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United States Patent [19]

Müller et al.

[11] Patent Number: 4,576,152

[45] Date of Patent: Mar. 18, 1986

[54] INJECTOR FOR BONE CEMENT

[75] Inventors: Maurice E. Müller, Berne; Otto Frey, Winterthur, both of Switzerland

[73] Assignee: Sulzer Brothers Limited, Winterthur, Switzerland

[21] Appl. No.: 543,238

[22] Filed: Oct. 18, 1983

[30] Foreign Application Priority Data

Oct. 21, 1982 [CH] Switzerland 6118/82

[51] Int. Cl.⁴ A61F 5/04

[52] U.S. Cl. ..... 128/92 R; 604/218; 128/92 E

[58] Field of Search ..... 128/92 R, 92 E; 604/218; 3/1.9

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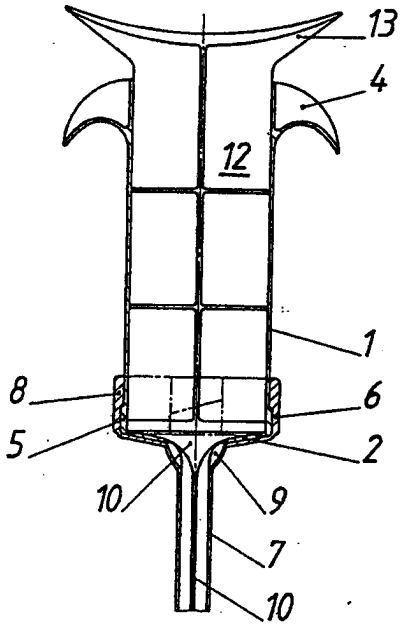
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Primary Examiner—Gene Mancene
Assistant Examiner—C. W. Shedd
Attorney, Agent, or Firm—Kenyon & Kenyon

[57] ABSTRACT

The injector is provided with an injection nozzle in the bottom of the cylinder tube for low pressure operation wherein large quantities of bone cement are to be injected. The injector also has a nozzle element which can be releaseably attached to the cylinder tube for high pressure injection. This nozzle element has a nozzle tube of reduced cross-sectional area through which a ram passes in the form of a piston in order to provide for high pressure injection.

8 Claims, 5 Drawing Figures



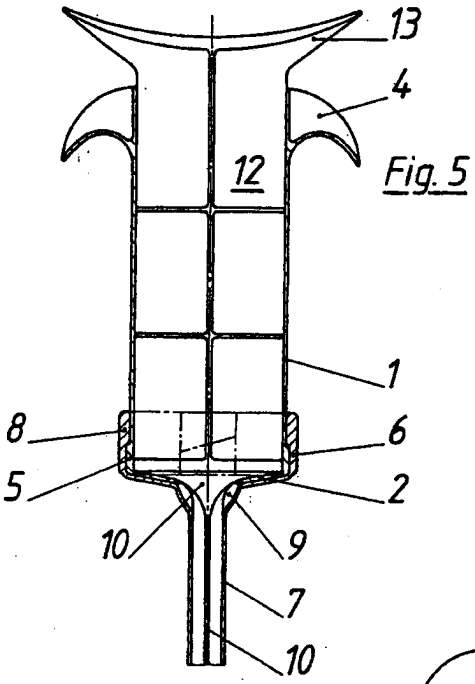


Fig. 5

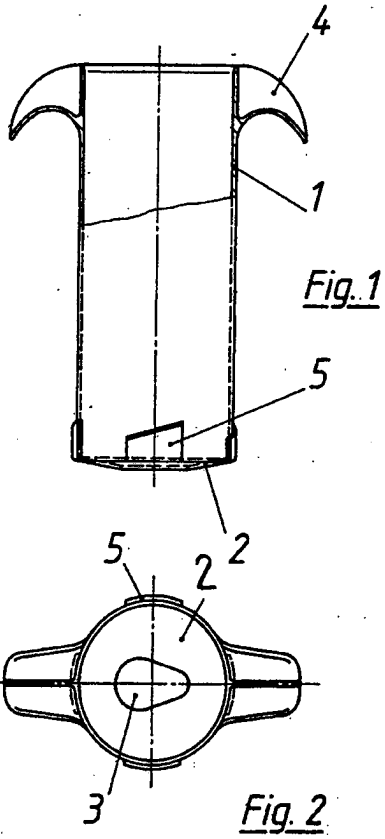


Fig. 1

Fig. 2

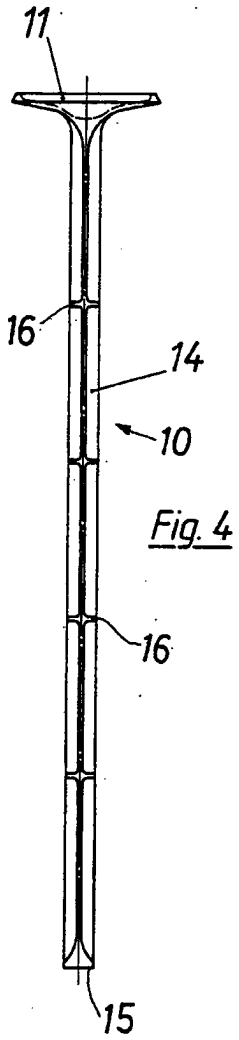


Fig. 4

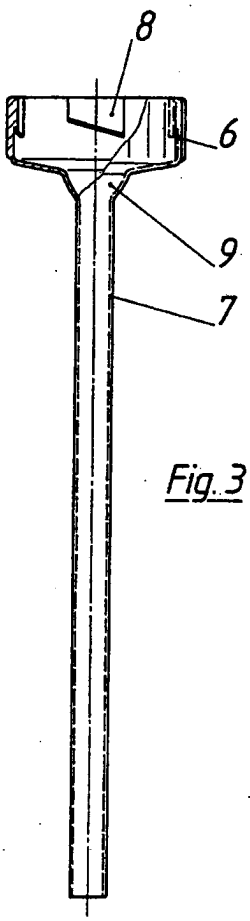


Fig. 3

INJECTOR FOR BONE CEMENT

This invention relates to an injector for bone cement. More particularly, this invention relates to an injector for injecting expandable bone cement into a surgically prepared bone cavity.

Heretofore, various types of injectors or syringes have been known for injecting bone cement into surgically prepared bone cavities. For example, as described in European Patent B 1-006430, one known bone cement injector consists of a piston and cylindrical tube to which a nozzle element having a nozzle tube of relatively narrow cross-section is attached. Such an injector is constructed so as to permit the mixing and extrusion of a pasty bone cement in a simple manner. In this regard, the nozzle tube is made as a two-part member of relatively narrow cross-section.

As is known, during some surgical operations, it is necessary to inject a relatively large quantity of bone cement at relatively low pressure and thereafter to inject a small quantity of bone cement at relatively high pressure without applying substantially increased force. The injector described in the above noted European patent is, however, not capable of performing both a "low pressure" and a "high pressure" injection where the pressure is increased about twenty-fold.

Accordingly, it is an object of the invention to provide a bone cement injector which is capable of extruding a relatively large quantity of bone cement at relatively low pressure and of extruding a small quantity of bone cement at relatively high pressure.

It is another object of the invention to provide a bone cement injector which is capable of use for a low pressure injection and a high pressure injection.

It is another object of the invention to provide an injector which is capable of operating sequentially for injecting bone cement under low pressure and high pressure.

Briefly, the invention provides an injector for injecting an expandable bone implant cement. This injector is comprised of a cylinder tube for receiving the bone cement, a piston, a nozzle element and a ram. The cylinder tube is provided with a bottom and an injection nozzle in the bottom for expelling bone cement therethrough.

The piston is movably mounted in the cylinder tube for displacing bone cement in the tube through the injection nozzle.

The nozzle element is secured to and extends from the cylinder tube and has a nozzle tube aligned with and of smaller cross-section than the injection nozzle to pass bone cement therethrough.

The ram is movably mounted in the nozzle tube to eject bone cement therefrom. In this respect, the ram is displaceable in the manner of a piston in the nozzle tube.

In use, with the nozzle element removed, a relatively large quantity of bone cement can be extruded through the injection nozzle in the bottom of the cylinder tube. The injection of the bone cement can then take place under low pressure.

For a high pressure injection of bone cement into a bone cavity, the nozzle element is secured to the cylinder tube. At this time, the piston in the cylinder tube is used to fill the nozzle tube of the nozzle element with bone cement. Further, the ram serves to eject the bone cement from the filled nozzle tube. Of note, when the nozzle element is attached to the cylinder tube, the ram is guided through the cylinder tube and through the injection nozzle into the nozzle tube. Alternatively, the nozzle element can be detached from the cylinder tube and used as a separator injector.

The nozzle element can be secured to the cylinder tube in any suitable fashion, for example via a bayonet connection.

Further, the nozzle element may include a reservoir between the injection nozzle and the nozzle tube.

If the injector is to be used in a combined operational step both as a "high pressure" and as a "low pressure" injector, it is advantageous if the cylinder tube takes up the content of more than one standard package of bone cement, preferably two standard packages. For example, where a standard package contains about 50 to 60 cubic centimeters, generally about 55 cubic centimeters, of bone cement, the cylinder tube defines a volume of about 125 cubic centimeters for receiving the bone cement.

The ram may also be provided with a dish-type bearing plate at one end which can be attached to the piston within the cylinder tube. The advantage of this is that the entire bone cement injector can be evacuated without releasing the bayonet connection.

