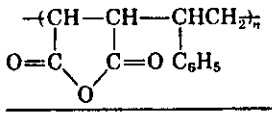


isotactic syndiotactic atactic

The isotactic polymer has only one species of configurational unit in a single quential arrangement and the syndiotactic polymer shows an alternation of nfigurational units that are enantiomeric, whereas in the atactic polymer the

Table 3. Examples of Systematic Structure-based Names for Polymers[a]

Structure	Structure-based name	Common (source-based) name
$-(CH_2CH_2)_n-$	poly(methylene)	polyethylene
$-(CHCH_2)_n-$ $\quad\quad\quad

	poly(difluoromethylene)	polytetrafluoroethylene
	poly[(2-propyl-1,3-dioxane-4,6-diyl)methylene]	poly(vinyl butyral)
	poly[1-(methoxycarbonyl)-1-methylethylene]	poly(methyl methacrylate)
	poly(oxyethylene)	poly(ethylene oxide)
	poly(oxy-1,4-phenylene)	poly(phenylene oxide)
	poly(oxyethyleneoxyterephthaloyl)	poly(ethylene terephthalate)
	poly(iminoadipoyliminohexamethylene)	poly(hexamethylenediamine-*co*-adipic acid) or poly(hexamethylene adipamide)
	poly[2,5-dioxotetrahydrofuran-3,4-diyl(phenylethylene)]	poly(maleic anhydride-*co*-styrene)

[a] Ref. 6. Courtesy of *Pure and Applied Chemistry*.

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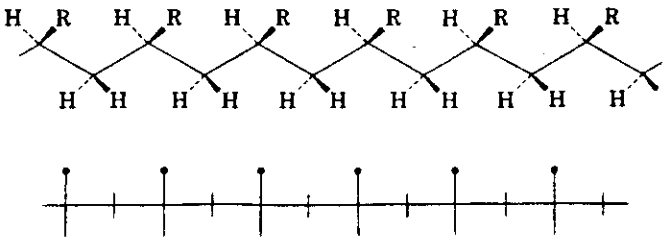
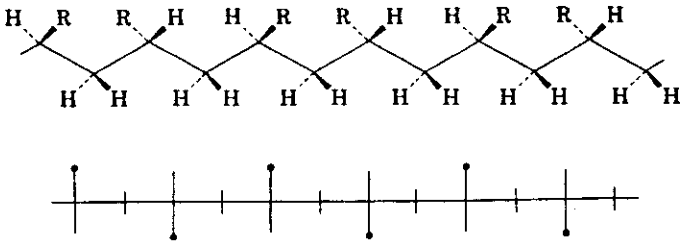
molecules have equal numbers of the possible configurational units in a random sequence distribution. This can be generalized as follows:

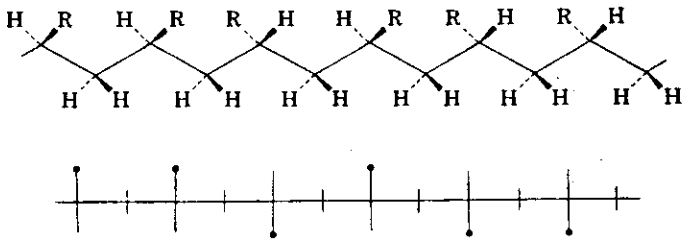
Isotactic:



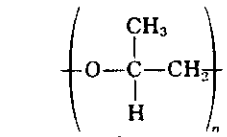
Syndiotactic:



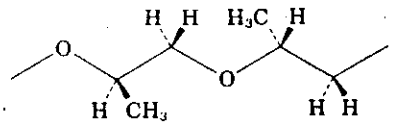
Atactic:

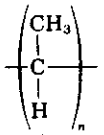


Further examples of tactic polymers are

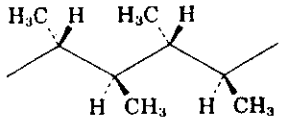


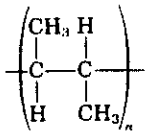
isotactic poly(oxypropylene)



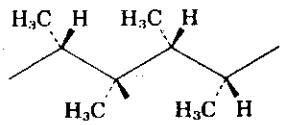


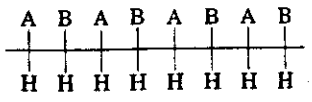
isotactic poly(ethylidene)

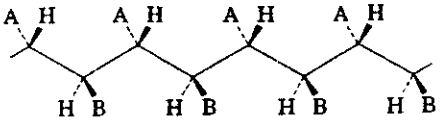




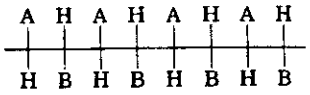
syndiotactic poly(ethylidene)

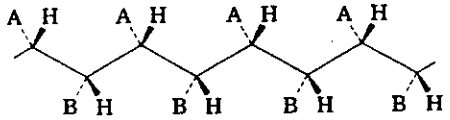




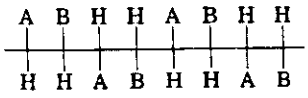


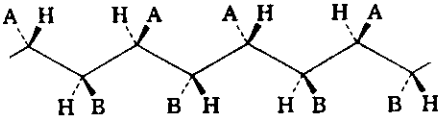
erythrodiisotactic polymer



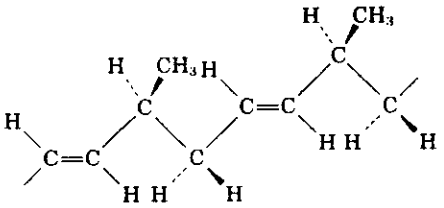


threodiisotactic polymer

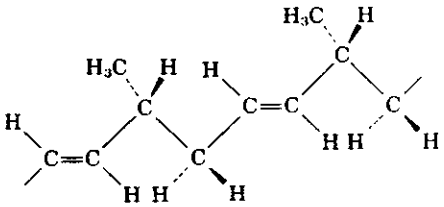




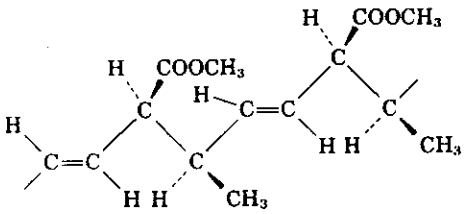
disyndiotactic polymer



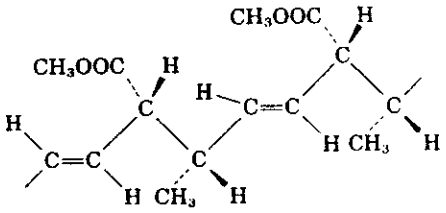
and/or



isotactic poly(3-methyl-*trans*-1-butenylene) or transisotactic poly(3-methyl-1-butenylene)

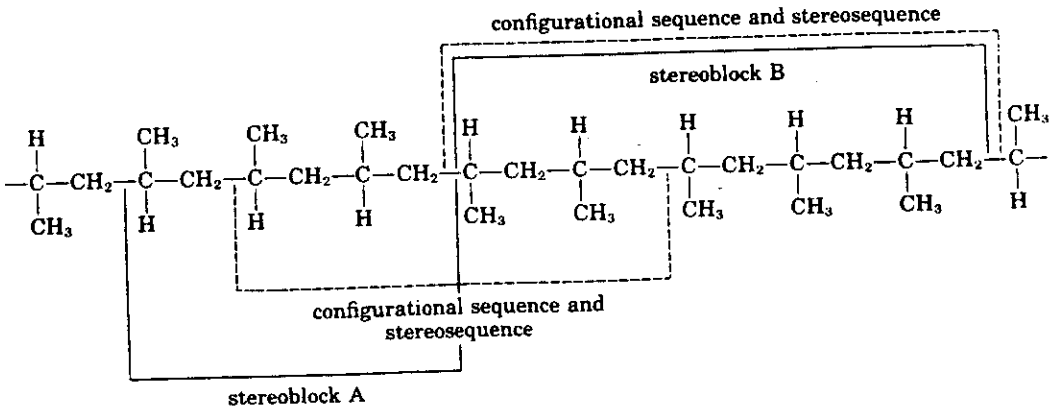


and/or



diisotactic poly[(*threo*-3(methoxycarbonyl)-4-methyl-*trans*-1-butenylene] or
transthreodiisotactic poly[3-(methoxycarbonyl)-4-methyl-1-butenylene]

The concept of a stereoblock is illustrated in the following example of a regular poly(propylene) chain, in which the stereoblocks are denoted by ⌐¬. The sequence of identical relative configurations of adjacent units that characterizes a stereoblock is terminated at each end of the block. The dashed line ⌐----¬ encloses a configurational sequence, which may or may not be identical with a stereoblock.



The published IUPAC document (4) should be consulted for more complex cases and for the notations used to designate conformations of polymer molecules (bond lengths, bond angles, torsion angles, helix sense, isomorphous and enantiomorphous structures, line repetition groups and symmetry elements, etc) as well as for the various stereochemical definitions (see also MICROSTRUCTURE; STEREOREGULAR POLYMERS).

Trade Names and Abbreviations

Because the systematic names of polymers can be cumbersome, trade names and abbreviations are frequently used as a shortcut in industrial literature and

Table 4. List of Abbreviations from the 1986 IUPAC Recommendations[a]

PAN	polyacrylonitrile
PCTFE	polychlorotrifluoroethylene
PEO	poly(ethylene oxide)
PETP[b]	poly(ethylene terephthalate)
PE	polyethylene
PIB	polyisobutylene
PMMA	poly(methyl methacrylate)
POM	poly(oxymethylene); polyformaldehyde
PP	polypropylene
PS	polystyrene
PTFE	polytetrafluoroethylene
PVAC	poly(vinyl acetate)
PVAL	poly(vinyl alcohol)
PVC	poly(vinyl chloride)
PVDC	poly(vinylidene dichloride)
PVDF	poly(vinylidene difluoride)
PVF	poly(vinyl fluoride)

[a] Ref. 9.
[b] The abbreviation PET is commonly used in the literature.

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oral communication. For example, the simpler generic name nylon-6,6 for a polyamide, where the first number refers to the number of carbon atoms of the diamine and the second number to that of the diacid fragment, appears often in the literature rather than the systematic name poly(iminoadipoyliminohexamethylene). Useful compilations of trade names for polymers can be found in Refs. 23 and 24.

Perhaps the most widely used shortcut is the use of abbreviations for common industrial polymeric materials. The IUPAC recognizes that there may be advantages in some cases to use abbreviations, but urges that each abbreviation be fully defined the first time it appears in the text and that no abbreviation be used in titles of publications. Because there are inherent difficulties in assigning systematic and unique abbreviations to polymeric structures, only a short list has the IUPAC's official sanction (9,10) (Table 4). ISO has published a more extensive list (25), and the American Chemical Society has compiled a master list of all known abbreviations in the polymer field (26).

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NORBERT M. BIKALES
National Science Foundation
Secretary (1978–1987), IUPAC Commission on Macromolecular Nomenclature

NONAQUEOUS DISPERSIONS. See COATINGS.

NONCOMBUSTIBLE FABRICS. See FLAMMABILITY.

NONDESTRUCTIVE TESTING. See TEST METHODS.

NON-NEWTONIAN FLOW. See VISCOELASTICITY.

NONWOVEN FABRICS

Survey, 204
Spunbonded, 227

SURVEY

Nonwoven fabrics are porous, textilelike materials, usually in flat she
form, composed primarily or entirely of fibers assembled in webs (1–3). The
fabrics, also called bonded fabrics, formed fabrics, or engineered fabrics, are ma
ufactured by processes other than spinning, weaving, or knitting. The thickn
of the sheets may vary from 25 μm to several centimeters, and the weight fr
10 g/m^2 to 1 kg/m^2. A sheet may resemble paper or a woven or knitted fabric
appearance and may have a unique texture or pattern. It may be as compact a
crisp as paper or supple and drapable as a conventional textile; it may be resili
or limp. Its tensile properties may be barely self-sustaining or so high that i
impossible to tear, abrade, or damage the sheet by hand. The fiber compone
one or several types, may be natural or synthetic, from 1–3-mm long to endl
The tensile properties may depend on frictional forces or a film-forming polym
additive functioning as an adhesive binder. All or some of the fibers may
welded by heat or solvent. A scrim, gauze, netting, yarn, or other conventi
sheet material may be added to one or both faces, or embedded within as r
forcement. The nonwoven fabric may be incorporated as a component in a c
posite structure.

Felted fabrics from animal hairs, eg, wool (qv), are not included even th

an·hy·drous \(')an'hīdrəs\ *adj* [modif. (influenced by *hydr-, hydro-*) of Gk *anydros* waterless, fr. *an-* + *-ydros* (fr. *hydōr* water) — more at WATER]: destitute of water — used of water of crystallization, dissolved or combined water, adsorbed water

TAB D

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INTERNATIONAL UNION OF PURE AND APPLIED CHEMISTRY

MACROMOLECULAR DIVISION
COMMISSION ON MACROMOLECULAR NOMENCLATURE*

GENERIC SOURCE-BASED NOMENCLATURE FOR POLYMERS

(IUPAC Recommendations 2001)

Prepared by a Working Group consisting of

R. E. BAREISS (Germany), R. B. FOX (USA), K. HATADA (Japan), K. HORIE (UK), A. D. JENKINS (UK), J. KAHOVEC (Czech Republic), P. KUBISA (Poland), E. MARÉCHAL (France), I. MEISEL (Germany), W. V. METANOMSKI (USA), I. MITA (Japan), R. F. T. STEPTO (UK), AND E. S. WILKS (USA)

Prepared for publication by
E. MARÉCHAL[1] AND E. S. WILKS[2,†]

[1]Université Pierre et Marie Curie (Paris VI), Laboratoire de Synthèse Macromoléculaire, Boîte 184, 4 Place Jussieu F-75252, Paris Cédex 05, France; [2]113 Meriden Drive, Canterbury Hills, Hockessin, DE 19707 USA

*Membership of the Commission during the preparation of this report (1993–1999) was as follows:
Titular Members: R. E. Bareiss (Germany, 1983–1993); M. Barón (Argentina, from 1996, Secretary from 1998); K. Hatada (Japan, 1989–1997); M. Hess (Germany, from 1998); K. Horie (Japan, from 1997); J. Kahovec (Czech Republic, to 1999); P. Kubisa (Poland, from 1999); E. Maréchal (France, from 1994); I. Meisel (Germany, from 2000); W. V. Metanomski (USA, 1994–1999); C. Noël (France, to 1997); V. P. Shibaev (Russia, to 1995); R. F. T. Stepto (UK, 1989–1999, Chairman to 1999); E. S. Wilks (USA, from 2000); W. J. Work (USA, 1987–1999, Secretary, 1987–1997); ***Associate Members:*** M. Barón (Argentina,1991–1995); K. Hatada (Japan, 1998–1999); J.-I. Jin (Korea, from 1993); M. Hess (Germany, 1996–1997); K. Horie (Japan, 1996–1997); O. Kramer (Denmark, from 1996); P. Kubisa (Poland, 1996–1998); E. Maréchal (France, 1991–1993); I. Meisel (Germany, 1997–1999); S. Penczek (Poland, from 1994); L. Shi (China, 1987–1995); V. P. Shibaev (Russia, 1996–1999); E. S. Wilks (USA, 1998–1999).

†Corresponding author

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Generic source-based nomenclature for polymers

(IUPAC Recommendations 2001)

Abstract: The commission has already published two documents on the source-based names of linear copolymers and nonlinear polymers; however, in some cases this nomenclature leads to ambiguous names. The present document proposes a generic source-based nomenclature that solves these problems and yields clearer source-based names. A generic source-based name comprises two parts:

1) polymer class (generic) name followed by a colon
2) the actual or hypothetical monomer name(s), always parenthesized in the case of a copolymer

The formula, the structure-based name, the source-based name, and the generic source-based name of the polymer are given for each example in the document. In some cases, only generic source-based give unambiguous names, for example, when a polymer has more than one name or when it is obtained through a series of intermediate structures. The rules concern mostly polymers with one or more types of functional group or heterocyclic system in the main chain, but to some extent they are also applicable to polymers with side-groups, carbon-chain polymers such as vinyl or diene polymers, spiro and cyclic polymers, and networks.

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2. SOURCE-BASED NOMENCLATURE FOR HOMOPOLYMERS
3. GENERIC NOMENCLATURE
   3.1 Fundamental principles
   3.2 General rules
4. FURTHER APPLICATIONS OF GENERIC NAMES
5. REFERENCES

1. INTRODUCTION

The IUPAC Commission on Macromolecular Nomenclature has published three documents [1–3] on the structure-based nomenclature for polymers that enable most polymers, except networks, to be named. The Commission has also produced two documents [4,5] on the source-based nomenclature of linear copolymers and nonlinear polymers. In general, source-based names are simpler and less rigorous than structure-based names. However, there are cases in which the simplicity of the source-based nomenclature leads to ambiguous names for polymers. For example, the condensation of a dianhydride (A) with a diamine (B) gives first a polyamide-acid, which can be cyclized to a polyimide; however, both products have the same name poly(A-*alt*-B) according to current source-based nomenclature. If the class name of the polymer "amide-acid" or "imide" is incorporated in the name, differentiation is easily accomplished. Even in cases where only a single product is formed, use of the class name (generic name) may help to clarify the structure of the polymer, especially if it is very complex.

Examples of ambiguous names exist also for homopolymers. The source-based name "polybutadiene" does not indicate whether the structure is 1,2-, 1,4-*cis*-, or 1,4-*trans*-; supplementary information is needed to distinguish between the possibilities.

It is the objective of the present document to introduce a generic nomenclature system to solve these problems, and to yield better source-based names.

Most trivial names, such as polystyrene, are source-based names. Hitherto, the Commission has not systematically recommended source-based names for homopolymers because it considered that the more rigorous structure-based names were more appropriate for scientific communications. However, since the publication of "Nomenclature of Regular Single-Strand Organic Polymers" in 1976, scientists, in both industry and academia, have continued to use trivial names. Even the Commission itself adopted (1985) a source-based nomenclature for copolymers owing to its simplicity and practicality. Based on these facts, the Commission has now decided to recommend source-based nomenclature as an alternative official nomenclature for homopolymers. In this document, the rules for generating source-based names for homopolymers are described. Consequently, source-based and structure-based names are available for most polymers.

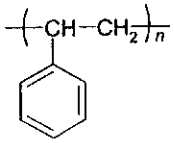
Names of the monomers in the source-based names of polymers should preferably be systematic but they may be trivial if well established by usage. Names of the organic groups, as parts of constitutional repeating units (CRU) in structure-based names, are those based on the principles of organic nomenclature and recommended by the 1993 *A Guide to IUPAC Nomenclature of Organic Compounds* [6].

2. SOURCE-BASED NOMENCLATURE FOR HOMOPOLYMERS

RULE 1

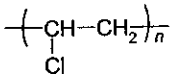
The source-based name of a homopolymer is made by combining the prefix "poly" with the name of the monomer. When the latter consists of more than one word, or any ambiguity is anticipated, the name of the monomer is parenthesized.

Example 1.1



Source-based name:
polystyrene
Structure-based name:
poly(1-phenylethylene)

Example 1.2



Source-based name:
poly(vinyl chloride)
Structure-based name:
poly(1-chloroethylene)

3. GENERIC NOMENCLATURE

3.1 Fundamental principles

The basic concept for generic source-based nomenclature is very simple; just add the polymer class name to the source-based name of the polymer. Addition of the polymer class name is frequently

OPTIONAL; in some cases, the addition is necessary to avoid ambiguity or to clarify. However, the addition is undesirable if it fails to add clarification.

The system presented here can be applied to almost all homopolymers, copolymers, and others, such as networks. However, generic source-based nomenclature should not be considered as a third nomenclature system to be added to the other two systems of nomenclature; it must be considered as an auxiliary system and a simple extension of current source-based nomenclature. When the generic part of the name is eliminated from the name of a polymer, the well-established source-based name remains.

3.2 General rules

RULE 2

A generic source-based name of a polymer has two components in the following sequence: (1) a polymer class (generic) name (polyG) followed by a colon and (2) the actual or hypothetical monomer name(s) (A, B, etc.), always parenthesized in the case of a copolymer. In the case of a homopolymer, parentheses are introduced when it is necessary to improve clarity.

polyG:A polyG:(B) polyG:(A-*co*-B) polyG:(A-*alt*-B)

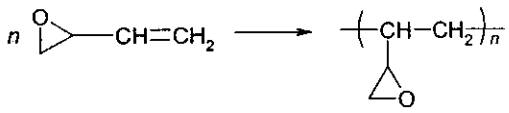
Note 1 The polymer class name (generic name) describes the most appropriate type of functional group or heterocyclic ring system.

Note 2 All the rules given in the two prior documents on source-based nomenclature [4,5] can be applied to the present nomenclature system, with the addition of the generic part of the name.

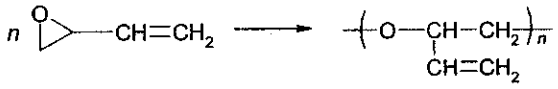
Note 3 A polymer may have more than one name; this usually occurs when it can be prepared in more than one way.

Note 4 If a monomer or a pair of complementary monomers can give rise to more than one polymer, or if the polymer is obtained through a series of intermediate structures, the use of generic nomenclature is essential (see examples 2.1, 2.3, and 2.4).

Example 2.1



I



II

Generic source-based name:

I. polyalkylene:vinyloxirane

II. polyether:vinyloxirane

Source-based names:

I and II have the same source-based name: poly(vinyloxirane).

Structure-based names:

I. poly(1-oxiranylethylene)

II. poly[(oxy(1-vinylethylene)]

Example 2.2



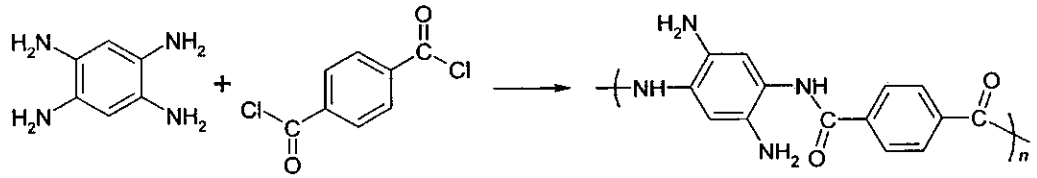
Generic source-based name:

polyoxadiazole:(4-cyanobenzonitrile *N*-oxide)

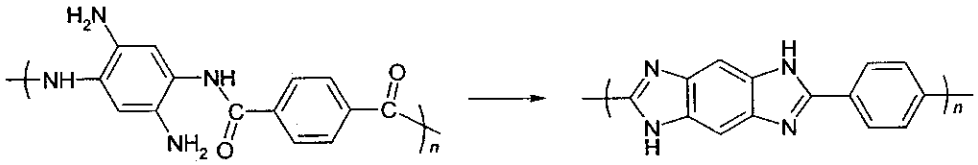
Structure-based name:

poly(1,2,4-oxadiazole-3,5-diyl-1,4-phenylene)

Example 2.3



I



I II

Generic source-based name:

I. polyamide:[(terephthaloyl dichloride)-*alt*-benzene-1,2,4,5-tetramine]

II. polybenzimidazole:[(terephthaloyl dichloride)-*alt*-benzene-1,2,4,5-tetramine]

Source-based name:

I and II have the same source-based name:

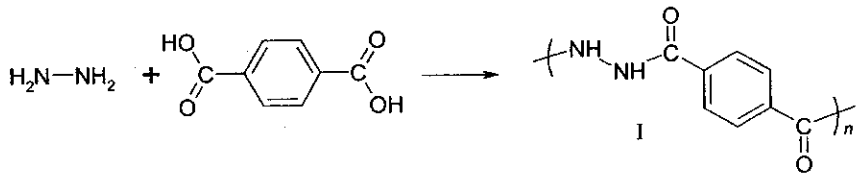
poly[(terephthaloyl dichloride)-*alt*-benzene-1,2,4,5-tetramine]

Structure-based names:

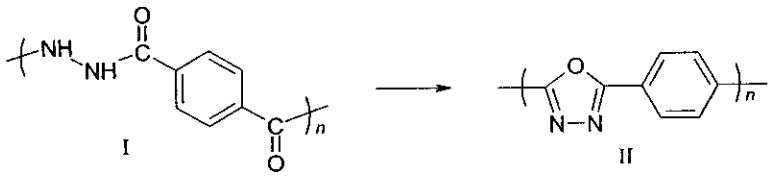
I. poly[imino (2,5-diamino-1,4-phenylene)iminoterephthaloyl]

II. poly[(1,5-dihydrobenzo[1,2-*d*:4,5-*d*′]diimidazole-2,6-diyl)-1,4-phenylene]

Example 2.4



I



I II

Generic source-based names:

I. polyhydrazide:[hydrazine-*alt*-(terephthalic acid)]

II. polyoxadiazole:[hydrazine-*alt*-(terephthalic acid)]

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Source-based name:

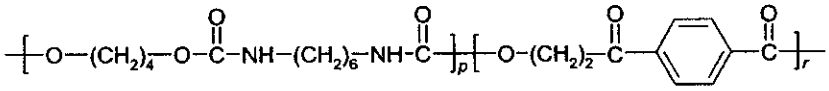
I and II have the same source-based name: poly[hydrazine-*alt*-(terephthalic acid)]

Structure-based names:

I. poly(hydrazine-1,2-diylterephthaloyl)

II. poly(1,3,4-oxadiazole-2,5-diyl-1,4-phenylene)

Example 2.5



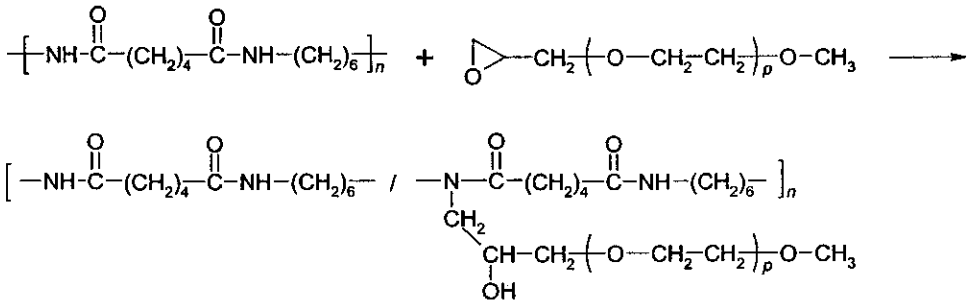
Generic source-based names:

polyurethane:[butane-1,4-diol-*alt*-(hexane-1,6-diyl diisocyanate)]-*block*-polyester:[(ethylene glycol)-*alt*-(terephthalic acid)]

Structure-based name:

poly(oxybutane-1,4-diyloxycarbonyliminohexane-1,6-diyliminocarbonyl)-*block*-poly(oxyethyleneoxyterephthaloyl)

Example 2.6



Generic source-based name:

polyamide:[hexane-1,6-diamine-*alt*-(adipic acid)]-*graft*-polyether:(ethylene oxide)

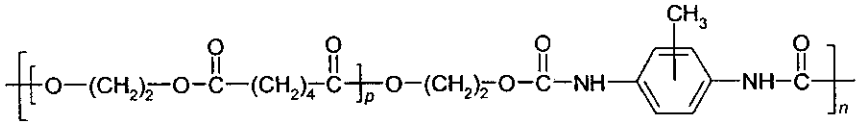
Note 5 It is assumed that this reaction is limited to only one graft for each CRU.

RULE 3

When more than one type of functional group or heterocyclic system is present in the polymer structure, names should be alphabetized; for example, poly(GG′):(A-*alt*-B).

Note 6 It is preferable, but not mandatory, to cite all generic classes.

Example 3.1



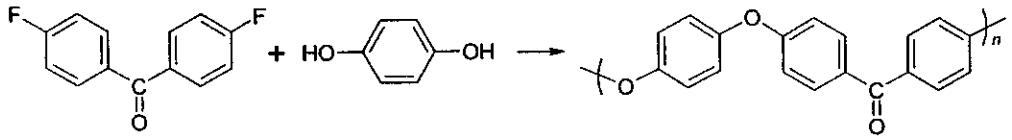
Generic source-based name:

polyesterurethane:{α,ω-dihydroxyoligo[(ethylene glycol)-*alt*-(adipic acid)]-*alt*-(2,5-tolylene diisocyanate)}

Structure-based name:

poly{[oligo(oxyethyleneoxyadipoyl)]oxyethyleneoxycarbonylimino(x-methyl-1,4-phenylene)iminocarbonyl)}

Example 3.2



Generic source-based name:

polyetherketone:(4,4′-difluorobenzophenone-*alt*-hydroquinone)

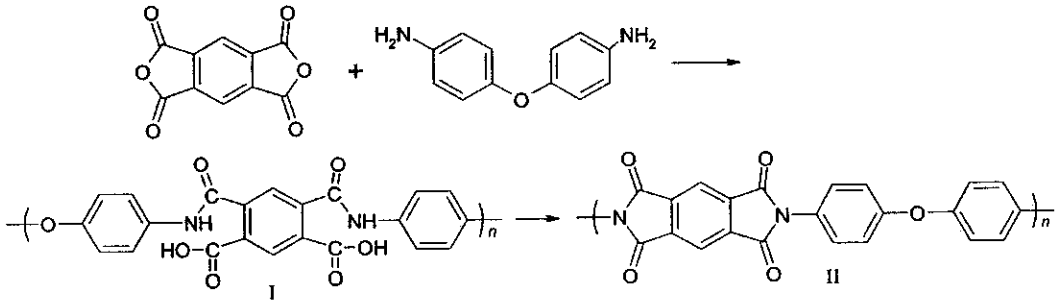
Structure-based name:

poly(oxy-1,4-phenyleneoxy-1,4-phenylenecarbonyl-1,4-phenylene)

RULE 4

Polymer class names relevant only to the main chain are specified in the name; names of side-chain functional groups may also be included after a hyphen if they are formed during the polymerization reaction.

Example 4.1



Generic source-based names:

I. poly(amide-acid):[(pyromellitic dianhydride)-*alt*-(4,4′-oxydianiline)]
(Both carboxy groups result from the polymerization reaction.)

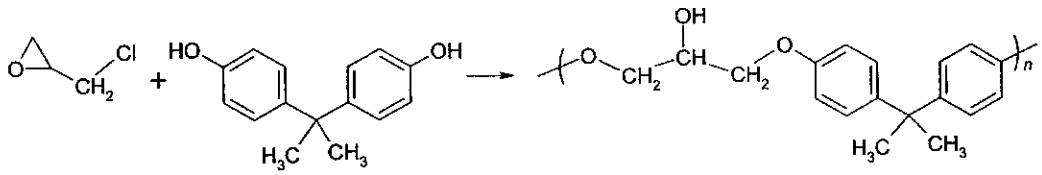
II. polyimide:[(pyromellitic dianhydride)-*alt*-(4,4′-oxydianiline)]

Structure-based names:

I. poly[oxy-1,4-phenyleneiminocarbonyl(4,6-dicarboxy-1,3-phenylene)carbonylimino-1,4-phenylene]

II. poly[(5,7-dihydro-1,3,5,7-tetraoxobenzo[1,2-*c*:4,5-*c*′]dipyrrole-2,6(1*H*,3*H*)-diyl)-1,4-phenyleneoxy-1,4-phenylene]

Example 4.2



Generic source-based names:

poly(ether-alcohol):(epichlorohydrin-*alt*-bisphenol A)

Structure-based name:

poly[oxy(2-hydroxypropane-1,3-diyl)oxy-1,4-phenylene(1-methylethane-1,1-diyl)-1,4-phenylene]

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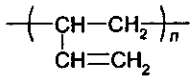
RULE 5

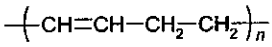
In the case of carbon-chain polymers such as vinyl polymers or diene polymers, the generic name is to be used only when different polymer structures may arise from a given monomeric system.

Example 5.1



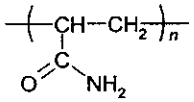
Generic source-based name:
polyalkylene:(buta-1,3-diene)
Source-based name:
poly(buta-1,3-diene)
Structure-based name:
poly(1-vinylethylene)

Example 5.2



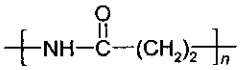
Generic source-based name:
polyalkenylene:buta-1,3-diene
Source-based name:
poly(buta-1,3-diene)
Structure-based name:
poly(but-1-ene-1,4-diyl)

Example 5.3



Generic source-based name:
polyalkylene:acrylamide
Structure-based name:
poly[1-(aminocarbonyl)ethylene]

Example 5.4



Generic source-based name:
polyamide:acrylamide
Structure-based name:
poly[imino(1-oxopropane-1,3-diyl)]

Note 7 The terms polyalkylene and polyalkenylene have been defined in ref. 7, p. 149.

4. FURTHER APPLICATIONS OF GENERIC NAMES

Generic source-based nomenclature can be extended to more complicated polymers such as spiro and cyclic polymers and networks.

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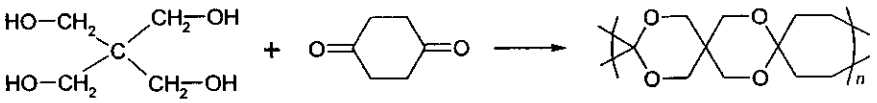
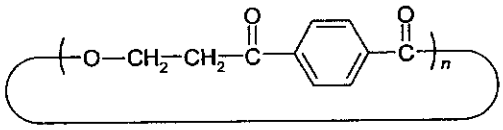
Example 6.1



Generic source-based name:
polyspiroketal:{[2,2-bis(hydroxymethyl)-propane-1,3-diol]-*alt*-cyclohexane-1,4-dione}
or polyspiroketal:(pentaerythritol-*alt*-cyclohexane-1,4-dione)
Structure-based name:
poly[2,4,8,10-tetraoxaspiro[5.5]undecane-3,3,9,9-tetrayl-9,9-bis(ethylene)]

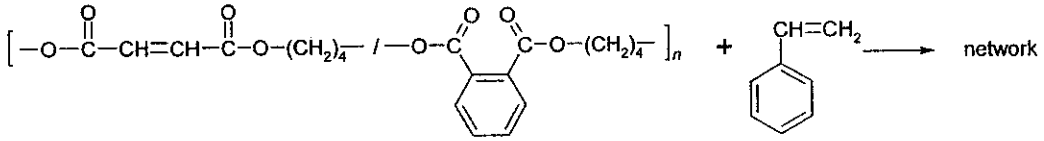
Example 6.2



Generic source-based name:
cyclo-polyester:[(ethylene glycol)-*alt*-(terephthalic acid)]

Note 8 There is no IUPAC nomenclature for cyclic polymers.

Example 6.3



Generic source-based name:
polyester:{butane-1,4-diol-*alt*-[(maleic anhydride);(phthalic anhydride)]}-*net*-polyalkylene:(maleic anhydride)-*co*-styrene]

5. REFERENCES

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2. "Nomenclature of regular double-strand (ladder and spiro) organic polymers 1993", *Pure Appl. Chem.* **65**, 1561–1580 (1993).
3. "Structure-based nomenclature for irregular single-strand organic polymers 1994", *Pure Appl. Chem.* **66**, 873–889 (1994).
4. "Source-Based Nomenclature for Copolymers 1985", *Pure Appl. Chem.* **57**, 1427–1440 (1985). Reprinted as chapter 7 in Ref. 7.
5. "Source-based nomenclature for non-linear macromolecules and macromolecular assemblies", *Pure Appl. Chem.* **69**, 2511–2521 (1997).
6. *A Guide to IUPAC Nomenclature of Organic Compounds*, R. Panico, W. H. Powell, J-C. Richer (Eds.), Blackwell Scientific Publications, Oxford (1993).
7. *Compendium of Macromolecular Nomenclature*, W. V. Metanomski (Ed.), Blackwell Scientific Publications, Oxford (1991).

TAB E

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a Massachusetts Corporation,

Plaintiff,

vs.

CIVIL ACTION
NO. 04-12457 PBS

Arthrex, Inc., a Delaware Corporation,

Defendant.
_____/

DEPOSITION OF: DONALD GRAFTON

DATE: March 14, 2006

TIME: 8:38 a.m. to 1:23 p.m.

LOCATION: The Ritz Carlton Golf Resort
2600 Tiburon Drive
Naples, FL 34112

TAKEN BY: Plaintiff

REPORTER: Deborah A. Krotz, RPR, CRR

VIDEOGRAPHER: Gene Howell, CLVS

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ultra-high molecular weight polyethylene or if it was braided or --
A. It's been too long ago. I can't tell you that.
Q. And your idea was to use the ultra-high molecular weight polyethylene as a suture?
A. Yes.
Q. Okay. And you had Mr. Hallett make a Size 2, I think you said?
A. Yes.
Q. Okay. Can you describe the construction of that first --
A. I don't remember now. It's been too long.
Q. Was it all ultra -- ultra-high molecular weight polyethylene?
A. Initially, yes, as a test prototype material.
Q. Was it braided?
A. Yes.
Q. Was it an eight-carrier or a sixteen-carrier?
A. I don't remember.
Q. You said it was a Size 2 though?
A. Yes.
Q. So it was a Size 2 ultra-high molecular weight polyethylene braided suture that did not have PET?
A. For the initial prototype material, that's correct.

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Q. Okay. And it didn't have nylon or any other material braided with it?
A. No.
Q. So the initial prototype was a ultra-high molecular weight polyethylene braided suture prototype, if you will?
A. Yes. Size 2.
Q. Size 2. And was the initial prototype, was it coated?
A. I don't remember.
Q. Okay. Do you know if the initial prototype went through any other manufacturing process like stretching or heating, twisting?
A. I don't recall.
Q. Was the initial prototype 100 percent ultra-high molecular weight polyethylene?
A. For the fourth time, yes.
Q. Okay. And you tested the initial prototype that was 100 percent ultra-high molecular weight polyethylene with Dr. Burkhart and Dr. Chen?
A. Dr. Casey Chen, correct.
Q. Okay. And the test that you conducted with Dr. Burkhart and Dr. Chen on the ultra-high molecular weight polyethylene was a knot strength test?
A. Knot security.

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Q. Knot security test?
A. Yes.
Q. Was that the test we drew in Exhibit Number 421?
A. That's correct.
Q. Okay. And you said the strength was excellent. I believe, of the initial prototype, but the knot slippage was poor; is that right?
A. Yes.
Q. Okay. When you say the slippage was poor of the initial prototype, what do you mean?
A. Less than the tensile strength capability of the existing Arthrex product.
Q. So the knot slippage was less than the Tevdek suture?
A. Yes.
Q. And it was -- knot slippage was such that it was determined that the 100 percent ultra-high molecular weight polyethylene suture prototype wasn't suitable to be developed?
A. That's correct. Yes.
Q. Okay. Ultra-high molecular weight polyethylene, you said the knot slippage was poor?
A. (Witness nods head affirmatively).
Q. Ultra-high molecular weight polyethylene, is that a lubricious material?

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A. Yes.
Q. And was the knot slippage of this ultra-high molecular weight polyethylene poor security because of the lubricity of polyethylene?
A. Yes.
Q. Yes?
A. Yes.
Q. So then you came up with the idea to braid PET with the ultra-high molecular weight polyethylene to reduce the knot slippage?
A. Yes.
Q. And when you say knot slippage, we're referring to this knot security test?
A. Yes.
Q. So are we using the terms knot slippage and knot security interchangeably here?
A. You are, yes.
Q. In your testimony?
A. Yes.
Q. So the knot security of the 100 percent ultra-high molecular weight polyethylene was poor, the prototype; right?
A. Yes.
Q. And your idea was to add the PET and to improve the knot security?

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

DEPUY MITEK, INC., a Massachusetts corporation, Plaintiff,	)	Civil Action
vs.	)	04-12457 PBS
ARTHREX, INC., a Delaware corporation, Defendant.	)	

- - - - -

The deposition of DEBI PRASAD MUKHERJEE was taken on Tuesday, June 13, 2006, commencing at 9:08 a.m., at the offices of Dickstein Shapiro Morin & Oshinsky LLP, 2101 L Street, N.W., Washington, D.C., before Susanne Bergling, Registered Merit Reporter and Notary Public.