The bone cement injector is intended to be used only once. Hence, the injector may consist of a plastic which is common for such injectors, for example polymethyl pentene (TPX). In this case, the parts of the injector can be manufactured primarily by injection molding or as pressed parts.

These and other objects and advantages of the invention will become more apparent from the following detailed description taken in conjunction with the accompanying drawings wherein:

FIG. 1 illustrates a part cross-sectional view of a cylinder tube of an injector constructed in accordance with the invention;

FIG. 2 illustrates a top view of the cylinder tube of FIG. 1;

FIG. 3 illustrates a part cross-sectional view of a nozzle element constructed in accordance with the invention;

FIG. 4 illustrates a side view of a ram constructed in accordance with the invention; and

FIG. 5 illustrates a partial view of an assembled injector in accordance with the invention.

Referring to FIG. 5, the injector for expelling bone cement is constructed of four parts namely, a tube 1 for receiving bone cement, a nozzle element 6, a ram 10 and a piston 12.

Referring to FIG. 1, the tube 1 is in the form of a cylinder and defines a volume of about 125 cubic centimeters for receiving bone cement, e.g. two standard packages of bone cement. The tube 1 has a bottom 2 which is slightly depressed conically in the center as well as an injection nozzle 3 (opening) which is formed substantially at the center of the bottom 2. The injection nozzle 3 is provided with a cross-sectional shape which is in rough approximation to the cross-sectional shape (see FIG. 2) of a shank of a femur head prosthesis (not shown). In addition, the upper end of the cylinder tube 1 is provided with two lateral flaps 4 which are arranged as abutments for the fingers of a hand. Further, the lower end of the cylinder tube 1 is provided with four rectangular reinforcements 5 which are distributed uniformly over the circumference of the tube 1. Each of the reinforcements 5 has an upper edge which is bev-

elled in the same direction so as to form part of a bayonet connection.

Referring to FIG. 3, the nozzle element 6 has a cylindrical cup-shaped portion at an upper end, as viewed, and an elongated nozzle tube 7. In addition, the cup-shaped portion has a plurality of circumferentially disposed inwardly directed projections 8 with bevelled lower edges. These projections 8 cooperate with the reinforcements 5 of the cylinder tube 1 in order to form a bayonet connection for securing the nozzle elements 6 in a releasable manner to the cylinder tube 1 as indicated in FIG. 5.

Referring to FIGS. 3 and 5, the nozzle element 6 also includes a reservoir 9 between the cup shaped portion and the nozzle tube 7. As indicated in FIG. 5, the reservoir 9 is located between the injection nozzle 3 and the nozzle tube 7 and is sized to have a volume of a few cubic centimeters.

Referring to FIG. 4, the ram 10 includes a dish type bearing plate 11 at an upper end, as viewed, and an elongated shank 14 of contoured cross-sectional shape. As indicated in FIG. 5, the bearing plate 11 is located within the cyliinder tube 1 above the bottom 3 and is of greater cross-sectional area than the cross-sectional area of the injection nozzle 3. The shank 14 of the ram 10 extends through the injection nozzle 3 and is adapted to the inside diameter of the nozzle tube 7 so as to function as a piston within the nozzle tube 7 during a "high pressure" injection. Of note, the bearing plate 11 is sized to a finger or thumb of a user. Further, the plate 11 may be attached to the piston 12 so that the piston 12 may be used to push the ram 10 within the cylinder tube 1 and through the nozzle tube 7.

Referring to FIG. 5, the piston 12 is of a diameter to slide within the cylinder tube in order to expel bone cement from the cylinder tube 1 through the injection nozzle 3. In addition, the piston 12 has hand grips 13 similar to the cylinder tube 1. These hand grips 13, in conjunction with the flaps 4 facilitate handling of the cement injector.

In order to use the injector for "low pressure" injection, the nozzle element 6 is removed. With bone cement filling the cylinder tube 1, the piston 12 can then be depressed so that the bone cement is expelled through the injection nozzle 3.

For "high pressure" injection, the nozzle element 6 is attached to the end of the cylinder tube 1 via the bayonet connection. As the piston 12 is then depressed, bone cement is expelled through the injection nozzle 3 into the reservoir 9 and then into the nozzle tube 7 which is of smaller cross-sectional area. As a result, the pressure on the bone cement increases without a significant increase in the force supplied to the piston 12. Since the shank 14 of the ram 10 extends through the injection nozzle 3, the shank 14 is suitably shaped in cross-section so as to permit the bone cement to be expelled. In this regard, it is noted that the cross-sectional area of the injection nozzle 3 is larger than the cross-sectional area of the shank 14 as well as the internal cross-sectional area defined by the nozzle tube 7.

Of note, it is possible to use both modes of use, each by itself as well as in combination. That is, first one and thereafter the other, in the same operational step.

The invention thus provides a bone cement injector which can be readily used for low pressure and high pressure injection in a simple manner.

Further, the invention provides an injector which can be used for low pressure injection where relatively large quantities of bone cement are required for injection into a bone cavity. Further, with the nozzle element attached, the injector can be used to inject relatively small quantities of bone cement at a high pressure, for example at approximately twenty times the low pressure.

It is the object of the reservoir 9 to soften the generation of whirls if the nozzle tube 7 has been mounted and the piston 12 is depressed down to the bottom 2.

The shank 14 of the ram 10 has a profile section as a cross. This cross profile ends in a piston-like circular end plate 15 (FIG. 4). Further spaced circular discs 16 (FIG. 4) interrupt the cross profile for stability of the shank and for guiding the ram 10 in the nozzle tube 7.

What is claimed is:

1. An injector for an expandable bone implant cement, said injector comprising

a cylinder tube for receiving bone cement, said tube having a bottom and an injection nozzle in said bottom for expelling bone cement therethrough;

a piston movably mounted in said tube for displacing bone cement in said tube through said injection nozzle;

a nozzle element secured to and extending from said tube, said nozzle element having a nozzle tube aligned with and of smaller cross-section than said injection nozzle to pass bone cement therethrough; and

a ram movably mounted in said nozzle tube to eject bone cement therefrom.

2. An injector as set forth in claim 1 wherein said nozzle element inlcudes a reservoir between said injection nozzle and said nozzle tube.

3. An injector as set forth in claim 1 wherein said cylinder tube defines a volume of about 125 cubic centimeters for receiving bone cement.

4. An injector as set forth in claim 1 wherein said nozzle element is removably secured to said tube.

5. An injector as set forth in claim 1 wherein said ram has a dish-type bearing plate at one end attached to said piston within said tube.

6. An injector for bone cement comprising

a tube for receiving bone cement, said tube having a bottom and an injection nozzle in said bottom for expelling bone cement therethrough;

a nozzle element removably secured to and extending from said tube, said nozzle element having a nozzle tube of smaller cross-section than said injection nozzle to pass bone cement therethrough;

a ram movably mounted in said nozzle tube to eject bone cement therefrom, said ram having a bearing plate at one end within said tube and a shank extending from said bearing plate through said injection nozzle and into said nozzle tube; and

a piston movably mounted in said tube for moving said ram into said nozzle tube while expelling bone cement through said injection nozzle.

7. An injector as set forth in claim 6 wherein said nozzle element includes a reservoir between said injection nozzle and said nozzle tube.

8. An injector as set forth in claim 6 having a bayonet connection removably securing said nozzle element to said tube.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 4,576,152

DATED : March 18, 1986

INVENTOR(S) : Maurice E. Muller

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the title page assignee should read

--(73)Assignee: Sulzer Brothers Limited, Winterthur, Switzerland and Protek AG, Berne, Switzerland --.

Signed and Sealed this

Eleventh Day of November, 1986

Attest:

DONALD J. QUIGG

Attesting Officer

Commissioner of Patents and Trademarks

[redacted]

B-4

United States Patent [19]

Clark

[11] **Patent Number: 4,801,263**

[45] **Date of Patent: Jan. 31, 1989**

[54] **OSSEOUS IMPLANT SYRINGE**

[76] Inventor: William C. Clark, P.O. Box 2777, Knoxville, Tenn. 37901

[21] Appl. No.: 87,597

[22] Filed: Aug. 19, 1987

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 867,065, May 27, 1986, abandoned.

[51] **Int. Cl.**[4] **A61C 5/04**

[52] **U.S. Cl.** 433/90; 604/60; 604/218; 604/241

[58] **Field of Search** 433/90, 89; 604/57–60, 604/218, 239, 241

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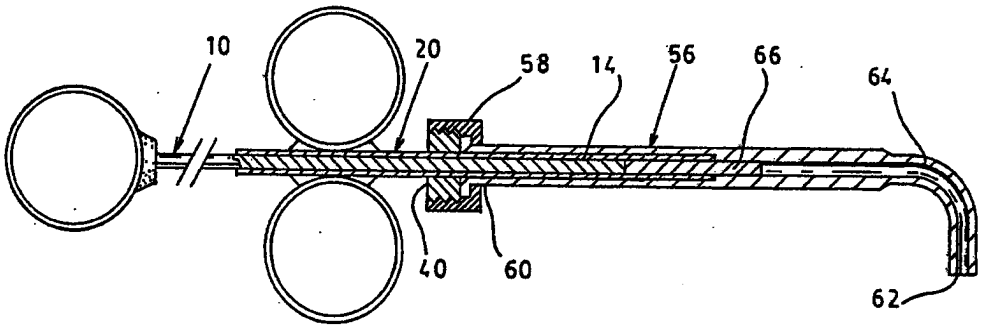
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Primary Examiner—Carroll B. Dority, Jr.
Attorney, Agent, or Firm—Pitts and Brittian

[57] **ABSTRACT**

A device to place osseous implant substances into interdental alveolar bone defects. This device is an osseous implant syringe with an axial lumen of consistent cross-section to allow movement of the granular substance through the lumen. The granular substance is moved through the lumen by use of a syringe plunger member. Barrel caps are provided to prevent spillage of the osseous implant substance when the syringe is not in use. The outlet of the syringe is sufficiently small to effectively enter alveolar bone defects. An extension nozzle member is provided for those areas that cannot be reached by the syringe barrel member alone. An outlet cap can be placed over the extension nozzle member to prevent spillage when it is not in use. Furthermore, a plunger extension lengthens the syringe plunger member to completely dispense the osseous implant substance from the extension member. A curved extension nozzle member can also be attached to the end of the syringe barrel member to reach those areas that cannot be reached with a straight barrel. A filling device is provided for fast and efficient loading of the syringe barrel members.

16 Claims, 3 Drawing Sheets



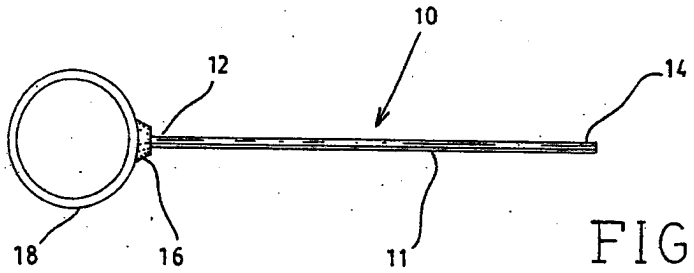


FIG. 1

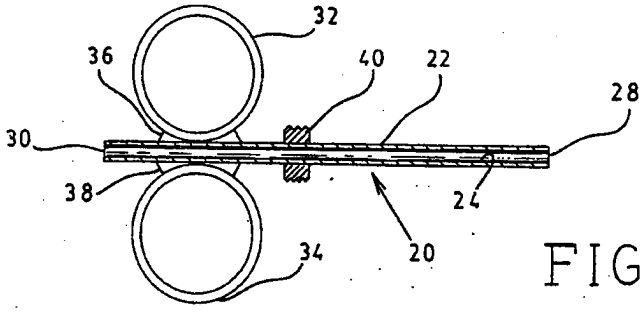


FIG. 2

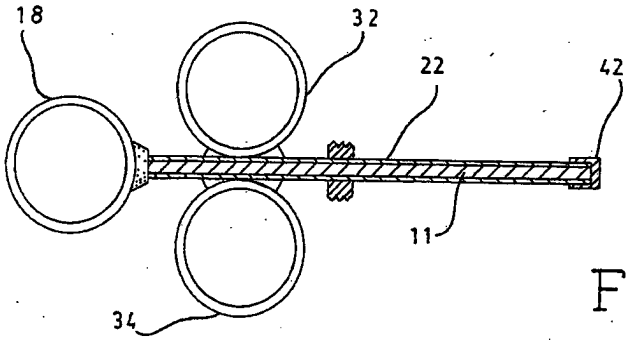


FIG. 3

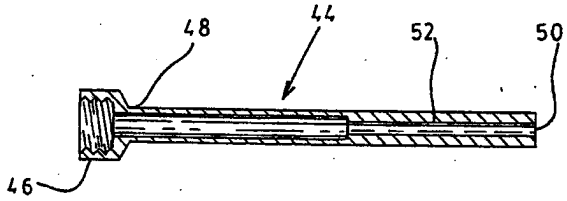


FIG. 4

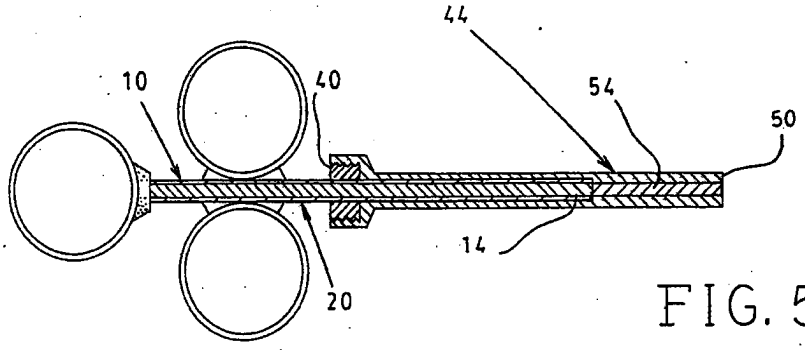


FIG. 5

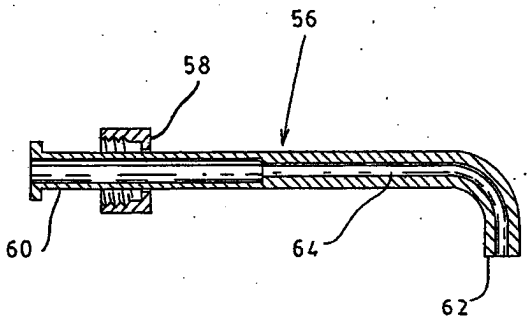


FIG. 6

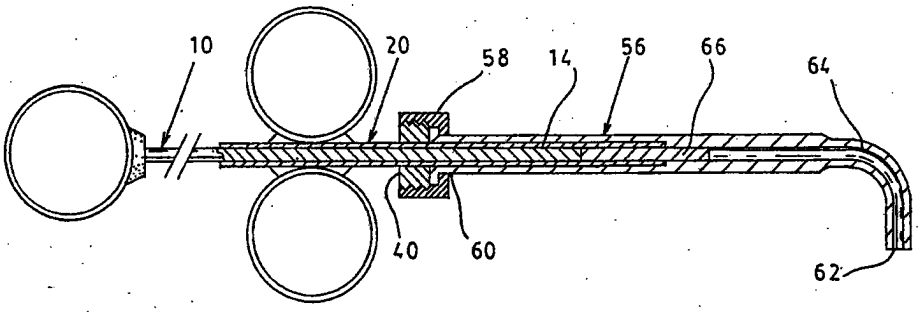


FIG. 7

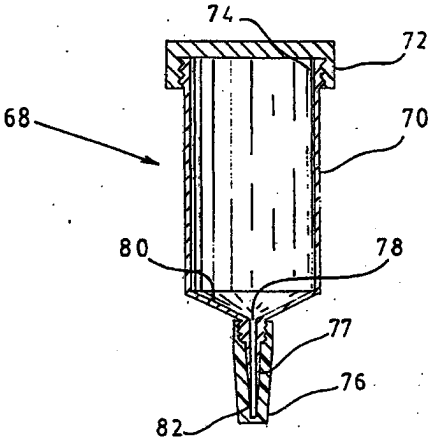


FIG. 8

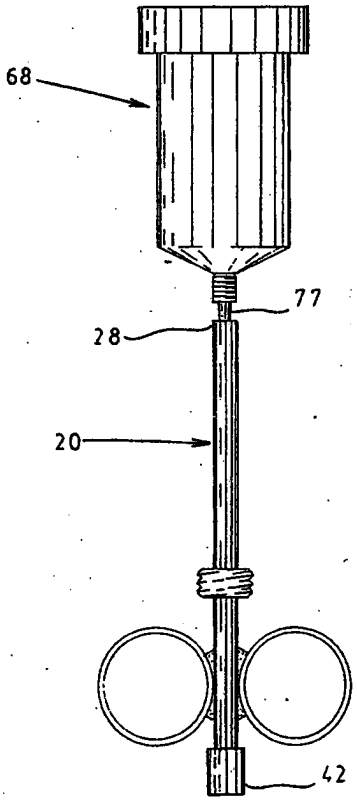


FIG. 9

OSSEOUS IMPLANT SYRINGE

This application is a continuation-in-part of U.S. patent application Ser. No. 867,065, filed May 27, 1986 and now abandoned.

TECHNICAL FIELD

This invention relates generally to a dental surgical device and is more specifically concerned with an osseous implant syringe capable of injecting osseous implant substances into interdental alveolar bone defects.

BACKGROUND

Osseous implant substances are used to fill interdental alveolar bone defects to effect bone grafts. These osseous graft materials are granular solids. The present technology for delivering osseous implant substances is to place the material in a sterile dappen dish and fill a delrin amalgam carrier from the dish. The osseous implant substance is then inserted into the graft site with the amalgam carrier. This process is slow, wasteful and difficult for the dentist and assistant as well. This technique requires many time consuming repetitions of the transfers on large or multiple grafts. The excessive time consumed in this method allows for slow hemorrhage of the graft site well before it is obturated, making firm condensation of the area more difficult and less effective. The surgeon's freedom to suction the defect area is curtailed on the transfer with an amalgam carrier because suction will remove any previously placed granular implant substances.