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A. Then polypropylene is twice, polyester is about twice -- I mean polyester -- polyethylene is twice, then -- ultra high molecular weight polyethylene is twice than polypropylene and twice than polyester, so they are probably significantly higher for the ultra high molecular weight polyethylene, knot pull strength.
Q. Do you know if -- does he provide the standard deviation for the knot pull strength?
A. He didn't, but just looking at the figures, I mean, I can say that, looking at 1.35 or 1.44, you have to say that.
Q. Okay. So, he did not provide standard deviation in this chart.
A. Not in this chart.
Q. Now, for the knot configuration four equals one equals one, do you see that?
A. Yes.
Q. The polyethylene failed at 0.35 gigapascals, which is lower than the failure value for the nylon, polypropylene and polyester for the four equals one equals one configuration, right?
A. Yes.
Q. Okay. And that's because the polyethylene slipped, right?

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A. I don't use the word "sucked."
Q. I said "slipped."
A. Slipped, okay. I thought I heard... sorry.
Q. So, the polyethylene failed at the 0.35 gigapascal level for the four equals one equals one configuration because of the polyethylene slipping, right?
A. Right.
Q. Okay. Polyethylene, including ultra high molecular weight polyethylene, is a lubricious material, right?
A. Yes.
Q. Okay.
A. It's also polypropylene -- excuse me.
Q. Sure.
A. Polypropylene is also a lubricious material.
Q. It is?
A. Yes, it is.
Q. Okay. How about nylon or polyester, are they lubricious?
A. Nylon is also -- again, is lubricious.
Q. How about polyester?
A. Polyester will be less.

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Q. And nylon is less lubricious than polypropylene and polyethylene, right?
A. Probably.
Q. Okay. Now, in that chart, do you see how going across there's different knot configurations, two equals two, three equals two equals one, four equals one equals one, four equals four and four equals four equals four?
A. Yes.
Q. So, going from left to right, two equals two to four equals four equals four, the two equals two is a simpler knot than the four equals four equals four, right?
A. It's not simple or complex. It depends on what the surgeon wants to do. So, he can put more knots to make sure, and in general, they do. They will not stop at two by two. They will probably go to four by four by four to make sure it is there, especially ophthalmic use.
Q. Okay. And if you turn to page ARM 25137 --
A. Thirty-seven, yeah.
Q. Okay, of Cohan, the last paragraph of the first column --
A. Yeah.
Q. -- do you see the sentence beginning

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"Although"? The first column --
A. Did you say first column?
Q. First column, last paragraph.
A. Last paragraph.
Q. The sentence beginning, "Although."
A. "Although," yes.
Q. Cohan states, "Although laboratory testing showed that the polyethylene fiber has a somewhat lower knot holding strength with simpler knots than the other three polymers, more complex knots than are commonly used would realize polyethylene's great knot pull strength."
Do you see that?
A. Yes.
Q. Okay. So, Cohan was calling the more -- the additional knot configurations more complex, right?
A. That's what -- if he meant by that.
Q. Well, did you understand that's what he means when you read this reference?
A. Well, I -- I think that normally for a surgeon, they will put as many knots they can to make sure it's secure, and it's nothing complex or simple about it.
Q. Well, if you look at the author, the author

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in the monomer?
A. Yeah -- well, it's not a monomer, in the polymer.
Q. In the polymer?
A. Yeah.
Q. I'm confused. Are you saying that the monomer unit in all types of polyethylene is the same or different?
A. Mostly same, yeah.
Q. Mostly same, okay.
Would one of ordinary skill in the art between 1988 and 1992 think that the term "polyethylene" refers to low-density polyethylene or includes -- should I say includes low-density polyethylene?
A. Yeah, it would.
Q. It would? But not ultra high? Is that your opinion?
A. Ah, they will also include ultra high, because there are different properties, so they will include also ultra high, as well as low-density.
Q. Okay. I'd like to turn to polypropylene as used in the '446 patent, Exhibit 3 to your first report. Do you see the '446 patent?

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A. Yeah.
Q. Exhibit 3?
A. Exhibit 3.
Q. Right.
A. Yeah, I'm at this.
Q. No, Exhibit 3. I'm sorry, that's Exhibit 3. I'm sorry. Yeah, if you would go to column 4, please.
A. Yeah.
Q. Okay. Beginning at line 9 through 32, do you see that?
A. Nine through 32, yeah.
Q. Okay. That paragraph says, "Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers."
Do you see that?
A. Yes.
Q. Is ultra high molecular weight polyethylene a nonabsorbable polymer?
A. Yes.
Q. Okay. Then it says, "In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the pliability, or compliance, and surface lubricity of the

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heterogenous braid."
Do you see that?
A. That is correct.
Q. Ultra high molecular weight is a lubricating yarn, right?
A. Yes.
Q. Okay. Then it says -- further down it says, "Such fiber forming polymers include perfluorinated polymers," and describes some of those, and then it says, "as well as non-perfluorinated polymers," and refers to polyethylene and PE, right?
A. Right.
Q. Okay. Ultra high molecular weight polyethylene came as fibers before 1992, right?
A. Yes.
Q. Okay. Now, do you see where in the end it says, "The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP"?
Do you see that?
A. Yes.
Q. Okay. That's column 4, lines 28 to 31.
Did you understand that sentence to refer to all types of polypropylene or just certain types of polypropylene?

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MR. TAMBURO: Objection, vague.
THE WITNESS: This is general purpose polyethylene, which it provides the lubricity and as well as pliability and compliance, not ultra high molecular weight polyethylene.
BY MR. BONELLA:
Q. Okay, that wasn't my question. Listen to the question.
Did you understand that sentence to refer to all types of polypropylene?
MR. TAMBURO: Objection, vague.
THE WITNESS: The fiber-forming polypropylene, yes.
BY MR. BONELLA:
Q. All types, okay.
Did you understand -- do you see where it refers to PVDF?
A. Yes.
Q. Did you understand this paragraph to be referring to all types of polyvinylidene fluoride?
A. Yes.
Q. Okay. Do you see where it refers to PTFE in that paragraph?
A. Yes.
Q. Did you understand it to be referring to

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all types of PTFE?
MR. TAMBURO: Objection, vague, assumes facts.
THE WITNESS: Frankly, I don't know how many PTFE are there, because it depends on the -- the tetrofluorylethylene, the construction, but I have to assume that whatever is available at that time, PTFE.
BY MR. BONELLA:
Q. Okay. Do you see the PVDF --
A. Yeah.
Q. -- material?
Did you understand the PVDF material in that paragraph to refer to all types of PVDF --
MR. TAMBURO: Same objection.
BY MR. BONELLA:
Q. -- that were available before 1992?
MR. TAMBURO: Same objection.
THE WITNESS: It has to be fiber-forming, because a Teflon is just that.
BY MR. BONELLA:
Q. Right, okay. So, did you understand the PVDF acronym in that paragraph to refer to all types of fiber-forming PVDF material before 1992?
MR. TAMBURO: Same objection.

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THE WITNESS: I have to assume. I don't know for sure at that time how many PVDFs there were there.
BY MR. BONELLA:
Q. Okay. But I'm talking what -- I'm talking about what was available in 1992.
A. I know. That's why I said, I don't remember what different types of PVDF were available at that time.
Q. So, whatever PVDFs were available in 1992, the term PVDF would refer to that?
MR. TAMBURO: Objection, mischaracterizes testimony, assumes facts, and is a vague question.
THE WITNESS: It has to be certain kind of PVDF fibers that are available.
BY MR. BONELLA:
Q. Right.
A. So, that's --
Q. Whatever PVDF fibers were available in 1992 or before 1992, that term PVDF refers to that?
MR. TAMBURO: Same attempt to mischaracterize the testimony.
THE WITNESS: Probably so.
BY MR. BONELLA:
Q. Okay. How about any of the other terms in

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that paragraph? Do any of the other anacronyms (sic) for the materials in that paragraph exclude any materials that were available in 1992?
A. Yes.
Q. Which ones?
A. Polyethylene.
Q. Any other ones?
A. Which excludes ultra high molecular weight polyethylene.
Q. Okay. Any other ones, any other terms exclude any type of fibers that had -- that would have had those acronyms?
A. I'm not sure --
MR. TAMBURO: Objection. Objection, assumes facts.
THE WITNESS: This is a polychlorofluoroethylene polymers, so there could be different ones here. I don't know which ones were included here.
BY MR. BONELLA:
Q. Well, I'm talking about the ones that are specifically referenced. So, do you see where it refers to FEP, PFA, FEP -- I'm sorry, the only ones I guess we hadn't talked about were FEP and PFA.

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Do you understand the -- those terms to refer to all types of FEP and PFA fibers that were available in 1992?
MR. TAMBURO: Objection, vague, assumes facts.
THE WITNESS: These are the general description. I don't know the perfluoroalkoxy, PFA polymers, how many different ones are there. They didn't say the alkoxy could be different groups.
BY MR. BONELLA:
Q. I guess I don't understand the answer to the question.
A. See, if you look at the chemical name, it could be -- the alkoxy group could be different.
Q. PFA?
A. PFA-something-something. So, not necessarily do they include everything here.
Q. Well, just -- not PFA plus something, just PFA fibers, all different types of PFA fibers, does the term PFA include all different types of PFA fibers as it's used in that paragraph?
MR. TAMBURO: Objection, vague and assumes facts.
THE WITNESS: Probably.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a Massachusetts Corporation,

Plaintiff,

vs.

CIVIL ACTION
NO. 04-12457 PBS

Arthrex, Inc., a Delaware Corporation,

Defendant.
_____/

DEPOSITION OF: DONALD GRAFTON

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Q. Okay. Can you describe the construction of that first --
A. I don't remember now. It's been too long.
Q. Was it all ultra -- ultra-high molecular weight polyethylene?
A. Initially, yes, as a test prototype material.
Q. Was it braided?
A. Yes.
Q. Was it an eight-carrier or a sixteen-carrier?
A. I don't remember.
Q. You said it was a Size 2 though?
A. Yes.
Q. So it was a Size 2 ultra-high molecular weight polyethylene braided suture that did not have PET?
A. For the initial prototype material, that's correct.

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Q. Okay. And it didn't have nylon or any other material braided with it?
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A. Yes. Size 2.
Q. Size 2. And was the initial prototype, was it coated?
A. I don't remember.
Q. Okay. Do you know if the initial prototype went through any other manufacturing process like stretching or heating, twisting?
A. I don't recall.
Q. Was the initial prototype 100 percent ultra-high molecular weight polyethylene?
A. For the fourth time, yes.
Q. Okay. And you tested the initial prototype that was 100 percent ultra-high molecular weight polyethylene with Dr. Burkhart and Dr. Chen?
A. Dr. Casey Chen, correct.
Q. Okay. And the test that you conducted with Dr. Burkhart and Dr. Chen on the ultra-high molecular weight polyethylene was a knot strength test?
A. Knot security.

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Q. Knot security test?
A. Yes.
Q. Was that the test we drew in Exhibit Number 421?
A. That's correct.
Q. Okay. And you said the strength was excellent. I believe, of the initial prototype, but the knot slippage was poor; is that right?
A. Yes.
Q. Okay. When you say the slippage was poor of the initial prototype, what do you mean?
A. Less than the tensile strength capability of the existing Arthrex product.
Q. So the knot slippage was less than the Tevdek suture?
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Q. And it was -- knot slippage was such that it was determined that the 100 percent ultra-high molecular weight polyethylene suture prototype wasn't suitable to be developed?
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Q. Okay. Ultra-high molecular weight polyethylene, you said the knot slippage was poor?
A. (Witness nods head affirmatively).
Q. Ultra-high molecular weight polyethylene, is that a lubricious material?

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A. Yes.
Q. And was the knot slippage of this ultra-high molecular weight polyethylene poor security because of the lubricity of polyethylene?
A. Yes.
Q. Yes?
A. Yes.
Q. So then you came up with the idea to braid PET with the ultra-high molecular weight polyethylene to reduce the knot slippage?
A. Yes.
Q. And when you say knot slippage, we're referring to this knot security test?
A. Yes.
Q. So are we using the terms knot slippage and knot security interchangeably here?
A. You are, yes.
Q. In your testimony?
A. Yes.
Q. So the knot security of the 100 percent ultra-high molecular weight polyethylene was poor, the prototype; right?
A. Yes.
Q. And your idea was to add the PET and to improve the knot security?

LEXSEE 1998 US DIST LEXIS 23054

BASF CORPORATION, Plaintiff, v. EASTMAN CHEMICAL CO., Defendant.

Civil Action No. 95-746-RRM

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

1998 U.S. Dist. LEXIS 23054; 56 U.S.P.Q.2D (BNA) 1396

March 24, 1998, Decided

CASE SUMMARY:

PROCEDURAL POSTURE: Plaintiff patent holder commenced a patent infringement action against defendant competitor. The competitor counterclaimed for a declaratory judgment of noninfringement and invalidity. The court held a non-jury trial on the issues of infringement, willful infringement, and invalidity.

OVERVIEW: The holder asserted that a process used by the competitor to prepare 2,5-dihydrofuran from the chemical epoxy 1 butene infringed a claim made by its patent. The court found in favor of the competitor. The scope of a patent claim was defined by its language. While a court was permitted to consider the prosecution history and the like in its interpretation, reliance on such extrinsic evidence was improper when the language unambiguously defined a claim's scope. Given those considerations, the holder's claim excluded the addition of a solubilizer, as that component would alter its basic and novel characteristics. Furthermore, the claim only provided that the catalysis had to occur in a liquid phase and did not exclude gas feed processes. Therefore, the competitor's process did not infringe the holder's claim. Moreover, that claim was invalid because every one of its elements had been reduced prior to the priority date of the holder's application. In that regard, the delay between that reduction and the competitor's patent application was not evidence of abandonment or concealment because scientists were entitled to a reasonable amount of time in which to refine their invention.

OUTCOME: The court found that the competitor had not infringed one of the claims contained in the holder's patent. The court further held that claim was invalid on the grounds of priority of invention and that the competitor had not abandoned, suppressed, or concealed the invalidating prior reductions to practice.

LexisNexis(R) Headnotes

Patent Law > Infringement Actions > Claim Interpretation > General Overview

[HN1] Before a court can decide issues such as infringement, willful infringement, and invalidity, the court must first construe the language of a claim made by a patent.

Patent Law > Claims & Specifications > Enablement Requirement > General Overview
Patent Law > Infringement Actions > Claim Interpretation > General Overview

[HN2] A court construes claims from the vantage point of a person of ordinary skill in the art at the time of the invention. However, the court may interpret a term in a patent claim to have a meaning other than the one a person of ordinary skill in the art would give it if it is apparent from the patent and the prosecution history that the inventor intended a different meaning.

Patent Law > Infringement Actions > Claim Interpretation > General Overview

[HN3] In construing a claim, a court looks first to the intrinsic evidence of record, namely, the language of the claim, the specification, and the prosecution history. The claim language itself defines the scope of the claim, and a construing court does not accord the specification, prosecution history, and other relevant evidence the same weight as the claims themselves, but consults these sources to give the necessary context to the claim language. Expert testimony may be considered if needed to assist the court in understanding the meaning or scope of technical terms in a claim. However, reliance on any extrinsic evidence is improper where the claims, specification, and file history unambiguously define the scope of the claim.

Patent Law > Infringement Actions > Claim Interpretation > General Overview

[HN4] Although the Court of Appeals for the Federal Circuit has held that claims should be read in light of the specification, that court has repeatedly cautioned against limiting the scope of a claim to the preferred embodiment or specific examples disclosed in the specification.

Patent Law > Infringement Actions > Claim Interpretation > General Overview

[HN5] The Court of Appeals for the Federal Circuit has stated that the limited phrase "consisting essentially of" does not exclude the addition of another ingredient which does not materially affect the characteristics of the invention. The Federal Circuit has also stated that "consists essentially of" does close the claims to other ingredients that do alter the basic and novel characteristics of the invention.

International Trade Law > Imports & Exports > General Overview
Patent Law > Infringement Actions > Infringing Acts > Sale
Patent Law > Infringement Actions > Infringing Acts > Use

[HN6] Section 271(a) of the Patent Act states that whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent. *35 U.S.C.S. § 271*(a).

Patent Law > Date of Invention & Priority > Abandonment, Concealment & Resumption of Activity
Patent Law > Date of Invention & Priority > Conception Date
Patent Law > Date of Invention & Priority > Reduction to Practice

[HN7] Section 102(g) of the Patent Act, *35 U.S.C.S. § 102*(g), provides that a person is entitled to a patent unless before the application's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Evidence > Procedural Considerations > Burdens of Proof > Clear & Convincing Proof
Patent Law > Infringement Actions > Burdens of Proof
Patent Law > Infringement Actions > Defenses > Patent Invalidity > Validity Presumption

[HN8] A claim contained in a patent is presumed to be valid. *35 U.S.C.S. § 282*. The challenging party bears the burden of proving invalidity by clear and convincing evidence. Clear and convincing evidence is shown when the trier of fact has an abiding conviction that the truth of the factual contentions is highly probable.

Patent Law > Anticipation & Novelty > General Overview
Patent Law > Date of Invention & Priority > Reduction to Practice

[HN9] To show prior reduction to practice, a party must show that its work meets every element of the claimed invention before the priority date of a patent application.

Patent Law > Anticipation & Novelty > General Overview

[HN10] There cannot be a reduction to practice of the invention without a physical embodiment which includes all limitations of the claim.

Patent Law > Anticipation & Novelty > General Overview
Patent Law > Statutory Bars > Abandonment & Forfeiture Bar > General Overview

[HN11] In order to show that it did not abandon, suppress, or conceal experiments within the scope of a claim, a party must show that it disclosed the process of the claim in a manner that would bring the benefit of the knowledge of the invention to the public, and that it did not unreasonably delay this disclosure.

Patent Law > Anticipation & Novelty > General Overview
Patent Law > Date of Invention & Priority > Abandonment, Concealment & Resumption of Activity
Patent Law > Statutory Bars > Abandonment & Forfeiture Bar > General Overview

[HN12] It is necessary to consider the nature and extent of activity during the period between reduction to practice and the filing of the patent application.

Patent Law > Anticipation & Novelty > General Overview

Patent Law > Date of Invention & Priority > Abandonment, Concealment & Resumption of Activity
Patent Law > U.S. Patent & Trademark Office Proceedings > Continuation Applications > Priority
[HN13] The Court of Appeals for the Federal Circuit has stated that when determining whether an inventor has abandoned, suppressed, or concealed an invention, a period of delay between completion of the invention and subsequent public disclosure is not always of legal significance.

Patent Law > Anticipation & Novelty > General Overview
Patent Law > Date of Invention & Priority > Abandonment, Concealment & Resumption of Activity
Patent Law > Statutory Bars > Abandonment & Forfeiture Bar > General Overview
[HN14] Mere delay, without more, is insufficient to demonstrate abandonment, suppression, or concealment.

Patent Law > Anticipation & Novelty > General Overview
Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Appeals
Patent Law > Ownership > Conveyances > Assignments
[HN15] Scientists should be given a reasonable amount of time to refine their invention. A reasonable amount of time should be allowed for completion of the research project on the whole series of new compounds, a further reasonable period should then be allowed for drafting and filing the patent application(s) thereon, without subjecting the prior inventor or his assignee to the risk of forfeiture of valuable patent rights due to alleged concealment or suppression of the invention.

COUNSEL: [*1] For plaintiff: Josy W. Ingersoll, Esquire, Young, Conaway, Stargatt & Taylor, Wilmington, Delaware.

For plaintiff: Richard L. Mayer, Esquire, Richard L. DeLucia, Esquire, Howard J. Shire, Esquire, Lynne Darcy, Esquire, Charles A. Weiss, Esquire, Kenyon & Kenyon, New York, New York.

For defendant: William J. Marsden, Jr., Esquire, Joanne Ceballos, Esquire, Michael S. McGinniss, Esquire, Potter, Anderson & Corroon, Wilmington, Delaware.

For defendant: Ralph A. Mittleberger, Esquire, Barry E. Bretschneider, Esquire, Howard Susser, Esquire, William R. Johnson, Esquire, Fish & Richardson, P.C., Washington, D.C.

For defendant: Frank P. Porcelli, Esquire, Ronald E. Myrick, Esquire, Fish & Richardson, P.C., Boston, Massachusetts.

For defendant: R. Danny Huntington, Esquire, B. Jefferson Boggs, Jr., Esquire, Nhat D. Phan, Esquire, Todd R. Walters, Esquire, Burns, Doane, Swecker & Mathis, LLP, Alexandria, Virginia.

JUDGES: Roderick McKelvie, District Judge.

OPINIONBY: Roderick McKelvie

OPINION:

REVISED MEMORANDUM OPINION

Dated: March 24, 1998

McKELVIE, District Judge

This is a patent case. Plaintiff BASF Corporation ("BASF") owns U.S. Patent No. *5,034,545* ("the *'545* [*2] patent"), which claims a process for the preparation of the chemical 2,5-dihydrofuran ("DHF") from the chemical epoxy 1 butene ("EpB"). BASF alleges that defendant Eastman Chemical Co.'s ("Eastman") process for the commercial production of DHF infringes claim 6 of the *'545* patent, and that Eastman is wilfully infringing. Eastman has denied infringement, asserted the affirmative defense of invalidity on the grounds of priority of invention, and counterclaimed for a declaratory judgment of noninfringement and invalidity.

From October 14 to October 22, 1997, the court held a non-jury trial on the issues of infringement, willful infringement, and invalidity. At trial, BASF alleged that the process Eastman is using at its Longview, Texas plant to commercially prepare DHF infringes claim 6 of the *'545* patent, and that Eastman is wilfully infringing claim 6. Eastman argues that it is not infringing claim 6 of the *'545* patent, as the process it uses in Longview is not covered by claim 6. Furthermore, Eastman argues that claim 6 of the *'545* patent is invalid on the grounds of priority of invention because experiments done by Eastman scientists before BASF filed the *'545* patent application [*3] constitute prior reductions to practice of claim 6, and Eastman scientists disclosed the results of these experiments in a patent application filed in March 1990.

The following is the court's decision on these issues.

I. FACTUAL AND PROCEDURAL BACKGROUND

The court draws the following facts from the pretrial order and from the evidence presented at the trial.

A. The Technology

The technology at issue in this matter involves the preparation of DHF from EpB. DHF is a solvent and starting material that can be used to make products such as Spandex and other products in the plastics industry. EpB is a compound with negligible commercial value. Through a chemical process known as catalysis, EpB can be transformed to DHF. Catalysis is the action of a catalyst, a substance which alters the rate of a chemical reaction without being depleted in the process. The catalyst creates a reaction that rearranges the manner in which the atoms that make up EpB are bound together, without altering the number of atoms. Because EpB can create end products other than DHF, the catalyst used for this rearrangement is critical to the process.

Scientists have explored many different methods [*4] for the catalytic rearrangement of EpB to DHF. In January 1976, the Patent and Trademark Office ("PTO") issued U.S. Patent No. *3,932,468* ("the Kurkov patent") to the Chevron Research Company. The Kurkov patent discloses a process for producing DHF using a catalyst of "hydrogen iodide or bromide and a homogenous transition metal compound in an organic solvent." In December 1976, the PTO issued U.S. Patent No. *3,996,248* ("the Wall patent") to Chevron. The Wall patent discloses a process for producing DHF using a catalyst of "hydrogen halide selected from the group consisting of hydrogen iodide or bromide and a Lewis acid."

Both processes claimed by the Kurkov and the Wall patents are solvent-based. One significant disadvantage of solvent-based processes is the need to remove the DHF from the reaction mixture through a distillation process. Distillation constitutes a separate step of the recovery process, and renders the process less efficient and less economical. Thus, during the 1980's, scientists at BASF and Eastman sought to create alternative catalyst systems for converting EpB to DHF without the disadvantages associated with the use of large amounts of solvent. The dates on which [*5] these scientists discovered and reduced to practice certain catalyst systems is integral to the dispute between BASF and Eastman.

B. The *'545* Patent

On May 23, 1990, BASF Aktiengesellschaft ("BASF AG"), a German corporation, filed a patent application with the PTO, which matured into the *'545* patent. The PTO issued the *'545* patent on July 23, 1991. Martin Fischer, the named inventor, assigned the *'545* patent to BASF AG, which subsequently assigned it to BASF.

In August 1989, approximately one year before filing the *'545* patent application, BASF AG filed an application in Germany. The *'545* patent application claimed priority to the German application, which means that the *'545* patent application received the benefit of the earlier filing date of August 8, 1989. See *35 U.S.C. § 119* (1997).

The *'545* patent teaches that the catalytic rearrangement of EpB can occur using a three part catalyst system at a temperature between 60 [degrees] and 200 [degrees] Celcius. This catalyst system includes component A, which "is a halide of an alkali metal or alkaline earth metal or an onium halide." Component A is the active ingredient that starts the reaction [*6] with the EpB. Component B dissolves component A so that it can mix with the liquid solution during catalysis. Component B "is an organic solubilizer for component A." Component C "is a Lewis acid or elemental iodine."

The original application for the *'545* patent included five claims. Claim 1 of the patent claimed a process for the preparation of DHF from EpB which

> comprises the rearrangement being catalyzed by a system which contains components A, B and C, at from 60 [degrees] to 200 [degrees] C., where
>
> A is a halide of an alkali metal or alkaline earth metal or an onium halide,
>
> B is an organic solubilizer for component A, and
>
> C is a Lewis acid or elemental iodine, with the proviso that at least one of components A or C is an iodide.

Claims 2 to 5 depended from claim 1.

The original application for the *'545* patent included a discussion of the amount of component B necessary to dissolve component A. As noted in the patent application, "the amount of solubilizer B required to solubilize component A greatly depends on the particular substance." The patent application also noted that onium halides, which may be used as component A, have a "certain intrinsic solubility [*7] in the organic reaction medium." Accordingly, the solubility of the "onium halides with four alkyl or aryl substituents may be so great in the reaction medium that virtually no addition of solubilizer B is necessary." This language, which constituted part of the original application filed with the PTO, is included at column 4, lines 36 to 58 of the *'545* patent.

On November 6, 1990, during the prosecution of the *'545* patent, the patent examiner relied on the language in the patent specification, and noted that solubilizer may

not be necessary when certain halides are used as component A. The examiner noted that "this 'no solubilizer' embodiment is intended to be covered by the claims." Thus, the examiner suggested what eventually became claim 6 of the *'545* patent.

On January 24, 1991, BASF AG added amended claim 6 to the *'545* patent. Claim 6 limits component A to onium halides that are "substantially soluble in the reaction medium," Claim 6 claims a process for the preparation of DHF from EpB which

> consists essentially of the rearrangement being catalyzed by a system which contains components A and C from 60 [degrees] to 200 [degrees] C where A is an onium halide, which [*8] is substantially soluble in the reaction medium, and C is a Lewis acid or elemental iodine with the proviso that at least one of the components A or C is an iodide.

C. Eastman's Catalytic Rearrangement

In the 1980's, Eastman scientists were also experimenting with different catalyst systems for converting EpB to DHF. In particular, three scientists focused their studies on the catalytic rearrangement of EpB Dr. Stephen Falling, Dr. John Monnier, and Dr. Howard Low.

In January 1987, Monnier notified Dr. Windell Watkins that he had discovered a process for cheaply manufacturing EpB from butadiene. Watkins invited Monnier to come from Eastman's Rochester, New York plant, to its Longview, Texas plant to give a seminar on his research on converting butadiene to EpB. On February 24, 1987, Watkins wrote a memo to Monnier and Steve Godleski, another research scientist at Rochester, indicating an interest in working with scientists at the Rochester plant to "develop a process for epoxy-butene and . . . to develop some other chemicals that are easily derived from EpB."

As a result of Watkins' memo, in December 1987, Eastman scientists held a meeting at the Rochester plant to discuss [*9] whether to convene a team to develop a process for preparing EpB and EpB derivatives. Following the meeting, the scientists created an EpB team comprised of, among others, Watkins, Godleski, Monnier, Low, and Falling. Watkins headed the EpB team. Although the scientists did not all work at the same Eastman plant, they kept one another informed of the results of their experiments. For example, beginning in the summer of 1988 and continuing through the end of 1990, Falling circulated monthly reports to other members of the EpB team documenting the progress of his experiments.

1. Falling's, Monnier's, and Low's experiments

In June 1988, Falling began to explore different processes for catalytically rearranging EpB to DHF. Falling's experiments always included EpB in liquid form. At trial, Falling testified about some of the experiments he conducted.

On June 9, 1988, Falling catalytically rearranged EpB to DHF by mixing a Lewis Acid (zinc chloride), an onium halide (tetrabutylammonium iodide), a solvent (toluene), and EpB at 100 [degrees] C, resulting in 4.4% DHF. On June 15, 1988, Falling mixed a Lewis acid (zinc chloride), an onium halide (tetrabutylammonium iodide), a solvent [*10] (toluene), and EpB at 150 [degrees] C. The end product was 21.2% DHF.

On June 28, 1988, Falling attempted an experiment with a different Lewis acid (zinc iodide), an onium halide (tetrabutylammonium iodide), a solvent (toluene) and EpB at 150 [degrees] C. Two days later, Falling ran a similar experiment, using dioxane instead of toluene. The result was 92.3% DHF. At trial, Falling noted that "this experiment was very successful. It showed even greater amounts of DHF" than the prior experiments.

On July 6, 1988, Falling conducted a "neat" experiment. An experiment is neat when neither solubilizer nor solvent is added. Falling obtained DHF by mixing EpB with only a Lewis acid (zinc iodide) and an onium halide (tetrabutylammonium iodide) at 66 [degrees] to 70 [degrees] C. This catalyst combination produced 71.2% DHF. Two days later, on July 8, 1988, in a monthly report from Falling to Watkins and other members of the EpB team, Falling reported that the "best catalyst system studied thus far is [zinc iodide / tetrabutylammonium iodide,]" which included the neat experiment, and the earlier experiment with dioxane. Falling also reported that "runs without solvent or in dioxane [*11] have been the most encouraging with regard to DHF/crotonaldehyde ratios. These runs appear to be clean and go to complete conversion of EpB."

Falling continued to experiment with various Lewis acids, onium halides, and solvents to obtain DHF. Falling also conducted more neat experiments. On July 18, 1988, Falling conducted a neat experiment, using tetrabutyltin iodide and tetrabutylphosphonium iodide at 66 [degrees] to 70 [degrees] C. Only trace amounts of DHF were detected, and Falling discarded the experiment. Falling concluded that "some reaction had occurred" and that "these conditions were not optimum for this particular reaction." On July 27, 1988, Falling conducted another neat experiment, using magnesium iodide and tetrabutylammonium iodide at 66 [degrees] to 70 [degrees] C,

resulting in a trace amount of DHF. Falling discarded this experiment. Falling testified at trial that 66 [degrees] to 70 [degrees] C is "just too low a temperature to achieve very much reaction," and that if he had run the experiment at a higher temperature, he predicted that he "would obtain much more reaction."

On October 3, 1988, Falling successfully produced 71.7% DHF when he mixed a [*12] Lewis acid (tributyltin iodide), an onium halide (tetrabutylphosphonium iodide), and a solvent (toluene), at 150 [degrees] C.

In most of the above experiments, except the neat experiments, Falling used a solvent. At trial, Falling testified that he used toluene as the solvent because EpB was in short supply and he had to conserve it, and "toluene had the purpose of diluting the mixture so as to cut down polymerization chemistry and to favor the rearrangement reaction."

Falling continued to experiment with various catalyst combinations throughout 1989 and 1990, circulating monthly reports documenting his progress. In an August 1, 1989 memo sent to members of the EpB team Falling wrote that "the screening of catalyst systems for the homogenous rearrangement of EpB to 2,5-DHF is still in progress."

At the same time that Falling worked on developing a process for converting EpB to DHF, Monnier and Low were also experimenting with various catalysts. Because of the equipment capabilities at the Rochester plant, all of their experiments were gas feed, which meant that they used EpB in gas form.

Monnier and Low testified at trial that they initially used metallic iodides as a catalyst. [*13] However, Watkins thought that Falling's use of an onium halide and a Lewis acid as a catalyst constituted a major breakthrough for converting EpB to DHF. Thus, from November 1988, to January 1990, Monnier and Low conducted several experiments using this catalyst to rearrange EpB to DHF. The experiments were run at approximately 110 [degrees] to 185 [degrees] C. Low testified that the conversion to DHF was "pretty successful" when they used onium halides and a Lewis acid.

2. The patent applications

On March 8, 1990, Eastman filed U.S. Patent Application Serial No. 07/490,208 ("the '208 application") which claimed a process for the catalytic rearrangement of EpB to DHF by mixing a Lewis acid and an onium halide. This process used neither a solubilizer nor a solvent at a temperature range of 60 [degrees] to 225 [degrees]. The '208 application was mainly based on the gas feed, liquid phase catalyst work done by Monnier and Low. Although the '208 application generally covered Falling's work, it did not include any working examples from Falling's notebooks, and Falling was not listed as an inventor on the application. Eastman filed the '208 application approximately two and [*14] a half months before BASF filed the *'545* application.

On July 23, 1990, Falling and Patricia Lopez-Maldonado, a scientist working with Falling since July 1989, completed an invention report and submitted it to Eastman's patent department. The report stated that "[a] catalytic process has been discovered with the rearrangement of vinyl epoxides to 2,5-dihydrofurans in good yield and selectivity. The process comprises contacting a vinyl epoxide [EpB] with a catalytic amount of an organotin or organoantimony compound and an organic-soluble iodide or bromide salt in an inert solvent at elevated temperatures." Organotins or organoantimony compounds are Lewis acids.

The report also stated that the "process is an improvement over the prior art in that it does not require the use of corrosive hydrogen halides or expensive tertiary amide solvents." The report stated that "although the rearrangement reaction can be performed in the absence of solvent, the use of an inert organic solvent or diluent is normally preferred for ease of materials handling. The vinyl epoxide rearrangement can be performed in any solvent which is unreactive towards epoxides and the catalysts."

This invention [*15] report became the basis for a December 14, 1990 addendum to the '208 application, a continuation in part ("CIP"). The CIP added to the '208 application working examples of the liquid phase experiments using a catalyst system of an onium halide and a Lewis acid that Falling had worked on during the summer of 1988. Because the CIP contained some new subject matter, the new subject matter had its own filing date of December 14, 1990.

Eastman filed the CIP as a new patent application, U.S. Application Serial No. 627,668 ("the '668 application"). The '668 application disclosed a process for converting EpB to DHF using a catalyst of an onium halide and a Lewis acid, and no solubilizer. Eastman eventually abandoned the '208 application in favor of the '668 application. The '668 application matured into U.S. Patent No. *5,082,956* ("the *'956* patent"), which the PTO issued to Eastman on January 21, 1992. Monnier, Godleski, Low, and Gerald W. Phillips, a scientist at the Longview plant, are listed as inventors. The *'956* patent discloses a process for converting EpB to DHF where the "catalyst may comprise a supported catalyst, an unsupported catalyst or a solution of the catalytically-active components [*16] in an inert, organic solvent."

During the early to mid-1990's, Eastman filed other patent applications as Eastman scientists continued experimenting with processes for catalytically rearranging

EpB into DHF. On February 10, 1994, Eastman filed U.S. Application Serial No. 08/194,655 ("the '655 application"), which claims a process for the catalytic rearrangement of EpB to DHF using a catalyst system of an onium halide and a Lewis acid. Falling is listed as the inventor on the '655 application.

The '655 application is a continuation in part of Application Serial No. 07/746,530, which was filed in August 1991, and which is a divisional application of the '668 application. The divisional application is based on the parent application, the '668 application, and it has the same specifications but different claims. The divisional application is entitled to the filing date for the '668 application, December 14, 1990. The '655 application is still pending.

On May 24, 1994, the PTO issued U.S. Patent No. *5,315,019* ("the *'019* patent") to Eastman. Phillips, Falling, Monnier, and Godleski are listed as the inventors. The *'019* patent discloses a "continuous process for the manufacture of [DHF] [*17] by the isomerization of [EpB] in the liquid phase in the presence of a catalyst system comprising an onium iodide compound and a Lewis acid and a process solvent comprising a mixture of the [DHF] product of the process and an oligomer of the [EpB] reactant." Thus, the *'019* patent discloses a process in which the onium halides are intrinsically soluble in the reaction medium, which essentially eliminates the need for added solvent.

At column 2, line 60, to column 3, line 3, the *'019* patent states that the "advantages provided by the continuous process disclosed herein include milder reaction conditions, simplified product separation and the ability to remove and replenish the catalyst system." Additionally, the "use of a mixture of the [DHF] product and an oligomer of the [EpB] reactant as the inert process solvent allows the reaction to be run at temperatures substantially lower than those used in vapor phase processes," and "as a result, the potential for catalyst deactivation or decomposition and by-product formation is decreased."

D. The Interference

On November 3, 1994, the PTO declared an interference between claims 1 to 6 of BASF's *'545* patent and Eastman's pending [*18] '655 application. (Monnier et al. v. Martin Fischer, Interference No. 103,455). The PTO declared the interference for the purpose of determining whether BASF or Eastman first catalytically rearranged EpB to DHF using a catalyst system of an onium halide and a Lewis acid.

On November 29, 1995, Administrative Patent Judge Marc L. Caroff declared unpatentable claims 1 to 5 of the *'545* patent because example 6 of the Wall patent disclosed a process for the preparation of DHF from EpB using a catalyst system that anticipated claims 1 to 5. Judge Caroff also determined that claim 6 of the *'545* patent is directed to the same invention Eastman claims, and that if Eastman's application matures into a patent, claim 6 of the *'545* patent will be declared invalid on the basis of Eastman's priority of invention.

The interference proceedings are still pending.

E. The Longview Process

Eastman is currently working on a method for commercially producing DHF from its plant in Longview, Texas. At Longview, Eastman commences the process of catalytically rearranging EpB to DHF using a specific onium halide, THF (tetrahydrofuran), which is a solubilizer, and a specific Lewis acid, at 70 [degrees] [*19] to 117 [degrees] C. Gerald Butler, a chemical engineer at Eastman, testified at trial about the Longview process.

At start-up, there is a one-to-one ratio of the onium halide to THF. The THF is added to the EpB to help dissolve the onium halide. Within six to twelve hours of adding both products distillation begins, and shortly thereafter a large portion of the THF is removed. The DHF produced soon outweighs the THF, and THF becomes less important to carry out the reaction. Eventually, no THF is left in the system.

When the EpB is added to the mixture of onium halide, THF, and Lewis acid, and DHF is produced, approximately 3% of the EpB is converted to oligomer. Eastman's expert in organic chemistry, Dr. John Swenton, testified at trial that the textbook definition of oligomer is a "substance composed of molecules containing a few of one or more species of atoms or groups of atoms . . . repetitively linked to each other." As the DHF is produced, it is stored separately, and the oligomer is recycled back into the system to convert EpB to DHF. The oligomer is eventually built up to where it constitutes a substantial proportion of the system. The oligomer replaces the solubilizing [*20] function of the THF at start-up and helps keep the onium halide in a liquid state. The oligomer is inherently produced during the reaction. By recycling the oligomer back into the process to act as a solubilizer, the process can be run for months at a time.

F. The Lawsuit

On December 7, 1995, BASF filed a complaint alleging that the Longview process infringes claim 6 of the *'545* patent, and that Eastman is wilfully infringing. On January 12, 1996, Eastman filed an answer denying infringement, asserting the affirmative defense of invalidity on the grounds of priority of invention, and counterclaiming for a declaratory judgment of noninfringement and invalidity.

On April 15, 1997, Eastman filed a motion for leave to amend its answer and counterclaim and to add BASF AG as a party. Eastman sought to add several affirmative defenses, including the affirmative defenses of fraud, inequitable conduct, and unclean hands. Eastman also sought to add additional counterclaims, including a counterclaim for unfair competition pursuant to Delaware common law and statutory law, and counterclaims for a declaratory judgment that the *'545* patent is unenforceable because of inequitable conduct, [*21] and that BASF is guilty of unclean hands. On July 31, 1997, the court granted Eastman's motion.