Various syringe devices have been devised for use in dentistry. One such device is shown in U.S. Pat. No. 2,754,590 issued to M. J. Cohen on Sept. 20, 1954. However, this device by Cohen would be ineffective to dispense the granular solid material that composes the osseous implant substance because of the inconsistent lumen dimensions; the granular material would pack at the change in lumen diameter and would not be expelled. Another such device is described in U.S. Pat. No. 2,505,028 issued to H. F. Boeger on Apr. 25, 1950. Again, this device cannot be used to dispense a granular material either because of the large reservoir going into the small dispensing outlet. There is no way at all to use this for a granular substance such as the osseous implant material. Furthermore, it would be difficult to use the invention shown by Boeger to reach the hard to reach areas of the gums because of the long distance from the tip of the needle to the body of the syringe. A final reference is made to U.S. Pat. No. 683,075 issued to A. Schneider on Sept. 24, 1901. The curved outlets from the syringe body would prevent the dispensing of any type of granular material. Furthermore, these outlets are too big to be used to insert into the small surgical incisions employed in dental surgery.

In any implant syringe it is necessary for the syringe to be the correct cross-sectional diameter to fit easily into graft sites through very small incisions. Smaller incisions are advantageous as they reduce the loss of implant substances after the procedure. The glass syringe presently used for edentulous augmentations is available in a variety of sizes, the smallest of which is 7 mm in diameter which is much too large to fit into most interdental osseous graft sites. It is also important for the implant syringe to contain a larger volume of implant substance than the capacity of an amalgam carrier to allow complete filling of osseous defects before the ever-present slow hemorrhage fills the defect. The implant syringe needs a curved nozzle to enable the surgeon an easier method to graft posterior and hard to reach areas. Preferably the syringe must have an outlet cap to prevent the spillage of implant materials and allow more than one barrel to be prepared at a time prior to the procedure which will reduce the procedure time ordinarily taken by reloading the amalgam carrier. Because no such satisfactory dental implant syringe exists serious problems arise due to the shortcomings of the prior art.

Accordingly, an object of the present invention is to provide an osseous implant syringe having a cross-sectional diameter that fits easily into graft sites through very small incisions. Smaller incisions are advantageous to reduce the amount of loss of the implant substances after the procedure.

It is another object of this invention to provide for a larger volume of implant substances than amalgam carriers which are now conventionally utilized. The greater volume allows complete filling of osseous defects before the ever-present slow hemorrhage fills the defect.

A further object of this invention is to provide a syringe for osseous implant applications that provides a curved delivery nozzle such that it is much easier for the surgeon to graft posterior and hard to reach areas.

It is also an object to provide a syringe constructed such that removable front and rear barrel caps allow one or more barrels to be prepared before the procedure starts which reduces the procedure time considerably and permits the possibility of grafting multiple osseous defects in a single procedure.

Still another object of this invention is to provide a syringe wherein the barrel is composed of delrin or a delrin-type material such that there is no chance of the device breaking while placed in an osseous defect and contaminating the graft site with glass fragments as is possible with glass syringes. Furthermore, since all components are made of delrin or flexible materials, the possibility of contaminating the implant substance with frictional debris from the syringe itself is reduced.

Still another object is to provide an osseous implant syringe that is autoclavable and thereby reusable, thereby permitting the surgeon to purchase synthetic osseous implant substances in bulk, load the barrels of the syringes according to the volume needed in each surgical procedure, and thus eliminate the waste inherent in fully pre-loaded syringes.

These and other features and advantages of the present invention will become apparent from a consideration of the following specification when taken in conjunction with the accompanying drawings.

SUMMARY OF THE INVENTION

The present invention provides an osseous implant syringe capable of injecting osseous implant substances into interdental alveolar defects. The syringe consists of a syringe plunger that is passed through an outer syringe barrel which contains the implant substances. As the syringe plunger is forced by hand through the syringe barrel, the displaced implant substances flow in a narrow stream from the outlet of the syringe barrel. When the syringe is not in use, a syringe barrel cap is placed on the outlet to keep the implant substances from flowing out of the outlet of the syringe barrel. A curved nozzle can be attached to the syringe barrel outlet to direct the implant substances to an area that is remote or

impossible to access with a straight syringe barrel. The nozzle and the barrel have a consistent lumen diameter throughout the length of the syringe so as not to impede movement of the implant substances. The curved nozzle is attached to the syringe barrel by a thread-bearing nozzle coupler that is mounted on the outside of the syringe barrel. The syringe barrel cap also fits on the outlet of the curved nozzle to prevent the implant substance from flowing from the curved nozzle when the syringe is not in use. When the curved nozzle is used, a flexible plunger extension can be placed at the end of the syringe plunger such that it will conform with the curvature of the curved nozzle to fully displace the implant substances through the curved nozzle. The loading of the implant substances into the syringe barrel is accomplished by use of a filling device.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view of the syringe plunger member of the present invention.

FIG. 2 is a longitudinal cross-sectional view of the syringe barrel member of the invention showing the lumen for closely receiving the syringe plunger member, and the threaded coupler for a nozzle.

FIG. 3 is a longitudinal cross-sectional view of an assembled syringe with the syringe plunger member of FIG. 1 fitted within the syringe barrel of FIG. 2, and showing a syringe barrel cap at the outlet of the syringe barrel.

FIG. 4 is a longitudinal cross-sectional view of a straight extension nozzle member.

FIG. 5 is a longitudinal cross-sectional view of the assembled syringe with the extension nozzle member attached to the syringe barrel member.

FIG. 6 is a longitudinal cross-sectional view of a curved nozzle member.

FIG. 7 is a longitudinal cross-sectional view of the implant syringe with the optional curved nozzle member connected to the nozzle coupler of the barrel member. Also shown in this drawing is a flexible plunger extension that is attached to the end of the syringe plunger member for the full displacement of the implant substances through the lumen of the curved nozzle member.

FIG. 8 is a cross-sectional view of a filling device for the syringe of the present invention with a cap on the inlet and a cap on the outlet to prevent spillage.

FIG. 9 is a side view of the filling device outlet attached to the syringe barrel outlet so as to load the implant substances from the filling device into the syringe barrel member.

DETAILED DESCRIPTION OF THE EMBODIMENT

Referring now to the drawings, and to the embodiment of the invention herein presented by way of illustration, FIG. 1 shows a syringe plunger member **10** as used in the invention. The syringe plunger member **10** consists of a piston rod **11** having a first end **12** and a second end **14**. The syringe plunger member **10** also consists of a handle **18** connected to the first end **12** of the piston rod **11** as by a web support **16**. In the preferred form, this syringe plunger member handle **18** is an open loop designed to accept a finger of the user.

Looking now to FIG. 2 of the drawings, it will be seen that the implant syringe includes a syringe barrel member **20**. This syringe barrel member consists of a barrel sleeve **22** having an axial lumen **24** in which the piston rod **11** of the syringe plunger member **10** is slidably received. The difference in the outer diameter of the piston rod **11** and the inner diameter of the axial lumen **24** is large enough to allow the piston rod **11** to readily slide through the axial lumen **24** without allowing the implant substance to get between the piston rod **11** and the wall of the barrel sleeve axial lumen **24**. As the piston rod **11** slides through the axial lumen **24**, any implant substance therein is displaced and forced through the axial lumen **24** and out the syringe barrel outlet **28**. It will also be seen that the syringe barrel member **20** consists of grasping members **32, 34** attached to the outer part of the barrel sleeve **22**. The grasping members **32, 34** are typically attached to the barrel sleeve **22** by web supports **36, 38**, respectively, attached to the outer surface of the barrel sleeve **22** and to the outside diameters of the grasping members **32, 34**. Once again, these grasping members in their preferred form consist of two open loops to each accept one finger of the user. It is important to note that the diameter of the axial lumen **24** is consistent (unchanging) between a syringe barrel inlet **30** and the syringe barrel outlet **28**.

In FIG. 3 of the drawings it will be seen that the syringe plunger member **10** of FIG. 1 is placed slidably within the syringe barrel member **20** of FIG. 2. This is accomplished by placing the piston rod **11** in the syringe barrel inlet **30** of the axial lumen **24** and slipping the piston rod through the consistent diametered axial lumen **24**. The piston rod **11**, as it slides through the axial lumen **24**, displaces any implant substance that is held within. This movement of the piston rod **11** is performed by exerting a force upon the syringe plunger member handle **18** toward the syringe barrel inlet **30** while exerting an equal and opposite force against the grasping members **32, 34**. It will also be seen that a syringe barrel cap **42** can be placed over the syringe barrel outlet **28** when implant syringe is not in use to prevent implant substance spilling out of the syringe barrel outlet **28**. A same type cap can be placed over the syringe barrel inlet **30** when the piston rod **11** is not placed within the axial lumen **24**. Typically, as can be seen from this picture, the length of the piston rod **11** is the same as the length of the axial lumen **24** so as to accomplish complete displacement of implant substances from the lumen **24**.

Referring now to FIG. 4, it can be seen that an extension nozzle member **44** can be provided for the implant syringe to reach those more distant areas of the mouth. The extension nozzle member **44** typically consists of an internally threaded extension member connector **46**. This threaded extension member connector **46** releasably attaches to the threaded nozzle coupler **40** (see FIG. 2). The extension nozzle member **44** has a first end **48** and a second end **50**. When this extension is attached to the syringe barrel member **20** the implant substance flows out of the syringe barrel outlet **28** and into the extension nozzle first end **48**. It should be noted that the diameter of the axial lumen **24** of the barrel member **20** is the same as the diameter of an extension nozzle lumen **52**.

Looking now at FIG. 5 of the drawings, it will be seen that the extension nozzle member **44** is placed on the syringe barrel member **20** by attaching the threaded nozzle coupler **40** to the threaded extension member connector **46**. In order to assure displacement of the osseous implant substance all the way through the extension nozzle lumen **52**, a plunger extension **54** is

placed on the second end 14 of the syringe plunger member 10.

In FIG. 6 of the drawings it will be seen that a curved nozzle member 56 can be utilized with the barrel member 20. This curved nozzle member is provided with a threaded connector nut 58, a first end 60 and a second end 62, and a curved nozzle lumen 64. This curved nozzle lumen 64 has the same diameter as axial lumen 24 of the syringe member barrel 20.

Referring now to FIG. 7 of the drawings, it will be seen that the curved nozzle member 56 of FIG. 6 can be attached over the syringe barrel member 20 to direct the flow of the implant graft substances to remote and hard-to-reach areas that are not reachable by the straight direction of the basic implant syringe or by the straight extension shown in FIGS. 4 and 5. The curved nozzle member 56 is attached to the threaded nozzle coupler 40 by the threaded coupler nut 58 which also allows the rotational angle of the curved nozzle member 56 to be adjusted. It can also be seen that when the curved nozzle member 56 is used, a flexible plunger extension 66 (similar to extension 54 of FIG. 5) can be placed on the second end 14 of the syringe plunger piston rod 11 so that the piston rod and its extension completely displace the implant substance through the curved nozzle lumen 64 of the curved nozzle member 56. Typically, the flexible plunger extentions 54, 66 can be fabricated of surgical quality rubber or the like. Likewise, the barrel caps 42 can be made of rubber or the like.

Referring now to FIG. 8 of the drawings, it will be seen that a filling device member 68 can be provided. This consists mainly of a filling device reservoir 70 which contains the implant substance until it is loaded into the syringe barrel member 20. The filling device is provided with an inlet cap 72 for the filling device inlet 74 which is removed for transferring gross quantities of implant substances into the filling device member 68. The filling device also has a cap 76 which is removed from the outlet neck 77 when the filling device is used to fill the syringe barrel member 20. The filling device reservoir 70 bottom has a sloping base 80 to allow the implant substance to more evenly flow into the outlet neck 77 and into the filling device outlet 78 for flow through a neck outlet 82. The substance is passed through the outlet neck 77 by a gentle shaking motion. The inlet cap 72 can be fastened to the filling device inlet by friction or by threads as shown. The cap 76 can be fastened to the outlet neck 77 by the same means.

Looking now at FIG. 9 it will be seen that the filling device member 68 is engaged with the syringe barrel member 20. The cap 76 (see FIG. 8) is taken off of the outlet neck 77 so that the filling device neck outlet 82 can be placed in the syringe barrel outlet 28. The granular substance is forced out of the filling device reservoir 70 down the outlet neck 77 and into the axial lumen 24 of the syringe barrel member 20 by a gentle shaking motion. This Figure also shows that the syringe barrel cap 42 can also be placed over the syringe barrel inlet 30 to prevent the granular material from flowing out of the inlet. The syringe barrel cap 42 allows for the syringe barrel member 20 to be filled and another syringe barrel cap 42 can be then placed over the syringe barrel outlet 28 after filling to prevent the escape of granular material from the syringe barrel outlet 28. This allows the syringe barrel member 20 to be set aside for quick and efficient usage when needed. With the exception of the flexible plunger extensions, each component is preferrably made of delrin or any sterilizable material capable of withstanding the forces necessary to apply the implant substance.

Although dimensions of the present invention are not critical, the following is an example of a typical syringe for osseous implant materials. The piston rod 11 of the syringe plunger member 10 has a 3 mm diameter and adapts closely to the axial lumen 24 of the syringe barrel member 20. The cross-sectional diameter of the outer part of the syringe barrel member 20 is approximately 4 mm to allow it to easily fit into a graft site through a very small incision. The length of the syringe barrel member 20 from the syringe barrel outlet 28 to the syringe barrel inlet 30 is approximately 4 inches. This length is a function of the required quantity of implant substance necessary for an implant and the distance over which the syringe is to traverse. The angle of the curved nozzle member 56 depends on the part of the mouth to be reached. As illustrated in FIGS. 6 and 7, it is typically 90 degrees, however other curvatures can be employed.

The use of the osseous implant syringe begins with the filling process. The inlet cap 72 of the filling device 68 is removed from the filling device inlet 74, and gross quantities of the osseous implant substances are transferred into the filling device inlet 74 by use of any suitable device. When the reservoir 68 is filled, the inlet cap 72 is replaced. The filling device member is then turned upside down and the cap 76 is removed from the outlet neck 77. With the barrel cap 42 removed, the syringe barrel member 20 is then placed such that the syringe barrel outlet 28 is upon the filling device neck outlet 82. A syringe barrel cap 42 is placed over the syringe barrel inlet 30. The units are then inverted such that the filling device member 68 is now resting on top of the syringe barrel member 20. The implant substance is then shaken through the outlet neck 77 and into the axial lumen 24 of the syringe barrel member 20. This process is continued until the osseous implant substance fills the axial lumen 24 of the syringe barrel member 20. The filling device member 68 is then removed and either the cap 76 is replaced or else another syringe barrel member 20 is filled using the same process. A syringe barrel cap 42 is then placed over the syringe barrel outlet 28.

When the syringe is to be used, the syringe barrel cap 42 is removed from the syringe barrel inlet 30 and the syringe plunger member 10 is placed in the axial lumen 24 through the syringe barrel inlet 30. The syringe barrel cap 42 on the syringe barrel outlet 28 is now removed and the syringe barrel outlet 28 is placed at the grafting site. If the syringe barrel member is too short to reach the graft site, the extension nozzle member 44 is placed onto the syringe barrel member 20 using the threaded nozzle coupler 40. A plunger extension 54 is placed at the second end 14 of the piston rod 11 of the syringe plunger member 10. A force is then applied to the syringe plunger member handle 18 by use of a thumb and an equal and opposite force is placed against the grasping members 32 and 34 by use of any two fingers such that the force pushes the granular substance through the axial lumen 24 and out the syringe barrel outlet 28. Once out of the syringe barrel outlet 28, the granular substance moves into the extension nozzle member 44, through the extension nozzle lumen 52, and out of the extension nozzle second end 50.

If however, a straight syringe barrel will not suffice, the curved nozzle member 56 can be attached to the syringe barrel member 20 by attaching the threaded

nozzle member connection 58 to the threaded coupler 40. In this case, a flexible plunger extention 66 is placed against the second end 14 of the syringe plunger member 10. This allows displacement through the axial lumen 24 of the syringe barrel member 20 and also displacement through the curved nozzle lumen 64 and out the curved nozzle second end 62. The rotational angle of the curved nozzle member 56 is set by the amount of rotation of the threaded curved nozzle member connector 58 with respect to the threaded nozzle coupler 40. The syringe barrel cap 42 can be placed over the curved nozzle second end 62 of the curved nozzle member 56 or over the extension nozzle second end 50 of the extension nozzle member 44 to prevent spillage of the granular material when it is not in use.

It will be understood by those skilled in the art that the particular embodiment of the invention here presented is in no way restrictive; therefore, numerous changes and modifications may be made, and the full use of equivalents noted to, without departing from the spirit or scope of the invention as defined in the appended claims and their equivalents.

I claim:

1. An osseous implant syringe designed for injecting an osseous implant substance into interdental alveolar bone defects, comprising:

a syringe plunger member having a piston rod and handle means connected at a first end of said piston rod;

a syringe barrel member having a syringe barrel provided with an axial lumen from an inlet to an outlet to closely receive said piston rod of said syringe plunger member, said lumen having a uniform cross section throughout its length;

grasping members attached to an external surface of said barrel sleeve proximate said barrel inlet; and

a threaded nozzle coupler attached exterior to said barrel member proximate said grasping members.

2. The implant syringe of claim 1 further comprising a first syringe barrel cap for placement over said syringe barrel outlet to prevent spillage of said implant substance from said axial lumen.

3. The implant syringe of claim 2 further comprising a further syringe barrel cap for placement over said syringe barrel inlet when said piston rod of said syringe plunger member is not inserted into said axial lumen of said syringe barrel member, said first and further barrel caps to prevent spillage of said implant substance from said axial lumen.

4. The implant syringe of claim 1 further comprising an extension nozzle member having a first end and a second end and provided with an extension nozzle lumen, said first end of said extension member adapted for releasable attachment to said syringe barrel member by use of the said threaded nozzle coupler, said extension nozzle lumen having a consistent cross-section with said axial lumen of said barrel member.

5. The implant syringe of claim 1 further comprising a curved nozzle member having a first end and a second end and provided with a curved nozzle lumen, said first end of said curved nozzle member adapted for releasable attachment to said syringe barrel member by use of the said threaded nozzle coupler, said curved nozzle lumen having a consistent cross-section with said axial lumen of said barrel member.

6. The implant syringe of claim 4 further comprising a syringe barrel cap for placement over said extension nozzle member second end to prevent spillage of said implant substance.

7. The implant syringe of claim 5 further comprising a syringe barrel cap for placement over said curved nozzle member second end to prevent spillage of said implant substance.