From October 14 to October 22, 1997, the court held a non-jury trial on the issues of infringement, willful infringement, and invalidity. At trial, BASF argued that the "virtually solvent-free process" which Eastman uses at Longview infringes claim 6 of the *'545* patent. Furthermore, BASF argued that Eastman knew about the *'545* patent before it commenced the production of DHF at Longview. Eastman argued that the Longview process does not infringe because of the use of a solubilizer, THF, at start-up, and the continuous use of a solubilizer, recycled oligomer, throughout the process. Furthermore, Eastman argued that Falling's neat experiments and his experiments using toluene as an inert solvent, and the gas feed work of Monnier and Low establish priority of invention. Therefore, Eastman argued that claim 6 of the *'545* patent is invalid. See *35 U.S.C. § 102*(g) (1997). BASF argued that if these experiments establish prior inventorship, claim 6 is not invalid because Eastman abandoned, suppressed, or concealed this work.

On November 24, 1997, the parties stipulated [*22] that resolution of all other issues would be stayed pending the court's decision on infringement, willful infringement, and invalidity.

II. DISCUSSION

[HN1] Before the court can decide the issues of infringement, willful infringement, and invalidity, the court must first construe the language of claim 6 of BASF's *'545* patent.

A. Claim Construction

[HN2] The court construes claims from the vantage point of a person of ordinary skill in the art at the time of the invention. See *Markman v. Westview Instruments, Inc., 52 F.3d 967, 986 (Fed. Cir. 1995)* (en banc), aff'd, *517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996).* However, the court may interpret a term in a patent claim to have a meaning other than the one a person of ordinary skill in the art would give it if it is apparent from the patent and the prosecution history that the inventor intended a different meaning. See *Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1579* (Fed. Cir.), cert. denied, *519 U.S. 911, 117 S. Ct. 275, 136 L. Ed. 2d 198 (1996).*

[HN3] In construing a claim, the court looks first to the intrinsic evidence of record, namely, [*23] the language of the claim, the specification, and the prosecution history. See *Insituform Tech. Inc. v. Cat Contracting, Inc., 99 F.3d 1098, 1105 (Fed. Cir. 1996).* The claim language itself defines the scope of the claim, and "a construing court does not accord the specification, prosecution history, and other relevant evidence the same weight as the claims themselves, but consults these sources to give the necessary context to the claim language." *Eastman Kodak Co. v. Goodyear Tire & Rubber Co., 114 F.3d 1547, 1552 (Fed. Cir. 1997).* Expert testimony may be considered if needed to assist the court in understanding the meaning or scope of technical terms in a claim. See *Hoechst, 78 F.3d at 1579.* However, reliance on any extrinsic evidence is improper where the claims, specification, and file history unambiguously define the scope of the claim. See *Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996).*

[HN4] Although the Court of Appeals for the Federal Circuit has held that claims should be read in light of the specification, *id. at 1582,* the court has repeatedly cautioned against limiting [*24] the scope of a claim to the preferred embodiment or specific examples disclosed in the specification. See e.g., *Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1303 (Fed. Cir. 1997);* see also *Intervet America, Inc. v. Kee-Vet Laboratories, Inc., 887 F.2d 1050, 1053 (Fed. Cir. 1989)* (explaining that it is "improper" to read an extraneous limitation from the specification into the claim).

Claim 6 of BASF's *'545* patent is the only claim at issue in this case. Claim 6 claims a process for the catalytic rearrangement of EpB to DHF

> which consists essentially of the rearrangement being catalyzed by a system which contains components A and C from 60 [degrees] to 200 [degrees] C where A is an onium halide, which is substantially soluble in the reaction medium, and C is a Lewis acid or elemental iodine with the proviso that at least one of the components A or C is an iodide.

BASF and Eastman dispute the meaning of two phrases of claim 6. They dispute the meaning of "consists essentially of," and "substantially soluble in the reaction medium."

1. What Does "Consists Essentially Of" Mean?

BASF argues that the phrase "consists essentially of" [*25] means virtually solvent free, and therefore, a small amount of component B, solvent or solubilizer, can be present in the reaction. Eastman argues that "consists essentially of" precludes the use of component B, solubilizers.

BASF argues that the terms solvent and solubilizer are synonymous, that component B includes both terms, and that claim 6 permits the addition of small amounts of either. Eastman distinguishes between the terms, arguing that solvents and solubilizers perform different functions, that component B encompasses solubilizers only, and that claim 6 excludes the addition of component B. Accordingly, before the court construes whether the phrase "consists essentially of" permits the addition of component B, the court must determine whether component B includes both solvents and solubilizers.

The patent describes component B as an organic solubilizer. At column 2, lines 61 to 66, the patent specification explains that because the only requirements that component B has to meet are "bringing about the dissolution of component A and otherwise being stable and inert under the reaction conditions, a large number of substances can be used as component B." Column 2, line 66 [*26] to column 3, line 50 of the *'545* patent gives examples of solubilizers that can be used in the catalyst system, including dioxane, tetrahydrofuran, and certain podands. Thus, the patent defines a solubilizer as an element which dissolves component A.

Column 3, line 68, of the patent discusses certain inert solvents, explaining that specific solvents can be used "for diluting the reaction mixture." The patent specification also gives examples of solvents that can be used for this purpose, including toluene and xylene. Thus, the patent defines a solvent as an element which dilutes the reaction mixture. Accordingly, the patent distinguishes between solubilizers and solvents, teaching that a solubilizer makes component A more soluble in the reaction medium, while a solvent dilutes the reaction medium.

Furthermore, during the prosecution of the *'545* patent, BASF's patent attorney specifically distinguished between solubilizers and solvents, emphasizing that "organic solubilizers" are distinct from solvents. The attorney wrote to the PTO:

> The term "organic solubilizer" is also carefully defined by the Fischer [*'545*] specification as being 'complexing agents for the salts A' or [*27] closely equivalent complexing solvents. This "organic solubilizer" is not an "inert solvent" such as those listed in col. 3, lines 64-68, including xylene and toluene, etc. Fischer makes it quite clear that such "inert solvents" are not suitable as an organic solubilizer but may be optionally added as a diluent.

Thus, the court concludes that solvents and solubilizers have distinct meanings and that component B, an "organic solubilizer," includes solubilizers only.

The court must now determine what the phrase "consists essentially of" means, and whether it permits the addition of component B. The phrase "consists essentially of" is not unique to the *'545* patent. [HN5] The Federal Circuit has stated that the "limited phrase 'consisting essentially of'" does not "exclude the addition of another ingredient which does not materially affect the characteristics of the invention." *Water Techs. Corp. v. Calco, Ltd., 850 F.2d 660, 666 (Fed. Cir. 1988).* The Federal Circuit has also stated that "consists essentially of" does "close the claims to other ingredients that do alter the basic and novel characteristics of the invention." *Neville Chem. Co. v. Resinall Corp., 915 F.2d 1584, 1990 WL 135903,* [*28] at *1 (Fed. Cir. 1990).

The *'545* patent originally included six claims. Claims 1 to 5 all included component B, an organic solubilizer, as an essential element of the catalyst system. Component B's role in the catalyst system was to bring component A into solution. Claim 6, however, covered a catalyst system in which component A, an onium halide, is "substantially soluble," thereby eliminating the need for an organic solubilizer. The patent specification refers to onium halides as having an "intrinsic solubility." If something is intrinsically soluble, it is inherently capable of dissolving and does not need an additional component to put it into solution. Because the court defines solubilizer as an element that makes component A soluble, it follows that something that is intrinsically soluble does not need a solubilizer to help it dissolve.

The patent specification also states that certain onium halides are soluble enough such that "virtually no addition of solubilizer B is necessary." BASF argues that "virtually no addition" means that some solubilizer B can be added. However, this statement must be read in connection with the following sentence which states that "[a] [*29] procedure of this type [with virtually no addition of solubilizer] is equivalent to the claimed process." This language was part of the patent specification prior to the addition of claim 6. Thus, the "claimed process" referred to is the process covered by claims 1 to 5, in which the addition of solubilizer, regardless of how little, constituted a basic and novel characteristic of the process.

During the prosecution of the original *'545* patent application, which included claims 1 to 5 only, the patent examiner relied on the specification language when he noted that solubilizer may not be necessary when certain halides are used as component A. On November 6, 1990, the examiner suggested what eventually became claim 6 of the *'545* patent when he wrote that "this 'no solubilizer' embodiment is intended to be covered by the claims."

As noted above, one of the "basic and novel characteristics" of claim 6 is that component A is "intrinsically soluble." Because it is "intrinsically soluble" component B does not need to be added to make it soluble. In fact, the reason BASF eventually added claim 6 was because of the patent examiner's recognition that certain onium halides do not need the [*30] addition of component B to bring them into solution. BASF even admits this, stating in their argument that "[a] basic and novel characteristic of claim 6 is that it is a catalytic process for converting EpB to DHF which can be carried out virtually neat." Therefore, the addition of component B, a solubilizer, is not necessary and would alter this inherent trait.

Accordingly, the court concludes that the phrase "consists essentially of" excludes the addition of any component B, a solubilizer.

2. What Does "Substantially Soluble in the Reaction Medium" Mean?

BASF argues that the phrase "substantially soluble in the reaction medium" can be construed in three different ways.

First, BASF argues that the term "reaction medium" is not limited only to the EpB reactant and the DHF product, and that the "reaction medium" includes the chemical components of the reaction or by-products of EpB, such as oligomer. Eastman argues that "reaction medium" means only the EpB reactant and DHF product.

Second, BASF argues that "substantially soluble in the reaction medium" means that small amounts of solubilizer or solvent can be added. Eastman argues that the phrase "substantially soluble in [*31] the reaction medium" means that no solubilizers need to be added.

Third, BASF argues that the phrase "substantially soluble in the reaction medium" only includes a liquid-phase homogenous process, which means a liquid EpB feed, liquid catalysts, and liquid end products. Eastman argues that the phrase does not preclude a process in which EpB is fed in gas form, the catalyst system is liquid, and the end product is in gas form, because having catalysis in a liquid phase is the only phase-related limitation implicit in claim 6.

a. Does the term "reaction medium" include only EpB and DHF?

At column 2, lines 56 to 61 of the *'545* patent, the specification states that "component B of the catalyst system must, because it acts as solubilizer for component A, be chosen such that the particular salts A dissolve in the reaction medium, i.e. in particular in the alkenyloxirane II and in mixtures thereof with the dihydrofuran I which are produced during the reaction." This is the only place in the patent where "reaction medium" is described. Because the language of the patent itself is not clear as to the definition of "reaction medium," the court will turn to the prosecution history for [*32] a definition of the term "reaction medium."

During the prosecution of the *'545* patent, BASF attorneys defined reaction medium as EpB and DHF alone, when they wrote about limiting component A to an onium halide "'which is substantially soluble in the liquid reaction medium,' i.e. in the epoxy-butene [EpB] itself or its dihydrofuran [DHF] product." BASF attorneys also wrote that "Fischer Claim 6 is applicable only to those onium halides which are substantially soluble in the liquid epoxybutene or its products. Otherwise it would be necessary to add the organic solubilizing component B as in Fischer Claim 1." Furthermore, the "advantage of the process of Fischer Claim 6 is that no other solvent is required except the liquid epoxyalkene reactant itself (or its products) as the solvent capable of acting as the organic solubilizer for the onium halide catalyst to produce a single homogenous liquid phase."

Accordingly, the prosecution history demonstrates that the reaction medium consists of the EpB and the DHF only.

b. Does the phrase "substantially soluble in the reaction medium" include the addition of solubilizer?

BASF argues that because component A, the onium halide, [*33] need only be "substantially soluble," some solubilizer can be added. However, there is no evidence that the patent requires that all of component A dissolve. Rather, the patent focuses on the reaction that occurs during the catalytic rearrangement of EpB to DHF. Thus, the onium halide need only be soluble enough for catalysis to occur. Thus, "substantially soluble" does not mean that some solubilizer must be added to dissolve any remaining portion of component A.

Additionally, as noted above, the language used in the prosecution history also demonstrates that the phrase "substantially soluble in the reaction medium" means that no solubilizer is necessary. During the prosecution of the *'545* patent, BASF attorneys contended that the language "substantially soluble in the liquid phase reaction medium" constitutes "an essential limitation which omits any need for a third component which is an organic solubilizer B as set forth in Fischer Claim 1." Furthermore, BASF wrote that "claim 6 was added to the

Fischer U.S. application to provide separate and explicit protection for this two-component catalyst system in the liquid phase reaction." This language makes it clear that claim 6 does [*34] not include the addition of any solubilizer.

Accordingly, the court concludes that the phrase "substantially soluble in the reaction medium" excludes the addition of any solubilizer.

c. Does the phrase "substantially soluble in the reaction medium" exclude gas feed processes?

As noted above, claim 6 precludes the addition of solubilizer because component A, the onium halide, is soluble enough for catalysis to occur without the addition of component B. Because component A is soluble it is capable of being dissolved, and if it is dissolved, it is in a liquid state. Therefore, if a required element of claim 6 is that component A is soluble in the reaction medium, it necessarily follows that the catalyst system must be in liquid phase.

Aside from the requirement that the catalyst system be in liquid phase, claim 6 does not impose any additional limitations on the form in which the catalytic rearrangement occurs. Rather, because claim 6 describes the catalyst system, and the reaction medium, it addresses the point at which catalytic rearrangement occurs, not any time before or after. Accordingly, there is no limitation on whether the EpB is added in gas form, or the DHF is removed [*35] as a gas, so long as the conversion from EpB to DHF occurs in a liquid phase. This comports with the court's construction of the term "reaction medium" to mean only EpB and DHF, as component A must be in liquid form as the EpB converts to DHF.

The court concludes that the only phase-related requirement of claim 6 is that the reactant and the catalyst are dissolved in the same liquid phase. Therefore, the phrase "substantially soluble in the reaction medium" does not exclude gas feed processes. Rather, it only means that the catalysis must occur in a liquid phase.

B. Infringement

BASF argues that Eastman's production of DHF at Longview infringes claim 6 of the *'545* patent, and that Eastman is wilfully infringing. Eastman argues that it is not infringing.

1. Does The Longview Process Infringe Claim 6 Of The *'545* Patent?

[HN6] Section 271(a) of the Patent Act states that "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." *35 U.S.C. § 271*(a).

BASF argues that the Longview process [*36] infringes claim 6 of the *'545* patent because Eastman catalytically rearranges EpB to DHF using a virtually solvent free process including a catalyst system of a Lewis acid and an onium halide which is "substantially soluble in the reaction medium" in a specific temperature range. Thus, BASF argues that the Longview process meets every element of claim 6. Eastman argues that claim 6 excludes the addition of solubilizer, and because the Longview process includes the addition of solubilizer Eastman is not infringing.

The Longview process begins with a catalyst system including onium halide, THF, and Lewis; acid. The purpose of adding the THF to the EpB is to help dissolve the onium halide. Accordingly, consistent with this court's definition, THF acts as a solubilizer because its purpose is to dissolve component A, the onium halide. The *'545* patent specification identifies THF as a solubilizer at column 3, line 59. Thus, at startup the Longview process does not infringe claim 6 of the *'545* patent because of the addition of a solubilizer. However, BASF argues that because the THF is promptly removed from the system, the Longview process is run solubilizer-free and therefore, infringes [*37] claim 6.

As the THF is removed from the system, and the DHF is produced, approximately 3% of the EpB is converted to oligomer. Eastman builds up the oligomer to where it constitutes a substantial proportion of the system, and recycles it back into the system. The purpose of the oligomer is to help keep the onium halide in a liquid state. Accordingly, consistent with this court's definition, the oligomer acts as a solubilizer. Dr. George W. Gokel, Eastman's chemistry expert, testified at trial that the oligomer used in the Longview process is a podand. At column 3, lines 36 to 51, of the *'545* patent, podands are identified as solubilizers. Thus, the Longview process is run with the continuous addition of solubilizer.

The court determined that claim 6 of the *'545* patent precludes the addition of solubilizer. The Longview process uses two different solubilizers, THF and oligomer, in the production of DHF. Accordingly, the Longview process does not infringe claim 6 of the *'545* patent.

2. Is Eastman Wilfully Infringing Claim 6 Of The *'545* Patent?

Because the court concludes that Eastman's production of DHF at Longview does not infringe claim 6 of the *'545* patent, the court concludes [*38] that Eastman is not wilfully infringing claim 6 of the *'545* patent.

C. Invalidity

Eastman argues that claim 6 of the *'545* patent is invalid on the grounds that Eastman's prior reductions to

practice establish priority of invention pursuant to § 102(g). [HN7] Section 102(g) provides that a person is entitled to a patent unless

> before the application's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

35 U.S.C. § 102(g). Eastman argues that the gas feed work of Monnier and Low, and Falling's experiments, constitute prior reductions to practice, and that the '208 application disclosed the results of their experiments. BASF argues that claim 6 of the *'545* patent is not invalid because Monnier and Low's work does not meet the limitations of claim 6, and because Falling abandoned, suppressed, [*39] or concealed his experiments.

[HN8] Claim 6 of the *'545* patent is presumed to be valid. See *35 U.S.C. § 282*. Eastman bears the burden of proving invalidity by clear and convincing evidence. See *Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 935* (Fed. Cir.), cert. denied, *498 U.S. 920, 112 L. Ed. 2d 250, 111 S. Ct. 296 (1990)*. Clear and convincing evidence is shown when the trier of fact has "an abiding conviction that the truth of [the] factual contentions [is] highly probable." *Colorado v. New Mexico, 467 U.S. 310, 316, 81 L. Ed. 2d 247, 104 S. Ct. 2433 (1984)*.

1. Does The Work Of Eastman's Scientists Constitute Prior Reduction to Practice Of Claim 6?

[HN9] To show prior reduction to practice, Eastman must show that its work "meet[s] every element of the claimed invention" before August 8, 1989, the priority date of the *'545* patent application. *Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1378 (Fed. Cir. 1986)*, cert. denied, *480 U.S. 947, 94 L. Ed. 2d 792, 107 S. Ct. 1606 (1987)*. See also *UMC Electronics Co. v. United States, 816 F.2d 647, 651 (Fed. Cir. 1987)*, [*40] cert. denied, *484 U.S. 1025, 98 L. Ed. 2d 761, 108 S. Ct. 748 (1988)* (stating that [HN10] "there cannot be a reduction to practice of the invention here without a physical embodiment which includes all limitations of the claim").

This court has construed claim 6 to mean the catalytic rearrangement of EpB to DHF at temperatures between 60 [degrees] and 200 [degrees] C, using a catalyst system including a Lewis acid and an onium halide that is "substantially soluble in the reaction medium," where the reaction medium includes the EpB and the DHF alone. The court concluded that claim 6 precludes the addition of any solubilizer, but permits the addition of solvent. Additionally, the court concluded that, as long as the catalysis occurs in a liquid phase, claim 6 has no other phase-related requirements. Thus, in order to establish a prior reduction to practice, Eastman must show an experiment that meets all of these elements of claim 6.

In December 1987, Eastman scientists created an EpB team to develop a process for converting EpB to DHF. This team included Falling, Monnier, and Low. In June 1988, Falling began to experiment with different catalyst systems for catalytically [*41] rearranging EpB to DHF. Falling's experiments included EpB in liquid form, liquid-phase catalysis, and the production of liquid DHF.

Eastman asserts that two types of experiments performed by Falling constitute a prior reduction to practice. First, Falling conducted solubilizer-free experiments using a catalyst system of an onium halide and a Lewis acid, and optionally including a solvent. Second, Falling conducted neat experiments, solubilizer- and solvent-free, using a catalyst system of an onium halide and a Lewis acid.

On June 9, 1988, Falling mixed a Lewis acid, an onium halide, and a solvent with EpB at 100 [degrees] C. This produced 4.4% DHF. Falling used tetrabutylammonium iodide as the onium halide. At trial, both Falling and Eastman's chemical engineering expert, Dr. Bruce Gates, testified that this particular onium halide is substantially soluble in EpB and DHF, the reaction medium. Falling conducted similar experiments on June 15, and June 28, and June 30, 1988, switching the temperature in the first, switching the Lewis acid in the second, and switching the solvent in the third. On October 3, 1988, Falling catalytically rearranged EpB to DHF by mixing a Lewis acid [*42] (tributyltin iodide), an onium halide (tetrabutylphosphonium iodide), and a solvent (toluene), at 150 [degrees] C.

Falling also conducted three neat experiments, without any solubilizer or solvent. On July 6, 1988, Falling obtained 71.2% DHF when he mixed EpB with a Lewis acid (zinc iodide) and an onium halide (tetrabutylammonium iodide) at 66 [degrees] to 70 [degrees] C. In a memo written two days latter to the EpB team, Falling reported that this mix of zinc iodide and tetrabutylammonium iodide is the "best catalyst system studied thus far." On July 18, and July 27, 1988, Falling conducted two more neat experiments, both of which resulted in the production of trace amounts of DHF.

While Falling conducted his experiments, Monnier and Low were also experimenting with various catalyst combinations to convert EpB to DHF. In November 1988, Monnier and Low began to experiment with the onium halide, Lewis acid catalyst system that Falling found so successful to the catalytic rearrangement of EpB to DHF. Between November 1988 and January 1990, Monnier and Low ran numerous experiments converting EpB to DHF using a catalyst system of a Lewis acid and an onium halide at 110 [degrees] [*43] to 185 [degrees] C. All of these experiments were conducted without solvent or solubilizer.

Monnier's and Low's experiments were all gas feed. However, the court has construed claim 6 to mean that only the catalysis must occur in liquid phase. Both Monnier and Low testified at trial that the catalysis occurred in a liquid phase. Monnier stated that

> somewhere in this region after the tetraoctylammonium iodide has melted and formed a liquid phase, we have a situation were the EpB, which was added as a gas composition, actually dissolves into the liquid octyl ammonium iodide and now we have a classic situation of homogenous catalysis where the reaction is occurring between EpB in the liquid phase and [octyl] ammonium iodide which is liquid-phase film.

Accordingly, all of these experiments conducted by Falling, Monnier, and Low, resulted in the catalytic conversion of EpB to DHF using component A, an onium halide, where component A is substantially soluble in the reaction medium, and component C, a Lewis acid, at the relevant temperature range. Although some of these experiments included the addition of a solvent, none included solubilizer, component B. Falling's, Monnier's, [*44] and Low's experiments, with or without solvent, successfully converted EpB to DHF meeting all of the limitations of claim 6.

Accordingly, Eastman has shown by clear and convincing evidence that these experiments constitute prior reductions to practice of claim 6 of the *'545* patent before August 8, 1989, and unless Eastman abandoned, suppressed or concealed the experiments, they establish priority of invention pursuant to § 102(g).

2. Did Eastman Abandon, Suppress, Or Conceal Its Experiments?

BASF admits that Falling's neat experiments are within the scope of claim 6. However, BASF argues that Eastman abandoned, suppressed, or concealed, these experiments. Furthermore, as discussed above, BASF argues that Monnier's and Low's experiments are not within the scope of claim 6, and therefore, the question of abandonment, suppression, or concealment is not relevant to their work.

[HN11] In order to show that Eastman did not abandon, suppress, or conceal experiments within the scope of claim 6, Eastman must show that it disclosed the process of claim 6 in a manner that would "bring the benefit of the knowledge of [the] invention" to the public, and that it did not unreasonably delay this [*45] disclosure. See *Checkpoint Systems, Inc. v. United States Int'l Trade Comm'n, 54 F.3d 756, 761 (Fed. Cir. 1995).* See also *National Presto Indus., Inc. v. Black & Decker (U.S.) Inc., 1995 U.S. App. LEXIS 15568,* Nos. 92-1388, -1476, *1995 WL 367072,* at *6 (Fed. Cir. June 20, 1995) (stating that [HN12] it "is necessary to consider the nature and extent of activity during the period between reduction to practice and the filing of the patent application"); *Lutzker v. Plet, 843 F.2d 1364, 1366 (Fed. Cir. 1988)* (noting that an invention that is not publicly disclosed is deemed abandoned, suppressed, or concealed).

Eastman filed the '208 patent application on March 8, 1990. This application primarily disclosed the gas feed, liquid phase catalyst work done by Monnier and Low, which constitutes prior reductions to practice of claim 6. Accordingly, they did not abandon, suppress, or conceal their experiments. Even if the court concluded that Monnier's and Low's work was not a prior reduction to practice of claim 6, the evidence shows that Eastman did not abandon, suppress, or conceal Falling's experiments which constitute prior reductions to practice.

Falling, Monnier, and Low [*46] worked from the early summer 1988 to the beginning of 1990 to create a successful process for catalytically rearranging EpB to DHF. During this time, Falling conducted numerous experiments which constitute prior reductions to practice of claim 6. Falling's monthly reports documented the progress of these experiments. Over a year after Falling first began to experiment with different catalyst systems, he wrote in an August 1, 1989, memo to the EpB team, that "the screening of catalyst systems for the homogenous rearrangement of EpB to 2,5-DHF is still in progress." Accordingly, it is clear that Eastman did not abandon Falling's experiments producing DHF from EpB. See *Checkpoint 54 F.3d at 762* (finding that a four year delay between the time the inventor disclosed his invention to his employer, "further tested" and improved the invention, and worked towards commercializing it, "establish that [the inventor] was diligent in working toward commercializing" the security system, and did not constitute abandonment).

Although Eastman did not abandon Falling's experiments which establish prior reduction to practice, if

Eastman suppressed or concealed them, they will not [*47] invalidate claim 6. Eastman filed the '208 application in March 1990, and the CIP in December 1990. BASF argues that neither the original application nor the CIP disclose Falling's work, and therefore, Eastman suppressed or concealed Falling's prior reductions to practice of claim 6.

Although the '208 application did not include any working examples of Falling's experiments, it generally covered Falling's work. The '208 application disclosed a process for the catalytic rearrangement of EpB to DHF using a catalyst system of an onium halide and a Lewis acid. In June 1988, Falling first discovered that mixing an onium halide and a Lewis acid would act as a successful catalyst. Monnier and Low began using this catalyst system in November 1988, after seeing the results Falling was obtaining with it.

The '208 application also discussed the optional use of an inert solvent, which Falling had experimented with. In particular, on page 14, lines 14 to 24, the '208 application states that the "organic onium iodide, optionally, in combination with a Lewis acid co-catalyst, may be used with an inert organic solvent if desired." It further refers to the "optional, inert organic solvent."

Furthermore, [*48] on page 3, lines 5 to 8 of the '208 application, it states that the process contemplated includes recovery of the DHF produced by various methods, including "decantation" and "filtration." Monnier testified at trial that both decantation and filtration mean the removal of a liquid-phase product. Falling's work was done entirely in liquid phase, whereas Monnier's and Low's work was gas feed of EpB and a gas product of DHF.

Eastman filed the CIP on December 14, 1990. The CIP was based on Falling's and Lopez-Maldonado's invention report. The CIP described the catalyst systems made up of onium halides and Lewis acids that Falling had worked on. Furthermore, the CIP added working examples of liquid phase experiments to the '208 application. Thus, the CIP clearly disclosed Falling's work on converting EpB to DHF.

[HN13] The Federal Circuit has stated that "when determining whether an inventor has abandoned, suppressed, or concealed an invention, a period of delay between completion of the invention and subsequent public disclosure" is not always of legal significance. *Checkpoint, 54 F.3d at 761.* Falling last conducted a reduction to practice of claim 6 on October 3, 1988. Eastman [*49] filed the '208 patent application on March 8, 1990, approximately seventeen months later. Eastman filed the CIP on December 14, 1990, approximately twenty-six months later. The amount of time that elapsed between Falling's last reduction to practice and the filing of the '208 patent application, and even the CIP, does not demonstrate suppression or concealment. See e.g., *Cochran v. Kresock, 530 F.2d 385, 393 (C.C.P.A. 1976)* (in a case involving a delay of over 18 months, stating that [HN14] "mere delay, without more, is insufficient" to demonstrate abandonment, suppression, or concealment); *Fisher and Speer v. Gardiner and Aymami, 215 U.S.P.Q. 620* (PTO Bd. of App. 1981) (finding that a delay of 25 months between reduction to practice of the invention and filing the patent application did not constitute suppression or concealment).

In *Engelhardt v. Judd, 54 C.C.P.A. 865, 369 F.2d 408, 412 (C.C.P.A. 1966),* the United States Court of Customs and Patent Appeals stated that [HN15] scientists should be given a reasonable amount of time to refine their invention. The Englehardt court stated that

> [a] reasonable amount of time should be allowed [*50] for completion of the research project on the whole series of new compounds, a further reasonable period should then be allowed for drafting and filing the patent application(s) thereon, without subjecting the prior inventor or his assignee to the risk of forfeiture of valuable patent rights due to alleged concealment or suppression of the invention.

Id. The seventeen to twenty-six month period that elapsed between Falling's reduction to practice and the filing of the '208 application and the CIP constitutes a reasonable amount of time. Thus, the court concludes that Eastman did not suppress or conceal the work Falling did during the summer and fall of 1988.

The court concludes that Eastman did not abandon, suppress, or conceal the prior reductions to practice of claim 6 of the *'545* patent, and therefore, claim 6 is invalid on the grounds of priority of invention pursuant to § 102(g).

III. CONCLUSION

For the reasons stated above, the court concludes that Eastman is not infringing claim 6 of the *'545* patent, claim 6 is invalid on the grounds of priority of invention pursuant to § 102(g), and Eastman did not abandon, suppress, or conceal the invalidating prior [*51] reductions to practice. The court will enter an order in accordance with this memorandum opinion.

LEXSEE 2006 US APP LEXIS 16665

MOMENTUS GOLF, INC., Plaintiff-Appellant, v. SWINGRITE GOLF CORPORATION (also known as Swingrite Corporation), Defendant-Appellee, and GRIPS FORE GOLF and J & M GOLF, INC., Defendants.

05-1614

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2006 U.S. App. LEXIS 16665

June 30, 2006, Decided

NOTICE: [*1] THIS DECISION WAS ISSUED AS UNPUBLISHED OR NONPRECEDENTIAL AND MAY NOT BE CITED AS PRECEDENT. PLEASE REFER TO THE RULES OF THE FEDERAL CIRCUIT COURT OF APPEALS FOR RULES GOVERNING CITATION TO UNPUBLISHED OR NONPRECEDENTIAL OPINIONS OR ORDERS.

PRIOR HISTORY: *Momentus Golf v. Swingrite Golf Corp., 2005 U.S. Dist. LEXIS 17850 (S.D. Iowa, Aug. 23, 2005)*

CASE SUMMARY:

PROCEDURAL POSTURE: In a patent infringement action, plaintiff applicant sought review of a decision of the U.S. District Court for the Southern District of Iowa, which granted summary judgment in favor of defendant golf corporation, finding that the prosecution history of the patent in question, which covered a golf club swing aide, disclaimed any device having more than 10 percent club head weight.

OVERVIEW: The issue was whether, during the prosecution of the patent, the applicant disclaimed devices having a club head weight of more than 10 percent. The appellate court concluded that the statement in the prosecution history that a hollow device having 10-25 percent club head weight could not meet the requirement in applicant's claims that the center of gravity of the trainer be substantially at the center of a solid round stock was open to more than one reasonable interpretation. Thus, according to the appellate court, the statement was not a clear and unmistakable disclaimer of all devices having 10-25 percent club head weight. At most, it disclaimed hollow devices having 10-25 percent club head weight. Accordingly, the federal district court erred in its claim construction to the extent that it determined that all devices having 10-25 percent club head weight fell outside of the scope of the claims of the patent. Therefore, the appellate court vacated the judgment of the district court and remanded for further proceedings consistent with its opinion.

OUTCOME: The appellate court reversed and remanded.

LexisNexis(R) Headnotes

Civil Procedure > Appeals > Standards of Review > De Novo Review
Patent Law > Infringement Actions > Claim Interpretation > General Overview
Patent Law > Infringement Actions > Summary Judgment > Claim Evaluation
Patent Law > Jurisdiction & Review > Standards of Review > De Novo Review
[HN1] The U.S. Court of Appeals for the Federal Circuit reviews a district court's grant of a motion for summary judgment of no infringement de novo. Similarly, it reviews the district court's claim construction de novo.

Patent Law > Infringement Actions > Claim Interpretation > General Overview
Patent Law > Infringement Actions > Prosecution History Estoppel > Abandonment & Amendment
[HN2] The purpose of the doctrine of prosecution disclaimer is to prevent a patentee from recapturing through claim interpretation meanings that he disclaimed during prosecution. Any such disclaimer must be clear and unmistakable. The U.S. Court of Appeals for the Federal Circuit has explained, however, that there is no clear and unmistakable disclaimer if a prosecution argument is subject to more than one reasonable interpretation, one of

which is consistent with a proffered meaning of the disputed term.

JUDGES: Before SCHALL, Circuit Judge, ARCHER, Senior Circuit Judge, and DYK, Circuit Judge. Opinion for the court filed by Senior Circuit Judge ARCHER. Dissenting opinion filed by Circuit Judge SCHALL.

OPINIONBY: ARCHER

OPINION: ARCHER, Senior Circuit Judge.

Momentus Golf, Inc. ("Momentus") appeals the judgment of the United States District Court for the Southern District of Iowa granting Swingrite Golf Corporation's ("Swingrite") motion for summary judgment. *Momentus Golf, Inc. v. Swingrite Golf Corp., 2005 U.S. Dist. LEXIS 17850, No. 4:02-cv-40252 (S.D. Iowa Aug. 23, 2005)*. Because the district court erred in concluding that the prosecution history of *U.S. Pat. No. 5,582,407* ("the *'407 patent*") disclaimed any device having more than 10% club head weight, we vacate the court's judgment and remand for further proceedings.

I

The *'407 patent* is directed to a golf club swing aide. Relevant to this appeal, claim 1 of the *'407 patent* states:

> A golf swing trainer [*2] consisting essentially of a golf grip fixed about one end of a length of round stock which is solid through it[s] length and cross-section, sol[i]d round stock, said trainer having a center of gravity substantially centered at a midpoint of a longitudinal axis of said length of roundstock, and the weight of said round stock being heavier than a typical golf club so that repeated swings of the trainer establishes a muscle memory of the path of the swing, breaking down the incorrect muscle memory and building the correct muscle memory of the path of the swing.

'407 patent, col. 5, ll. 4-13. Claim 9 adds the element of a "golf club head fixed to another end of said length of stock." Id. at col. 4, ll. 12-13.

Momentus sued Swingrite for infringement of the *'407 patent*. n1 When construing claim 1, the district court concluded that "during the prosecution of its claim, Momentus conceded that the center of gravity of a device with a club head weight of 10-25 percent would not be substantially centered at a midpoint of the shaft and therefore cannot meet the requirements of Momentus' claims." *Momentus Golf, Inc. v. Swingrite Golf Corp., 312 F. Supp. 2d. 1134, 1143 (S.D. Iowa 2004)* [*3] ("Claim Construction Order"). Based on this perceived disclaimer and the fact that the "novel property of the Momentus trainer is that its center of gravity is substantially centered at the midpoint of its solid round shaft," *id. at 1144*, the district court "construe[d] the phrase 'consisting essentially of' in Claim 1 as excluding any element [that] if added to the device would constitute more than 10 percent club head weight, because such an element would materially alter the novel property of the invention," *id. at 1144*.

> n1 Grips Fore Golf and J & M Golf were named defendants in the originally filed suit. Neither party, however, participated in this appeal.

Following the district court's claim construction ruling, Swingrite filed a motion for summary judgment of no infringement, which the district court granted. Momentus appeals, arguing that there was no prosecution disclaimer and that the district court erred by reading into the claim a requirement that the weight of the club head constitute less than ten percent of the device's weight. We have jurisdiction pursuant to *28 U.S.C. § 1295(a)(1)*.

II [*4]

[HN1] We review the district court's grant of Swingrite's motion for summary judgment of no infringement de novo. *Hilgrave Corp. v. McAfee Assocs., Inc., 224 F.3d 1349, 1352 (Fed. Cir. 2000)*. Similarly, we review the district court's claim construction de novo. *Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998)* (en banc).

The issue in this case is whether, during the prosecution of the *'407 patent*, the applicant disclaimed devices having a club head weight of more than 10%. [HN2] The purpose of the doctrine of prosecution disclaimer is to prevent a patentee from recapturing through claim interpretation meanings he disclaimed during prosecution. *SanDisk Corp. v. Memorex Prods., Inc., 415 F.3d 1278, 1286 (Fed. Cir. 2005)* (citations omitted). Any such disclaimer must be clear and unmistakable. Id. (stating "[w]hen the patentee makes clear and unmistakable prosecution arguments limiting the meaning of a claim term in order to overcome a rejection, the courts limit the relevant claim term to exclude the disclaimed matter" (citing *Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1324 (Fed. Cir. 2003)*)). [*5] We have explained, however, that "[t]here is no 'clear and unmistakable' disclaimer if a prosecution argument is subject to more than one reasonable interpretation, one of which is consistent

with a proffered meaning of the disputed term." *Id. at 1287* (citing *Golight, Inc. v. Wal-Mart Stores, Inc., 355 F.3d 1327, 1332 (Fed. Cir. 2004)*; *Cordis Corp. v. Medronic Ave, Inc., 339 F.3d 1352, 1359 (Fed. Cir. 2003)* (finding no disclaimer because "the statements in the prosecution history are subject to multiple reasonable interpretations, they do not constitute a clear and unmistakable departure from the ordinary meaning of the term [at issue]").

During prosecution of the *'407 patent*, the examiner initially rejected the claims as being anticipated by or obvious in view of *U.S. Pat. No. 3,231,281* ("Wallo"). Wallo describes a golf club swing aide that "provide[s] effective and proper toning and strengthening of the body muscles while simultaneously and automatically guiding the body movements into proper coordination." Wallo at col. 1, ll. 31-36. It accomplishes this by using a "club" that is three to five times the weight of a standard golf club. [*6] Id. at col. 2, ll. 9-10. Wallo's golf club swing aide is described as hollow, id. at col. 1, ll. 71-72, col. 2, line 37; however, the patent also explains that if the shaft and head are made of lighter material, "the proper weight may be provided by filling the hollow shaft and head with a material of appropriate density," id. at col. 2, ll. 36-39.

In responding to the examiner's rejection, the '407 applicant distinguished the claimed invention from Wallo:

> The shaft [in Wallo] is hollow. The overall weight of the trainer is such as to require a firmer grip, to strengthen the hands and to slow the swing. The down swing is resisted by the "excessive weight of the club." The trainer causes "toning and strengthening of the muscles by swinging the excessive weight." Unlike Wallo, applicant's trainer has a solid shaft, uses no club head and substantially 100% of the trainer weight is non club head weight. A hollow device having 10-25% club head weight cannot meet the requirement in applicant's claims that the center of gravity of the trainer be substantially at the center of a solid round stock. Furthermore, as explained above, and as set forth in greater detail [*7] in claim 11 and in even greater detail in claim 12 of the present application, the claimed weighting of applicant's device is related to changing the memory and not the strength of the muscles involved in the swing and to changing the path of the swing due to balance rather than changing the speed of the swing due to weight. Applicant therefore submits that applicant's present invention is neither anticipated by Wallo, which does not disclose the structure claimed by applicant, nor obvious over Wallo, which teaches an entirely different concept of golf swing training and is not applicable to the principles taught by applicant.

(key sentence in dispute emphasized). Because the claimed invention could not be distinguished from Wallo solely on the grounds of being solid, the district court interpreted the underlined sentence above as identifying another distinction between the claimed invention and Wallo; namely, club head weight. Based on this, the court viewed the statement as a "conce[ssion] that the device with a club head having 10-25 percent of its weight at the end of the shaft opposite the grip would fall outside the scope of the [claimed] trainer." Claim Construction [*8] Order at 1143. This reading is fathomable. However, we agree with Momentus that this sentence is open to another interpretation: the applicant was simply stating that a hollow club having 10-25% club head weight (a device described by Wallo) could not meet the claim limitation in the *'407 patent* that the club shaft have a center of gravity at the center of a solid shaft. Such a reading does not suggest that all clubs having a 10-25% club head weight are outside the scope of the invention; rather, only hollow clubs with such a characteristic fall outside the scope of the claims.