8. An osseous implant syringe for injecting an osseous implant substance into interdental alveolar bone defects, which comprises:

a barrel member having a syringe barrel inlet at a first end and a syringe barrel outlet at a further end, said barrel member provided with an axial lumen of a selected uniform cross section from said syringe barrel inlet to said syringe barrel outlet, said barrel member further provided with attached grasping members at said syringe barrel inlet;

a syringe plunger member defined by a piston rod having first and second ends, said plunger member provided with handle means at said first end, said piston rod for being closely received in said lumen of said syringe barrel member;

first coupler means attached to an external surface of said barrel member proximate said grasping members in a direction toward said further end of said barrel member; and

a barrel extension member for releasable attachment to said syringe barrel member, said barrel extension nozzle member having a first end and a second end, said first end provided with further coupler means for releasable engagement with said first coupler means, said barrel extension nozzle member having an axial passage at said first end to accept said further end of said barrel member, and provided with a lumen from said first end to said second end of said barrel extension consistent in cross-section with said axial lumen of said syringe barrel member.

9. The syringe of claim 8 further provided with first and further barrel caps to releasably close said first end of said barrel member and said second end of said extension member, respectively, when said piston rod is withdrawn from said lumen of said barrel member.

10. The syringe of claim 8 further comprising a piston rod extension attached axially to said piston rod at said second end whereby said piston rod and piston rod extension extend from said first end of said barrel member to said second end of said barrel extension member.

11. The syringe of claim 8 wherein said barrel extension member is an axial extension for said barrel member, and wherein said lumen of said extension member is an axial extension of said lumen of said barrel member.

12. The syringe of claim 10 wherein said barrel extension member is curved from said first end thereof to said second end thereof, and thereby said lumen of said extension member is curved, and said piston rod extension is flexible to follow said curved lumen of said extension member as said piston rod is moved axially in said lumen of said barrel member.

13. The syringe of claim 8 wherein said first coupler means is an externally threaded collar attached to said barrel member, and said further coupler means is an internally threaded collar to cooperatively and releasably attach said barrel extension member to said barrel member.

14. The syringe member of claim 8 wherein said grasping members of said barrel means and said handle means of said plunger member are open loop-type members for accepting fingers of a user whereby said

plunger member can be moved axially with respect to said barrel member.

15. An osseous implant syringe for injecting an osseous implant substance into interdental alveolar bone defects to effect bone grafts, which comprises:

a substantially cylindrical barrel member having a first end and a further end, said barrel member provided with an axial lumen of a selected uniform cross-section from said first end to said further end, said barrel member further provided with loop-type grasping members at said first end to accept fingers of a user of said syringe;

a plunger member defined by a piston rod having a first and further end, said piston rod provided with a loop-type handle at said first end to accept a finger of said user, said piston rod configured to be closely received in said lumen of said barrel member;

an externally threaded coupler collar attached to an exterior surface of said barrel member proximate said grasping members in a direction toward said further end of said barrel member;

a barrel extension member for releasable attachment to said barrel member, said extension member having a first end and a further end and being curved from said first end to said further and, said extension member provided with a curved lumen having a cross section consistent with said lumen of said barrel member;

an internally threaded coupler collar carried by said first end of said extension member for releasable engagement with said coupler collar of said barrel member to effect said releasable attachment of said extension member and said barrel member; and

a flexible piston rod extension attached to said further end of said piston rod whereby said piston rod extension traverses said curved lumen of said extension member as said piston rod traverses said lumen of said barrel member.

16. The syringe of claim 15 further comprising first and further barrel caps to releasably close said first end of said barrel member and said further end of said extension member when said piston rod is removed from said lumen of said barrel member.

* * * * *

B-5

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United States Patent [19]

Scholten et al.

[11] Patent Number: 5,108,404

[45] Date of Patent: * Apr. 28, 1992

[54] SURGICAL PROTOCOL FOR FIXATION OF BONE USING INFLATABLE DEVICE

[76] Inventors: **Arie Scholten**, 4175 Tamayo St., Fremont, Calif. 94536; **Mark A. Reiley**, 333 63rd St., Oakland, Calif. 94618

[*] Notice: The portion of the term of this patent subsequent to Nov. 13, 2007 has been disclaimed.

[21] Appl. No.: **567,862**

[22] Filed: **Aug. 15, 1990**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 308,724, Feb. 9, 1989, Pat. No. 4,969,888.

[51] **Int. Cl.**[5] **A61B 17/56**

[52] **U.S. Cl.** **606/94**; 606/60; 606/95

[58] **Field of Search** 606/60, 94, 95, 191, 606/192, 193, 194

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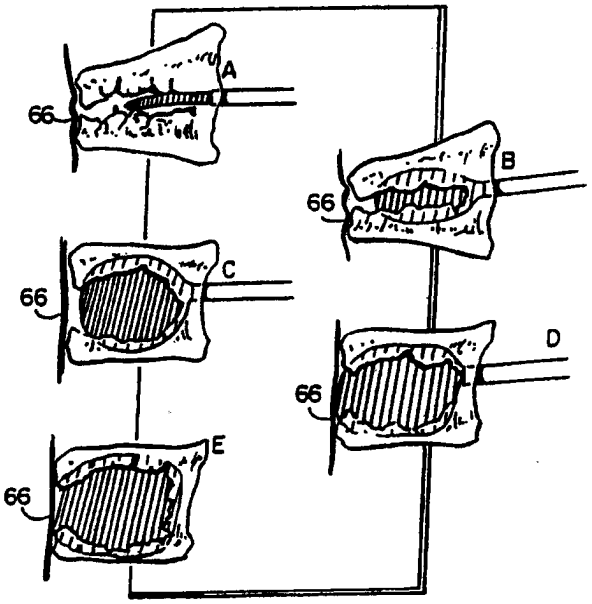
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Primary Examiner—Robert A. Hafer
Assistant Examiner—Kevin G. Rooney
Attorney, Agent, or Firm—Townsend and Townsend

[57] **ABSTRACT**

A method and apparatus for the fixation of osteoporotic and non-osteoporotic bones and especially vertebral body compression fractures, Colles' fractures and fractures of the proximal humerus. The method of the present invention includes a series of steps including penetrating the bone having the fracture with a guide pin, drilling the bone marrow of the bone to enlarge the cavity to be treated, following which a bone specific inflatable device is inserted in the cavity and inflated. The expansion of the device causes a compacting of the bone marrow against the inner surface of the outer wall of the bone to be treated to further enlarge the cavity. When this occurs, a flowable synthetic bone material or methyl methacrylate cement is directed into the cavity and allowed to set to a hardened condition. Following this, the instruments are removed. In the fixation of vertebral body fractures, an elliptical inflatable device is first used to initiate the compacting of the bone marrow, following which a substantially cylindrical inflatable device is inserted into the cavity to further compact the bone marrow in all directions. In the fixation of Colles' fractures and proximal humerus fractures, a gourd-shaped inflatable device is used to compact the bone marrow.

29 Claims, 11 Drawing Sheets



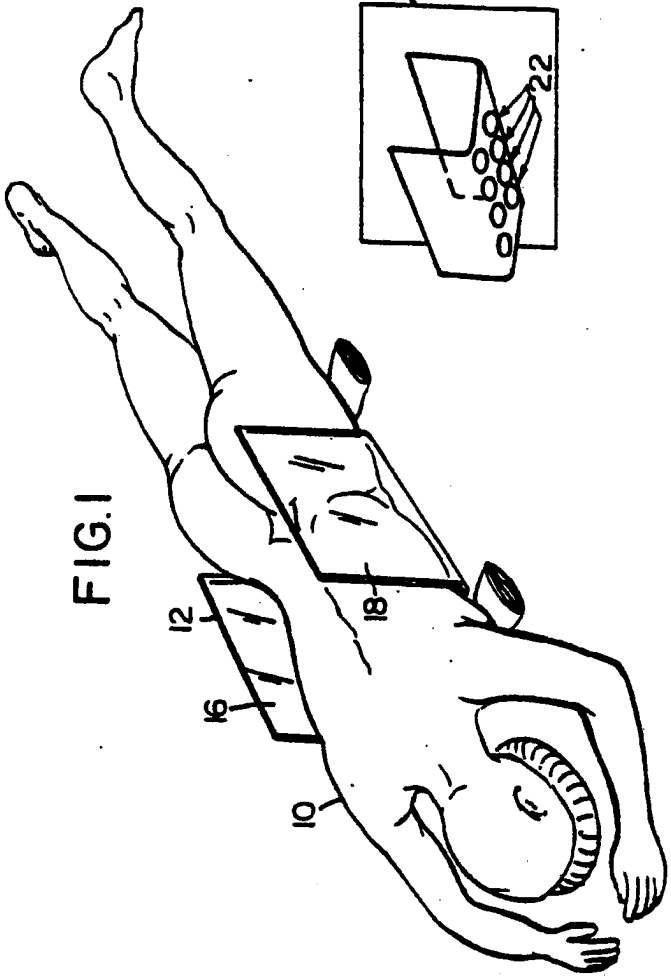


FIG. 1

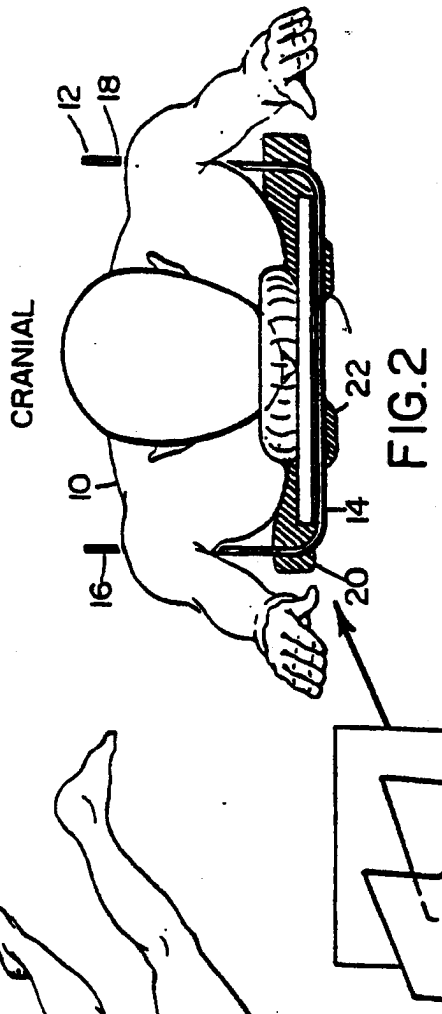


FIG. 2

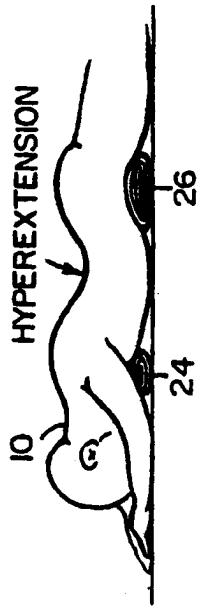


FIG. 3

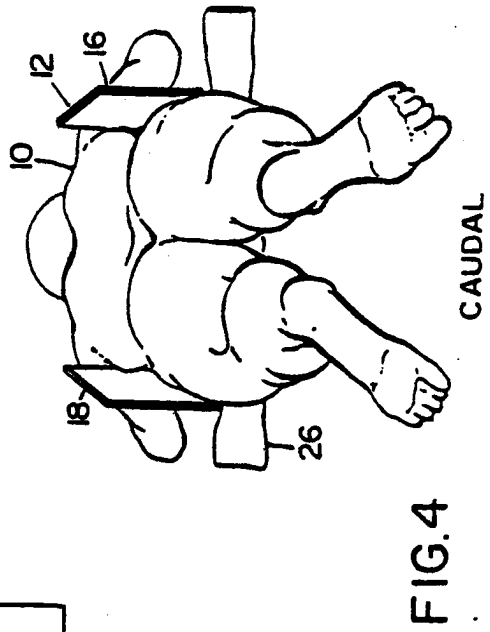


FIG. 4

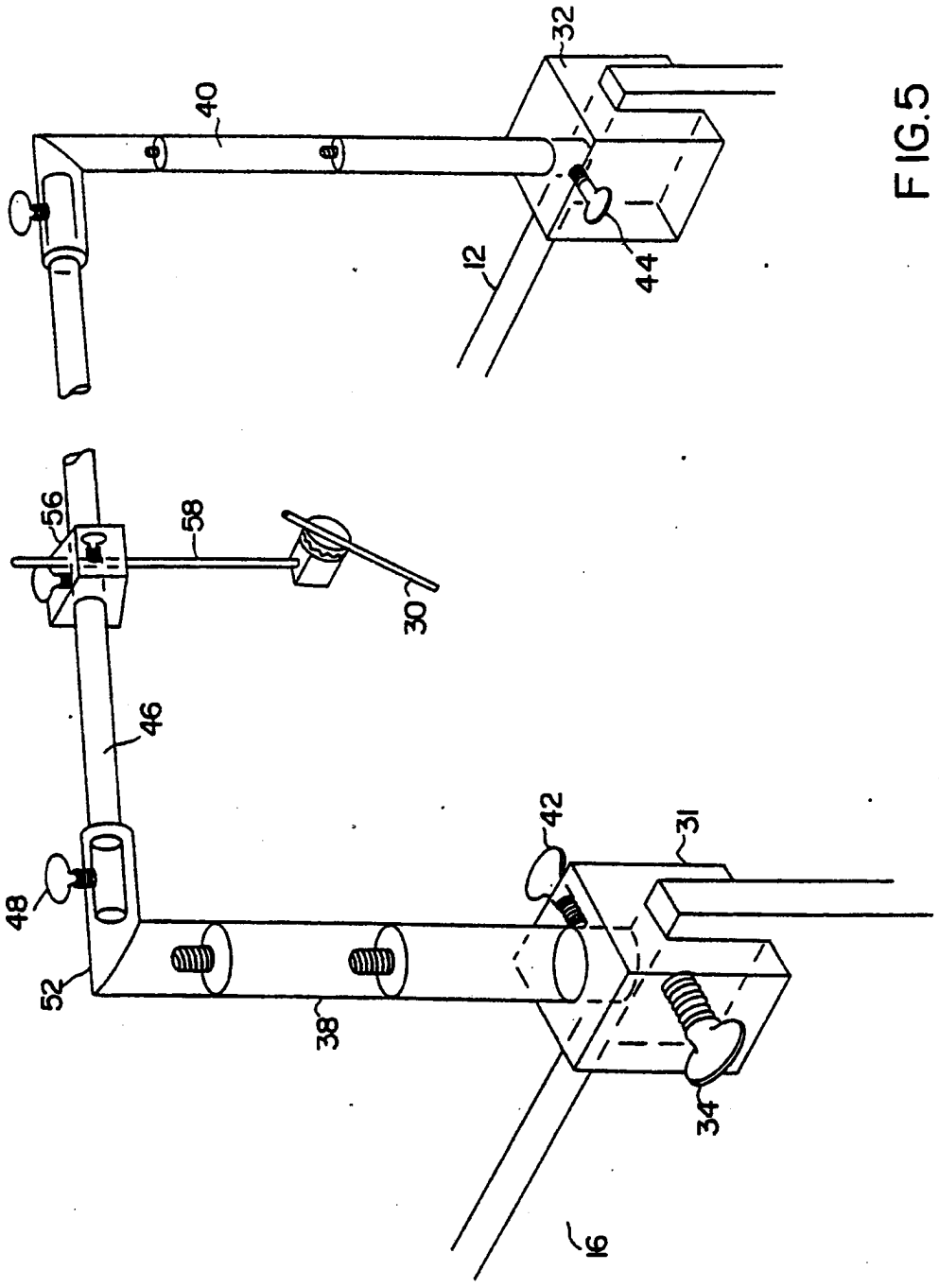


FIG.5

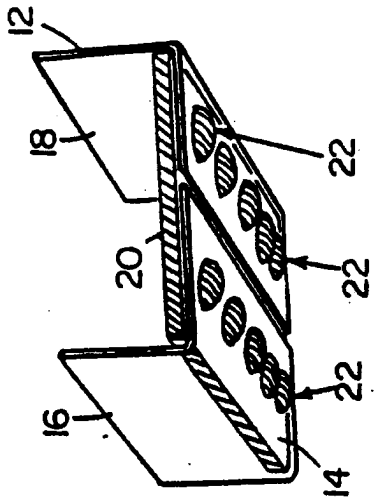


FIG.7

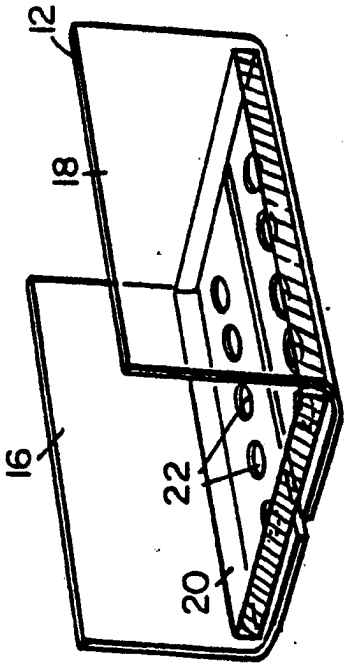


FIG.6

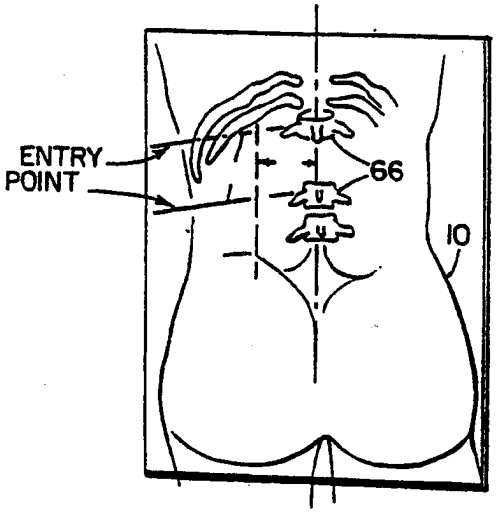


FIG.8