Interpreting the prosecution history in this manner does not affect the applicant's argument that the claimed invention was not anticipated by, or obvious in view of, Wallo. The applicant of the *'407 patent* distinguished the claimed invention from Wallo on grounds other than "solidness"; namely, that the two devices functioned in totally different ways. Specifically, the applicant noted that the claimed invention worked by changing the user's muscle memory and the path of the user's swing due to balance while the Wallo device worked by strengthening the user's muscles and changing the speed of the [*9] user's swing due to weight. The examiner recognized this as the distinguishing feature of the claimed invention. Thus, in an examiner's amendment prior to allowance, the examiner added language to the claim to reflect this distinction; namely, "and the weight of said round stock being heavier than a typical golf club so that repeated swings of the trainer establishes a muscle memory of the path of the swing, breaking down the incorrect muscle memory and building the correct muscle memory of the path of the swing."

We conclude that the statement in the prosecution history that "[a] hollow device having 10-25% club head weight cannot meet the requirement in applicant's claims that the center of gravity of the trainer be substantially at the center of a solid round stock," (emphasis added), is open to more than one reasonable interpretation. Thus the statement was not a clear and unmistakable disclaimer of all devices having 10-25% club head weight. See *SanDisk, 415 F.3d at 1287*; *Cordis, 339 F.3d at 1359*. At most it disclaims hollow devices having 10-25% club head weight.

Accordingly, the district court erred in its claim construction to the extent [*10] it determined that all devices having 10-25% club head weight fall outside of the scope of the claims of the *'407 patent*. Therefore, we vacate the judgment of the district court and remand for further proceedings consistent with this opinion.

DISSENTBY: SCHALL

DISSENT: SCHALL, Circuit Judge, dissenting.

I would affirm the grant of summary judgment of non-infringement. In my view, the district court correctly held that, during prosecution of the application that resulted in *U.S. Patent No. 5,582,407* ("the *'407 patent*"), the inventor disclaimed golf swing trainers having more than 10% club head weight.

Claim 1 of the *'407 patent* describes a golf swing trainer with a shaft of "sol[i]d round stock, said trainer having a center of gravity substantially centered at a midpoint of a longitudinal axis of said length of round stock." *'407 patent*, col. 5, ll. 6-8. Claim 1 was rejected during prosecution as anticipated or obvious in view of *U.S. Patent No. 3,231,281* ("the Wallo patent"). The inventor responded to the rejection by distinguishing the golf swing trainer disclosed by the Wallo patent as follows:

> In Wallo, from 75 to 90% of the weight of the trainer is in the shaft, resulting [*11] in from 10 to 25% of the weight being in the head of the trainer (col 2, lines 18-24). The shaft is hollow (col 2, lines 25-40). The overall weight of the trainer is such as to require a firmer grip, to strengthen the hands and to slow the swing (col 2, lines 41-49). The down swing is resisted by the "excessive weight of the club" (col. 2, lines 58-59). The trainer causes "toning and strengthening of the muscles by swinging the excessive weight" (col. 2, lines 69-70). Unlike Wallo, applicant's trainer has a solid shaft, uses no club head and substantially 100% of the trainer weight is non club head weight. A hollow device having 10-25% club head weight cannot meet the requirement in applicant's claims that the center of gravity of the trainer be substantially at the center of a solid round stock. Furthermore, as explained above, and as set forth in greater detail in claim 11 and in even greater detail in claim 12 of the present application, the claimed weighting of applicant's device is related to changing the memory and not the strength of the muscles involved in the swing and to changing the path of the swing due to balance rather than changing the speed of the swing due to weight. [*12] Applicant therefore submits that applicant's present invention is neither anticipated by Wallo, which does not disclose the structure claimed by applicant, nor obvious over Wallo, which teaches an entirely different concept of golf swing training and is not applicable to the principles taught by applicant.

(emphasis added). Based on the above passage, the district court found that the inventor disclaimed trainers with a club head weight between 10-25% of the weight of the trainer because those trainers would not have a center of gravity substantially centered at the midpoint of the trainer's shaft. *Momentus Golf, Inc. v. Swingrite Golf Corp., 312 F. Supp. 2d 1134, 1143 (S.D. Iowa 2004)*.

The majority concludes, however, that the above-quoted passage does not comprise a "clear and unmistakable disclaimer" of devices having 10-25% club head weight because the underlined portion of the passage can reasonably be interpreted as disclaiming golf swing trainers with a hollow shaft instead of disclaiming golf swing trainers with 10-25% club head weight. Majority Op. at 5-6. I am unable to read the passage as the majority reads it.

I read the underlined sentence of [*13] the passage as clearly and unmistakably disclaiming both (i) a device having 10-25% club head weight and also (ii) a device having a hollow shaft. The underlined sentence states, "A hollow device having 10-25% club head weight cannot meet the requirement in applicant's claims that the center of gravity of the trainer be substantially at the center of a solid round stock." (emphases added). The Wallo device differs, according to this key sentence, because it is (i) hollow rather than solid and (ii) has 10-25% club head weight as opposed to a center of gravity substantially at

the center of the shaft. The remainder of the passage, it seems to me, confirms that the underlined sentence is making two distinct disclaimers. In the first sentence of the passage, the inventor sets forth the framework for the club head weight disclaimer by noting that the Wallo device has 10-25% of its weight in the club head. In the second sentence, the inventor states that the Wallo device has a hollow shaft. Thus, the inventor sets forth these two features of the Wallo device separately. The inventor then states that "[u]nlike Wallo, applicant's trainer has a solid shaft, uses no club [*14] head and substantially 100% of the trainer weight is non club head weight." (emphases added). Again, the composition of the shaft and the club head weight are set forth as separate features by the inventor. Thus, in my view, the key sentence and the surrounding passage clearly and unmistakably disclaim both devices with a hollow shaft and devices with 10-25% club head weight. I think that this is the only reasonable interpretation of the above passage. In short, I agree with the district court's construction of "substantially centered," which limited claim 1 of the *'407 patent* to devices with less than 10% club head weight. I would thus affirm the grant of summary judgment of non-infringement. I therefore respectfully dissent.

LEXSEE 2000 US DIST LEXIS 21851

RHEOX, INC., Plaintiff, v. ENTACT, INC., Defendant.

Civil Action No. 98-3731 (MLC)

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

2000 U.S. Dist. LEXIS 21851

August 21, 2000, Filed; August 21, 2000, Entered

NOTICE: [*1] NOT FOR PUBLICATION

SUBSEQUENT HISTORY: *Affirmed by Rheox, Inc. v. Entact, Inc., 276 F.3d 1319, 2002 U.S. App. LEXIS 236* (Fed. Cir., 2002)

DISPOSITION: Defendant's motion for summary judgment GRANTED.

CASE SUMMARY:

PROCEDURAL POSTURE: Defendant sought summary judgment pursuant to *Fed. R. Civ. P. 56* on plaintiff, patent holder's, claims alleging infringement of United States Patent No. 5,162,600 (the 600 patent).

OVERVIEW: The patent holder alleged that the defendant infringed one or more claims of the '600 patent through its use of triple superphosphate (TSP) arguing that TSP was included within the definition of calcium orthophosphate in claim 1 of the '600 patent because TSP consisted primarily of monocalcium orthophosphate, which is a form of calcium orthophosphate. The alleged infringer filed the instant motion for summary judgment premised solely on the argument that the term "calcium orthophosphate," contained in claim 1 of the '600 patent, did not encompass TSP. The district court held that the prosecution history revealed that the alleged infringer limited the definition of calcium orthophosphate to tricalcium orthophosphate. The court further found that the chronology of the patent process revealed that the patent holder deleted references to TSP from its claims after the Examiner expressed objections to TSP and that this was done to overcome the Examiner's objections to the inclusion of TSP in the patent application. Accordingly, the alleged infringer's use of TSP did not infringe the '600 patent.

OUTCOME: Defendant's motion for summary judgment was granted.

LexisNexis(R) Headnotes

Civil Procedure > Summary Judgment > Burdens of Production & Proof > Movants
Civil Procedure > Summary Judgment > Standards > General Overview
[HN1] A court shall enter summary judgment when the moving party demonstrates that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. *Fed. R. Civ. P. 56(c)*. Once the moving party has satisfied this initial burden, the opposing party must establish that a genuine issue of material facts exists. The opposing party cannot rest on mere allegations; rather, it must present actual evidence that creates a genuine issue of material fact. Issues of fact are genuine only if the evidence is such that a reasonable jury could return a verdict for the non-moving party.

Civil Procedure > Summary Judgment > Standards > Appropriateness
Patent Law > Infringement Actions > Summary Judgment > Claim Evaluation
[HN2] Summary judgment is as appropriate in a patent case as in any other case when the standard for summary judgment is met. Where the parties do not dispute any relevant facts regarding the accused product, but disagree over possible claim interpretations, the question of literal infringement collapses into claim construction and is amenable to summary judgment.

Patent Law > Inequitable Conduct > General Overview
Patent Law > Infringement Actions > Claim Interpretation > Fact & Law Issues
Patent Law > Preclusion > General Overview

[HN3] Patent claim construction is a legal question to be determined exclusively by the court. The determination of infringement requires a two-step analysis. First, the claims must be construed, i.e., the legal meaning and scope of each cited claim must be determined. Second, it must be determined whether the claims so construed cover an accused product or process, i.e., whether, in fact, every limitation found in a claim is present in the accused product or process. Because claim interpretation is purely a question of law, the parties' dispute over the meaning of claim elements does not raise a genuine issue as to any material fact, so as to preclude the grant of summary judgment.

Civil Procedure > Summary Judgment > Standards > Appropriateness
Patent Law > Infringement Actions > Burdens of Proof
Patent Law > Infringement Actions > Summary Judgment > General Overview
[HN4] Once the claim construction aspect of the infringement inquiry is performed, the next step in analyzing a claim of literal infringement requires that the properly interpreted claims be compared to the accused product or device. The determination of whether the properly construed claims read on the accused device is typically a question of fact. To determine the proper meaning of a claim term, a court must consider the so-called intrinsic evidence, i.e., the claims, the written description, and, if in evidence, the prosecution history. In defining claims, courts should first look to words of the claims. The general rule is that terms in the claim are to be given their ordinary and accustomed meaning. In determining the ordinary meaning of a claim, a court should construe the claim language according to the standard of what those words would have meant to one skilled in the art as of the application date. In ascertaining the meaning of claim language to a person of ordinary skill in the art, a court may rely upon expert testimony. Courts may also rely on dictionary definitions when construing claim terms, so long as the dictionary definitions do not contradict any definition found in or ascertained by a reading of the patent documents.

Patent Law > Infringement Actions > Prosecution History Estoppel > General Overview
[HN5] A patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history.

Patent Law > Infringement Actions > Prosecution History Estoppel > General Overview
[HN6] The prosecution history contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims. As such, the record before the Patent and Trademark Office is often of critical significance in determining the meaning of claims. The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution.

Patent Law > Infringement Actions > Claim Interpretation > General Overview
[HN7] The general rule is that a claim should not be interpreted to exclude the preferred embodiment expressed in the written description. Defining a claim so that the only embodiment in the written description falls outside the scope of the patent claim is rarely, if ever, correct, and would require highly persuasive evidentiary support.

COUNSEL: For RHEOX, INC., plaintiff: LOUIS E GRANATA, GRANATA, WERNIK & ZACCARDI, ESQS., MATAWAN, NJ.

For ENTACT, INC., defendant: GUY V. AMORESANO, GIBBONS, DEL DEO, DOLAN, GRIFFINGER & VECCHIONE, PC, NEWARK, NJ.

For ENTACT, INC., counter-claimant: GUY V. AMORESANO, GIBBONS, DEL DEO, DOLAN, GRIFFINGER & VECCHIONE, PC, NEWARK, NJ.

For RHEOX, INC., counter-defendant: LOUIS E GRANATA, GRANATA, WERNIK & ZACCARDI, ESQS., MATAWAN, NJ.

For ENTACT, INC., third-party plaintiff: GUY V. AMORESANO, GIBBONS, DEL DEO, DOLAN, GRIFFINGER & VECCHIONE, PC, NEWARK, NJ.

For RMT, INC., third-party defendant: VINCENT JOHN PALUZZI, STERNS & WEINROTH, PC, TRENTON, NJ.

JUDGES: MARY L. COOPER, United States District Judge.

OPINIONBY: MARY L. COOPER

OPINION:

MEMORANDUM AND ORDER

COOPER, District Judge

This matter comes before the Court on the motion by defendant Entact, Inc. ("Entact") for summary judgment pursuant to *Federal Rule of Civil Procedure 56*. For the reasons stated, the motion for summary judgment is granted.

BACKGROUND

Plaintiff Rheox, Inc. ("Rheox") is the owner of United States Patent [*2] No. 5,162,600 (hereinafter the " '600 patent"). The '600 patent is entitled "Method of Treating Lead Contaminated Soil."

Claim 1 of the '600 patent provides:

> 1. A method of treating lead contaminated soil to reduce the amount of mobile lead contained in said soil, the method which comprises:
>
> (a) providing an agent consisting essentially of calcium orthophosphate;
>
> (b) contacting said agent with said soil to react said agent with mobile lead contained in the soil and form immobilized, water-insoluble lead compounds.

(Pl.'s Ex. 1 col. 7.)

Rheox commenced the present lawsuit on August 7, 1998. The Complaint alleges that Entact infringed one or more claims of the '600 patent through its use of triple superphosphate ("TSP"). (Compl. P8.) Rheox argues that TSP is included within the definition of calcium orthophosphate in claim 1 of the '600 patent because TSP consists primarily of monocalcium orthophosphate, which is a form of calcium orthophosphate. (Pl.'s Br. in Opp'n at 18.)

Entact filed the instant motion for summary judgment on October 21, 1999. Entact premised the motion solely on the argument that the term "calcium orthophosphate," contained in claim 1 [*3] of the '600 patent, does not encompass TSP. Entact argues that the prosecution history reveals that calcium orthophosphate cannot be interpreted to include monocalcium orthophosphate. (Def.'s Proposed Findings of Facts and Conclusions of Law ("Def.'s Facts and Conclusions") P8.) Instead, Entact argues that the term "calcium orthophosphate" is limited to an "essentially water-insoluble" material which has a solubility not substantially different from .002 grams/100 grams of H[2]O, which would include tricalcium orthophosphate but not monocalcium orthophosphate. n1 (Def.'s Br. in Reply at 1-2.) The parties have agreed that if the term "calcium orthophosphate" does not include monocalcium orthophosphate, then none of the asserted claims of the '600 patent are infringed by Entact's use of TSP. (Def.'s Facts and Conclusions P5; Pl.'s Response to Def.'s Statement of Undisputed Facts P20.)

> n1 It is undisputed that the solubility of tricalcium orthophosphate is .002 grams/100 grams of water and the solubility of monocalcium phosphate is 1.8 grams/100 grams of water. (Pl.'s Ex. 13 P3.3.)

[*4]

Rheox filed its patent application on December 28, 1990. The patent application contained 18 claims. Claim 1, as originally filed with the U.S. Patent and Trademark Office ("PTO") provided:

> 1. A method of treating lead contaminated soil to reduce the amount of mobile lead contained in said soil, the method which comprises:
>
> (a) providing an agent selected from the group consisting of calcium, zinc, magnesium or ammonium phosphate compounds, calcium, zinc, magnesium or ammonium phosphite compounds and mixtures thereof; and
>
> (b) contacting said agent with said soil to react said agent with mobile lead contained in the soil and form immobilized, water-insoluble lead compounds.

(Pl.'s Ex. 2 at 2.30.)

The original claim 2 referred specifically to TSP. Claim 2 provided:

> 2. The method of claim 1, wherein said agent comprises a calcium phosphate fertilizer selected from the group consisting of triple superphosphate and superphosphate.

(Id.)

Claim 18 also referred to TSP:

> 18. A method of treating lead contaminated soil to reduce the amount of mobile lead contained in said soil, the method which comprises:
>
> (a) providing an agent selected [*5] from the group consisting of triple superphosphate, phosphate rock, hydroxyapatite and mixtures thereof; and
>
> (b) contacting said agent with the soil in an amount of from about 1 to about 60% by weight, based on the total weight of said soil, to react said agent with said lead and form immobilized, water-insoluble lead phosphate compounds.

(Id. at 2.32.)

The written description, which is also known as the specification, of the '600 patent states that "in a preferred aspect of the invention," the calcium, zinc, magnesium or ammonium phosphate compounds should be selected from a list of compounds set forth in the patent. (Pl.'s Ex. 1 at 3.) The description then provides that "especially preferred sources of calcium phosphate treating compounds include phosphate rock, as well as fertilizers such as triple superphosphate and superphosphate." (Id.) The written description further states that (1) the phosphate agent is preferably provided in the form of a fertilizer; (2) particularly useful fertilizers include TSP and superphosphate; and (3) TSP is preferred over superphosphate. (Id. col. 4.)

The written description also contains a table of experimental runs illustrating [*6] the treatment of lead contaminated soil according to the process of the invention. (Id. col. 6.) Several of the runs were conducted using TSP as the treating agent. (Id.) The written description states that TSP provided "superior lead stabilization results." (Id. col. 7.)

As part of the original application, Rheox also filed an Information Disclosure Statement. (Pl.'s Ex. 2 at 2.38.) The Information Disclosure Statement listed as prior art, inter alia, O'Hara et al., U.S. Patent No. 4,737,356 ("O'Hara" or the "O'Hara patent"). (Id.) O'Hara discloses a method for remediating lead in the residue or "fly ash" that comes from burning solid waste in a factory. (Id.) O'Hara teaches that this contamination can be remediated by use of water soluble phosphates and that "calcium phosphate, Ca[3](PO[4])[2], is 'inoperative' in immobilizing lead" in the O'Hara invention. n2 (Id. at 2.39.)

n2 We note that the term "calcium orthophosphate" is often condensed to calcium phosphate. (Tr. of Hr'g dated 1-26-00 at 204.) The Court will use the terms interchangeably.

[*7]

The Court will now set forth the prosecution history of the '600 patent. The PTO Examiner issued his first office action on July 9, 1991, rejecting all 18 of Rheox's proposed claims. (Id. at 2.126.) The Examiner rejected the claims pursuant to *35 U.S.C. § 102*(b) as anticipated by, or alternatively under *35 U.S.C. § 103* as made obvious by, the application of commercial fertilizers such as TSP. (Id. at 2.127.) The Examiner stated in pertinent part:

> It is well known in the art that fertilizers are routinely bound (agglomerated) with conventional binders such as clays and are routinely spread and plowed into the soil. It would have been obvious to one of ordinary skill in the art to employ phosphate fertilizers for the treatment of a soil, i.e. their intended use. Immobilization of the lead present would inherently occur during or as a result of a fertilizer application for the prior art . . . .

(Id. at 2.128.)

The Examiner also rejected the claims as being unpatentable under the O'Hara patent. (Id.) The Examiner stated in pertinent part:

> O'Hara fairly teaches the use of phosphate to fix lead in particular [*8] solids. While it is granted that O'Hara exemplifies fly ash, as shown in claim 1 he is not limited thereto. The use of phosphate taught by O'Hara to fix lead in particular solids such as fly [ash] would suggest to one of ordinary skill in the art [to] similarly fix lead in other particular solids such as soil . . . .
>
> The possible urging [by Rheox] of solubility has been considered[;] however the instant compounds are water soluble to some degree. Otherwise they would not be suitable for their well known use as fertilizer.

(Id. at 2.129-28.)

Rheox filed a response to the first office action on October 4, 1991. Rheox argued that it was proposing a new and unobvious use for commercial fertilizers. (Id. at 2.172.) In support of this argument, Rheox submitted a Supplemental Information Disclosure Statement, in which Rheox cited a discussion of fertilizers contained in Van Nostrand's Scientific Encyclopedia. (Id. at 2.161, 2.173.) According to Rheox, the treatise did not suggest that fertilizers could be used to immobilize lead in contaminated soils. (Id. at 2.173-74.) Rheox also argued that the fact that fertilizers may have been used in lead contaminated [*9] soil, and therefore may have accomplished lead immobilization without the knowledge of the fertilizer user, did not render the novel use of the materials unpatentable. (Id. at 2.175.)

Rheox also addressed the argument that the claims were unpatentable under O'Hara. (Id. at 2.177.) Rheox argued, inter alia, that (1) O'Hara stated that "calcium phosphate is ineffective as a phosphate source in the immobilization of lead" under O'Hara's invention, and (2) calcium phosphate fertilizers were among the preferred materials for carrying out Rheox's invention. (Id. at 2.176-77.)

The PTO Examiner issued his second office action on January 2, 1992, again rejecting all 18 claims; however, he premised his decision only on the claims being unpatentable under O'Hara. (Id. at 2.184.) He noted that O'Hara teaches the treatment of lead contaminated solids through the formation of lead phosphate and that Rheox's application would be expected by one of ordinary skill in the art. (Id. at 2.185-86.) The Examiner rejected Rheox's attempt to distinguish its application on the basis of solubility. (Id. at 2.186.) The Examiner noted in pertinent part:

> It is well known to [*10] one of ordinary skill in the art that monocalcium phosphate is water soluble and is routinely available as super phosphate . . . and triple super phosphate. . . . The selection of water soluble phosphates such as monocalcium phosphate, known water soluble phosphates, readily available as super phosphate and triple superphosphate and sold in bulk quantities as fertilizers as water soluble phosphate for use in the process of [O'Hara] would be obvious to one of ordinary skill in the art.

(Id. at 2.186-87.)

The attorney for Rheox met with the Examiner on March 26, 1992. The Examiner's somewhat cryptic notes (the "Interview Notes") concerning the meeting provide: "Attorney urge [sic] difference based on the use of slightly soluble phosphates versus the soluble phosphates of O'Hara . . . Solubility of instant compound and compounds of O'Hara to be provided. . . ." (Id. at 2.195.)

Rheox filed a second response on April 2, 1992 (the "April 2, 1992 Response" or the "Response") that, inter alia, canceled claim 2 and amended claims 1 and 18. (Id. at 2.197.) Claim 1 no longer stated that the treating agent would be selected from a list of compounds but instead identified [*11] the agent as "consisting essentially of calcium orthophosphate." (Id. at 2.197-98.) Rheox canceled claim 2, which had identified the agent as comprising a calcium phosphate fertilizer selected from the group consisting of triple superphosphate and superphosphate. (Id. at 2.198.) Rheox also amended claim 18 to delete the reference to TSP. (Id.)

Rheox stated that it was canceling claim 2, and amending claims 1 and 18, to clarify the invention, to advance its patenability, and to distinguish the invention from the water-soluble compounds and method of treatment taught by O'Hara. (Id. at 2.198-99.) In support of this contention, Rheox "pointed out that the solubility of calcium orthophosphate is 0.002 grams/100 grams of H[2]O" and that O'Hara described this material as insoluble. n3 (Id. at 2.202.) Rheox also asserted that the water-soluble phosphates discussed by O'Hara "are believed to be thousands of times more water soluble than Applicant's preferred (and presently claimed) calcium orthophosphate material." (Id.) Rheox noted that the substantial insolubility of "the claimed compound" provides a substantial advantage--prevention of water washout of the lead [*12] immobilizing agent--which cannot be achieved by the prior art. (Id.)

> n3 It is undisputed that the solubility referred to by Rheox is the solubility of tricalcium orthophosphate: .002 grams/100 grams of water. (Pl.'s Ex. 13 P3.3.)

Rheox also stated that the prior art did not suggest that "the calcium orthophosphate material" utilized in its invention could be substituted for the materials used in O'Hara. (Id. at 2.202-03.) Rheox again noted that O'Hara indicated that "calcium orthophosphate, Ca[3](PO[4])[2]," is inoperative for immobilizing lead under the O'Hara method. (Id. at 2.203.)

The PTO granted the '600 patent on November 10, 1992. To assist in interpreting the term "calcium orthophosphate," this Court held a three-day Markman hearing

from January 26 to January 28, 2000. See *Markman v. Westview Instr., Inc., 517 U.S. 370, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996).*

DISCUSSION

[HN1] A court shall enter summary judgment when the moving party demonstrates that "there [*13] is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Fed. R. Civ. P. 56(c)*; see *Celotex Corp. v. Catrett, 477 U.S. 317, 322-23, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986).* Once the moving party has satisfied this initial burden, the opposing party must establish that a genuine issue of material facts exists. *Jersey Cent. Power & Light Co. v. Township of Lacey, 772 F.2d 1103, 1109 (3d Cir. 1985).* The opposing party cannot rest on mere allegations; rather, it must present actual evidence that creates a genuine issue of material fact. *Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986)* (quotation omitted); *Schoch v. First Fidelity Bancorporation, 912 F.2d 654, 657 (3d Cir. 1990).* Issues of fact are genuine only "if the evidence is such that a reasonable jury could return a verdict for the non-moving party." *Anderson, 477 U.S. at 248.*

[HN2] Summary judgment is as appropriate in a patent case as in any other case when the standard for summary judgment is met. *Johnston v. IVAC Corp., 885 F.2d 1574, 1576-77 (Fed. Cir. 1989).* [*14] "Where the parties do not dispute any relevant facts regarding the accused product, . . . but disagree over possible claim interpretations, the question of literal infringement collapses into claim construction and is amenable to summary judgment." *General Mills, Inc. v. Hunt-Wesson, Inc., 103 F.3d 978, 980 (Fed. Cir. 1997).*

[HN3] It is now well-settled that patent claim construction is a legal question to be determined exclusively by the court. *Markman v. Westview Instruments, Inc., 52 F.3d 967* (Fed. Cir.), aff'd, *517 U.S. 370, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996).* The determination of infringement requires a two-step analysis. *Id. at 976.* First, the claims must be construed, i.e., the legal meaning and scope of each cited claim must be determined. Id. Second, it must be determined whether the claims so construed cover an accused product or process, i.e., whether, in fact, every limitation found in a claim is present in the accused product or process. Id. Because claim interpretation is purely a question of law, the parties' dispute over the meaning of claim elements does not raise a "genuine issue as to any [*15] material fact," so as to preclude the grant of summary judgment. *Id. at 983.*

[HN4] Once the claim construction aspect of the infringement inquiry is performed, the next step in analyzing a claim of literal infringement requires that the properly interpreted claims be compared to the accused product or device. *Southwall Tech. Inc. v. Cardinal IG Co., 54 F.3d 1570, 1575 (Fed. Cir. 1995).* The determination of whether the properly construed claims read on the accused device is typically a question of fact. Id. In the instant matter, Rheox and Entact agree that if the Court determines that the claimed term "calcium orthophosphate" does not include monocalcium orthophosphate, summary judgment should be granted for Entact. (See Def.'s Facts and Conclusions PP5-6.)

To determine the proper meaning of a claim term, a court must "consider the so-called intrinsic evidence, i.e., the claims, the written description, and, if in evidence, the prosecution history." *Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1344 (Fed. Cir. 1998).* In defining claims, courts should first look to words of the claims. *Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996).* [*16] The "general rule is . . . that terms in the claim are to be given their ordinary and accustomed meaning." *Johnson Worldwide Assoc., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed. Cir. 1999).*

In determining the ordinary meaning of a claim, a court should "construe the claim language according to the standard of what those words would have meant to one skilled in the art as of the application date." *Wiener v. NEC Elec., Inc., 102 F.3d 534, 539 (Fed. Cir. 1996);* see *Zelinski v. Brunswick Corp., 185 F.3d 1311, 1315 (Fed. Cir. 1999)* (where claim language is a term of art, "it is given the ordinary and accustomed meaning as understood by those of ordinary skill in the art."). In ascertaining the meaning of claim language to a person of ordinary skill in the art, a court may rely upon expert testimony. *Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1309 (Fed. Cir. 1999).* Courts may also rely on dictionary definitions when construing claim terms, so long as the dictionary definitions do not contradict any definition found in or ascertained by a reading of the patent documents. n4 *Vitronics, 90 F.3d at 1584.* [*17]

> n4 The Court notes that "[HN5] a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." *Vitronics, 90 F.3d at 1582.* The '600 patent, however, does not provide its own definition of calcium orthophosphate.

I. The Definition of Calcium Orthophosphate

The parties offered several treatises and technical dictionaries addressing the definition of calcium orthophosphate. Rheox alleges that the ordinary meaning is a family of compounds containing a "Ca" atom and a "PO[4]" ion. (Pl.'s Proposed Conclusions of Law ("Pl.'s Conclusions") P8.) According to Rheox, the family includes monocalcium orthophosphate, dicalcium orthophosphate, tricalcium orthophosphate and hydroxyapatite. (Id.)

It is undisputed that the plural of calcium orthophosphate refers to a family of compounds. (See Tr. of Hr'g dated 1-27-00 at 264-65, 276; Pl.'s Ex. [*18] 7: Lindsay, Chemical Equilibria in Soils; Pl.'s Ex. 9: J.C. Elliott, Structure and Chemistry of the Apatites and other Calcium Orthophosphates, Studies in Inorganic Chemistry; Pl.'s Ex. 10: Corbridge, Phosphorus: An Outline of its Chemistry, Biochemistry, and Technology, Studies in Inorganic Chemistry; Pl.'s Ex. 15: Kirk-Othmer, Encyclopedia of Chemical Technology; Def.'s Ex. 23: Mello's Comprehensive Treatise on Inorganic and Theoretical Chemistry; see also Def.'s Ex. 21: The Farm Chemical Handbook '94 (referring to calcium phosphate as monocalcium phosphate, dicalcium phosphate and tricalcium phosphate); Def.'s Ex. 22: The Merck Index (containing separate definitions for monocalcium phosphate, dicalcium phosphate and tricalcium phosphate but without a separate definition for calcium orthophosphate).)

The Court finds limited support for Entact's assertion that calcium orthophosphate is generally used as a synonym for tricalcium orthophosphate. The Chemical Abstract Service Registry Handbook (the "CAS Registry"), which is a compilation of all synonyms used to describe a specific chemical compound, identifies calcium orthophosphate as synonymous [*19] with tricalcium orthophosphate. (Def.'s Ex. 20; Tr. of Hr'g dated 1-27-00.) The Court is not especially persuaded by the CAS Registry as the CAS Registry only demonstrates that at least one journal has referred to the compound with the formula Ca[3](PO[4])[2] as both tricalcium orthophosphate and calcium orthophosphate. (Tr. of Hr'g dated 1-27-99 at 295-299.) Several other authorities do not identify calcium orthophosphate as a synonym for tricalcium orthophosphate. n5 (See, e.g., Pl.'s Ex. 3: CRC Handbook; Pl.'s Ex. 15: Kirk-Othmer, Encyclopedia of Chemical Technology.) The Court would likely deny Entact's motion for summary judgment if the only evidence concerning the meaning of calcium orthophosphate in the '600 patent came from the treatises and dictionaries cited by the parties.

n5 We note, however, that O'Hara refers to tricalcium orthophosphate as calcium orthophosphate in accordance with the CAS Registry. (Pl.'s Ex. 2 at 2.99.)

II. The Prosecution History

The Court, [*20] however, finds that the prosecution history reveals that Rheox excluded monocalcium orthophosphate, and consequently TSP, from the definition of calcium orthophosphate in claim 1 of the patent. [HN6] The prosecution history "contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims. As such, the record before the Patent and Trademark Office is often of critical significance in determining the meaning of claims." *Vitronics, 90 F.3d at 1582.* The prosecution history "limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution." *Southwall, 516 U.S. 987, 133 L. Ed. 2d 424, 116 S. Ct. 515.*

The chronology of the patent process reveals that Rheox deleted references to TSP from its claims after the Examiner expressed objections to TSP. In the second office action, the PTO Examiner rejected the argument that the invention used insoluble compounds whereas O'Hara did not. (Pl.'s Ex. 2 at 2.186.) The Examiner focused on the inclusion of TSP in the patent application:

> It is well known to one of ordinary skill [*21] in the art that monocalcium phosphate is water soluble and is routinely available as . . . triple super phosphate. . . . The selection of water soluble phosphates such as monocalcium phosphate, known water soluble phosphates, readily available as super phosphate and triple superphosphate and sold in bulk quantities as fertilizers as water soluble phosphate for use in the process of [O'Hara] would be obvious to one of ordinary skill in the art.

(Id. at 2.186-87.)

The record reveals considerable support for the Examiner's statement that TSP is water soluble. For example, Van Nostrand's Scientific Encyclopedia, which Rheox submitted to the Examiner to demonstrate that fertilizers had not been used in lead remediation, states that "fortunately, monocalcium phosphate, Ca(H[2]PO[4])[2], is soluble in water and all moist soils." (Pl.'s Ex. 2 at 2.167.) In addition, the Wahlberg

patent, which Rheox submitted to the Examiner with its original application as an example of prior art, also states that monocalcium phosphate is soluble in water. (Pl.'s Ex. 2 at 90 col. 4.)

Rheox responded to the Examiner's rejection of its claims by canceling claim 2, which had identified [*22] the agent as comprising a calcium phosphate fertilizer selected from the group consisting of triple superphosphate and superphosphate, and by amending claim 18 to delete the reference to TSP. In addition, claim 1 was changed from stating that the treating agent would be selected from a list of compounds to stating that it would be "consisting essentially of calcium orthophosphate." Rheox in its April 2, 1992 Response stated that it was canceling claims to distinguish the invention from the water-soluble compounds and method of treatment taught by O'Hara as well as to clarify the invention and advance the "patentability" of its application. (Pl.'s Ex. 2 at 2.198-99.) Rheox did not suggest in its April 2, 1992 Response that the patent still encompassed TSP. The simple chronology of the prosecution history supports a conclusion that Rheox narrowed its claims to exclude TSP so that the patent application would be approved. n6

N6 Rheox acknowledges that "in many cases claims are canceled to get around the prior art" and that if the term "calcium orthophosphate" included TSP as Rheox alleges, Rheox would not have been required to cancel claim 2 and strike the reference to TSP in claim 18. (Pl.'s Proposed Findings of Fact ("Pl.'s Facts") at 3.59.) Rheox, however, offers two alternative reasons, which it describes as "plausible," for why the references to TSP may have been stricken. First, Rheox's patent expert theorized that by narrowing the treating agent in claim 1 from among several broad groups to only calcium orthophosphate, while adding the "consisting essentially of" language, Rheox revised claim 1 to cover a class of compounds that included TSP and therefore simplified the claim structure by deleting references to TSP in other claims. (Tr. of Hr'g dated 1-27-00 at 88.) This speculation is not supported by any language in the April 2, 1992 Response. The Court also notes that the deletion of TSP in later claims, if TSP were intended to still be covered by the invention, could hardily be described as clarifying the patent application.

Secondly, Rheox's expert suggested that it was arguing patentability on the basis of solubility and that the reference to TSP was dropped because as a commercial fertilizer, TSP may have varying solubilities. (Id. at 87-88.) We reject this argument as implausible by noting that nowhere in the prosecution history is there any suggestion that (1) the Examiner was concerned with the possibility of various solubilities for TSP, which he simply deemed water soluble, or (2) Rheox deleted references to TSP for this reason.

[*23]

Rheox's April 2, 1992 Response supports a conclusion that the term "calcium orthophosphate" in claim 1 does not include TSP. The Court finds that, in the April 2, 1992 Response, Rheox presented calcium orthophosphate to the Examiner not as representing an entire family of compounds but as referring only to tricalcium orthophosphate. We note in this regard that Rheox referred to the compound claimed by the patent in the singular. (See Pl.'s Ex. 2 at 2.201 (Rheox states that "the presently claimed compound (calcium orthophosphate) is substantially water insoluble"); id. at 2.201 ("The substantial water-insolubility of the claimed compound . . .").) n7

n7 The Examiner also uses the singular form when referring to Rheox's invention in the Interview Notes. (Pl.'s Ex. 2 at 195 ("Solubility data of instant compound and compounds of O'Hara to be provided.").) Rheox correctly notes, however, that the Examiner's comment that "attorney urge [sic] difference based on the use of slightly soluble phosphates versus the soluble phosphates of O'Hara" suggests that Rheox was claiming more than one compound. (Id.) The Court will decline to give weight to the Examiner's notes in light of this inconsistency and the evidence that the handwritten notes were not done with great care, e.g. "attorney urge [sic] . . . ."

[*24]

In the April 2, 1992 Response, Rheox also identified calcium orthophosphate as having the solubility of tricalcium orthophosphate. (See Pl.'s Ex. 2 at 2.202 ("Applicant points out that the solubility of calcium orthophosphate is 0.002 grams/100 grams of H[2]O."). Rheox further asserted that the water-soluble phosphates discussed by O'Hara "are believed to be thousands of times more water soluble than Applicant's preferred (and presently claimed) calcium orthophosphate material." (Id.) This sentence does not make sense if "calcium orthophosphate material" included monocalcium orthophosphate, which has a water solubility of 1.8 grams/100 grams of H[2]O, more than 500 times the solubility of tricalcium orthophosphate. (See Tr. of Hr'g dated 1-26-00 at 195, 197.) It is undisputed that the phosphates discussed in O'Hara do not have solubilities of 1,000 or above but have solubili-

ties more than a thousand times higher than tricalcium orthophosphate. n8 (Pl.'s Ex. 13: Expert Report of Gary Pierzynski, Ph.D. at 3-5.)

> n8 Rheox suggests that the April 2, 1992 Response refers only to the solubility of tricalcium orthophosphate because O'Hara specifically discussed tricalcium orthophosphate. However, it is clear from the context of the April 2, 1992 Response that Rheox was limiting its definition of calcium orthophosphate to tricalcium orthophosphate. On the bottom of page 5 of the Response, Rheox stated that "the presently claimed compound (calcium orthophosphate) is substantially water-insoluble." (Pl.'s Ex. 2 at 2.201.) The next line provides: "In this regard, Applicants point out that the solubility of calcium orthophosphate is 0.002 g/100 g H[2]O." (Id. at 2.202.) The juxtaposition of the phrase "presently claimed compound" with the solubility of tricalcium orthophosphate, tied together by the clause "in this regard," reveals that Rheox was not merely responding to the example used in O'Hara but was instead limiting calcium orthophosphate to tricalcium orthophosphate.

[*25]

Rheox also stated in the April 2, 1992 Response that "calcium orthophosphate, Ca[3](PO[4])[2]," was identified by O'Hara as inoperative for immobilizing lead. (Pl.'s Ex. 2 at 2.203.) The inclusion of the empirical formula for tricalcium orthophosphate beside the term "calcium orthophosphate" also indicates that Rheox was limiting the definition of calcium orthophosphate. n9 In light of our analysis of the prosecution history, the Court finds that (1) Rheox eliminated references to TSP to satisfy the Examiner's objections that TSP is water soluble and therefore obvious under O'Hara, and (2) the term "calcium orthophosphate" in claim 1 refers only to tricalcium orthophosphate.

> n9 It is undisputed that Ca[3](PO[4])[2] is the empirical formula for tricalcium orthophosphate. The formula for monocalcium orthophosphate is Ca(H[2]PO[4])[2]. See note 1 supra for the solubility of these compounds.

Rheox offers an alternative explanation of how the Examiner's objections to the inclusion of TSP [*26] were placated. The O'Hara patent states as follows in its written description:

> Any convenient source of water soluble phosphate may be used in the practice of this invention. By a water soluble phosphate is meant a phosphate soluble in water at about 20 [degrees] C. at least to the extent of about five weight volume percent. n10

(Pl.'s Ex. 6 col. 6.) Rheox notes that all of the calcium orthophosphates, including monocalcium orthophosphate, would be considered insoluble under the O'Hara benchmark. (Pl.'s Facts P3.40.) Rheox therefore suggests that the Examiner did not have any basis for objecting to the inclusion of TSP in the patent because monocalcium orthophosphate would not be considered water soluble under O'Hara. (Id. P3.38.)

> n10 There is no dispute that "five weight volume percent" is the equivalent of 5 grams/100 grams H[2]O. (Tr. of Hr'g dated 1-26-00 at 13; Tr. of Hr'g dated 1-27-00 at 289-90.)

There is no evidence, however, that Rheox ever made this argument to the Examiner or [*27] that the Examiner considered the O'Hara benchmark. The Examiner simply stated: "It is well known to one of ordinary skill in the art that monocalcium phosphate is water soluble." (Pl.'s Ex. 2 at 2.186.) The Examiner's statement that monocalcium phosphate is known to be water soluble is supported in the literature presented to the Examiner by Rheox. (See Pl.'s Ex. 2 at 2.167: Van Nostrand's Scientific Encyclopedia; Pl.'s Ex. 2 at 90 col. 4: the Wahlberg patent).

In addition, the Examiner stated that the use of TSP, which he identified as water soluble, "would be obvious" for use in the process of O'Hara. (Id. at 2.186-87.) The Examiner did not state that the use of TSP would infringe the O'Hara patent. The Examiner's statement is therefore consistent with the O'Hara solubility benchmark because even if the solubility of monocalcium orthophosphate is lower than the O'Hara benchmark of 5 grams/100 grams of water, its use could still be obvious under O'Hara.

Rheox also cites statements in the April 2, 1992 Response that would allegedly be inconsistent unless monocalcium orthophosphate were meant to be included within the definition of calcium orthophosphate. Rheox notes that [*28] page 10 of the April 2, 1992 Response referred to phosphate rock and hydroxyapatite as "forms of calcium orthophosphate." (Pl.'s Facts P3.51.) If the term "calcium orthophosphate" is limited to tricalcium

orthophosphate, Rheox argues that the Responses's identification of phosphate rock and hydroxyapatite as "forms" of calcium orthophosphate would not make sense.

We note, however, that the statement in the April 2, 1992 Response provided in full: "Applicants point out that phosphate rock and hydroxyapatite are forms of calcium orthophosphate (hydroxyapatite is precipitated calcium orthophosphate); these materials therefore have the water-insolubility of calcium orthophosphate." (Pl.'s Ex. 2 at 2.206.) Entact's technical expert testified that phosphate rock can contain tricalcium orthophosphate and that hydroxyapatite can be precipitated from tricalcium orthophosphate. (Tr. of Hr'g dated 1-28-00 at 38-42: Schwartz test.) Consequently, the statement in the April 2, 1992 Response that phosphate rock and hydroxyapatite are forms of calcium orthophosphate is not inconsistent with limiting calcium orthophosphate to tricalcium orthophosphate.

Moreover, the statement in the April 2, 1992 Response [*29] that phosphate rock and hydroxyapatite have the water-insolubility of calcium orthophosphate makes sense only if referring to one of the compounds included in the family of calcium orthophosphates, instead of the entire family of calcium orthophosphates, because the calcium orthophosphates have different solubilities. (Tr. of Hr'g dated 1-28-00 at 42-43: Schwartz test.) Accordingly, we find that this section of the April 2, 1992 Response is not inconsistent with a definition of calcium orthophosphate as referring to tricalcium orthophosphate. n11

n11 Rheox points out another alleged inconsistency in the April 2, 1992 Response created by limiting the term "calcium orthophosphate" to tricalcium orthophosphate. On pages 8-10 of the April 2, 1992 Response, Rheox sets forth a list of ways that its invention differs from O'Hara, including that O'Hara did not teach the use of an agent comprising a mixture of calcium orthophosphate and hectorite gangue. Rheox argues that the only explicit reference to using hectorite gangue with another substance in the written description is found in a table listing experimental runs, which contains references to hectorite gangue mixed with TSP. (Pl.'s Facts P3.50.)

We note, however, that the written description also states that hectorite gangue may be used with other agents. (Pl.'s Ex. 1 col. 6.) Thus, the reference in the April 2, 1992 Response could refer to a mixture of tricalcium orthophosphate and hectorite gangue and would therefore not be inconsistent with the reference to hectorite gangue in the written description. Even if an inconsistency were created by the reference to hectorite gangue in the April 2, 1992 Response, however, we would find the inconsistency to be insignificant when compared to the major inconsistencies created in the April 2, 1992 Response if calcium orthophosphate were defined to encompass TSP. (See, e.g., Pl.'s Ex. 2 at 2.202 (stating that calcium orthophosphate has a solubility of .002 grams/100 grams H[2]O).)

[*30]

In conclusion, the Court finds that the prosecution history reveals that Rheox limited the definition of calcium orthophosphate to tricalcium orthophosphate. There is no evidence in the prosecution history to explain the deletion of all references to TSP except that it was done to overcome the Examiner's objections to the inclusion of TSP in the patent application.

III. Written Description

Rheox argues that the written description of the '600 patent supports finding that calcium orthophosphate encompasses monocalcium orthophosphate and that Entact's use of TSP therefore infringes the patent. Before addressing each argument, the Court notes that the written description did not change from the date of the original patent application to the date of publication of the patent. (Compare Pl.'s Ex. 1 with Pl.'s Ex. 2 at 2.11 to 2.30.) The claims, which were amended, govern what is patented, not the written description. See *Southwall, 516 U.S. at 987.*

Rheox argues that TSP is the preferred embodiment of the invention in the written description and that the term "calcium orthophosphate" should not be interpreted to exclude the use of the preferred embodiment. [*31] (Pl.'s Conclusions P19.) The written description states that (1) the treating agent is preferably provided in the form of a fertilizer; (2) particularly useful fertilizers include TSP and superphosphate; and (3) TSP is preferred over superphosphate. (Pl.'s Ex. 1 col 4.)

[HN7] The general rule is that a claim should not be interpreted to exclude the preferred embodiment expressed in the written description. *Vitronics, 90 F.3d at 1583.* In Vitronics, the Federal Circuit stated that defining a claim so that the only embodiment in the written description falls outside the scope of the patent claim is "rarely, if ever, correct, and would require highly persuasive evidentiary support." Id. The instant matter, however, is distinguishable because there is more than one embodiment in the written description. (See Pl.'s Ex. 1 col. 3 (stating that "in a preferred aspect of the invention," the agents are selected from a group consisting of,

inter alia, tricalcium orthophosphate); id. col. 4 (identifying several "useful inorganic compounds," including tricalcium orthophosphate).)

We hold in this case that the prosecution history, as analyzed above, reveals that the [*32] claims were narrowed to exclude TSP. Therefore, the language remaining in the written description which is inconsistent with that construction is not controlling. In Vitronics, the Federal Circuit reversed a lower court ruling that construed a claim so that it did not cover the sole embodiment of the invention listed in the patent even though there was no issue of claims being limited during the prosecution history. *90 F.3d at 1583.* This Court has found that TSP was specifically excluded by Rheox when it amended its patent application. We accordingly find that interpreting calcium orthophosphate so as not to include TSP is correct even if the written description states that TSP is preferred. See *Ultra-Temp Corp. v. Advanced Vacuum Sys., Inc., 11 F. Supp. 2d 141, 146-47 (D. Mass. 1998)* (finding that some of the embodiments listed in the written description no longer fell under the "purview" of the claim at issue in light of the amending of the claim to overcome an objection raised by the patent examiner).

Rheox also refers to a table in the written description listing experimental runs to illustrate the treatment of lead contaminated soil according [*33] to the process of the invention. (Pl.'s Facts P2.11.) The table includes several runs using TSP, and the written description states that "triple superphosphate provided superior lead stabilization results, and reduced the level of hazardous leachable lead to less than 5 ppm." (Pl.'s Ex. 1 col. 7.) Rheox argues that, if calcium orthophosphate is limited to tricalcium orthophosphate, none of the agents in the table would fall within that definition. (Pl.'s Facts P2.12.)

We note, however, that Rheox told the Examiner in the April 2, 1992 Response that phosphate rock and hydroxyapatite are forms of calcium orthophosphate. (See Pl.'s Ex. 2 at 2.206; discussion supra.) According to the table, several of the runs were done with hydroxyapatite. (Pl.'s Ex. 1 col. 6.) Defining calcium orthophosphate as limited to tricalcium orthophosphate would therefore not lead to the conclusion that the table fails to include any runs using the ultimately claimed agent. Accordingly, we find that the table is not inconsistent with interpreting calcium orthophosphate as limited to tricalcium orthophosphate. n12

n12 There is one statement in the written description that is inconsistent with a definition of calcium orthophosphate as limited to tricalcium orthophosphate. The written description provides that "analysis by X-ray diffraction and infrared spectroscopy indicated that the bulk of triple superphosphate [used in the experiment] was calcium orthophosphate." (Pl.'s Ex. 1 col. 7.) This statement does not make sense if "calcium orthophosphate" is defined as only tricalcium orthophosphate because monocalcium orthophosphate is the primary ingredient of TSP. Entact's chemistry expert stated that an effective analysis of TSP using X-ray diffraction could not have been done, (Tr. of Hr'g dated 1-27-00 at 253: Schwartz test.), but his statement is irrelevant to an analysis of the meaning of the term "calcium orthophosphate" as used in the written description.

The Court's ultimate conclusion is not affected, however, by the use of the term "calcium orthophosphate" in this manner given that it occurred prior to both the Examiner's rejection of the patent application and Rheox's defining of calcium orthophosphate in a limited manner so as to be awarded the patent.

[*34]

In conclusion, the Court finds that the term "calcium orthophosphate" as contained in claim 1 does not include monocalcium orthophosphate. Therefore, Entact's use of TSP does not infringe the '600 patent. Accordingly, we will grant Entact's motion for summary judgment.

IT IS THEREFORE on this 17th day of August, 2000 **ORDERED** that defendant's motion for summary judgment be and hereby is **GRANTED.**

MARY L. COOPER

United States District Judge

LEXSEE 1998 US DIST LEXIS 22648

UNIVERSITY OF FLORIDA RESEARCH FOUNDATION, INC., U.S. BIOMATERIALS CORPORATION, and BLOCK DRUG CORPORATION, Plaintiffs, v. ORTHOVITA, INC., and PAUL DUCHEYNE, Defendants.

CASE NO. 1:96-cv-82-MMP

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF FLORIDA, GAINESVILLE DIVISION

1998 U.S. Dist. LEXIS 22648

April 20, 1998, Decided
April 20, 1998, Filed; April 23, 1998, Entered

DISPOSITION: [*1] Plaintiffs' motion for summary judgment for literal patent infringement (doc. 88) DENIED, and Defendants' motion for summary judgment with respect to Count I of the supplemental complaint (doc. 93) GRANTED. Defendants' alternative motion for summary judgment of patent invalidity DENIED. Defendant Ducheyne's motion to dismiss MOOT with respect to claims of infringement, motion GRANTED to all remaining claims.

CASE SUMMARY:

PROCEDURAL POSTURE: Plaintiff patent owner, patent licensee, and distributor filed claims against defendant corporation and defendant board chairman for patent infringement, false advertising, unfair competition, and trade disparagement. The corporation and the board chairman asserted defenses of inequitable conduct, unclean hands, and equitable estoppel. The matter was before the court on the parties' various motions for summary judgment.

OVERVIEW: The patent at issue involved a composition of glass particles for use in the repair of periodontal osseous defects. Looking to the claim language, the patent specification, and the prosecution history, the court determined that the patent owner, the patent licensee, and the distributor had failed to prove literal infringement or infringement under the doctrine of equivalents. The court also held that the corporation and the board chairman had failed to prove that the patent was invalid and that the board chairman could not be held personally liable because he never participated in any of the acts alleged. Regarding the false advertising claims, the corporation's statements, which amounted to mere puffery, were not actionable under § 43(a) of the Lanham Act, codified at *15 U.S.C.S. § 1125*(a), the alleged false statements were not shown to have been literally false, and the accused false advertisement was not shown to have misled consumers. The claims against the corporation for trade disparagement under state law failed, as did the corporation's counterclaims for false patent marking and its defenses of inequitable conduct, unclean hands, and equitable estoppel.

OUTCOME: The court granted summary judgment in favor of the corporation on the patent infringement claim, dismissed the claims against the board chairman, denied summary judgment in favor of the patent owner, the patent licensee, and the distributor on the claims for false advertising, unfair competition, and trade disparagement, and entered summary judgment against the corporation on its counterclaims and its defenses.

LexisNexis(R) Headnotes

Civil Procedure > Summary Judgment > Opposition > General Overview
Civil Procedure > Summary Judgment > Standards > Legal Entitlement
Civil Procedure > Summary Judgment > Standards > Materiality
[HN1] In evaluating a motion for summary judgment, the trial court must examine whether the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits show that there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law. *Fed. R. Civ. P. 56(c)*. All of the evidence and reasonable factual inferences drawn from the evidence must be construed in a

light most favorable to the party opposed to a motion for summary judgment.

Civil Procedure > Summary Judgment > Standards > Appropriateness
Patent Law > Infringement Actions > Summary Judgment > General Overview
[HN2] Summary judgment is as appropriate for cases involving patent law as any other civil litigation.

Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
Patent Law > Infringement Actions > Summary Judgment > Claim Evaluation
Patent Law > U.S. Patent & Trademark Office Proceedings > Continuation Applications > General Overview
[HN3] Where no issue of material fact is present, district courts should not hesitate to proceed to disposition by summary judgment in patent infringement cases. The district court should look beyond mere denials and arguments with respect to the scope and content of prior art and other factual matters. Where the parties disagree not over relevant facts regarding the allegedly infringing product, but rather disagree over the proper scope and interpretation of the claims contained within the patent at issue, the trial court may decide the issue of literal infringement as a matter of law in a motion for summary judgment.

Patent Law > Infringement Actions > Doctrine of Equivalents > General Overview
Patent Law > Infringement Actions > Infringing Acts > General Overview
[HN4] Patent infringement analysis is a two-step process, with the first step being the trial court's construction of the claims asserted by the plaintiff in order to establish their proper meaning and scope, and the second step being the trial court's application of the construed claims to the allegedly infringing product of the defendant. The first prong is an issue of law, reserved exclusively for the trial court. The latter prong of the analysis may be established either by literal infringement of the patent or by infringement under the doctrine of equivalents.

Patent Law > Infringement Actions > Infringing Acts > General Overview
[HN5] Literal infringement occurs when a limitation of the patent is literally found in the accused device that is, the accused device contains every limitation of the asserted claim.

Patent Law > Claims & Specifications > Enablement Requirement > General Overview
Patent Law > Infringement Actions > Claim Interpretation > General Overview
[HN6] In order to determine the proper construction and scope of patent claims, the trial court should first look to the literal meaning of the words of the claims themselves, including both asserted and non-asserted terms. The proper standard to be applied in claim construction of technical terms is what one of ordinary skill in the art would have understood the terms of the patent claims to mean at the time of the invention. The trial court should next evaluate the claim specification, which is a written description of the invention that functions as a dictionary of sorts, explaining the invention and often times defining terms used therein. The specification is highly relevant to the analysis of claim construction and it is often dispositive; it is described as the single best guide to the meaning of a disputed term.

Patent Law > Infringement Actions > Claim Interpretation > General Overview
Patent Law > U.S. Patent & Trademark Office Proceedings > Reissues > General Overview
Trademark Law > Protection of Rights > Registration > Disclaimer of Unregistrable Matter
[HN7] As a final source of intrinsic evidence regarding the proper construction of a claim, the trial court should evaluate the claim's prosecution history or file wrapper, which gives insight into the proceedings before the United States Patent and Trademark Office. The prosecution history can limit the terms of claims to exclude any interpretation which was disclaimed or surrendered by the patentee during the patent's prosecution. As with the specification, the prosecution history may not be used to enlarge, diminish, or vary the limitations in the claims.

Patent Law > Infringement Actions > Claim Interpretation > General Overview
[HN8] The claims, specification, and prosecution history of a patent constitute the public record upon which the public may rely, thus it is generally inappropriate for a court to consider extrinsic evidence beyond that available to the public, such as expert testimony, when defining the scope of the patent claims. However, the trial court may consider extrinsic evidence for the purpose of its own understanding of the meaning or scope of technical terms used in the claims, but as noted previously, not for the purpose of varying or contradicting the terms of the claims.

Patent Law > Claims & Specifications > Claim Language > General Overview
[HN9] Under *35 U.S.C.S. § 112,* a dependant claim shall be construed to incorporate by reference all the limitations of the claim to which it refers. Additionally, a dependant claim shall specify a further limitation on the subject matter of the claim to which it is referenced.

Patent Law > Infringement Actions > Defenses > Patent Invalidity > Validity Presumption
Patent Law > U.S. Patent & Trademark Office Proceedings > Continuation Applications > General Overview
[HN10] It is axiomatic in patent law that all patent claims, be they independent or dependant in nature, are presumed to be valid regardless of the validity of other claims. Furthermore, the presumption of validity of patent claims is based upon the presumption of administrative correctness associated with the actions of an agency which is charged with patentability evaluation.

Patent Law > Infringement Actions > Claim Interpretation > General Overview
[HN11] It is legally improper to read from the specification and into the patent, a process limitation which is simply not there. Additionally, a patent claim cannot be limited by the examples listed within the patent specification.

Patent Law > Infringement Actions > Claim Interpretation > General Overview
[HN12] It is not appropriate for the trial court to consider extrinsic evidence such as the testimony of experts, prior art, dictionaries, and treatises in determining the scope of a claim if the claim language, specification, and prosecution history unambiguously define the terms at issue. Even where extrinsic evidence should be considered to evaluate an ambiguous term, expert testimony is the least favored form of extrinsic evidence available to the trial court since such information would not be available to the general public for their consideration in advance of infringement litigation.

Patent Law > Infringement Actions > Claim Interpretation > General Overview
[HN13] Extrinsic evidence may be considered when the claim language, specification and prosecution history do not unambiguously define the scope of a disputed term, however, prior art and other forms of extrinsic evidence are all preferable to the use of expert testimony since the public has no access to litigation inspired expert testimony and reports.

Patent Law > Infringement Actions > Claim Interpretation > General Overview
[HN14] The trial court is unwilling to read into a patent claim the subjective intent of the patentee regarding the scope of the claim, when such intent is not clearly expressed in any of the patent documents.

Patent Law > Infringement Actions > Claim Interpretation > General Overview
[HN15] The use of expert testimony is extremely disfavored when interpreting the scope of patent claims. While expert testimony may be useful in resolving an ambiguous term not clearly addressed in either the claim language or specification, it is not useful or appropriate when the trial court is faced with two conflicting interpretations, both of which find adequate support in the claim language and specification.

Patent Law > Infringement Actions > Claim Interpretation > General Overview
[HN16] Extrinsic evidence, and more specifically expert testimony, may not be used to vary claim language or contradict the import of other parts of the specification.

Patent Law > Claims & Specifications > Claim Language > General Overview
Patent Law > Claims & Specifications > Theory of Invention
[HN17] The drafter of the patent has the burden of claiming with specificity what it is that his invention covers. *35 U.S.C.S. § 112* P2 states that the specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention. That is often referred to as the requirement that the patentee give notice to the public, in order to guide them in determining what area is precluded from any future development or enterprise. One of the objectives of requiring a patentee to distinctly claim the scope of the invention is to apprise the public of what is still open to them. The public should be able to review the public record, apply the established rules of claim construction, ascertain the scope of the patentee's claimed invention, and, thus, design around the claimed invention.

Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview

Patent Law > Infringement Actions > Claim Interpretation > General Overview
[HN18] The Federal Circuit instructs that the trial court should seek to construe the claims of a patent in such a manner as to preserve their validity.

Patent Law > Infringement Actions > Claim Interpretation > General Overview
[HN19] When a court is faced with two competing interpretations, one broad, and one narrow, and when the narrow has a legitimate basis in the claims, the narrow should be used, since doing otherwise would violate the requirement that the public be put on notice as to what would constitute an infringement of the claims.

Patent Law > Claims & Specifications > Description Requirement > General Overview
Patent Law > Infringement Actions > Claim Interpretation > General Overview
[HN20] Where there is an equal choice between a broader and a narrower meaning of a claim, and there is an enabling disclosure that indicates that the applicant is at least entitled to a claim having the narrower meaning, the appellate court considers the notice function of the claim to be best served by adopting the narrower meaning.

Patent Law > Claims & Specifications > Description Requirement > General Overview
Patent Law > Infringement Actions > Doctrine of Equivalents > General Overview
Patent Law > U.S. Patent & Trademark Office Proceedings > Reissues > General Overview
[HN21] Where a patent seeks to protect an invention which is merely an improvement over prior art and is not a pioneer in the relative field, the patent claims are not entitled to the broad construction of claims which would ordinarily be granted the pioneer.

Patent Law > Inequitable Conduct > General Overview
Patent Law > Infringement Actions > Burdens of Proof
Patent Law > Infringement Actions > Summary Judgment > General Overview
[HN22] When a limitation of a patent is literally found in the allegedly infringing device, literal infringement occurs. And, in order to establish literal infringement, each claim limitation must be found in the accused product, exactly. The patentee bears the burden of establishing literal infringement by a preponderance of the evidence. Furthermore, the determination of whether an allegedly infringing composition falls within the scope of the patent claims that have been interpreted as a matter of law by the trial court, is a factual application and may only be decided in a motion for summary judgment where there is no dispute as to any material fact to be applied to the claims as construed.

Patent Law > Infringement Actions > Infringing Acts > General Overview
[HN23] One may infringe an independent claim and not infringe a claim dependant on that claim. The reverse is not true. One who does not infringe an independent claim cannot infringe a claim dependant on, and thus containing all the limitations of, that claim.

Patent Law > Infringement Actions > Doctrine of Equivalents > General Overview
[HN24] Where no literal infringement can be established, the trial court may still find an accused product infringing of a patent under the doctrine of equivalents.

Patent Law > Inequitable Conduct > General Overview
Patent Law > Infringement Actions > Doctrine of Equivalents > Elements > Equivalence
[HN25] The doctrine of equivalents requires that the accused device must perform substantially the same function in substantially the same way to achieve substantially the same overall result as the claimed invention. The essential inquiry, whether equivalency is to be established by use of the triple identity test which evaluates function, way, and result, or by use of the insubstantial differences analysis, is whether the accused device contains elements which are identical or equivalent to each claimed element of the claimed invention. In making its comparison, the Federal Circuit cautions that courts may not compare the accused product with the commercial embodiment of the patentee's claimed invention, rather the comparison must be made to the individual claims of the patent. The doctrine of equivalents is considered the exception rather than the rule, and should not be employed by the court merely to rescue a patentee's claim from a finding of non-infringement.

Patent Law > Infringement Actions > Doctrine of Equivalents > General Overview
[HN26] It is error for a trial court to compare in its infringement analysis the accused product with the patentee's commercial embodiment. Rather, an accused device should be compared with the patent claims.

Civil Procedure > Pleading & Practice > Pleadings > Counterclaims > General Overview
Civil Procedure > Summary Judgment > Standards > Appropriateness
Civil Procedure > Summary Judgment > Standards > Genuine Disputes
[HN27] Summary judgment is not appropriate where there is a genuine dispute as to material facts, such that a reasonable juror could return a verdict for the non-moving party based thereupon. All reasonable factual inferences shall be drawn in a light most favorable to the non-moving party.

Trademark Law > Federal Unfair Competition Law > False Advertising > Elements
Trademark Law > Federal Unfair Competition Law > False Designation of Origin > Elements
Trademark Law > Federal Unfair Competition Law > Trade Dress Protection > General Overview
[HN28] Section 43(a) of the Lanham Act, codified at *15 U.S.C.S. § 1125*(a)(1)(B), creates a civil remedy for those injured by a competitor's misleading or false advertisements.

Trademark Law > Federal Unfair Competition Law > False Advertising > Elements
Trademark Law > Federal Unfair Competition Law > Lanham Act > General Overview
[HN29] Section 43(a)(1)(B) of the Lanham Act, codified at § 1125(a)(1)(B), states that any person who, in connection with any goods or services, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in civil action by any person who believes that he or she is or is likely to be damaged by such act.

Antitrust & Trade Law > Consumer Protection > False Advertising > Lanham Act
Trademark Law > Federal Unfair Competition Law > False Advertising > General Overview
Trademark Law > Federal Unfair Competition Law > Trade Dress Protection > General Overview
[HN30] False advertising may be established under § 43(a) of the Lanham Act, codified at *15 U.S.C.S. § 1125*(a), in one of two ways: 1) by establishing that the advertisement is facially false; or 2) by establishing that an advertisement, though literally true, is likely to confuse or mislead the consumers to which it is directed. In the former situation, the plaintiff need not demonstrate that there would be any adverse affect on purchasing consumers, and must only show that the advertising is false, that the defendant's goods are sold in interstate commerce, and that injury to the plaintiff is likely. Accordingly, when the advertising material cannot be shown to be facially false, the plaintiff must establish the remaining elements set forth above, that is, that the alleged deceptive advertisements were material, and that the accused advertising had already, or is likely to, have an impact on consumer purchasing decisions.

Trademark Law > Federal Unfair Competition Law > False Advertising > General Overview
[HN31] Unless a claim that a product is better than a competitor's is backed-up with false allegations that tests prove superiority when no such tests or only unreliable tests exist to support such a claim, the superiority claim constitutes no more than unactionable puffery. For non-puffing superiority claims, an affirmative showing that the claim is false is required, that is, a showing that defendant's product is equal or inferior.

Antitrust & Trade Law > Consumer Protection > False Advertising > General Overview
Trademark Law > Federal Unfair Competition Law > False Advertising > General Overview
[HN32] A plaintiff may establish false advertising by showing that the accused advertisement, though literally true, is likely to confuse or mislead the consumers to which it is directed. In that situation, a plaintiff must establish that the alleged deceptive advertisements were material, and that the accused advertising had already, or is likely to, have an impact on consumer purchasing decisions.

Torts > Business Torts > Trade Libel > General Overview
Trademark Law > Federal Unfair Competition Law > Lanham Act > Remedies
Trademark Law > Federal Unfair Competition Law > Trade Dress Protection > General Overview
[HN33] A plaintiff is not entitled to summary judgment for trade disparagement under Section 43(a) of the Lanham Act, codified at *15 U.S.C.S. § 1125*(a), by simple virtue of the fact that no such claim for relief was ever made in the supplemental complaint.

Antitrust & Trade Law > State Civil Action
Torts > Business Torts > Trade Libel > Elements

[HN34] Under Florida law, an action for trade disparagement must establish that the defendant intentionally made a false statement about the plaintiff's product, and that as a result thereof, plaintiff has suffered a special injury or damage. Mere negligence or the lack of reasonable grounds for a defendant's belief in the veracity of a statement is not grounds for a trade disparagement claim.

Trademark Law > Federal Unfair Competition Law > False Advertising > General Overview
Trademark Law > Federal Unfair Competition Law > False Designation of Origin > Elements
Trademark Law > Federal Unfair Competition Law > Trade Dress Protection > General Overview
[HN35] The standard to be applied under Florida's statutory and common law for unfair competition and false advertising claims based thereupon, mirrors that to be applied under the 43(a) of the Lanham Act, codified at *15 U.S.C.S. § 1125*(a).

Patent Law > Inequitable Conduct > Burdens of Proof
Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > Effect of Inequitable Conduct
Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > Elements
[HN36] The Federal Circuit has stated that inequitable conduct may consist of failure to disclose material information coupled with an intent to deceive. The party asserting inequitable conduct as a defense bears the burden of establishing the threshold elements of materiality and intent by clear and convincing evidence. The district court must consider these threshold elements in light of all the circumstances in order to determine whether a finding of inequitable conduct is appropriate, and the determination in this regard is committed to the court's discretion.

Evidence > Procedural Considerations > Burdens of Proof > Clear & Convincing Proof
Patent Law > Inequitable Conduct > Burdens of Proof
[HN37] Because a finding of inequitable conduct eliminates all of the patentee's rights and the professional or commercial reputation of the patentee could be seriously damaged, such consequences demand that the moving party bear a heavy burden of persuasion. The clear and convincing evidence must show that the applicant had the specific intent to mislead the Patent and Trademark Office.

Patent Law > Inequitable Conduct > Burdens of Proof
[HN38] The alleged inequitable conduct must not amount merely to the improper performance of, or omission of, an act one ought to have performed. Rather, clear and convincing evidence must prove that an applicant had the specific intent to accomplish an act that the applicant ought not to have performed, viz., misleading or deceiving the Patent and Trademark Office. In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference.

Evidence > Relevance > Circumstantial & Direct Evidence
Patent Law > Inequitable Conduct > Burdens of Proof
[HN39] In order to shoe inequitable conduct, it is imperative that the applicant be shown to have known of the materiality of the undisclosed reference. The evidence of intent need not be direct in form, rather an inference of intent to deceive may be found from the circumstantial evidence, however, if the circumstantial evidence leads only to the conclusion that an applicant was grossly negligent in failing to disclose information to the Patent and Trademark Office, no inference of intent to deceive can result therefrom.

Civil Procedure > Summary Judgment > Standards > Legal Entitlement
Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > Fact & Law Issues
Patent Law > U.S. Patent & Trademark Office Proceedings > General Overview
[HN40] When the material facts are not in dispute, and both parties have moved for summary judgment based thereupon, the trial court may decide the issue of inequitable conduct as a matter of law.

Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > Cumulative Information
Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > Elements
[HN41] Information is material for purposes of an inequitable conduct analysis if there is a substantial likelihood that a reasonable examiner would have considered the undisclosed information to be important in the decision as to the patentability of application claims. Where undisclosed information is either cumulative to or is not as relevant as information already before the United States Patent and Trademark Office, the failure to disclose such information can not serve as the basis for inequitable conduct.

Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
Patent Law > U.S. Patent & Trademark Office Proceedings > Examinations > General Overview
Patent Law > U.S. Patent & Trademark Office Proceedings > Filing Requirements > Fees
[HN42] Under *37 C.F.R. § 1.313(b)*, at a time after the issuance fee has been tendered and the patent has been given an issue date and patent number, the application is not to be withdrawn except for the following reasons (1) mistake on the part of the Patent and Trademark Office, (2) a violation of *37 C.F.R. § 1.56*, which includes the duty of disclosure, or illegality of the application, (3) unpatentability of one or more claims, or (4) for interference.

Patent Law > Inequitable Conduct > Burdens of Proof
[HN43] The intent to mislead need not be shown by direct evidence, but rather may be inferred from actions which have natural consequences that are intended by the actor.

Patent Law > Inequitable Conduct > Burdens of Proof
[HN44] The Federal Circuit explicitly instructs that gross negligence will not support a claim for inequitable conduct based upon intentional nondisclosure.

Patent Law > Remedies > Bad Faith Enforcement
[HN45] The unclean hands defense is subsumed in the analysis of inequitable conduct which has been defined as the unclean hands defense as applied to specific conduct before the Patent and Trademark Office. Thus, where a claim of inequitable conduct fails, so must the claim under the equitable doctrine unclean hands.

COUNSEL: For UNIVERSITY OF FLORIDA RESEARCH FOUNDATION INC, US BIOMATERIALS, BLOCK DRUG CORPORATION, plaintiffs: JOHN PHILIP FONS, ESQ, MACFARLANE AUSLEY FERGUSON & MCMULLEN, TALLAHASSEE, FL. JOHN R BERANEK, ESQ, AUSLEY & MCMULLEN, TALLAHASSEE, FL. MARC A LIEBERSTEIN, ESQ, EDWARD A MEILMAN, ESQ, OSTROLENK FABER GERB ETC, NEW YORK, NY.

For ORTHOVITA INC, PAUL DUCHEYNE, defendants: THOMAS M ERVIN, ESQ, ERVIN VARN JACOBS ETC, TALLAHASSEE, FL. DALE M HEIST, ESQ, JOHN J MACKIEWICZ, MICHAEL P STRAHER, ESQ, DOREEN YATKO TRUJILLO, ESQ, WOODCOCK WASHBURN KURTZ ETC, PHILADELPHIA, PA.

JUDGES: MAURICE M. PAUL, SENIOR DISTRICT JUDGE.

OPINIONBY: MAURICE M. PAUL

OPINION:

ORDER

This matter came before the Court for a hearing on the various pending motions for summary judgment in this case on [*2] Friday, February 6, 1998. At the hearing, the parties indicated that the Court's resolution of Plaintiffs' motion for summary judgment for patent infringement (doc. 88) and Defendants' motion for summary judgment with respect to Count I of the supplemental complaint (doc. 93), both of which address the proper construction of the patent involved herein and whether there was infringement by Defendants, would assist them in shaping the issues for trial and preparing the pre-trial stipulation. Only those two motions, and the cross-motions related to Defendants' inequitable conduct and unclean hands defenses were argued at the hearing. The following motions for summary judgment are also pending before the Court: Defendant Paul Ducheyne's motion for summary judgment (doc. 92); Plaintiffs' motion for summary judgment on their false advertising, unfair competition, and trade disparagement claims and their motion for summary judgment on Defendants' counterclaims (doc. 89); Plaintiffs' motion for summary judgment on Defendants' inequitable conduct and unclean hands defenses (doc. 90) and Defendants' cross-motion for summary judgment on the same (doc. 107); as well as Plaintiffs' motion for summary [*3] judgment on Defendants' equitable estoppel defense (doc. 91).

As is set forth in greater detail below, and based upon the motions, the memoranda filed in support thereof and in opposition thereto, and upon the argument received at the February 6, 1998 hearing, the Court is of the opinion that Plaintiffs' motion for summary judgment for literal patent infringement (doc. 88) should be and the same is hereby DENIED, and Defendants' motion for summary judgment with respect to Count I of the supplemental complaint (doc. 93) should be and the same is hereby GRANTED. The remaining summary judgment motions are addressed below.

BACKGROUND:

In the mid-1980s, researchers at the University of Florida ("UF") began experimenting with different compositions of glass particles for use in the repair of periodontal osseous defects. n1 The researchers discovered that glass particles of a particular composition and within

a particular range of particle sizes, when placed in a periodontal pocket would actually promote new bone growth, and that the glass filler would inhibit the invasion of soft tissue into the pocket, as well as help to control bleeding in the area. Additional benefits, such as [*4] increased ease of manipulability over prior applications n2 of such bioactive glass particles, also resulted from their research.

n1 When the bone structure supporting a tooth is destroyed by periodontal disease, a pocket, known as the periodontal osseous defect, becomes subject to invasion by the surrounding soft tissue, resulting in a loss of support for the tooth, and ultimately resulting in tooth loss.

n2 See Hench et al., *J. Biomed. Mater. Res.*, 5:117-141 (1971) (initially establishing the composition of the preferred glass particles, i.e. 45S5 glass particles, involved in the '046 patent.)

In 1985, the UF researchers applied for a patent for the resultant composition of glass particles which they determined was best suited for the repair of periodontal osseous defects, which patent was ultimately issued on July 25, 1989, as United States Patent No. *4,851,046* to Low, et al. (" *'046* patent" or "Low patent"). Plaintiff University of Florida Research Foundation, Inc. ("UFRF") is the assigned [*5] owner of the *'046* Patent, while Plaintiff U.S. Biomaterials, Inc. ("Biomaterials") is the exclusive licensee under the patent, and Plaintiff Block Drug Corporation ("Block") n3 is the exclusive distributor of the commercial embodiment of the patent which is marketed and sold under the trademark PerioGlas TM.

n3 Plaintiffs UFRF, Biomaterials, and Block may be referred to collectively as "Plaintiffs."

The *'046* patent contains a total of nine claims, all of which, excluding claims five and nine, are being asserted by Plaintiffs in this action. The relevant claims, as asserted by Plaintiffs, are as follows:

1. A composition adapted for the repair of periodontal osseous defects consisting essentially of particulate bioactive and biocompatible glass, said particulate glass having a particle size in the range of from about 355 to about 710 [mu]m [microns] and the following weight percentage composition:

Composition	Weight Percentage
SiO[2]	40-52
CaO	10-50
Na[2]O	10-35
P[2]O[5]	2-8
CaF[2]	0-25
B[2]O[3]	0-10

[*6]

2. The composition of claim 1 wherein said particulate glass has a particle size in the range of from about 355 to about 500 [mu]m.

3. The composition of claim 1 wherein said particulate glass has a particle size in the range of from about 500 to 710 [mu]m.

4. The composition of claim 1 consisting essentially of a mixture of (1) said particulate glass having a particle size in the range of from about 90 to 350 [mu]m, (2) said particulate glass having a particle size in the range of from about 355 to 500 [mu]m, and (3) said particulate glass having a particle size in the range of from about 500 to 710 [mu]m.

6. The composition of claim 1 additionally containing a liquid in admixture with said particulate glass in an amount sufficient to wet the particles of said glass.

7. The composition of claim 6 wherein said liquid is aqueous.

8. The composition of claim 6 wherein said liquid is blood.

United States Patent No. *4,851,046*, column 11, lines 36-39, column 12, lines 1-38.

In April, 1992, Defendant Paul Ducheyne ("Ducheyne"), a former doctoral fellowship mentee of Dr. Larry Hench, one of the original inventors of the *'046* patent, [*7] founded Defendant Orthovita, Inc. ("Orthovita") n4 of which he is currently the chairman of the board of directors. Defendants produce BioGran (R), which is also a composition of glass particles n5 adapted for the repair of periodontal osseous defects. Defendants contend that BioGran (R) contains only glass particles which are smaller than 355 [mu]m when measured by conventional sieving techniques, thus placing it outside the scope of enforcement of the *'046* patent. (Doc. 93, p.1).

n4 Defendants Orthovita and Ducheyne may be referred to collectively as "Orthovita" or as "Defendants."

n5 Like Plaintiffs' PerioGlas TM, BioGran (R) consists wholly of particulate bioactive and biocompatible glass known in the industry as 45S5 glass.

SUMMARY JUDGMENT IN PATENT CASES:

[HN1] In evaluating Plaintiffs' and Defendants' motions for summary judgment, this Court must examine whether "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits ... show that there [*8] is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law." *Fed. R. Civ. P. 56(c)*. All of the evidence and reasonable factual inferences drawn from the evidence must be construed in a light most favorable to the party opposed to a motion for summary judgment. See *Atlantic Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 332, 110 S. Ct. 1884, 1888, 109 L. Ed. 2d 333 (1990)* (citing *Matsushita Electric Industrial Co. v. Zenith Radio Corp., 475 U.S. 574, 587, 106 S. Ct. 1348, 1356, 89 L. Ed. 2d 538 (1986))*.

The fact that this case involves complex, and highly technical factual issues, does not render it unsuitable for disposition via summary judgment on the issues of infringement and claim validity. [HN2] Summary judgment is as appropriate for cases involving patent law as any other civil litigation. See *General Elec. Co. v. Nintendo Co., 983 F. Supp. 512, 518 (D.N.J. 1997)*. [HN3] Where no issue of material fact is present, district courts should not hesitate to proceed to disposition by summary judgment. See id. (citing *Chore-Time Equip. v. Cumberland Corp., 713 F.2d 774, 778-79 (Fed. Cir. 1983))*. The district [*9] court should look beyond mere denials and arguments with respect to the scope and content of prior art and other factual matters. See id. Where, as in this case, the parties disagree not over relevant facts regarding the allegedly infringing product, but rather disagree over the proper scope and interpretation of the claims contained within the patent at issue, n6 the Court "may decide the issue of literal infringement as a matter of law in a motion for summary judgment." *Howes v. Zircon Corporation, 992 F. Supp. 957, 1998 WL 34989* at *1 (N.D. Ill. 1998) (citing *Athletic Alternatives, Inc. v. Prince Mfg., 73 F.3d 1573 (Fed. Cir. 1996))*.

n6 See Transcript of Feb. 6, 1998 hearing (Doc. 125 at p. 4, lines 19-21, p. 44, lines 7-9).

DISCUSSION:

A. Plaintiffs' Motion for Summary Judgment for Patent Infringement (doc. 88) and Defendants' Motion for Summary Judgment for Non-Infringement or Alternatively for Patent Invalidity (doc. 93)

[HN4] Patent [*10] infringement analysis is a two-step process, with the first step being the Court's construction of the claims asserted by the plaintiff in order to establish their proper meaning and scope, and the second step being the Court's application of the construed claims to the allegedly infringing product of the defendant. See *Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1581-82 (Fed. Cir. 1996)* (citing *Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995), aff'd 517 U.S. 370, 383, 116 S. Ct. 1384, 1393, 134 L. Ed. 2d 577, (1996))*. The first prong is an issue of law, reserved exclusively for the Court. See *Markman, 52 F.3d at 977*. The latter prong of the analysis may be established either by literal infringement of the patent or by infringement under the doctrine of equivalents. See *General Electric v. Nintendo, 983 F. Supp. at 519*. In this case, Plaintiffs have moved for summary judgment based only on literal infringement, reserving the issue of infringement under the doctrine of equivalents for trial should the literal infringement argument fail. [HN5] Literal infringement [*11] occurs when a limitation of the patent is literally found in the accused device, i.e. the

accused device contains every limitation of the asserted claim. See id.

1. First Prong - Claim Construction

[HN6] In order to determine the proper construction and scope of patent claims, the Court should first look to the literal meaning of the words of the claims themselves, including both asserted and non-asserted terms. See Nova Biomedical Corp. v. i- *STAT Corp., 980 F. Supp. 614, 615 (D. Mass. 1997)* (citing *Vitronics, 90 F.3d at 1582).* The proper standard to be applied in claim construction of technical terms is what one of "ordinary skill in the art" would have understood the terms of the patent claims to mean at the time of the invention. See *Markman, 52 F.3d at 986.*

The Court should next evaluate the claim specification, which is a written description of the invention that functions as a dictionary of sorts, explaining the invention and often times defining terms used therein. See *General Elec. v. Nintendo, 983 F. Supp. at 519.* The specification is highly relevant to the analysis of claim construction and it is [*12] often dispositive; it has been described as "the single best guide to the meaning of a disputed term." *Vitronics, 90 F.3d at 1582.*

[HN7] As a final source of intrinsic evidence regarding the proper construction of a claim, the Court should evaluate the claim's prosecution history or "file wrapper," which gives insight into the proceedings before the United States Patent and Trademark Office. See id. The prosecution history can limit the terms of claims to exclude any interpretation which was disclaimed or surrendered by the patentee during the patent's prosecution. See *Howes, 1998 WL 34989* at *2. As with the specification, the prosecution history may not be used to "'enlarge, diminish, or vary' the limitations in the claims." *Markman, 52 F.3d at 980* (quoting *Goodyear Dental Vulcanite Co. v. Davis, 102 U.S. 222, 227, 26 L. Ed. 149 (1880)).*

[HN8] The claims, specification, and prosecution history of a patent constitute the "public record" upon which the public may rely, thus it is generally inappropriate for a court to consider extrinsic evidence beyond that available to the public, such as expert testimony, when defining [*13] the scope of the patent claims. *Vitronics, 90 F.3d at 1583.* However, the Court may consider extrinsic evidence for the purpose of its own understanding of the meaning or scope of technical terms used in the claims, but as noted previously, not for the purpose of "varying or contradicting the terms of the claims." *Markman, 52 F.3d at 981.*

In this case, the parties seek the Court's interpretation of the scope of the *'046* patent claims as they relate to the range of particle sizes covered therein, and of the particle size measurement technique called for and required by the *'046* patent claims.

a. Construction of *'046* Patent Claims - Regarding the Exclusion or Non-Exclusion of Particles With Sizes Below 355 [mu]m.

Claim 1 of the *'046* patent recites a composition "consisting essentially of" particulate glass, which glass has individual particle sizes in the range of "from about 355 to about 710 [mu]m." The parties agree that in order for Claim 1 to be infringed, particles in this range must be present; however, they disagree over whether or not the existence of smaller particles in the particulate glass composition would prevent a finding [*14] of infringement. It is the Defendants' position that the proper construction of Claim I is that all particles must be within the cited range, while Plaintiffs contend that Claim I should be read in conjunction with dependant Claim 4 to permit infringement when there is the presence of particles below the cited range. This distinction is extremely important as the BioGran (R) product indisputably contains particles which are smaller than 355 [mu]m regardless of whether traditional sieving or scanning electron microscopy is utilized to determine particle size. In order to determine the proper scope of the *'046* patent claims, the Court will consider the language of the claims in conjunction with the patent specification and prosecution history.

i. The Claim Language and Specification

a. Does Claim 1 Exclude Particles Smaller Than 355 [mu]m?

Claim 1 of the *'046* patent identifies a composition adapted for the repair of periodontal osseous defects "consisting essentially of" particulate glass, said glass having particles within a cited range of sizes. The phrase "consisting essentially of' was deliberately inserted by the patent applicants to replace the phrase "comprised [*15] of' which was used in Claim 1 of the original patent application in an effort to narrow that broader application claim. See Application for Patent, June 19, 1985, at p.22 (Doc. 106, Exh.5). An 'essential' ingredient is one which is indispensable or fundamental. Plaintiffs contend that this language is intended to allow the presence of items which do not materially affect the basic characteristic, or "essence" of the composition. See Transcript of Feb. 6, 1998 hearing (Doc. 125 at 10). The Court agrees. See *Water Technologies v. Calco Ltd., 850 F.2d 660, 666 (Fed. Cir. 1988).*

With regard to the language of Claim 1, the Court concludes that in order to be infringing, a composition must, at a very minimum, contain glass particles within the cited particle size range; however, the claim language does not preclude the existence of other materials which

do not materially affect the essential characteristics of the composition of Claim 1. Yet the question remains, can those "other materials" be particulate glass with particle sizes below 355 [mu]m? In other words, does the presence of particles smaller than 355 [mu]m, materially affect the essential characteristics [*16] of the invention claimed in the *'046* patent? In order to answer these questions, the Court must determine what the essential characteristics of the claimed invention are.

The Plaintiffs' claimed invention is a powder comprised of bioactive and biocompatible glass particles within such a range of particle sizes with the following essential characteristics: that when it is combined with an aqueous solution, it not only promotes bone growth, stops the invasion of soft tissue into the periodontal osseous defect, and helps control bleeding, but it also forms a paste that is cohesive, is easily manipulable, and which resists breakdown when subjected to irrigation or suction. See *'046* Patent, col. 4, lines 23-68 (Doc. 106, Exh. 1). These characteristics are based upon the improved performance of the claimed invention over prior art in the same field. The patent specification suggests that the most advantageous composition is one with the widest range of particle sizes, i.e. 90 to 710 [mu]m, and more specifically, the specification notes that the most superior performance resulted from testing a hypothesized formulation containing particles in equal thirds, each third having particles [*17] within the three ranges cited in Claim 4. The characteristics of three compositions of differing size ranges are summarized in column 5, table 1 of the *'046* patent, n7 the relevant portions of which provide:

Materials	Particle Size (um)	Ease of Manipulation	Cohesiveness with blood	Appearance in Periodontal Defect
Glass 45S5 or 45S5F	500-710	good remained on instrument	good	moderately, densely packing of particles filing defect
Glass 45S5 or 45S5F	90-355	very good easy to handle & transport	very good easily packed	very good dense packing resistant to irrigation
Glass 45S5 or 45S5F ['046 patent Claim 5]	90-710(8)	excellent superb adhesion to instrument, superb ease of transport	excellent superior packing	very dense packing in site, translucent, appears in site as if bone resistant to irrigation and suction

n7 This table lacks any indication of the performance characteristics which result from the use of particles either largely or solely within a range similar to that used in Defendants' product, i.e. 300 to 355 [mu]m or within the range of Claim 1, i.e. 355 to 710 [mu]m.

n8 The optimal characteristics of the composition, with particles in the range of 90 to 710 [mu]m, are predicated upon the use of glass particles within the each of the three size ranges set forth in dependant Claims 4 and 5.

Plaintiffs argue that the evidence confirms that the additional presence of particles sized below 355 [mu]m in a composition under Claim 1, does not affect the basic characteristics of the composition, but rather only affects the degree of resultant cohesiveness of the composition, [*18] i.e. its performance. However, it was the improved performance of a broader range of particle sizes cited in the *'046* patent claims which served as the impetus for the patent application, and which has been cited as the distinguishing characteristic of Plaintiffs' product over the prior art. See United States Patent No. *4,851,046*, col. 3, 11. 58-68, col. 4, 11. 1-45. The improved performance derives from the use of particles in the ranges cited in Claim 5, i.e. one which contains no more than one-third of its particles in the 90 to 355 [mu]m size

range. It, therefore, seems apparent that the basic characteristics of the claimed invention are inextricably intertwined with the degree of performance associated with the use of particles within the cited ranges.

Defendants likewise contend that the presence of a greater number of the smaller glass particles does affect the characteristic of the composition, and they point to the existence of smaller particles in Plaintiffs' own product PerioGlas TM n9 and the Patent Office's subsequent issuance of the Schepers patent as evidence of the same. Defendants do agree that the smaller particles which are present in the BioGran (R) product [*19] affect the performance of the composition, but unlike Plaintiffs, they contend that the marked difference in performance brought about by the inclusion of a greater percentage of smaller particles does materially alter the characteristics of the composition at issue. They cite to the Patent Office's issuance of a separate patent to Schepers et al., for a composition restricted solely to particles of a smaller range than that of the *'046* patent, n10 and which restricted size range and smaller particle characteristics "result[] in a quantitatively greater amount of bone formation than the particles as disclosed by [the *'046* patent]." See (Doc. 126, Attach. B) (citing to Patent Office's reaffirmation of patentability of the claims in the Schepers patent). Defendants contend this is evidence that, by increasing the amount of bone formation, the presence of a greater number of smaller particles does change the basic characteristics of the composition in Claim 1 of the *'046* patent.

n9 Defendants have properly noted that there is no evidence of any composition being produced with particles solely within the range cited in Claim 1 of the *'046* patent, i.e. from about 355 to 710 [mu]m. In fact, analysis using a Microtrac Particle Size Determination method ("Microtrac"), which Plaintiffs contend is equivalent to Scanning Electron Microscopy ("SEM"), reveals that Plaintiffs' own PerioGlas TM is composed of a percentage of particles smaller than 355 [mu]m, as high as 57.83%. See Corning Analysis (Doc. 88, Exh. 12 at p. 4).

[*20]

Thus, Defendants argue that the "consisting essentially of" language, which Plaintiffs have argued only excludes from Claim 1 those other materials or particles which materially affect the essential characteristic of the claimed invention, does in fact exclude the smaller sized glass particles found in the BioGran (R) product from the scope of Claim 1, since BioGran's smaller particles appear in much larger quantities than those contemplated by the *'046* patent claims, and because, according to the Patent Office's holding in the Schepers patent, the presence of the greater number of smaller particles changes the characteristics of the *'046* claimed invention. Defendants' argument relies on the Patent Office's conclusions regarding the Schepers patent, which patent and the resultant product characteristics cited therein, are based on the presence of particles which are *solely* within a smaller particle size range, and which does not deal with smaller particles co-existing with larger sized particles, as would be required under the *'046* patent claims. However, this Court agrees with Defendants, and with the Patent Office's conclusion in the Scheper's patent, that the presence of a [*21] greater number of smaller particles does affect the performance of the composition to the point that it alters its basic characteristics, especially in light of the fact that the characteristics of the claimed invention are based upon its improved performance over prior art in the field. And while the claims within, and the findings of the Patent Office with regards to the Schepers patent, do not qualify as being part of the *'046* patent, its patent specification, its prosecution history, or the relevant *prior* art which this Court can properly consider when construing the meaning and scope of the terms thereof, this Court finds them to be instructive in determining what amount of smaller particles are anticipated by Claim I of the *'046* patent. Accordingly, the Court concludes that a larger presence of particles smaller than the range cited in Claim 1, especially where the percentage thereof is greater than the one-third fraction cited in Claim 5, could easily lead to the conclusion that the basic characteristic of the claimed invention would be altered by the variance in performance brought about by their inclusion. Indeed, were a hypothetical composition to be comprised of more [*22] than two-thirds of its particles below 355 [mu]m, it would be difficult to argue that the composition consists "essentially of" particles within the range of 355 to 710 [mu]m.

n10 Claim 1 of the Schepers patent calls for a composition in which at least 95% of the particles are within the particle size range of from between 280 and 425 [mu]m. Dependant Claim 2 requires the composition of Claim 1 wherein 2/3 of the particles are between 300 and 360 [mu]m, and dependant Claim 3 requires a composition of Claim 2 wherein at least 90% of the particles are between 300 and 360 [mu]m. See United States Patent No. *5,204,106*, column 8, lines 56-61.

This Court, therefore concludes that the basic characteristics of a composition consistent with Claim 1 of the *'046* patent, i.e. a composition of particles with sizes in the range of from about 355 to 710 [mu]m, may not be

altered by the inclusion of smaller particles in an potentially infringing composition. Thus, Claim 1 is amenable to infringement actions [*23] against compositions which not only contain particles within the size range of 355 to 710 [mu]m recited in Claim 1, but which also contain particles with sizes smaller than 355 [mu]m. However, the Court also concludes that the presence of substantially more than one-third of a composition's particles below the range cited in Claim 1 would very likely affect the performance in a manner sufficient to alter the basic characteristics of the composition claimed in the *'046* patent, and therefore, would remove the composition from infringement of Claim 1, which, though it allows for and even anticipates the presence of smaller particles, does not anticipate the presence of smaller particles in much greater a quantity than the one-third weight percentage cited in Claim 5 thereof. The inclusion of particles smaller than 355 [mu]m in compositions alleged to infringe upon *'046* patent Claim 1 must remain subject to the limitations of dependant Claims 4 and 5, which narrow the scope of Claim 1 by allowing the additional presence of up to one-third of the particles in the size range of 90 to 355 [mu]m.

b. Does Claim 4 Permit the Presence of Particles Smaller Than 355 [mu]m?

In [*24] order to determine whether the *'046* patent, and specifically Claim 1, can be interpreted to allow for compositions which include other glass particles sized below 355 [mu]m, Plaintiffs suggest that the Court look to the dependant Claim 4. The fourth claim is for the composition of Claim 1, wherein that composition is defined as consisting "essentially of' a mixture of particulate glass within the following three, separately delineated particle size ranges: (I) from about 90 to 350 [mu]m, (2) from about 355 to 500 [mu]m, and (3) from about 500 to 710 [mu]m. [HN9] Under *35 U.S.C. § 112,* a dependant claim "shall be construed to incorporate by reference all the limitations of the claim to which it refers." Id. Additionally, a dependant claim shall specify a further limitation on the subject matter of the claim to which it is referenced. See id. Dependant Claim 4 adds a limitation to independent Claim 1, by requiring not only the presence of particles in the size range contained in Claim 1, but also the presence of particles in the 90 to 350 [mu]m range. Claim 4 further requires that the particles within the 355 to 715 [mu]m range of Claim 1 be comprised [*25] of particles from the two more specific ranges already claimed in dependant Claims 2 and 3, i.e. the 355 to 500 [mu]m and 500 to 710 [mu]m ranges. Plaintiffs contend that, by implication, Claim 1 must be sufficiently broad to accommodate the further restriction of dependant Claim 4. Indeed, the Patent Examiner specifically approved of the revised text of Claim 1 knowing that the dependant Claim 4 was based upon it. In doing so, the Examiner implicitly found that the scope of Claim 1 does not exclude the presence of particles smaller than 355 [mu]m.

[HN10] It is axiomatic in patent law that all patent claims, be they independent or dependant in nature, are presumed to be valid regardless of the validity of other claims. See *Applied Materials, Inc. v. Advanced Semiconductor Materials, 98 F.3d 1563, 1569 (Fed. Cir. 1996), cert. denied 520 U.S. 1230, 117 S. Ct. 1822, 137 L. Ed. 2d 1030 (1997); see also, 35 U.S.C. § 282.* Furthermore, the presumption of validity of patent claims is based upon the presumption of administrative correctness associated with the actions of an agency which is charged with patentability evaluation. See *Applied Materials, 98 F.3d at 1569.* [*26] Accordingly, this Court must give due weight to the presumption of validity of the patentability determinations of the United States Patent Office as manifested by its approval of dependant Claim 4 in conjunction with Claim 1 of the *'046* patent. See id. (citing *Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1139 (Fed. Cir. 1985)).*

The Court concludes that based upon the claim language as interpreted by the Patent Office, the presumptively valid dependant Claim 4 could not exist but for the amenability of Claim 1 to the inclusion of compositions that contain particles below 355 [mu]m, so long as the composition in question also contains those essential particle sizes in the range of 355 to 710 [mu]m. Claim 1 is sufficiently broad to include particle sizes smaller than 355 [mu]m, especially when, as required by Claim 4, the smaller particles co-exist in a mixture with particles that have sizes in the range of 355-500 [mu]m, and with particles that have sizes in the range of 500-710 [mu]m. Furthermore, as stated above, the Court agrees that the basic characteristics of the patented invention would not be altered by the presence of additional smaller [*27] particles below the range state in Claim 1, so long as those smaller particles were subject to the limitations of dependant Claims 4 and 5 which allow for the presence of up to one-third of the composition's particles in the range below 355 [mu]m.

Scope of the Term "Mixture" in Claim 4

In interpreting the meaning and scope of the claims of the *'046* patent, the Court must now consider what is meant by the term "mixture" in dependant Claims 4 and 5. Of these two claims, Plaintiffs have only asserted infringement of Claim 4, which encompasses:

> The composition of claim 1 consisting essentially of a mixture of (1) said particulate glass having a particle size in the range of from about 90 to about 350

> [mu]m, (2) said particulate glass having a particle size in the range of from about 355 to about 500 [mu]m, and (3) said particulate glass having a particle size in the range of from about 500 to about 710 [mu]m.

United States Patent No. *4,851,046*, column 12, lines 18-24.

Defendants have argued Claim 4 dictates, that in order for a product containing smaller sized particles to be infringing, it must have been created by "mixing" three separate compositions [*28] of glass, each of the three said compositions consisting only of particles in each of the three ranges cited. With regard to the language in dependant Claim 4, which claims a composition that consists 'essentially of a mixture,' Defendants state that the term "mixture" in that claim "must be interpreted to require the preparation and subsequent combination of the three compositions. n11 (Doc. 93, p.16 n. 12). To construe it otherwise say the Defendants, would be to resurrect the scope of application Claim 1 which was held unpatentable by the Board of Appeals, and such a construction would effectually broaden, rather than narrow the scope of independent Claim 1, all in violation of *35 U.S.C. § 112*. Defendants state that "'the dependant claim tail cannot wag the independent claim dog.'" (Doc. 93, p.16 n.12) (quoting *North American Vaccine, Inc. v. American Cyanamid Co., 7 F.3d 1571, 1577 (Fed. Cir. 1993))*.

> n11 According to Defendants, Claims 5 and 6 require that the claimed composition be
>
> > "a 'mixture' of three compositions, each having a different range of particle sizes. Thus one composition [with] a particle size range of from about 90 to 350 [mu]m, a second composition [with] a particle size range of from about 355 to 500 [mu]m, and the third composition [with] a particle size range of from about 500 to 710 [mu]m."
>
> (Doc. 93, p.15 n.11).

[*29]

The Court cannot accept Defendants' interpretation of the term 'mixture' for several reasons. First, the plain meaning of the term 'mixture' is that which consists of different elements; it is a noun which refers to what is contained in a composition, not how a composition is created. Specifically, a mixture has been defined as "a portion of matter consisting of two or more components that do not bear a fixed proportion to one another and that however thoroughly commingled are regarded as retaining a separate existence." WEBSTER'S THIRD NEW INTERNATIONAL UNABRIDGED DICTIONARY 1149 (1968). Thus, one would be able to identify the components of a mixture because each component would retain its own composition.

In this case, the resultant embodiment of the patented claims is a powder consisting of bioactive and biocompatible glass particles. If three compositions of glass particles, i.e. three powders, each falling within the three respective size ranges cited in Claim 4, were to be combined with one another, they would no longer remain recognizable in any of the three separate composition forms which they embodied prior to being mixed together, rather they would form a new powder [*30] which would only be identifiable as having particles somewhere within each of the three cited ranges. The individual glass particles would retain their original characteristics, but if three powder compositions consisting of particles within three separate ranges were mixed, those three separate powder compositions would no longer be distinguishable. n12 For example, if Powder-A, containing only particles in the range of 90 to 350 [mu]m, were combined with Powder-B containing particles in the range of 355 to 500 [mu]m, it would not be possible to identify Powder-A within the new Powder-AB, much less to distinguish Powder-AB from another composition powder that was simply created directly from particles in the size range of 90 to 500 [mu]m. Consistent with the above-referenced definition of a mixture, if particles are mixed together to form a resultant powder by any process, each particle will retain its own size characteristics within the mixture, thus, it matters not how the resultant powder composition is formed. The relevant inquiry regarding the "mixture" cited in Claim 4, is whether the resultant mixture contains particles in each of the three cited ranges, not whether three [*31] separate compositions of glass particles were mixed to form one.

> n12 This is inconsistent with Defendants' proffered interpretation of the term 'mixture' as meaning a process of combining three separate compositions together to form the resultant product.

The Court concludes that the term 'mixture' as used in dependant Claim 4 of the *'046* patent means a composition of particulate glass which contains a mixture of glass particles, said particles having sizes within each of the three size ranges cited in Claim 4, and that the term does not mean a mixture comprised of three separately composed compositions of glass particles mixed with one another to form a compound composition as argued by Defendants. The Court's interpretation of the term 'mixture' as used in the context of Claim 4 of the *'046* patent is consistent with the definition cited above. As construed, Claim 4 deals with a mixture of glass particles of various sizes, which particles would each retain their own identity within the mixture; it does not [*32] deal with a mixture of three separately composed compositions of particles, which compositions' individual identities would be lost in, or subsumed by, the resultant mixture comprised thereof.

Citing to the *'046* patent specification at column 4, lines 48-57, Defendants contend that the specification refers to a process of blending three different particle size range components to obtain the 'mixture' referred to in Claim 4. (Doc. 106, pp. 9-10). However, the reference in the specification is an explanation of the patentee's hypothesis that a composition of glass particles with a broader range of particle sizes, i.e. within each of the three cited ranges, yields the most effective osseous defect repair mechanism. The reference is included as support for the proposition that powders containing glass particles over a wider range of particle sizes would improve the cohesiveness and workability of the resultant product. The Court must reject Defendants interpretation of the term 'mixture' on these grounds because [HN11] it is legally improper to read from the specification and into the patent, a process limitation which is simply not there. Additionally, a patent claim cannot be limited by the [*33] examples listed within the patent specification. See *Modine Mfg. Co. v. United States Int'l Trade Comm'n, 75 F.3d 1545, 1551* (Fed. Cir.), *cert. denied, 518 U.S. 1005, 116 S. Ct. 2523, 135 L. Ed. 2d 1048 (1996)* (citing *Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed. Cir. 1988)).*

Defendants' argument that construction of the term mixture to mean anything other than the process of mixing three separate compositions would improperly resurrect the application claim rejected by the Board of Appeals and impermissibly broaden, rather than limit the scope of independent Claim 1, is also wrong. Defendants mistakenly assume that if the term mixture is construed to mean the resultant particulate glass composition, regardless of how it is formed, that such a construction would transform Claim 4 into the equivalent of application Claim 1 which cited a range of particles sizes from about 90 to 710 [mu]m. Application Claim 1 was refused because it was too broad and could be construed to encompass a composition containing glass particles only in the size range below 355 [mu]m, without a requirement that larger particles be present as well. [*34] Claim 4, by construing the term 'mixture' to mean the resultant composition, regardless of the process by which it was formed, encompasses those compositions in which the smaller particles *co-exist* with particles in the 355 to 500 [mu]m range and with particles in the 500 to 710 [mu]m range. Thus, the scope of the *'046* patent Claim 4 is substantially different than application Claim 1. The Court must also reject Defendants' argument that this interpretation of Claim 4 broadens rather than narrows the scope of independent Claim 1, in violation of *35 U.S.C. § 112.* Claim 1 involves a composition containing glass particles within the size range of 355 to 710 [mu]m. Claim 4 further restricts this claim by also requiring the additional presence of particles within the range of about 90 to 350 [mu]m, thus narrowing the scope of Claim 1.

Having considered the patent claims themselves and the specification provided therefor, the Court concludes that the proper interpretation of the scope of the *'046* patent, and specifically Claim 1, is that it not only allows for, but anticipates *via* Claims 4 and 5, the presence of glass particles with sizes smaller [*35] than 355 [mu]m, however, it excludes from Claim 1 the presence of those smaller particles when they occur in a number sufficient to affect the performance in such a manner that they also alter the basic characteristics of the claimed invention. Additionally, the presence of smaller particles allowable under Claim 1 remains subject to the further limitations of dependant Claims 4 and 5, which narrow the scope of Claim 1 by allowing the additional presence of up to one-third of the particles in the size range of 90 to 355 [mu]m. Thus, where a composition contains *substantially* more than one-third of its particles in the smaller range (e.g. two-thirds or more), it will not be within the scope of Claim 1.

ii. The Prosecution History

The prosecution history of the patent is also relevant to the proper construction of the claims therein. As will be discussed below, the prosecution history of the *'046* patent also reveals that it encompasses not only those compositions of particulate glass which consist *only* of particles sized within the range of from 355 to 710 [mu]m, but that it also encompasses compositions with particles in the range of 355 to 710 [mu]m that also [*36] include particles sized smaller than 355 [mu]m.

Claim 1, which originally cited a particle size range of from about 90 to about 710 [mu]m, was rejected by the Patent Examiner under *35 U.S.C. § 103* as unpatentable over prior art, the Gross et al. Patent No. 4,239,113 ("Gross patent"). The examiner concluded that

Claim 1 was too broad and could theoretically encompass the prior art Gross patent which required the presence of much smaller particles (those in the range of 10 to 200 [mu]m). On appeal of the examiner's rejection of Claim 1, the Patent Office Board of Patent Appeals and Interferences ("Board of Appeals") held that any of the claims which could be construed as requiring only smaller particles were not patentable, but it noted that those claims which required the presence of larger particles were indeed patentable. The original Claim 5, which was re-numbered as Claim 4 in the *'046* patent, was found to be patentable by the Board of Appeals because it cited and required the presence of particles within size ranges substantially larger than anything disclosed in the Gross patent. See Opinion on Appeal, No. 88-0461 at p.13 (Doc. 88, Exh. 10 at [*37] OVIT 00368).

Defendants have argued under their fourth defense, that the additional subject matter of Claim 4, i.e. the range of particles from 90 to 350 [mu]m, was "ceded" to the public domain when the Patent Examiner rejected the original broad Claim 1 in favor of the more restrictive Claim 1 that cited particle sizes in the range of about 355 to 710 [mu]m. See Transcript of Feb. 6, 1998 hearing (Doc. 125, p.27, lines 2-5); see also (Doc. 106, p.4). Defendants argue that "the purported scope of claim 1, as now advanced by [Plaintiffs], was 'disclaimed during prosecution,' and, cannot be adopted now." Id. (quoting *Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995)).* However, Southwall and the other cases cited by Defendants, deal with situations where the patentee construed a term one way in order to obtain its allowance in the patent, and then sought to construe it the opposite way against accused infringers. See *Southwall, 54 F.3d at 1576.* In this case, what was originally claimed was a range of particle sizes which could be construed to include *only* smaller particles to the exclusion of larger [*38] ones, thus violating a prior art patent regarding the smaller particles. What is now claimed is a composition which includes particles within the lower range of particle sizes, but only where the co-presence of larger particles is explicitly required as well. This construction is not inconsistent with the position previously taken by Plaintiffs, and all that was ceded to the public domain, or that was "disclaimed" during the prosecution of the original patent application, that can now limit the interpretation of dependant Claim 4, was any claim which permitted the presence of *only* the smaller particles to the exclusion of any larger particles. No portion of the original Claim 5, re-numbered as Claim 4, was ever disclaimed or rejected by the Board of Appeals such that Plaintiffs are now forbidden from advancing an interpretation of its current patent claims consistent therewith. Thus Defendants' fourth defense of prosecution history estoppel must fail.

Plaintiffs had wanted to patent the original broader range because their testing indicated that those compositions with the broadest range, i.e. with particles in the range of from 90 to 710 [mu]m, created the most adhesive and [*39] manipulable resultant product; this was a clear advantage over the prior art Gross patent material, and this advantage served as the impetus for the original application to patent the range of 90 to 710 [mu]m. See *'046* Patent, col. 4, lines 23-68 (Doc. 106, Exh. 1). However, since the originally requested open range was denied because it was so open and broad as to potentially encompass the Gross patent, Claim 1 was cut back to provide Plaintiffs with an open range from 355 to 710 [mu]m. Claims 2 and 3 concern two separate ranges within the broader initial range of Claim 1, and Claims 4 and 5 allow Plaintiffs to claim rights to a composition consisting of a mixture which is subject to Claim 1 and which also contains particles in the lower range. This allowed the Plaintiffs to have a patent over a composition with particles in the most desirable range of 90 to 710 [mu]m, but only so long as the composition consists of a mixture of glass particles across the entire range of particle sizes, so as to avoid the problem of the original claim 1 which would have overlapped the Gross patent. n13 The revised versions of the *'046* patent claims allowed the Plaintiffs to take as full [*40] advantage as possible of the benefits which flow from the use of the broadest range of particle sizes, and to prevent potential infringers from duplicating or mimicking the composition of PerioGlas TM only to avoid an infringement claim by simply adding in some smaller sized particles.

n13 The only way the Gross patent ever falls within the *'046* patent is in compositions under Claim 4, but even then, the *'046* patent is distinct because it requires the co-presence of particles from two separate size ranges larger than those cited in the Gross patent.

In this case, the prosecution history only serves to bolster this Court's conclusion that the *'046* patent claims do not exclude the presence of smaller particles, and it is consistent with this Court's determination that the claims of the *'046* patent, while requiring the presence of particles within the size range of from 355 to 710 [mu]m, do not exclude the possible presence of particles with sizes smaller than 355 [mu]m.

Thus, having considered the patent [*41] claims themselves, the patent specification, and the prosecution history thereof, this Court concludes that as a matter of law, the *'046* patent, and more specifically, Claim 1, is not restricted to an interpretation that all particles be between 355 and 710 [mu]m, as suggested by Defendants.

It is sufficient for a finding of infringement of the *'046* patent claims, that a composition contain either particles solely within the range cited in Claim 1, from about 355 to 710 [mu]m, or that the composition contain additional smaller particles in such quantities that do not affect the basic characteristic of the claimed composition or which occur in a manner consistent with the additional limitations of dependant Claims 4 and 5. However, while infringement of Claim 1 cannot be avoided by the mere additional presence of particles smaller than 355 [mu]m when those smaller particles either do not affect the material characteristics of the composition, or appear in a manner consistent with Claims 4 and 5, a composition which contains a substantially greater number of its particles in the smaller range than is explicitly referred to in Claim 5, can only be found infringing in the unlikely [*42] event that Plaintiffs can show that the basic characteristics of the claimed invention are not altered by the presence of so great a number of smaller particles.

b. Construction of the *'046* Patent Regarding the Appropriate Method for Particle Size Measurement

The second claim interpretation issue which this Court must consider is the method which must be used to measure the bioactive glass particles involved in the claims and Defendants' product. Plaintiffs argue vociferously that the *'046* patent claims call for particle size to be measured by scanning electron microscopy ("SEM") or an equivalent technique, while Defendants contend that particle size should be measured using sieving. n14 The Court recognizes, from the various test data which has been placed on the record, the sharp contrast in results which can be achieved using these two particle size measuring techniques. Indeed, utilizing the results of SEM or what the Plaintiffs contend is an equivalent method, it would appear that Defendants' product BioGran (R) clearly infringes upon the ranges of particle sizes cited in Claims 1 and 4 of the *'046* patent. See, e.g., Corning CELS Analytical Report, (Doc. 106, Exh. [*43] 6 at p.16) (showing particles in each of the three size ranges cited in Claim 4 of the *'046* patent using a Microtrac particle analyzer); Aveka, Inc. Analytical Report, (Doc. 106, Exh. 7 at p. 19) (showing the same). However, utilizing the sieving test data proffered by Defendants for their product, such a finding is not nearly as readily apparent; in fact, from the sieving data on the record, the Court could very well draw the opposite conclusion. Plaintiffs have conceded that should sieving be found to be the controlling measurement technique, there is at least a disputed issue of material facts as to whether Defendants' BioGran (R) infringes the *'046* patent claims. See Plaintiffs' Responsive Memorandum (Doc. 102, p.15).

> n14 SEM technology uses a beam of emitted electrons to scan particles individually in order to determine the shape and morphology of individual particles within a sample, and in order to measure both particle size and size distribution within the sample. Sieving, on the other hand measures particle size by passing a composition through a series of mesh screens, each screen having differing opening sizes. Particles larger than a screen's aperture will be retained on the screen, while those particles smaller than the screen's aperture will pass through to the next sized screen. Sieving is essentially a process of sifting the sample material and collecting individual particles in between the nominal sized screens.

[*44]

In order to determine the proper construction of the *'046* patent claims regarding which particle size measuring technique is to be employed in determining infringement, the Court must again look to the claim language, the patent specification, and the prosecution history of the patent. As mentioned, *supra,* [HN12] it is not appropriate for the Court to consider extrinsic evidence such as the testimony of experts, prior art, dictionaries, and treatises in determining the scope of a claim if the claim language, specification, and prosecution history unambiguously define the terms at issue. See *Vitronics, 90 F.3d at 1584.* Even where extrinsic evidence should be considered to evaluate an ambiguous term, expert testimony is the least favored form of extrinsic evidence available to the Court since such information would not be available to the general public for their consideration in advance of infringement litigation. See *id. at 1585.* The disfavorability of expert testimony is premised on the idea that the public has a right to know just what the patent is claiming protection over so that it can design around the patented claims. See *id. at 1583* [*45] (citing *Markman, 52 F.3d at 978-79,* and stating that "competitors are entitled to review the public record, apply the established rules of claim construction, ascertain the scope of the patentee's claimed invention, and, thus, design around the claimed invention").

i. The Claim Language

Plaintiffs contend that the claim language of the *'046* patent itself should guide the Court to the conclusion that the terminology found therein is consistent with measuring particle size by SEM and not sieving. Defendants, on the other hand, assert that the claim language is consistent with the interpretation that particle size can be determined using sieve analysis. Alternatively, Defendants assert that the patent should be held invalid for its failure

to specify which particle size measurement method is to be employed.

Plaintiffs assert that the claim language qualifies the claimed particle size values with the word 'about,' and that this terminology is consistent with SEM analysis reporting yet inconsistent with sieve analysis reporting. (Doc. 102, p.9). Defendants contend that the use of the term "about" in reference to particle size is consistent with measurement by sieve [*46] analysis, and that it accounts for the "permissible variation in sieve size from the nominal size of standard test sieves." (Doc. 93 p.19 n.17). Plaintiffs state that their experts have made it clear that the "about" language indicates measurement by SEM analysis, but as stated earlier, this Court cannot allow extrinsic evidence, especially in the form of expert testimony, to alter the meaning of a term which is set forth in the claim language, specification, and prosecution history of the patent. Even if the Court were to consider Plaintiffs' experts' testimony as to this issue, those experts have stated that the term "about" could be representative of the margin of error which accompanies measurement by sieve analysis. See Horowitz Deposition (Doc. 93, Exh.2, pp. 109-113). Additionally, the prior art Gross patent, which no party has contended calls for particle size measurement by any technique other than sieving and which patent not once refers to SEM, utilizes the "about" terminology to refer to particle size. See Gross Patent No. 4,239,113 at col. 6, 11.15-35. The Court is unconvinced that the "about" language clearly establishes that SEM is the contemplated measurement [*47] technique called for in the *'046* patent.

Aside from the "about" language of the claims, Plaintiffs have not directed the Court to any other direct claim language to support their contention that SEM is the particle size measurement technique called for in the *'046* patent. To the contrary, Defendants note that, with the exception of one typographical error, n15 out of all of the outer limits of the particle size ranges cited in the existing *'046* patent claims as well as those claims originally applied for, each numerical limit contained therein corresponds precisely with standard sieve opening sizes which were in existence both at the time the patent application was made and when the *'046* patent issued. n16 Thus, Defendants argue, one skilled in the art of measuring particles would recognize the limits of the *'046* patent claims as referring to the standard sized sieve openings generally available to those in the industry. Despite this, a review of the claim language itself is still insufficient for this Court to make a conclusive determination as to which particle size measurement technique is to be read into the *'046* patent claims.

n15 Claim 4 refers to a smaller particle size range of "from about 90 to about 350 [mu]m." The Court agrees with Defendants that the numeral '350' is clearly one of several typographical errors contained within the *'046* patent. The only occurrence of the numeral '350' is within Claim 4, all other references to the same numerical limit cite it as '355'. As noted by Defendants, '350' was first inserted into the patent by amendment without being underlined, and contrary to PTO rules any intended change by amendment would have been indicated by underscoring the same. See (Doc. 106, p.19, n.11) (citing *37 C.F.R. § 1.121*). The Court notes that another typographical error, in the form of transposed numbers, occurs in Figure 1 of the *'046* patent where the obvious particle size range of '90 to 710 [mu]m' is scripted as being '70 to 910 [mu]m' instead. This Court is unwilling to base its construction of these claims on what is obviously a typographical error, and Plaintiffs' attempt to rebut the obvious correlation between the limits of the stated claims and standard sieve sizes, by stating that there "is not a standard sieve size of '350' [mu]m," is completely devoid of merit.

[*48]

n16 The standard sized sieves which were available on the filing date of the *'046* patent were as follows: 90, 106 125, 150, 180, 212, 250, 300, *355,* 425, 500 600, and 710 [mu]m. See (Doc. 106, p.18). The particle size range limits of the *'046* patent claims are underlined.

ii. The Specification

Perhaps the biggest point of contention between the parties regarding the measurement claim interpretation issue, is with regard to what the patent *specification* contemplates as being the appropriate measurement method. Both parties argue vociferously that the specification makes explicit reference to their preferred method of particle size measurement.

Plaintiffs suggest that the specification is replete with references that would lead one skilled in the art to conclude that SEM is called for by the patent. They begin by pointing out that the very first page of the *'046* patent contains a large graphic image of a scanning electron micrograph of the patented product, which image appears again on the second page of the patent as "Figure 1." n17 Additionally, Plaintiffs [*49] note that "Figure 3" is a histogram representing the number of particles within each of fourteen size intervals, which data was

purportedly obtained from scanning electron microscopy. However, the Court notes that aside from identifying the smallest interval on the histogram as representing a particle sized at approximately 90 [mu]m, Figure 3 is lacking either a descriptive title identifying it as representing SEM results or any meaningful description of the limits of the size intervals contained therein, nor for that matter does the histogram indicate which dimension of the particle was measured to determine its "particle size." Next, Plaintiffs direct the Court's attention to the reference to Figure 3 in column 10 of the *'046* patent as evidence that SEM is contemplated. The pertinent reference provides:

> Even a dry arrangement of this broad size range of glass powders, such as shown in a scanning electron micrograph (FIG. 1) illustrates how the particles can fit together in a tightly packed array. FIG. 3 shows the size distribution as measured in the micrograph of FIG. 1.

United States Patent No. *4,851,046*, column 10, lines 13-18.

> n17 As noted at *supra* note 15, the particle size range cited on the cover sheet and in Figure 1 of "70-910 [mu]m" is clearly a typographical error and should read "90-710 [mu]m."

[*50]

Plaintiffs contend that these references in the patent specification are conclusive proof that the specification calls for particle size to be measured by SEM and not sieving. Considering only these references, the Court agrees that one could conclude that SEM appears to be the contemplated method, however, these references cannot be considered in isolation from the remainder of the specification.

Defendants have directed the Court's attention to those references in the specification which they argue would lead one skilled in the art to the opposite conclusion than that proffered by Plaintiffs, i.e. that sieving should be used to determine particle size, not SEM. Defendants have repeatedly pointed to the language in the patent specification related to the "lone" example of the claimed invention cited therein. The example describes a test of the *'046* patentees' hypothesis that compositions containing glass particles within a wider range of particle sizes would perform in a preferred manner. In describing how the various test compositions used in the test were prepared, the specification provides:

> Bioactive glasses (Table 2) were prepared by placing the premixed components [*51] into a covered platinum crucible ... The resultant glass fit was washed with acetone, ground with a mortar and pestle and *sized with a series of calibrated sieves*. Three different particle size ranges were obtained.

United States Patent No. *4,851,046*, column 5, lines 54-60 (emphasis supplied).

Defendants contend that this direct reference to "sizing" of particles with sieves is evidence that "on its face, the patent specification confirms that sieving was the method of particle size determination used to establish the numerical limitations of the particle size ranges to which the patent claims are directed." (Doc. 106, pp.17-18). Defendants also re-direct the Court's attention to the fact that each and every particle size referred to in the specification, and every numerical limitation thereof, corresponds precisely with standard sieve sizes, i.e. 90, 355, 500, and 710 [mu]m, respectively. Thus, in isolation it would appear that the reference to sizing by sieves, and the fact that the patent's particle size range limits correspond exactly with standard sieve sizes, would lead one skilled in the art to conclude that the *'046* patent contemplates sieving as the appropriate [*52] method for determining particle size. Yet, as this Court has noted above, these references must be considered in light of the entire specification.

Based upon the specification of the *'046* patent, even when read in conjunction with the claim language, the Court is unable to conclude that either of the two measurement techniques championed by the parties is more explicitly called for than the other.

iii. The Prosecution History

According to Plaintiffs, the prosecution history of the *'046* patent is "silent" with regard to the appropriate particle size measurement technique to be employed in evaluating claims of infringement thereof. However, Defendants are quick to point out that the prosecution history does reveal some evidence which supports a finding that sieving should be used. Defendants note that when the original patent application Claim 1 for a range from 90 to 710 [mu]m was rejected over the prior art Gross patent which cited a range of particles from about 10 to 200 [mu]m, the Plaintiffs did not amend their application to cite a range of from 201 to 710 [mu]m, but rather chose the next standard sieve size interval as its lower limit for Claim 1, i.e. 355 [mu]m. [*53] This,

according to Defendants, is evidence that the prosecution history, rather than being silent, supports a finding that the *'046* patent claims contemplate the use of sieving as the method for measuring particle size. Yet, in spite of this argument, the Court is still unable to conclude without doubt that the patent claim calls for one of either sieving or SEM any more than it does for the other.

Unfortunately, consideration of the patent claim language, the specification, and the prosecution history of the *'046* patent does not yield a clear and unambiguous answer as to which of the two possible interpretations. i.e. measurement by sieving or measurement by SEM, should be adopted by the Court. Indeed, even after a thoroughly comprehensive and detailed consideration of even the most minute details of the *'046* patent, this Court was unable to resolve to its own satisfaction, which measurement technique one skilled in the art would follow, even though each of the alternative techniques were adequately supported by the claim language, specification, and prosecution history of the patent. The Court must, therefore, turn to an evaluation of the extrinsic evidence presented by the parties [*54] in an effort to resolve the conflict between the two seemingly equal choices of particle size measuring techniques.

iv. Extrinsic Evidence

[HN13] Extrinsic evidence may be considered when the claim language, specification and prosecution history do not unambiguously define the scope of a disputed term, however, prior art and other forms of extrinsic evidence are all preferable to the use of expert testimony since the public has no access to litigation inspired expert testimony and reports. See *Vitronics, 90 F.3d at 1583* (citing *Southwall Tech. v. Cardinal IG Co., 54 F.3d 1570, 1578 (Fed. Cir. 1995)).* In this case, the prior art Gross patent is virtually silent with regard to the method for measuring particle size, except that as mentioned, *supra,* it also contains the "about" language in reference to particle size. As was noted by Defendants, the treatises available at the time the *'046* patent issued, which treatises Plaintiffs' experts Klimpel and Horowitz conceded were authoritative, contradict the experts' opinions by their reference to the fact that sieving was the most widely used and accepted method for measuring particles larger than 50 [*55] [mu]m, n18 and that standardization methods for sieving had been published by the American Society for Testing and Materials ("ASTM") regarding the measurement of those materials covered by the patent claims. See ASTM Manual on Test Sieving Methods (Doc. 106, Exh.11).

n18 See, e.g., J. T. Jones and M. F. Berard, Ceramics (Doc. 106, Exh. 13, p.140) (in the field of glass ceramics, sieving is the standard method for measuring particles coarser than 50 [mu]m).

Plaintiffs have focused a great deal of their argument regarding the proper interpretation of the claims regarding particle size measurement, on the testimony and reports of its two retained-for-litigation experts, Richard Klimpel, and Emanuel Horowitz. Through its experts, Plaintiffs have spent considerable time explaining why SEM is a superior method for determining micron particle size measurements, and how SEM is more accurate, consistent, and reproducible. n19 However, this Court is hesitant to afford any considerable amount of weight [*56] to the experts' theories as to why certain references in the specification or claim language necessarily imply that SEM is what is called for. The Court finds that, as noted above, there are a substantial, if not an equal number of references within the patent specification and claim language that could lead one skilled in the art to the opposite conclusion espoused by Plaintiffs' experts. Despite the experts conclusions regarding what was intended by certain references included by the patentees in the specification and claim language, [HN14] the Court is unwilling to read into the patent claims the subjective intent of the patentee regarding the scope of the claims, when such intent is not clearly expressed in any of the patent documents. See *Shanklin Corp. v. American Packaging Machinery, Inc., 1998 U.S. Dist. LEXIS 966,* No. 95 C1617, 1998 WL 30691 at *4 (N.D. Ill. 1998). Furthermore, as this Court has already acknowledged, [HN15] the use of expert testimony is extremely disfavored when interpreting the scope of patent claims. See *Vitronics, 90 F.3d at 1584, Shanklin, 1998 WL 30691* at *4. While expert testimony may be useful in resolving an ambiguous term not clearly addressed [*57] in either the claim language or specification, it is not useful or appropriate when, as here, the Court is faced with two conflicting interpretations, both of which find adequate support in the claim language and specification. Thus, this Court is unable to utilize Klimpel's and Horowitz's testimony that SEM is the appropriate measurement technique to contradict the conflicting interpretation that sieving is appropriate, since as has been shown, the latter interpretation has been adequately expressed in the patent documents. See *Shanklin, 1998 U.S. Dist. LEXIS 966,* at *13, *1998 WL 30691* at *4 (stating that [HN16] extrinsic evidence, and more specifically expert testimony, may not be used to vary claim language or "contradict the import of other parts of the specification"). Thus, even after evaluating the extrinsic evidence in conjunction with all of the intrinsic evidence, the Court is left with the choice between two equally supported interpretations of the claims regarding which particle size measurement technique is called for.

n19 The Court agrees with Plaintiffs that SEM is apparently a more accurate, precise, and reproducible method for measuring particle size, and it agrees that in a biomedical product, precision should be highly regarded, however, the Court cannot excuse Plaintiffs' failure to clearly articulate the necessity of using such an accurate technique as SEM within the patent, nor their failure to indicate which dimension of the particle the term "particle size" refers, i.e. the maximum or average dimension. As will be discussed, *infra,* Plaintiffs' failure to clearly articulate these matters is contrary to their burden of drafting the patent claims so as to provide notice to the public as to what is being claimed.

[*58]

v. Resolving the Conflict

In deciding which of the two measurement techniques are called for by the patent, the Court must start with the proposition that [HN17] the drafter of the patent has the burden of claiming with specificity what it is that his invention covers. See *35 U.S.C. § 112* P2 (stating that the "specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention"). This is often referred to as the requirement that the patentee give notice to the public, in order to guide them in determining what area is precluded from any future development or enterprise. See *Athletic Alternatives, Inc. v. Prince Mfg., 73 F.3d 1573, 1581 (Fed. Cir. 1996)* (citing among others, *McClain v. Ortmayer, 141 U.S. 419, 424, 12 S. Ct. 76, 77, 35 L. Ed. 800 (1891)* (stating that one of the objectives of requiring a patentee to distinctly claim the scope of the invention is to "apprise the public of what is still open to them")). As noted, *supra,* the public should be able to "review the public record, apply the established rules of claim construction, [*59] ascertain the scope of the patentee's claimed invention, and, thus, design around the claimed invention." *Vitronics, 90 F.3d at 1583* (citing *Markman, 52 F.3d at 978-79).*

The claim language of the *'046* patent does not explicitly state how particle size is to be measured. And more importantly, in referring to particle "size," the claim language is silent as to which dimension of the particles should be evaluated in the measurement process. Traditionally, sieving measurements are expressed in terms of the nominal particle size, i.e. the minimum dimension of the particles. In other words, sieving typically reports a particle's smallest dimension. The SEM method suggested by Plaintiffs is generally known by those skilled in the art as a method which measures either the average or mean particle size. Furthermore, the laser light-scattering particle size determination method, suggested by Plaintiffs as an equivalent of SEM, measures yet another different particle dimension, its mean diameter. See (Doc. 93, Exh.2, pp.156-57). The claim language is noticeably lacking any mention of either the method for measuring particle size or which particle dimension [*60] is intended to be the benchmark for determining infringement. Its silence in these respects is important.

Plaintiffs contend that SEM is implied by the patent claims because the glass particles involved therein are irregularly shaped, and that SEM or its equivalent is the appropriate method for measuring odd-shaped particles. While this Court agrees with Plaintiffs that SEM may be the most accurate and reproducible method for measuring irregularly shaped particles, it notes that the measurement of irregular particles usually involves reference to the particle's maximum or largest dimension. n20 See *Application of John E. Ehrreich, 590 F.2d 902, 907-908 nn.3-4 (C.C.P.A. 1979)* (stating that one skilled in the art, who had knowledge of techniques used to measure irregularly-shaped particles, would measure those particles with reference to the particle's largest dimension). Thus, where it is common in the art to refer to the particle size of irregularly-shaped particles as having a "maximum dimension," and not by reference merely to "particle size," the *'046* patent's failure to refer to the particle size of the glass particles therein by use of the term "maximum" or even [*61] "average size" or "average diameter," concerns the Court.

n20 The Court also notes that SEM is generally used for the measurement of much smaller particles than those involved in the *'046* patent claims. Indeed, SEM is considered to be the preferred method for measuring particles sized smaller than 5 [mu]m according to admittedly authoritative texts. See Terrence Allen, Particle Size Measurement (Doc. 106, Exh. 8, p.56). And, according to authoritative texts, sieving has generally been held to be the appropriate method for determining particle size distribution in ceramic powders coarser than 50 [mu]m. See J. T. Jones and M. F. Berard, Ceramics (Doc. 106, Exh. 13, p.140).

Defendants have argued that Plaintiffs' failure to include a specific reference in the patent claims to either the measurement technique to be employed or the dimension of the particle to be measured in determining infringement, necessarily indicates that they have failed

to satisfy their drafting burden, and since the [*62] patent is indefinite as to these matters, the claims should be ruled invalid. Contrary to Defendants' assertions, this Court finds that the *'046* patent is not invalid for failing to specify a measurement method, rather the two methods for particle size measurement which have been championed by the parties each find support in the patent claims, specification, and prosecution history of the *'046* patent. Accordingly, Defendants' alternative motion for summary judgment of invalidity of the *'046* for failing to satisfy the definiteness requirement of *35 U.S.C. § 112* (doc. 93) is DENIED. What is involved in this case is a situation where the Court is faced with two optional interpretations, a broader reading of the claims which requires particle measurement by SEM and a narrower construction which requires the use of sieving. Thus, the issue for the Court is not whether Plaintiffs' failure to include a specific reference to the required measurement technique renders the claims invalid, rather the issue becomes which of the two conflicting measurement techniques the Court should adopt as the proper interpretation of the claims. Additionally, [HN18] the Federal Circuit has [*63] instructed that this Court should seek to construe the claims of a patent in such a manner as to preserve their validity. See *Applied Materials, Inc. v. Advanced Semiconductor Materials, 98 F.3d 1563, 1569 (Fed. Cir. 1996), cert. denied 520 U.S. 1230, 117 S. Ct. 1822, 137 L. Ed. 2d 1030 (1997).*

In this situation the Court is guided by the Federal Circuit, which recently held in *Athletic Alternatives, Inc. v. Prince Mfg., 73 F.3d 1573 (Fed. Cir. 1996),* that [HN19] when a court is faced with two competing interpretations, one broad, and one narrow, and when the narrow has a legitimate basis in the claims, the narrow should be used, since doing otherwise would violate the requirement that the public be put on notice as to what would constitute an infringement of the claims. See *id. at 1581.* Specifically the Federal Circuit stated:

> [HN20]
> Where there is an equal choice between a broader and a narrower meaning of a claim, and there is an enabling disclosure that indicates that the applicant is at least entitled to a claim having the narrower meaning, we consider the notice function of the claim to be best served by adopting the narrower [*64] meaning.

Athletic Alternatives, 73 F.3d at 1581. As is more fully discussed above, in this case, the narrower interpretation, i.e. that the proper measurement method is sieving, is clearly supported by "enabling disclosures" in the *'046* patent.

Additionally, [HN21] where a patent seeks to protect an invention which is merely an improvement over prior art and is not a pioneer in the relative field, the patent claims are not entitled to the broad construction of claims which would ordinarily be granted the "pioneer." See, e.g., *PennWalt Corp. v. Durand Wayland, Inc., 833 F.2d 931, 964 (Fed. Cir. 1987)* (quoting *Brothers v. United States, 250 U.S. 88, 89, 39 S. Ct. 426, 63 L. Ed. 859,* (1919) ('plaintiffs invention was broadly new, a pioneer in its line, and the patent [was] entitled to a broad construction and the claims to a liberal application of the doctrine of equivalents")); see also *Georgia Kaolin Co. v. Thiele Kaolin Co., 228 F.2d 267, 273 (5th Cir. 1955)* (stating that a mere improvement process does not merit pioneer recognition which would justify a broad construction of claims).

Based upon the foregoing, this Court concludes [*65] that to resolve the conflict, it must adopt the narrower construction of particle size measurement which permits measurement of potential infringement by sieving. n21 Accordingly, for the purpose of determining infringement, this Court interprets the *'046* patent claims as requiring measurement of particle size by sieving.

> n21 The Court notes that had the patent explicitly referred to the particles' average or maximum dimension instead of merely to "particle size," SEM could impliedly be the preferred particle size measurement technique.

2. Second Prong - Literal Infringement or Infringement by Equivalency

Having interpreted the claims, and having determined their meaning and scope as set forth above, the Court now turns to the determination of whether each and every limitation of the properly construed claims occurs in the Defendants' accused device, BioGran (R). See *Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995), aff'd 517 U.S. 370, 384, 116 S. Ct. 1384, 1393, 134 L. Ed. 2d 577, (1996).* [*66] [HN22] When a limitation of a patent is literally found in the allegedly infringing device, literal infringement occurs. See *General Electric Co. v. Nintendo Co., 983 F. Supp. 512, 519 (D.N.J. 1997)* (citing *SmithKline Diagnostics, Inc. v. Helena Labs, Corp., 859 F.2d 878, 889 (Fed. Cir. 1988)).* And, in order to establish literal infringement, each claim limitation "must be found in the accused product, *exactly." Sanders Brine Shrimp Co. v. Bonneville Artemia Int'l, Inc., 970 F. Supp. 892, 910 (D. Utah 1997)* (emphasis supplied) (citing *Becton Dickin-*

son and Co. v. C.R. Bard, Inc., 922 F.2d 792, 796 (Fed. Cir. 1990)). The patentee bears the burden of establishing literal infringement by a preponderance of the evidence. See id. Furthermore, the determination of whether an allegedly infringing composition falls within the scope of the patent claims that have been interpreted as a matter of law by the Court, is a factual application and may only be decided in a motion for summary judgment where there is no dispute as to any material fact to be applied to the claims as construed.

In this case, Plaintiffs have relied exclusively [*67] on their position that Claim 1 not only allows for, but anticipates the presence of particles smaller than 355 [mu]m, and upon their position that SEM is the appropriate measurement technique. Specifically, Plaintiffs have argued that Claim 1 is infringed when any more than a *de minimis* amount of a composition's particles are within the 355 to 710 [mu]m range and smaller particles are present as well. See (Doc. 102, p.17). Should the Court disagree with their claim interpretation argument regarding the method of particle size measurement, Plaintiffs contend that there is at least a disputed issue of fact as to infringement which would prevent the entry of summary judgment of non-literal infringement. See (Doc. 102, pp.15, 19).

Plaintiffs first contend that Defendants' own contradictory sieving data creates a disputed issue of fact. They argue that in numerous lots of the BioGran (R) product, there is greater than a *de minimis* amount of particles larger than 355 [mu]m if the Court takes into account the number of "lost" particles which were not counted in the data. Yet, even if the Court were to count the "lost" particles against Defendants, the result would be [*68] that in only 16 of 251 compositions tested were there more than five percent of the composition's particles above 355 [mu]m; and of those 16, never were there more than 8.72 percent of the particles by weight above 355 [mu]m. n22 See (Doc. 93, Exh. 28). Plaintiffs further note that when Lot # 382 of BioGran (R) was tested as part of Defendants' quality control process, 2.52 percent of the particles were measured larger than 355 [mu]m, and when a portion of the same lot was analyzed using sieving as reported in Defendants' Exhibit 12, the results were that only 1.4 percent of the particles were larger than 355 [mu]m. Cf., (Doc. 93. Exh. 28, p.4), with (Doc. 93, Exh. 12, p.3). While the Court agrees that this apparent ambiguity creates a disputed issue of fact, this disputed fact is not material.

n22 These results were extrapolated from Defendants' quality control data (Doc. 93, Exh. 28) for the following 16 lots of the 251 reported therein:

lot #	percentage>355um	percentage lost	percentage assumed>355um
228	4.51	4.21	8.72
259	3.87	3.18	7.05
328	0.49	5.44	5.93
330	1.25	4.46	5.71
376	5.67	0.88	6.55
377	2.37	3.85	6.22
381	4.61	1.04	5.65
398	4.33	3.24	7.57
407	5.26	0.88	6.14
411	2.60	3.60	6.20
412	4.88	0.72	5.60
419	5.22	0.78	6.00
425	3.84	1.42	5.26
449	5.50	0.78	6.78
451	4.46	1.76	6.22
456	3.12	2.70	5.82

Additionally, Plaintiffs' [*69] arguments mistakenly assume that Claim 1 has been interpreted to mandate a finding of infringement based on a threshold of merely a *de minimis* amount of particles above 355 [mu]m. To the contrary, this Court has construed Claim 1 to exclude from infringement those compositions which

contain substantially greater than the one-third fraction cited in Claim 5 of its particles below 355 [mu]m, since the presence of so great a number of smaller particles would necessarily affect the performance of the composition in such a manner as to also alter its basic characteristics. As this Court has previously stated, in order to infringe Claim 1, Defendants' product must consist "essentially of" particles between 355 and 710 [mu]m. And simply put, compositions which contain no more than 8.72 percent of their particles larger than 355 [mu]m, cannot be said, even under a strained interpretation, to consist "essentially of" particulate glass with a particle size range of "from about 355 to about 710 [mu]m" as required by Claim 1 of the *'046* patent.

Plaintiffs next contend that the "about" language used in the patent claims actually lowers the limits contained therein by five percent, [*70] so that infringement of Claim 1 may be found where it is shown that a composition consists essentially of particles from "337 to 710 [mu]m" instead of the 355 to 710 [mu]m which is facially apparent. This Court agrees with Defendants and concludes that the "about" language contained in the *'046* patent claim language merely acknowledges the inherent discrepancies associated with measuring particle size by sieving, which this Court has already determined is the measurement technique that must be used to determine infringement. Furthermore, since the size identity of particles on either side of a claim limit cannot be measured using standard sieves, the upper and lower infringement limits stated in a claim's particle size range cannot be extended to accommodate the particles which may fall on either side of the expressed limits. Indeed, because only SEM is capable of precisely measuring those particles on either side of a limit, the variance resulting from the "about" language is relevant only where SEM is the method to be used to measure particle size; however in this case, for the reasons set forth in greater detail above, the *'046* patent's claim language, specification, prosecution [*71] history, and the extrinsic evidence available to the Court, all dictated that the claims therein be construed to require sieving as the appropriate measurement technique. Additionally, the Court notes that it seems likely that the variation of five to ten percent which Plaintiffs contend is anticipated by the "about" language, has manifested itself in the sieve testing results proffered by Defendants, wherein no more than 8.72 percent of the particles measured by sieve analysis were actually larger than the upper limit sought by use of the 355 [mu]m standard sieve.

And while Plaintiffs vigorously contend that Defendants' proffered sieve testing data is disputed and unreliable, in contravention of their burden in establishing infringement by a preponderance of the evidence, they have failed to produce *any* independent evidence that, using sieving, the Defendants' BioGran (R) consists "essentially of" bioactive glass particles in the size range of 355 to 710 [mu]m such that it infringes Claim 1. See *Sanders Brine Shrimp Co., 970 F. Supp. at 910* (citing *SRI Int'l v. Matsushita Elec., 775 F.2d 1107, 1123 (Fed. Cir. 1985))*. Furthermore, even were [*72] the Court to assume that Claim 1 was infringed by Defendants' product, which it is not, there is absolutely no evidence in the record which could establish infringement of Claims 2, 3, or 4, using sieving. The only evidence of sieve testing contained in the record of this case is that proffered by the Defendants, and that evidence only indicates what percentages of particles are larger than 355 [mu]m. In no manner does this evidence indicate where along the continuum of particle sizes above 355 [mu]m, the particles in those percentages lie. Therefore, the Court is without any evidence to conclude that the BioGran (R) product contains particles which would satisfy any of the size ranges of Claims 2, 3, or 4, i.e. from about 355 to about 500 [mu]m, from about 500 to 710 [mu]m, or within each of the three ranges of from about 90 to 355 [mu]m, from about 355 to about 500 [mu]m, and from about 500 to about 710 [mu]m, respectively. However, consideration of infringement of the dependant Claims 2, 3, and 4 is unnecessary when, as here, the patentee has failed to establish as a matter of law that the independent claim upon which the dependant claims rely is infringed. See [*73] *Wahpeton Canvas Co. v. Frontier, Inc., 870 F.2d 1546, 1552 n.9 (Fed. Cir. 1989).* Specifically, the Wahpeton Canvas court stated:

> [HN23]
> One may infringe an independent claim and not infringe a claim dependant on that claim. The reverse is not true. One who does not infringe and independent claim cannot infringe a claim dependant on (and thus containing all the limitations of) that claim.

Id. (citing *Teledyne McCormick Selph v. United States, 214 Ct. Cl. 672, 558 F.2d 1000, 1004 (Ct. Cl. 1977)).*

Based upon the foregoing, this Court concludes that there is no dispute as to any material fact related to the determination of literal infringement of the *'046* patent claims. Accordingly, as is set out more fully above, the evidence before the Court regarding the particle size distribution of Defendants' BioGran (R) compels the conclusion that, with no more than 8.72 percent of its particles sized larger than 355 [mu]m, BioGran (R) does not consist "essentially of" glass particles within the size range of "from about 355 to about 710 [mu]m," and therefore is not literally infringing of Claim 1 of the *'046*

patent. Furthermore, the Court concludes that the [*74] substantially large number of particles sized below 355 [mu]m in the BioGran (R) product (at least 91.28 percent), would affect the performance of Plaintiffs claimed invention such that its basic characteristics would be significantly altered, which conclusion also supports this Court's finding of non-literal infringement of Claim 1. Having concluded that Defendants are not literally infringing the only independent claim of the *'046* patent, it is axiomatic that there is also no literal infringement of the dependant claims predicated thereon which have been asserted by Plaintiffs. See *Wahpeton Canvas Co., 870 F.2d at 1552 n.9.* Plaintiffs having failed to satisfy their burden of establishing literal infringement as a matter of law, and the Court is of the opinion that Defendants' motion for summary judgment with respect to Count I of the complaint (doc. 93), i.e. of non-literal infringement, should be and the same is hereby granted. Accordingly, Plaintiff's motion for summary judgment for literal patent infringement (doc. 88) should be and the same is hereby denied.

Doctrine of Equivalents

[HN24] Where no literal infringement can be established, the Court may still [*75] find an accused product infringing of a patent under the doctrine of equivalents. See *Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, , 117 S. Ct. 1040, 1045, 137 L. Ed. 2d 146, (1997).* In their motion for summary judgment (doc. 88), Plaintiffs "reserved for trial" any issue related to the finding of infringement under the doctrine of equivalents. See (Doc. 88, p.13). Defendants assert that Plaintiffs have put forth no evidence which this Court may properly consider in determining equivalency, and summary judgment in their favor is therefore appropriate.

[HN25] The doctrine of equivalents requires that the accused device must "perform substantially the same function in substantially the same way to achieve substantially the same overall result as the claimed invention." *General Electric Co. v. Nintendo Co., 983 F. Supp. 512, 520 (D.N.J. 1997)* (citing *Graver Tanker & Mfg. v. Linde Air Prods., 339 U.S. 605, 608, 70 S. Ct. 854, 856, 94 L. Ed. 1097, (1950)).* The essential inquiry, whether equivalency is to be established by use of the "triple identity" test which evaluates function, [*76] way, and result, or by use of the "insubstantial differences" analysis, is whether the accused device contains elements which are "identical or equivalent to each claimed element of the claimed invention[.]'" Id. (quoting *Warner-Jenkinson, 117 S. Ct. at 1054).* In making its comparison, the Federal Circuit has cautioned that courts may not compare the accused product with the commercial embodiment of the patentee's claimed invention, rather the comparison must be made to the individual claims of the patent. See *Zenith Labs. v. Bristol-Myers Squibb Co., 19 F.3d 1418, 1423* (Fed. Cir.), *cert. denied, 513 U.S. 995, 115 S. Ct. 500, 130 L. Ed. 2d 409 (1994).* The doctrine of equivalents is considered the exception rather than the rule, and should not be employed by the court merely to rescue a patentee's claim from a finding of non-infringement. See id.

Defendants asserted in their motion for summary judgment of non-infringement that Plaintiffs had produced no evidence in the form of expert reports or testimony regarding equivalency which could support a finding of infringement under the doctrine of equivalents, and they sought [*77] summary judgment of non-infringement under the doctrine. See (Doc. 93, p.24). Plaintiffs responded by contending that while they had not produced expert testimony or reports on the issue, other evidence of equivalency was available, which evidence would preclude summary judgment in favor of Defendants. Plaintiffs assert that two studies carried out by Drs. Rieger and Wheeler, independent researchers at the University of Texas and the University of Oregon, respectively ("the Rieger and Wheeler studies"), show equivalence. See (Doc. 102, p.20). According to Plaintiffs, both of these researchers compared the Defendants' accused BioGran (R) product with the commercial embodiment of the *'046* patentee's invention, PerioGlas TM, and each concluded that

> the products do substantially the same thing (treat periodontal osseous defects) in substantially the same way (by promoting the formation of new bone) to achieve substantially the same result (filling of the periodontal defect or pocket). Exh. 17; Exh. 18. Both studies concluded that the accused BioGran product and the patented product PerioGlas were indistinguishable.

(Doc. 102, p.20). Plaintiffs also responded that [*78] they had further evidence of equivalence in Defendants' own submission to the Food and Drug Administration ("FDA") and Defendant Ducheyne's publications, both of which asserted that the two products, PerioGlas TM and BioGran (R) are "equivalent." See id. at 20-21 (citing to Exhs. 19, 20). Plaintiffs argue that these combined showings are sufficient to establish a *prima facie* case for infringement under the doctrine of equivalents. See id. at 21.

Defendants responded to these arguments by turning the Court's attention to *Rule 56(c) of the Federal Rules of Civil Procedure*, arguing that none of the available evidence which Plaintiffs referred to fall within the catego-

ries of evidence, i.e. pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, which the Court can consider in a motion for summary judgment. As such, Defendants contend that at least the Rieger and Wheeler studies, especially since neither researcher has been deposed or supplied an affidavit, are inadmissable hearsay which cannot prevent the entry of summary judgment on the doctrine of equivalents. See (Doc. 126, p.5).

Regardless of the inadmissability or propriety [*79] of the Court's consideration of such evidence, the Court concludes that the Rieger and Wheeler studies, and Defendants' FDA submission n23 are fatally deficient in that, they compare the accused BioGran (R) product, not to the patent claims, but to the commercial embodiment of the patentee's invention in contravention of *Zenith Labs. v. Bristol-Myers Squibb Co., 19 F.3d 1418, 1423 (Fed. Cir. 1994),* in which the Federal Circuit stated that [HN26] it would be "error for a court to compare in its infringement analysis the accused product ... with the patentee's commercial embodiment." Id. Rather, an accused device should be compared with the patent claims. See id.; see also *Martin v. Barber, 755 F.2d 1564, 1567 (Fed. Cir. 1985)* (stating that "infringement, either literal or by equivalence, is determined by comparing the accused device with the claims in suit, not with the preferred or commercial embodiment of the patentee's claimed invention") (and citing *ACS Hosp. Sys. v. Montefiore Hosp., 732 F.2d 1572, 1578 (Fed Cir. 1984); Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 902 (Fed. Cir. 1984)* (stating that infringement [*80] is determined by comparison with the claimed invention, not the patentee's marketed product)). Finally, Plaintiffs' remaining "evidence" of equivalence are publications authored by Defendant Ducheyne, one of which was published in 1985, four years prior to issuance of the *'046* patent. Thus, the appropriate comparison between the *'046* patent claims and the accused device, which incidently was not even made or sold until 1995, could not even have been made in this paper since the claims upon which a comparison must necessarily have been made were not yet in existence. The Court agrees that Plaintiffs have failed to put forth any evidence under the doctrine of equivalents which the Court could properly consider in determining whether the Defendants' accused BioGran (R) product is substantially equivalent to the *'046* patent claims and not the commercial embodiment thereof.

> n23 As Defendants note, the Court cannot use the FDA 510(k) notification in considering infringement by equivalence, since in addition to comparing the commercial embodiment of the *'046* patentee's invention, instead of the patent claims, in contravention of the authority cited, *infra,* the FDA filing is controlled by a separate regulatory scheme. See *Mahurkar v. C.R. Bard, Inc., 1993 U.S. Dist. LEXIS 9259,* No. 92 C 4803, *1993 WL 259446* at *9 n.16 (N.D. Ill. Jul. 6, 1993). The Court notes that references in this FDA submission to the patentee's commercial embodiment, PerioGlas TM refer to it as a predicate device, and the technical comparison chart therein notes the marked difference between the two with regard to one of the essential *'046* patent claims, particle size. Thus, comparing the accused BioGran (R) with the patent claims, the 510(k) technical comparison charts shows that the two are not substantially equivalent with regard to the relevant claimed particle ranges.

[*81]

Defendants also note, that while Plaintiffs have failed to put forth any evidence which this Court may properly consider in deciding infringement under the doctrine of equivalents, the fact that the Defendants' product obtained subsequent patent approval of its own, is evidence which the Court could consider in determining non-equivalence, i.e. such evidence establishes the substantiality of the differences between the claims and accused device. See *Zygo Corp. v. Wyko Corp., 79 F.3d 1563, 1570 (Fed. Cir. 1996).* Thus, despite their protestations otherwise, the Court concludes that Plaintiffs have failed, as a matter of law, to make a *prima facie* showing of infringement of the *'046* patent by the Defendants' accused BioGran (R) product, under the doctrine of equivalents.

Based upon the foregoing considerations, the Court is of the opinion that Defendants' motion for summary judgment of non-infringement under the doctrine of equivalents (doc. 93) should be and the same is hereby granted.

3. The Defense of Patent Invalidity

Defendants have contended in their alternative motion for summary judgment of patent invalidity, that the *'046* patent claims, if construed [*82] as urged by Plaintiffs, should be held invalid for violating the definiteness requirement of *35 U.S.C. § 112,* because they fail to indicate what percentage of particles must be within the range cited in Claim 1 to avoid infringement, and because they fail to explicitly state which measurement technique is to be used in determining infringement. With respect to the failure to explicitly enumerate which percentage of particles must be within the range cited in Claim 1, Defendants have failed to satisfy their burden of setting forth clear and convincing evidence that the claims are indefinite, especially in light of the Court's

obligation to construe the claims in such a manner as to preserve their validity. See *Applied Materials, Inc. v. Advanced Semiconductor Materials, 98 F.3d 1563, 1569 (Fed. Cir. 1996)*. With respect to the second claim interpretation issue, this Court has previously stated, the patent claims, specification, and prosecution history do not fail to indicate a measurement technique, rather they indicate both sieving and SEM, and both of these alternative methods find adequate support in the patent claim language, specification, [*83] and prosecution history. Thus, an action for invalidity on the grounds of inadequate disclosure cannot survive, and the resulting issue for the Court, i.e. which of the two alternative measurement techniques should be employed, has been resolved above. Furthermore, having already found non-infringement of the valid *'046* patent claims, neither literal nor under the doctrine of equivalents, the Court is of the opinion that Defendants' alternative motion for summary judgment should be and the same is hereby denied.

B. Defendant Ducheyne's Motion for Summary Judgment to Dismiss Claims Against Him

Individual Defendant, Paul Ducheyne, has separately moved for summary judgment seeking dismissal of all claims against him individually (doc. 92). Based upon this Court's findings on non-infringement above, Ducheyne's motion as it relates to the claims of patent infringement asserted against him is moot. With respect to the remaining claims (counts II through VI), which deal with false advertising, unfair competition, and trade disparagement, Ducheyne asserts that he did not himself participate in the acts complained of, and that he is merely the chairman of Orthovita's Board of Directors [*84] who has co-authored several academic journal articles. It is his contention that he can not be personally liable as a corporate officer for these actions if he merely controls corporate affairs. See (Doc. 92, memorandum at p.3) (citing *McCarthy on Trademarks and Unfair Competition* at § 25:24).

Plaintiffs have responded to Ducheyne's motion by asserting that this Court's denial of a similar motion to dismiss filed by Ducheyne previously, bars him from representing the same issues under the law of the case doctrine, yet this argument overlooks the differing standards applied to motions to dismiss under 12(b)(6) and for summary judgment. Plaintiffs also note that Ducheyne has failed to file a statement of undisputed material facts contemporaneously with his motion for summary judgment as required by Local Rule 56.1(A). This Court's Local Rule explicitly warns that the "failure to submit such a statement constitutes grounds for denial of the motion." However, in this case, the undisputed facts presented by Plaintiffs in their response are sufficient for the Court's use in determining whether summary judgment is appropriate.

Aside from the technical justifications for denying [*85] Ducheyne's motion, Plaintiffs only evidence that Paul Ducheyne individually participated in the acts of unfair competition and false advertising is that he reviewed the scientific content of Orthovita's literature which is accused of falsely describing technical aspects of the BioGran (R) product. The remainder of Plaintiffs' arguments for maintaining the claims asserted against Ducheyne revolve around the claims of infringement, which this Court has already determined are moot. In order to maintain an action against a corporate officer individually, it must be shown that the officer personally took part in the accused activities or that he directed employees to do so. With respect to the claims of unfair competition and false advertising alleged in Counts II through VI, the Court finds that the undisputed material facts, as presented by Plaintiffs in their response to Ducheyne's motion for summary judgment, reveal that Paul Ducheyne was not personally involved in the activities complained of therein, but rather served only as chairman of the Board of Directors, controlling corporate affairs. Accordingly, the Court is of the opinion that Ducheyne's motion for summary judgment to dismiss [*86] the claims against him (doc. 92) with respect to the claims in Counts II through VI should be and the same is hereby granted. As noted above, the motion with respect to the claim of infringement is moot based upon this Court's finding of non-infringement.

C. Plaintiffs' Motion for Summary Judgment on False Advertising, Unfair Competition, and Trade Disparagement Claims, and for Summary Judgment on Defendants' Counterclaims

Plaintiffs have also moved for summary judgment on their false advertising, unfair competition, and trade disparagement claims brought under Section 43(a) of the Lanham Act and Florida state law, as well as for summary judgment on Defendants' counterclaims for false patent marking. In considering this motion, the Court will be guided by the principle that [HN27] summary judgment is not appropriate where there is a genuine dispute as to material facts, such that a reasonable juror could return a verdict for the non-moving party based thereupon. See *Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S. Ct. 2505, 2510, 91 L. Ed. 2d 202, (1986)*. All reasonable factual inferences shall be drawn in a light most favorable to the non-moving [*87] party. See *Atlantic Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 332, 110 S. Ct. 1884, 1888, 109 L. Ed. 2d 333 (1990)* (citing *Matsushita Electric Industrial Co. v. Zenith Radio Corp., 475 U.S. 574, 587, 106 S. Ct. 1348, 1356, 89 L. Ed. 2d 538 (1986))*.

False advertising and unfair competition under Section 43(a) of the Lanham Act

Plaintiffs first assert that they are entitled to judgment as a matter of law on their claims of false advertising and unfair competition under Section 43(a) of the Lanham Act. [HN28] This section of the Lanham Act creates a civil remedy for those injured by a competitor's misleading or false advertisements. Specifically, the relevant statutory provision states:

> [HN29]
> (a)(1) Any person who, ... in connection with any goods or services ... uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which-
> (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial [*88] activities, shall be liable in civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a)(1)(B).

Generally, a party must establish the following five elements in order to succeed on a claim for false advertising under the Lanham Act:

> 1) That the defendant made a false or a misleading statement concerning the plaintiff's product in advertising materials;
>
> 2) That the advertisements actually, or had the tendency to deceive a significant number of the consumers to which they were directed;
>
> 3) That the defendant's deception was material, i.e. that it likely influenced consumers' purchasing decisions;
>
> 4) That the advertised product of the defendant traveled in interstate commerce; and,
>
> 5) That the plaintiff is likely to be, or already has been, injured by the misleading or false advertising as evidenced by either declining sales or a loss of goodwill among consumers.

See *Tire Kingdom, Inc. v. Morgan Tire & Auto, Inc., 915 F. Supp. 360, 364 (S.D. Fla. 1996)* (citing among others *Ditri v. Coldwell Banker, 954 F.2d 869, 872 (3d Cir. 1992)* [*89] (internal citations omitted)). [HN30] False advertising may be established under the Lanham Act in one of two ways: 1) by establishing that the advertisement is facially false; or 2) by establishing that an advertisement, though literally true, is likely to confuse or mislead the consumers to which it is directed. See *Johnson & Johnson v. GAC Int'l, Inc., 862 F.2d 975, 977 (2d Cir. 1988)*. In the former situation, the plaintiff need not demonstrate that there would be any adverse affect on purchasing consumers, and must only show that the advertising is false, that the defendant's goods are sold in interstate commerce, and that injury to the plaintiff is likely. See *Castrol Inc. v. Pennzoil Co., 987 F.2d 939, 943 (3d Cir. 1993); Energy Four, Inc. v. Dornier Med. Sys., Inc., 765 F. Supp. 724, 732 (N.D. Ga. 1991)*. Accordingly, when the advertising material cannot be shown to be facially false, the plaintiff must establish the remaining elements set forth above, i.e. that the alleged deceptive advertisements were material, and that the accused advertising had already, or is likely to, have an impact on consumer purchasing decisions.

Plaintiffs [*90] contend that Defendants' advertisements are literally false in five respects, and that no showing of consumer confusion or impact is therefore required in order for the Court to enter summary judgment against Defendants for false advertising under the Lanham Act. However, Defendants argue that Plaintiffs have presented "no proof - let alone any undisputed facts - establishing that Orthovita's advertisements are either literally false, or are likely to mislead and confuse consumers." (Doc. 105, p.4.) The Court will now consider each of the five categories of alleged falsehoods, and the amenability of each to disposition at the summary judgment stage will be addressed below.

1. Claims of superiority.

Plaintiffs' first argue that Defendants' advertisements falsely claim that BioGran (R) is superior to PerioGlas TM. This allegation is based upon the fact that Defendants' brochures state "BIOGRAN - The superior alternative for your patients and you" and also state that "BioGran provides clinicians with the best alternatives for their patients." See (Doc. 89, Exhs. 7,8). And since BioGran (R) and PerioGlas TM are the only two commercially available bioactive glass products [*91] on the market, Plaintiffs insist that these remarks can only be understood to assert superiority over Plaintiffs' PerioGlas TM. According to Plaintiffs, there is ample evidence,

some of which was commissioned by Defendants themselves, which establishes the equivalency of the two products, and that the tests relied upon by Defendants to support this claim are unreliable.

Defendants contend first that the "superior choice" statements are not actionable as a matter of law because they constitute mere puffery. The Court agrees that, [HN31] unless a claim that a product is "better" than a competitor's is "backed-up" with false allegations that "tests prove" superiority when no such tests or only unreliable tests exist to support such a claim, the superiority claim constitutes no more than unactionable puffery. See *Nikkal Indus. v. Salton, Inc., 735 F. Supp. 1227, 1234 n.3 (S.D.N.Y. 1990).* For non-puffing superiority claims, an affirmative showing that the claim is false is required, i.e. a showing that defendant's product is equal or inferior. See *Castrol, Inc. v. Quaker State Corp., 977 F.2d 57, 63 (2d Cir. 1992).* In this case, Defendants have not even implied [*92] in their advertisements that "tests prove" superiority of the BioGran (R) product, thus the existence or reliability of tests supporting the statement of superiority is irrelevant, and as mere puffery, the statement is not actionable as a matter of law under Section 43(a) of the Lanham Act.

Furthermore, Defendants also note that Plaintiffs interpretation of these "superior choice" statements as referring to the only choices as either BioGran (R) or PerioGlas TM is improper when viewed in full context of the market for periodontal restoratives. That market is dominated, not by these two bioactive glass compositions, but is rather a crowded market of various similar products, with freeze-dried bone compositions taking the lion's share of the market. Thus, in context, these "superior choice" statements more accurately reflect Defendants' efforts at convincing clinicians that a bioactive glass composition, like BioGran (R) *or* PerioGlas TM is the superior alternative to freeze-dried bone compositions. Indeed, a closer examination of Orthovita's advertising materials reveals an emphasis on how a bioactive glass composition has the advantage of easing consumer weariness about having [*93] bone matter, which has been extracted from a cadaver and thrice sanitized, implanted into their mouths. See e.g., (Doc. 89, Exh. 7). Thus, even were the Court to have concluded that the superiority puffery statements were actionable as false advertising under the Lanham Act, which they are not, the dispute created by the context in which the advertised claims are made, constitutes a genuine dispute as to a material fact sufficient to preclude entry of summary judgment in Plaintiffs' favor.

As further evidence creating a genuine dispute as to the material facts of this claim, Defendants note the existence of a separate patent for the BioGran (R) product based on its "improved performance" over prior the relevant prior art, thus creating a dispute as to whether or not Defendants' product truly is superior in some aspect to PerioGlas TM.

2. Claims that all of the particles in BioGran (R) are between 300 and 355 [mu]m.

Plaintiffs next argue that Defendants' claims within promotional materials that the BioGran (R) glass particles are all within the optimal particle size range of from 300 to 350 [mu]m are literally false. In one instance, a document which appears to [*94] be an outline for a visual presentation, and not any document which is itself distributed as advertising, contains the statement that "100% of the BioGran TM granules is the optimal range for healthy bone growth. Only 9% of PerioGlas TM is in the optimal size range; the balance is either too small or too large to be fully effective." See (Doc. 89, Exh. 6, at P7). Plaintiffs also refer to tests which conclusively show that Defendants' BioGran (R) contains glass particles both larger and smaller than the 300 to 355 [mu]m range. Furthermore, Plaintiffs note that even Defendants own internal quality control data indicates that only 80% of the particles in BioGran (R) must fall in the cited range in order to be marketable, and that in most cases 15 to 20% of the particles in BioGran (R) fall outside of the cited range. These undisputed facts, according to Plaintiffs, establish that Defendants' statements that all of the BioGran (R) particles are within the optimal 300 to 355 [mu]m size range are literally false.

Defendants, on the other hand, assert that the very facts relied upon by Plaintiffs are the subject of dispute, and that in proper context, their claims are true. Defendants [*95] note that the tests relied upon by Plaintiffs were conducted using measurement methods other than sieving, which this Court has already determined is the appropriate measurement method for patent infringement analysis. Defendants note also that the consumers to which these advertising statements are directed understand sieving to be the proper measurement technique, and that like Plaintiffs' own experts, these individuals understand that the nominal sizes of a sieve-based particle size range will naturally encompass a margin of error of plus or minus of upwards of 10%. These assertions again create a genuine dispute as to material facts which necessarily preclude this Court from entering summary judgment of literal false advertising in favor of Plaintiffs with regard to these of Defendants' claims.

3. Claims that PerioGlas TM does not regenerate bone and that particles larger than 355 [mu]m have inferior characteristics.

Next, Plaintiffs argue that Defendants have false represented that PerioGlas TM does not regenerate bone and that bioactive glass particles sized larger than 355 [mu]m have incomplete glass reaction, no reactant glass

core, and no protective pouch. [*96] These allegations arise from the following statements in one of Defendants' brochures:

> when bioactive glass granules of a smaller size range than BioGran were implanted, many of the particles became completely or almost entirely resorbed as indicated by the many particle fragments. Although some of the largest particles in this small size range excavated, there is little evidence of new bone formation.
>
> ... when bioactive glass granules larger than BioGran were implanted, cracks formed as the material chemically reacted, but no real excavation was seen as the chemical reactions were limited to the surface. Again, minimal or no bone formation was seen.

(Doc. 89, Exh. 4, at BL 00304, BL 000306).

According to Plaintiffs, these statements "clearly indicate[] that PerioGlas, the only other bioactive glass product known to have particle sizes below 300 [mu]m or above 355 [mu]m is bad, and that such particles are not present in BioGran." n24 (Doc. 89, p.17). Plaintiffs argue that Defendants have made these statements despite the fact that more than one half of the particles in their own BioGran (R) product are either smaller or larger than the cited range, and despite [*97] the fact that their own studies (e.g. the Rieger and Wheeler studies, Doc. 89, Exhs. 17, 19) show that excavation and hollowing out of the particles' central core occurs in particles of bioactive glass of smaller and larger size ranges.

> n24 Such an indication is not as "clear" to the Court as Plaintiffs assert. Facially, these statements appear to compare the results of compositions which contain only particles which are either smaller or larger than the 300 to 355 [mu]m range, not to compositions which contain some additional particles smaller or larger than the range.

Defendants respond to Plaintiffs' argument that BioGran (R) itself contains greater than 50% of its particles either smaller or larger than the cited range, by repeating the fact that this assertion relies on measurement of particle size by methods other than sieving. They also note that the Rieger study relied upon by Plaintiffs involved a non-periodontal application of the bioactive glass in the ilium of New Zealand White rabbits.

At a [*98] very minimum, there is a dispute as to whether the various studies indicate that the additional presence of glass particles larger and smaller than the cited 300 to 355 [mu]m range, has a negative effect on the process of bone regeneration in periodontal applications. This is sufficient to preclude a grant of summary judgment of literal false advertising in favor of Plaintiffs on these claims.

4. Claims that inflammation occurs with particles smaller than 250 [mu]m.

Plaintiffs have also argued that Defendants have falsely informed the public through their advertising that particles smaller than 250 [mu]m "react too quickly leading to full particle resorption, [and] inflammatory response follows." (Doc. 89, Exh. 4, at BL 000298). According to Plaintiffs, the only evidence which Defendants have to support this claim is the research of Schepers and Ducheyne and an article written by Wilson and Low, which indicate that particles up to 40 [mu]m may cause inflammation. According to Plaintiffs, there is no evidence that particles in the 90 to 250 [mu]m range cause inflammation, and this makes the claim that particles smaller than 250 [mu]m cause inflammation unsupported [*99] and thus literally false.

Referring to Dr. Ducheyne's declaration, made in response to Plaintiffs' challenge of the patentability of the Schepers patent, and to other of his writings and deposition testimony, Defendants simply assert that their claims that particles smaller than 250 [mu]m tend to dissolve more rapidly, thus leading to an inflammatory response, is well grounded and is not "unsupported" as Plaintiffs would have the Court believe. Again, Defendants' assertions create the necessary dispute as to a material fact, i.e. the alleged falsity of the statement, which precludes entry of summary judgment on this claim in Plaintiffs' favor.

5. Claims regarding products' FDA approval.

Plaintiffs lastly argue that Defendants' advertising that "BioGran is the only bioactive glass product which has FDA market clearance for periodontal defects, extraction sites, and ridge augmentations" was false. See (Doc. 89, Exh. 7, at OVIT 01768). Defendants had previously represented to this Court that it had stopped distributing this statement, but it was later discovered that some materials containing this statement were disseminated, though allegedly by inadvertence. Defendants [*100] consented to the entry of an injunction by this Court prohibiting any further distribution of materials making this claim.

Defendants note that until September of 1996, they were the only ones who had secured FDA approval for marketing *all three* of the indications of periodontal defects, extraction sites, and ridge augmentations. Until that time, Plaintiffs only had FDA approval for periodontal defects. It is Defendants position, that aside from the few, inadvertently distributed leftover brochures noting this disparity between the two parties' products, it discontinued the use of this claim as soon as PerioGlas TM was approved for all three indications as well. To the extent that this claim is still relevant, there is a dispute as to the extent to which Defendants either did or did not advertise this claim after September of 1996, thus rendering summary judgment of false advertising based thereupon, inappropriate.

Plaintiffs have failed to establish that any of the five alleged false statements categorized above, are literally false, and since none of the alleged falsities are undisputed, summary judgment of literal false advertising is therefore, inappropriate. Having failed [*101] to establish the literal falsity of the accused advertising, [HN32] Plaintiffs may alternatively establish false advertising by showing that the accused advertisement, though literally true, is likely to confuse or mislead the consumers to which it is directed. See *Johnson & Johnson v. GAC Int'l, Inc., 862 F.2d 975, 977 (2d Cir. 1988).* In this situation, Plaintiffs must establish the remaining elements set forth above, i.e. that the alleged deceptive advertisements were material, and that the accused advertising had already, or is likely to, have an impact on consumer purchasing decisions. In this case, however, aside from mere allegations, Plaintiffs have failed to put forth any evidence that the challenged advertisements actually deceived any of the parties' customers or that they had a tendency to deceive a substantial percentage of the targeted audience, nor have the Plaintiffs put forth any evidence that the alleged deception was material in that it influenced any consumer purchasing decisions. See *Tire Kingdom, Inc. v. Morgan Tire & Auto, Inc., 915 F. Supp. 360, 365 (S.D. Fla. 1996)* ("to survive a motion for summary judgment, the Plaintiff must support [*102] each element of its Lanham Act claim with more than mere allegations")(citing *McLaughlin v. City of La Grange, 662 F.2d 1385 (11th Cir. 1981), cert. denied, 456 U.S. 979, 102 S. Ct. 2249, 72 L. Ed. 2d 856 (1982)).* Plaintiffs failure in this respect "fatally flaws" the claims for false advertising under the Lanham Act at the summary judgment stage. See id. Based upon the foregoing, consideration of the remaining elements of false advertising would be an exercise in futility, and the Court is of the opinion that Plaintiffs' motion for summary judgment on their false advertising claims under the Lanham Act should be and the same is hereby denied.

Trade disparagement under Section 43(a) of the Lanham Act and Florida law

In addition to summary judgment on their false advertising claims, as part of the same motion, Plaintiffs also seek summary judgment on their claims of trade disparagement under the Lanham Act and under Florida law. As a preliminary matter, the Court must note that [HN33] Plaintiffs are not entitled to summary judgment for trade disparagement under Section 43(a) of the Lanham Act by simple virtue of the fact that no such claim for [*103] relief was ever made in the supplemental complaint. Rather, in Count VI of the supplemental complaint, Plaintiffs have only pleaded "a count for trade disparagement under the common law of Florida for Defendants [sic] false statements to the public concerning Plaintiffs' PerioGlas product." (Doc. 51, p.12).

According to Plaintiffs, Defendants have made statements that "in essence, PerioGlas is what we throw in the garbage." See, e.g., (Doc. 89, Exh. 34). The evidence cited to demonstrate that these statements have been made includes internal memoranda and marketing tips to sales members, which were not distributed to purchasing consumers. Additionally, while Plaintiffs would have the Court believe that all of the cited examples of disparagement say that "Orthovita throws out PerioGlas," some of the cited examples state "PerioGlas uses the particle sizes that we throw away." See, e.g., (Doc. 89, Exhs. 36, 37). Furthermore, the deposition testimony cited for the same proposition involves statements that "words to the effect of" PerioGlas TM being what Orthovita throws away were used, not those precise words See,e.g., (Doc. 89, Exh. 13 at pp.33-34, Exh. 35 at p. 25). Only [*104] Ms. Knudsen's deposition avers that the precise reference that PerioGlas was the garbage from BioGran's production was ever made, yet her testimony is based solely on multiple hearsay which is inappropriate as a basis for granting summary judgment.

[HN34] Under Florida law, an action for trade disparagement must establish that the defendant intentionally made a false statement about the plaintiff's product, and that as a result thereof, plaintiff has suffered a special injury or damage. See *State Farm Fire & Casualty Co. v. Compupay, Inc., 654 So. 2d 944, 948 (Fla. 3d DCA 1995).* Mere negligence or the lack of reasonable grounds for a defendant's belief in the veracity of a statement is not grounds for a trade disparagement claim. See *Collier County Pub. Co. v. Chapman, 318 So. 2d 492, 494 (Fla. 2d DCA 1975), cert. denied, 333 So. 2d 462 (Fla. 1976)* (addressing the standard for injurious falsehoods). The Defendants' intent in making the statements is clearly in dispute in this case, with Plaintiffs asserting that Defendants intended to imply that PerioGlas TM is garbage material, and with Defendants asserting that the intent was to note that [*105] the

smaller and larger particle sizes found in PerioGlas TM are systematically eliminated from the composition of BioGran (R). This dispute renders summary judgment on Plaintiffs' trade disparagement claim, inappropriate.

False advertising under Chapter 817 of the Florida Statutes and Unfair competition under Florida law and the Florida Deceptive and Unfair Trade Practices Act

The parties agree that [HN35] the standard to be applied under Florida's statutory and common law for Plaintiffs' unfair competition and false advertising claims based thereupon, mirrors that to be applied under the Lanham Act. Having already determined that summary judgment on the claims brought under the Lanham Act is inappropriate, analysis of these claims under state law would be futile, and the Court is of the opinion that the motion for summary judgment on these claims brought under state law should also be and the same is hereby denied.

Defendants' counterclaims of false patent marking

Lastly, Plaintiffs have moved for summary judgment on Defendants' counterclaims of false patent marking pursuant to *35 U.S.C. § 292,* and for false designation of origin and false descriptions [*106] under Section 43(a) of the Lanham Act. Defendants assert in these counterclaims that Plaintiffs' PerioGlas TM product, which is sold in containers marked with the *'046* patent, is not covered by that patent.

Plaintiffs first allege that the counterclaims are improperly before the Court, since, as compulsory counterclaims, they should have been asserted in the first responsive pleading, i.e. the original answer. Thus, according to Plaintiffs, the counterclaims should be deemed to have been waived. Defendants contend that they were unaware of these claims at the time they served their original answer and that allowing the claims now would not be prejudicial to the Plaintiffs. Despite Defendants' failure to timely assert their counterclaims, and to properly seek leave to file compulsory counterclaims after the first responsive pleading was served, the Court agrees that Plaintiffs will suffer no prejudice by the Court permitting the Defendants to assert these counterclaims now.

Plaintiffs next assert, that based upon the merits, the undisputed facts demonstrate that PerioGlas TM does in fact contain particles within each of the three size ranges cited in the *'046* patent, in compliance [*107] with Claims 1 and 4 thereof. Defendants incorrectly construe Plaintiffs' loosely worded allegation that PerioGlas TM contains "bioactive glass particles within the size range 90-710 microns, which the various Low et al. patent claims recite" as trying to improperly allege compliance with the original application Claim 1 which was rejected by the PTO and the Board of Appeals. This statement more accurately reflects an assertion that the particle size range of PerioGlas TM is consistent with Claims 1 and 4 of the *'046* patent which anticipate the presence of particles over the entire range of 90 to 710 [mu]m, but only where there are particles present in each of the three individual ranges cited in Claim 4. As evidence of *'046* patent claim compliance, Plaintiffs direct the Court's attention to several undisputed studies of the composition of PerioGlas TM which they argue indicate compliance with the claims of the *'046* patent.

The results and conclusions of these studies are not disputed, however, Defendants attempt to create a dispute by arguing first that some of these tests rely on the improper particle size measurement method, and do not use sieving, the appropriate method. This [*108] Court refuses to accept this argument since as discussed more fully, *supra,* sieving was determined to be the appropriate method for measuring others' infringement of the Plaintiffs' patent. Indeed, this Court specifically noted that since both particle size measurement techniques found support in the *'046* patent, the least restrictive method should be employed in order to determine infringement. To imply that sieving should be used against Plaintiffs to determine infringement of their own patent defies logic and the Court rejects such a suggestion, especially where SEM has been determined to be far more precise at determining actual particle dimensions. Defendants next try to create a dispute as to Plaintiffs' evidence by noting that two of the references deal with a study that tested bioactive glass in the ilium of rabbits, not in periodontal applications. However, the method of testing is irrelevant to whether or not the particles in PerioGlas TM fall within the ranges cited in the *'046* patent, which these references establish it does. Finally, Defendants contend that the one exhibit showing sieve test results on PerioGlas TM indicates that its composition falls well outside [*109] of the *'046* patent claims. The Court finds the opposite to be true, in that this exhibit shows that PerioGlas TM contains particles within each of the three ranges cited in Claim 4, and the Court can presume only that Defendants arguments to the contrary are based upon its claim interpretation argument, which this Court rejected, *supra,* that in order to comply with Claim 1, all particles must be in the 355 to 710 [mu]m range. See (Doc. 89, Exh. 24, pp.4-5).

Defendants have failed to direct this Court's attention to any disputed issue of material fact which would preclude it from entering summary judgment on Defendants' counterclaims in favor of Plaintiffs. Thus, the Court is of the opinion that Plaintiffs motion for sum-

mary judgment, to the extent that it relates to Defendants' counterclaims, should be and the same is hereby granted.

D. Cross-Motions for Summary Judgment of Defenses of Inequitable Conduct and Unclean Hands

In yet another attempt to have this Court conclude that the *'046* patent is "unenforceable," Defendants have asserted the defense of inequitable conduct and unclean hands by Plaintiffs' predecessor's counsel in obtaining approval of the *'046* [*110] patent, and both Plaintiffs and Defendants have moved for summary judgment thereupon. [HN36] The Federal Circuit has stated that inequitable conduct may "consist[] of ... failure to disclose material information ... coupled with an intent to deceive.'" *Micro Chemical, Inc. v. Great Plains Chem. Co., 103 F.3d 1538, 1549 (Fed. Cir. 1997)* (quoting *Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995))*. The party asserting inequitable conduct as a defense bears the burden of establishing "the threshold elements of materiality and intent by clear and convincing evidence." Id. The district court must consider these threshold elements in light of all the circumstances in order to determine whether a finding of inequitable conduct is appropriate, and the determination in this regard is committed to the court's discretion. See id.; see also *Consolidated Aluminum Corp. v. Foseco Int'l, Ltd., 910 F.2d 804, 809 (Fed. Cir. 1990)* (stating that the court must determine whether the conduct, in its totality, "manifests a sufficient culpable state of mind to warrant a determination that it was inequitable").

[HN37] Since a finding of inequitable [*111] conduct eliminates all of the patentee's rights and the professional or commercial reputation of the patentee could be seriously damaged, such consequences demand that the moving party bear "a heavy burden of persuasion." *KangaROOS U.S.A. v. Caldor Inc., 778 F.2d 1571, 1576* (Fed. Cir. 1985 see also *Kolmes v. World Fibers Corp., 107 F.3d 1534, 1541 (Fed. Cir. 1997);* Tol-O-Matic, Inc. v. Proma Produkt-Und Marketing Gesellschaft m.b. *H., 945 F.2d 1546, 1554 (Fed. Cir. 1991)* (stating that forfeiture of patent enforceability is not favored as a remedy where actions are not shown to be "culpable"). The clear and convincing evidence must show that the applicant had the specific intent to mislead the PTO. In Molins, the Federal Circuit stated

> Thus, [HN38] the alleged conduct must not amount merely to the improper performance of, or omission of, an act one ought to have performed. Rather, clear and convincing evidence must prove that an applicant had the specific intent to accomplish an act that the applicant ought not to have performed, *viz.*, misleading or deceiving the PTO. In a case involving nondisclosure of information, clear and [*112] convincing evidence must show that the applicant made a deliberate decision to withhold a *known* material reference.

Molins, 48 F.3d at 1181 (emphasis supplied). [HN39] It is imperative that the applicant be shown to have known of the materiality of the undisclosed reference. The evidence of intent need not be direct in form, rather an inference of intent to deceive may be found from the circumstantial evidence, however, if the circumstantial evidence leads only to the conclusion that an applicant was grossly negligent in failing to disclose information to the PTO, no inference of intent to deceive can result therefrom. See id. (citing *Kingsdown Medical Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 876 (Fed. Cir. 1988), cert. denied, 490 U.S. 1067, 109 S. Ct. 2068, 104 L. Ed. 2d 633 (1989))*. n25

n25 In Molins, the court noted

> This court's *in banc* decision in *Kingsdown* resolved conflicting precedent regarding whether a finding of gross negligence compels a finding of intent to deceive. *Compare J.P. Stevens & Co. v. Lex Tex, Ltd., 747 F.2d 1553, 1564, 223 U.S.P.Q. (BNA) 1089, 1092 (Fed. Cir. 1984), cert. denied, 474 U.S. 822, 106 S. Ct. 73, 88 L. Ed. 2d 60 (1985)* (gross negligence was sufficient to prove intent, whereas simple negligence, oversight, or an erroneous judgment made in good faith was insufficient) *with FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1415 n. 9, 5 U.S.P.Q.2D (BNA) 1112, 1116 n. 9 (Fed. Cir. 1987)* (gross negligence alone did not mandate a finding of intent to mislead).

Molins, 48 F.3d at 1181 n.11.

[*113] [HN40]

When, as here, the material facts are not in dispute, and both parties have moved for summary judgment based thereupon, the Court may decide the issue of inequitable conduct as a matter of law. In this case, the original patent application was filed on June 19, 1985, at which time the inventors and Plaintiff UFRF's assignor, the University of Florida, were represented by Dennis Clarke ("Clarke"), an outside attorney. The PTO examiner initially rejected the application claims in the PTO's first Office Action on March 19, 1986, over the prior art Gross patent, which prior patent cited a particle size range of about 10 to 200 [mu]m. On June 19, 1986, Clarke filed a written response to the first Office Action, amending the application claims with respect to glass composition, and he presented arguments relating to the differences between the chemical compositions of the two glasses. He did not mention particle size as a basis for patentability. Also in June of 1986, Clarke filed a patent application in Europe which corresponded to the claims sought from the PTO.

On August 28, 1986, the PTO issued its Final Office Action in which the examiner maintained his previous rejection of the [*114] application claims. Mr. Clarke again responded in writing to the rejection, but to no avail. On May 26, 1987, Clarke filed a notice of appeal and brief in support thereof. In his brief, Clarke argued the differences between the two glass compositions, without ever specifically citing particle sizes. The PTO examiner filed his responsive brief directing the Board of Appeal's attention to the fact that the application claims cited particle size ranges found in the Gross patent. Clarke filed a reply brief on November 12, 1987, arguing patentability based upon the differences in chemical compositions and uses of the two glass compositions.

One month after filing his reply brief on the appeal of the United States PTO's Final Office Action, in December of 1987, Clarke received a prior art search report which had been issued in conjunction with the pending European patent application. The search report noted six references, three of which were noted collectively within a category "Y." According to the report, each of the references in category "Y" were "particularly relevant if combined with another document in the same category." (Doc. 90, Exh. 7 at FL001171). The three items noted in category [*115] "Y" were: first) a Dutch patent ("De Groot patent") deemed relevant to claims 1, 2, 7, and 8; second) an article entitled Biomedical applications and glass corrosion, authored by L. L. Hench and deemed relevant to claims 1, 2, 3, 7, and 8, and; third) the Bluethgen patent deemed relevant to claims 1, 2, and 3. Clarke notified his clients about the receipt of the European search report and indicated that he felt the European examiners would reject the claims based upon a combination of the references contained therein.

On September 16, 1988, the United States PTO's Board of Appeals rendered its opinion affirming in part and reversing in part the PTO examiner's rejection of the U.S. patent application claims. The Board distinguished the particle size ranges of the application claims and the prior art and stated that the group of claims reciting larger particle size ranges was patentable. Clarke accepted the Board's allowance of narrower ranged claims on December 30, 1988, and the PTO examiner revised the application claims to reflect the Board's decision. Clarke paid the patent issuance fee on March 30, 1989, and the *'046* patent was formally issued on July 25, 1989.

Approximately [*116] one month prior to issuance of the *'046* patent, on June 20, 1989, Clarke received from the European Patent Office ("EPO") its Official Letter regarding the pending European application. In it, the EPO allowed one claim and rejected the remainder based upon a combination of the three references previously disclosed in the search report. The European examiner specifically noted that the Dutch De Groot patent cited a particle size range of 200 to 250 [mu]m, that the Hench paper failed to cite a particle range, and that the Bluethgen patent cited a particle size range of 90 to 250 [mu]m. On August 31, 1989, Clarke wrote to his European correspondent attorney, Mr. Hedley, providing instructions on how to respond to the EPO's Official Letter. Clarke advised Mr. Hedley to amend the European application to reflect the particle size ranges allowed in the *'046* patent. In his correspondence, Clarke indicated to Mr. Hedley that the most pertinent reference cited by the EPO was the Dutch patent which cited a particle range similar to that of the Gross patent, which was relied upon by the PTO in the United States. After receiving the EPO's rejection, Clarke conceded that he made a conscious [*117] decision not to disclose the EPO's reference to the Bluethgen patent to the United States PTO. His decision in this regard is the subject of the inequitable conduct defense presently before this Court.

Defendants have based their inequitable conduct defense on Clarke's failure to disclose the Bluethgen patent to the PTO, which patent makes a singular reference to a particle size of 500 [mu]m in its specification. Defendants have not contested Plaintiffs' assertion that aside from the singular reference to the 500 [mu]m value, the Bluethgen patent is cumulative to the prior art Gross patent cited by the PTO examiner as the basis for his rejection of the application claims. n26 This is important since Plaintiffs have no obligation to report to the PTO any prior art which is cumulative or less relevant than information already before the PTO. See *37 C.F.R. § 1.56(b)*.

n26 The 500 [mu]m value cited in the Bluethgen patent is found in the specification which refers to a material with a particle size range of about between about 50 [mu]m and 500 [mu]m and "preferably between about 90 [mu]m and about 250 [mu]m." Indeed, the Bluethgen patent claims themselves, cite only a range of 90 [mu]m to 250 [mu]m.

[*118]

As noted above, in order to establish inequitable conduct based upon Clarke's failure to disclose Bluethgen to the PTO, Defendants must establish by clear and convincing evidence both the materiality of the Bluethgen patent and Clarke's intent to mislead the PTO by not disclosing it. See *Molins, 48 F.3d at 1178.*

1. First Prong- Materiality

[HN41] Information is material for purposes of an inequitable conduct analysis if there is a substantial likelihood that a "reasonable examiner" would have considered the undisclosed information to be important in the decision as to the patentability of application claims. See *Molins, 48 F.3d at 1179.* And as noted above, where undisclosed information is either cumulative to or is not as relevant as information already before the United States PTO, the failure to disclose such information can not serve as the basis for inequitable conduct. See id.

Plaintiffs concede that as of today, the Bluethgen patent may be assumed to be material, but that at the time of the alleged inequitable conduct, i.e. when he received notification of the EPO's rejection of the foreign application, Clarke was unaware that Bluethgen [*119] was material. It is their position that at the time, Clarke felt that the Bluethgen patent was at best cumulative to the Gross patent and that he therefore had no duty to disclose it. According to Plaintiffs, Clarke's contemporaneous correspondence with his foreign associate indicates that he was unaware of the 500 [mu]m reference in the Bluethgen specification. They note that even the EPO itself, which rejected patent claims based partially upon Bluethgen in its Official Letter, never mentioned the 500 [mu]m figure, but rather explicitly stated that Bluethgen involved a particle size range of 90 to 250 [mu]m. It is the Plaintiff's position that Clarke never saw the 500 [mu]m reference in Bluethgen when he first reviewed it, and that its materiality was therefore unknown at the time of the alleged inequitable conduct.

Defendants contend that Bluethgen was material since the Board's allowance of certain claims in the *'046* patent was premised upon assuring that the particle sizes cited therein were larger than those cited in the prior art Gross patent. Thus, according to Defendants, the higher range cited in the specification of Bluethgen was relevant, in that certain of the [*120] claims allowed in the *'046* patent would not have been permitted if the PTO was aware of prior art citing such a range. Defendants argument is premised on the assumption that the range of the Bluethgen patent is for particles sized between 50 and 500 [mu]m instead of the 90 to 250 [mu]m range explicitly stated in the claims thereof. Defendants have stated that "it is inescapable that claims 1 and 2 of the 046 patent would not have issued had the examiner been advised of the Bluethgen patent." (Doc. 104, p. 7). Yet, this assertion overlooks the EPO's rejection which was explicitly based upon the range of 90 to 250 [mu]m cited in Bluethgen; like Clarke, the EPO failed to recognize the relevant range of the Bluethgen patent as being 50 to 500 [mu]m. Defendants also note that Clarke is chargeable with knowing the materiality of any prior art which he reviewed, thus what he claims to have been unaware of today is irrelevant. See *FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1415 (Fed. Cir. 1987).* In this case, Clarke admitted that he reviewed the Bluethgen patent, but contends that he missed the 500 [mu]m reference since the range cited by the EPO led him to believe [*121] that Bluethgen was material only to the extent that it cited a range of 90 to 250 [mu]m.

While this Court disagrees with Defendants' suggestion that the singular 500 [mu]m reference in Bluethgen, had it been disclosed to the PTO, would have necessarily resulted in rejection of certain *'046* patent claims, and while the Court agrees with Plaintiffs that Clarke was unaware of the materiality of the 500 [mu]m reference at the time of the alleged inequitable conduct, it does find that Bluethgen was nonetheless material to the *'046* patent application, though not so highly material as to lower Defendants' burden in establishing the intent to mislead the PTO, as Defendants have argued is the case. n27

n27 Defendants have argued that the 500 [mu]m reference in Bluethgen was so highly material that a lesser showing of intent is required in order to find inequitable conduct. See (Doc. 104, p. 8) (citing *Critikon v. Becton Dickinson Vascular Access, Inc, 120 F.3d 1253, 1257 (Fed. Cir. 1987)).* The cases relied upon by Defendants for this position involve situations where the undisclosed reference would have clearly led to rejection by the PTO. In this instance, the Court is not convinced that the PTO would have rejected the *'046* patent claims based upon Bluethgen. As evidence of this, the Court notes the EPO's failure to recognize the relevant particle size range of Bluethgen as being 50 to 500 [mu]m instead of the range of 90 to 250 [mu]m which is explicitly recited in the Bluethgen claim language. Furthermore, the Critikon case involved a situation

where the attorney for the patentee knew of the material disclosure in a withheld reference, had studied that reference in prior litigation, had cited the same reference in other patent proceedings, and was unable to provide an explanation for failing to disclose the reference. These facts are wholly incongruent with those of the case pending in this Court.

[*122]

2. Second Prong- Intent

The determination that the undisclosed Bluethgen reference was material does not, in and of itself, establish inequitable conduct. To prevail on this defense, Defendants must also establish by clear and convincing evidence that Clarke had the specific intent to mislead the PTO. See *Molins, 48 F.3d at 1181.*

It is undisputed in this case that Clarke made a conscious decision not to disclose the Bluethgen patent to the PTO when he learned of it from the European Patent Office's search report. Plaintiffs contend that this conscious decision was made based upon Clarke's belief that Bluethgen was less pertinent than the DeGroot patent cited by the EPO and was cumulative to the Gross patent already under consideration by the United States PTO. Thus, contrary to Defendants' assertion, Plaintiffs argue that Clarke was under no obligation to file a petition with the PTO to withdraw the application from consideration so that the PTO could re-consider the claims in light of Bluethgen. n28 It was Clarke's belief that Bluethgen was cumulative to Gross, and he had no reason to file a petition to withdraw the application, since pursuant to *37 C.* [*123] *F.R. § 1.56(b)*, such otherwise material information need not be disclosed, even where as Defendants have noted here, an "especially strong" inference of materiality arose from the EPO's use of Bluethgen to reject the foreign application claims. See PTO Manual of Patent Examining Procedure § 2001.06(a). Based upon the undisputed evidence, it is clear that Clarke intentionally chose not to disclose Bluethgen to the PTO, however, the same can not be said with regard to whether or not he intended to mislead the PTO by withholding disclosure thereof.

n28 It is important to note that, [HN42] under *37 C.F.R. § 1.313(b)* (1988), at a time after the issuance fee has been tendered and the patent has been given an issue date and patent number, the application is not to be withdrawn except for the following reasons "(1) mistake on the part of the Office, (2) a violation of § 1.56 [which includes the duty of disclosure] or illegality of the application, (3) unpatentability of one or more claims, or (4) for interference."

[*124]

This Court agrees with Defendants that [HN43] the intent to mislead need not be shown by direct evidence, but rather may be inferred from actions which have natural consequences that are intended by the actor. See *Molins, 48 F.3d at 1180.* However, in this case the undisputed evidence is unlike that in the cases relied upon by Defendants where the totality of the circumstances surrounding the non-disclosing attorney's actions established enough culpability "to require a finding of intent to deceive." *Halliburton Co. v. Schlumberger Tech. Corp., 925 F.2d 1435, 1443 (Fed. Cir. 1991).* This Court is convinced that at the time of the alleged inequitable conduct, Mr. Clarke was unaware of the materiality of Bluethgen, and this fact alone is sufficient to lead this Court to the conclusion that Clarke did not have the requisite intent to mislead the PTO which would warrant a finding of inequitable conduct. See *Molins, 48 F.3d at 1181.* And furthermore, despite the fact that Clarke could be charged with knowledge of the materiality of any reference in prior art reviewed by him, the Court concludes that in the circumstances involved herein, such a [*125] charge against Clarke would be inequitable in itself, since it is clear that the EPO, which rejected the foreign application claims based upon Bluethgen, implied in its Official Letter that the only material particle size range contained therein was that which was explicitly stated in the claim language. Indeed the EPO explicitly noted that Bluethgen cited a particle size range of "90 to 250 [mu]m" without once referring to the 500 [mu]m reference in the Bluethgen specification which Defendants now assert is so crucial.

In this case, the Court concludes that the Defendants have failed to present clear and convincing evidence that the undisclosed Bluethgen reference was known to be material or that Mr. Clarke had the requisite intent to mislead or deceive the PTO. Furthermore, even if knowledge of the materiality thereof were to be imputed to Clarke, based upon the totality of the circumstances involved, his failure to disclose could at best, be described as grossly negligent, which [HN44] the Federal Circuit has explicitly instructed will not support a claim for inequitable conduct based upon intentional nondisclosure. See *Halliburton, 925 F.2d at 1442-43* (stating that [*126] gross negligence does not rise to the level of clear and convincing evidence which would justify an inference of intent to deceive the PTO); see also *Molins, 48 F.3d at 1181* (stating that no inference of intent to deceive may be drawn from circumstantial evidence which leads only to the conclusion that the applicant was grossly negligent in failing to disclose) (citing

Kingsdown Medical Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 876 (Fed. Cir. 1988)).

Thus, having considered the undisputed material facts in light of all of the circumstances, this Court concludes that Mr. Clarke's actions do not rise to level of culpability which would compel a finding of inequitable conduct. And based upon the foregoing, the Court is of the opinion that Plaintiffs' motion for summary judgment on Defendants' fifth and seventh affirmative defenses of inequitable conduct and unclean hands n29 (doc. 90) should be and the same is hereby granted. Accordingly, the Court is also of the opinion that Defendants' cross-motion for summary judgment on the same (doc. 107) should be and the same is hereby denied.

n29 [HN45] The unclean hands defense, though sparsely mentioned by either party in their cross-motions, is subsumed in the analysis of inequitable conduct which has been defined as the unclean hands defense as applied to specific conduct before the PTO. See *Consolidated Aluminum Corp. v. Foseco Int'l Ltd., 910 F.2d 804, 812 (Fed. Cir. 1990)* (citations omitted). Thus, where a claim of inequitable conduct fails, so must the claim under the equitable doctrine unclean hands.

[*127]

E. Plaintiffs' Motion for Summary Judgment on Defendants' Equitable Estoppel Defense

Plaintiffs filed a separate motion for summary judgment on Defendants' sixth defense of equitable estoppel (doc. 91). The equitable estoppel defense revolves around the Defendants' contention that, based upon Plaintiffs' own actions or inaction, it would be inequitable to allow Plaintiffs to proceed with their claims of patent infringement. It is the Defendants' position that Plaintiffs engaged in misleading conduct that created a reasonable inference that Plaintiffs had abandoned any claim for patent infringement, and that as a result of reliance on that inference, Orthovita has suffered prejudice. This defense relates solely to the claims of patent infringement asserted by Plaintiffs. Having already determined that the Defendants' BioGran (R) product does not infringe the *'046* patent, the Court is of the opinion that the Plaintiffs' motion for summary judgment on the defense of equitable estoppel (doc. 91) should be and the same is hereby denied as moot.

Having properly construed the *'046* patent claims as set forth above, having applied the undisputed material facts thereto, and having [*128] applied all other undisputed facts to the various pending motions for summary judgment, it is hereby,

ORDERED AND ADJUDGED:

(1) Plaintiffs' motion for summary judgment of patent infringement (doc. 88) is DENIED in all respects;

(2) Defendants' motion for summary judgment with respect to Count I of the complaint, non-infringement, (doc. 93) is GRANTED to the extent that the Court finds no infringement, either literal or under the doctrine of equivalents, and this Court having concluded that the properly construed claims are valid under *35 U.S.C. § 112,* Defendants' alternative motion for summary judgment of patent invalidity is DENIED.

(3) Defendant Ducheyne's motion to dismiss all claims against him (doc. 92) is MOOT with respect to claims of infringement brought against him, since this Court has already held that the BioGran (R) product does not infringe the *'046* patent, and for the reasons set forth above, the motion is GRANTED with respect to all remaining claims asserted against him. Accordingly, the Clerk is hereby directed to dismiss Paul Ducheyne as a Defendant in this action on the remaining Counts II, III, IV, [*129] V. and VI.

(4) Plaintiffs' motion for summary judgment on Plaintiffs' false advertising, unfair competition, and trade disparagement claims (Counts II, III, IV, V, and VI), and on Defendants' counterclaims (doc. 89) is GRANTED only to the extent that it relates to Defendants' counterclaims, and is DENIED in all other respects.

(5) Plaintiffs' motion for summary judgment on Defendants' inequitable conduct and unclean hands defenses (doc. 90) is GRANTED and Defendants' cross-motion for summary judgment on the same defenses (doc. 107) is DENIED.

(6) Plaintiffs' motion for summary judgment on Defendants' equitable estoppel defense (doc. 91) is MOOT.

(7) The attorneys for the parties are hereby directed to meet with one another no later than May 11, 1998 for the purposes of preparing the pre-trial stipulation, and the pre-trial stipulation on all remaining claims (Counts II, III, IV, V, and VI) shall be filed with the Court no later than May 25, 1998.

(8) A pre-trial conference shall be held in this matter on May 28, 1998 at 1:00 p.m.

(9) The parties are hereby advised that, prior to the trial on the remaining issues, the [*130] Court will require each side to prepare and submit to the Court, in both hard-copy and on diskette (WordPerfect version 6.0 or higher), their proposed findings of fact and conclusions of law.

DONE AND ORDERED in Chambers this 20th day of April, 1998.

MAURICE M. PAUL, SENIOR DISTRICT JUDGE