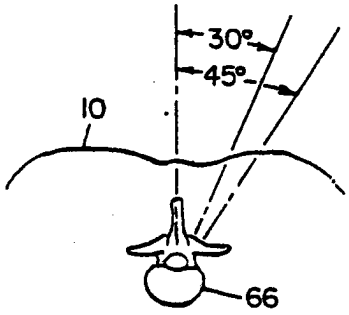


FIG.9

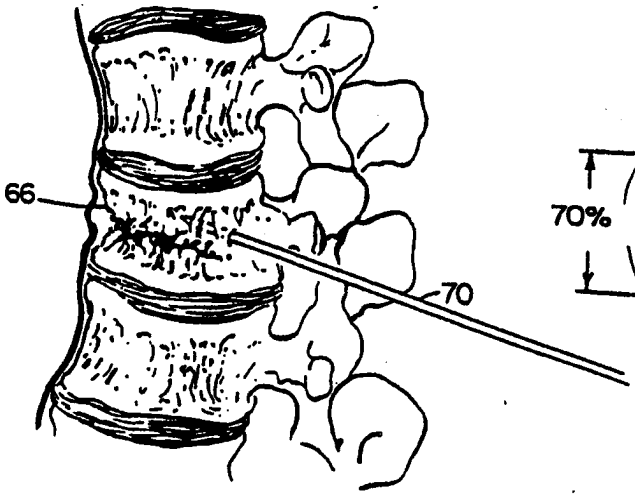


FIG.10

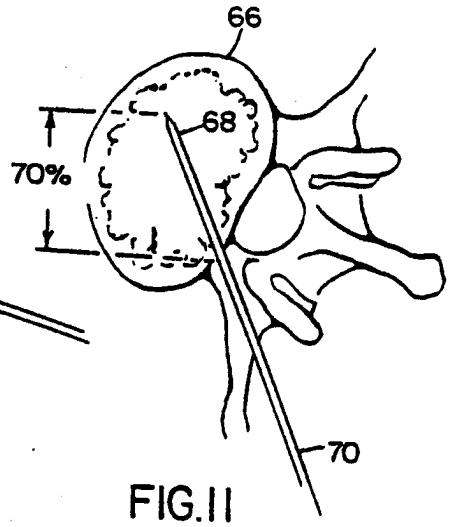


FIG.11

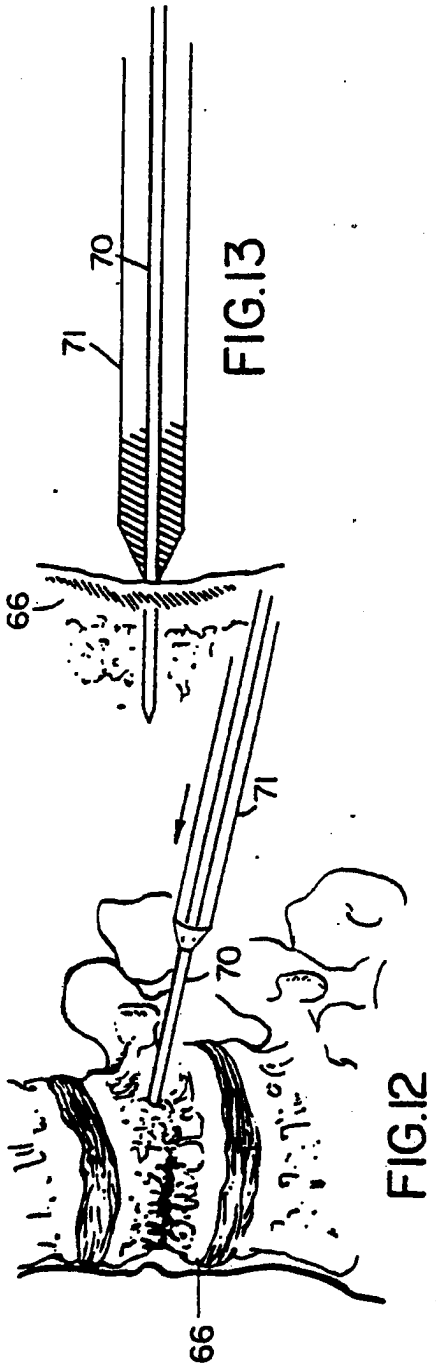


FIG.13

FIG.12

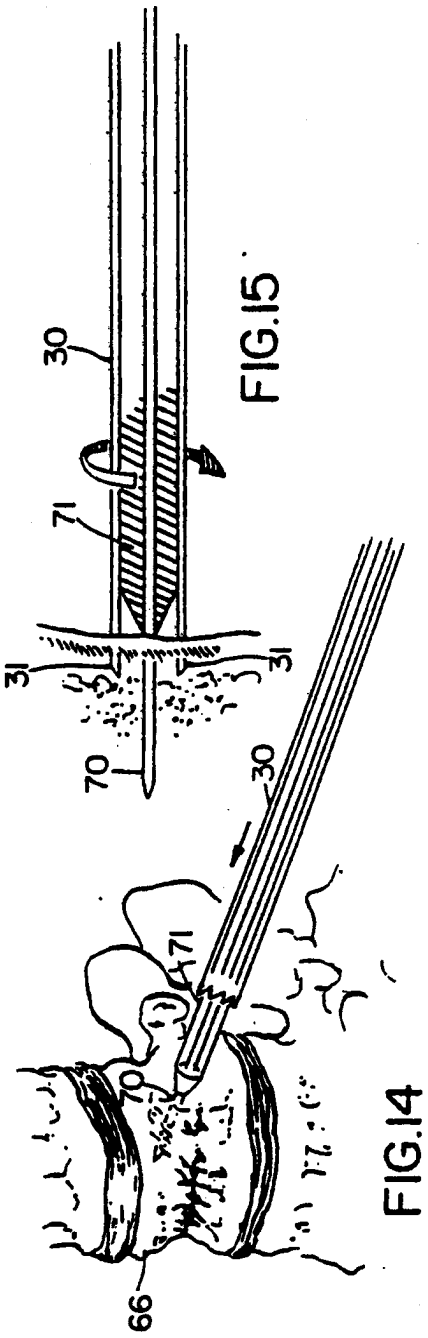


FIG.15

FIG.14

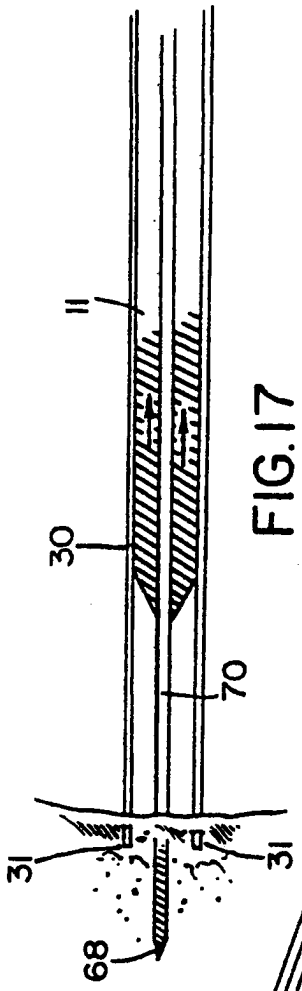


FIG.17

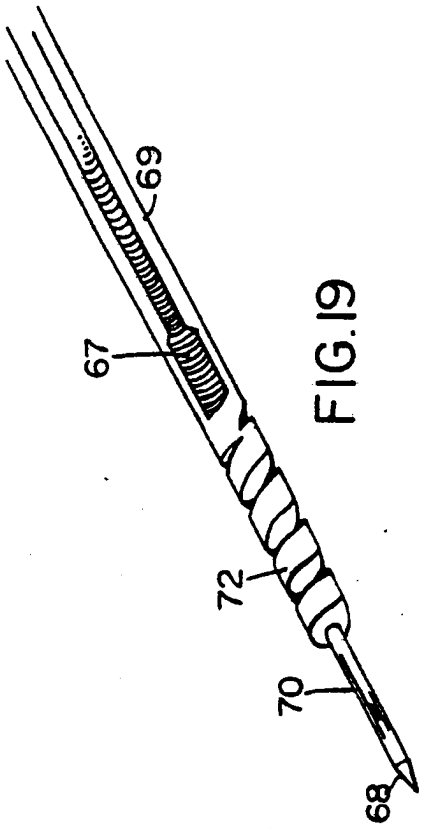


FIG.19

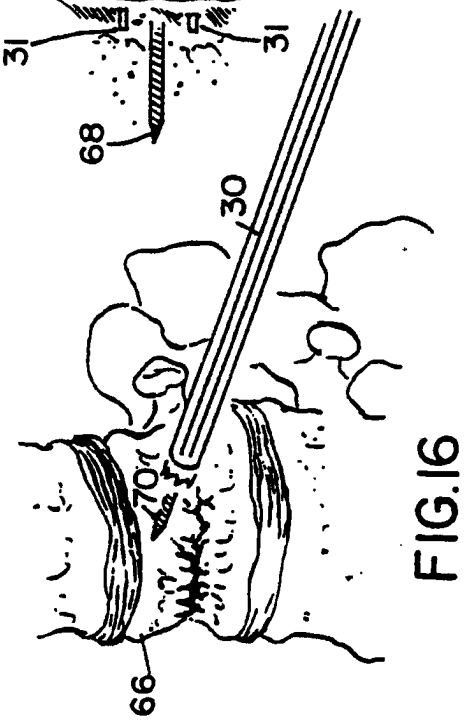


FIG.16

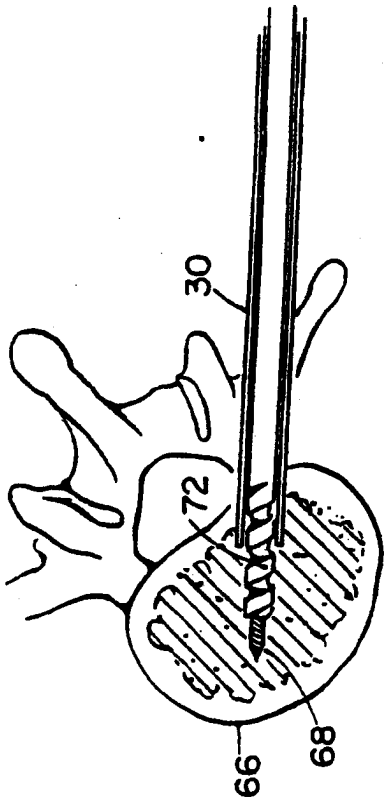


FIG.18

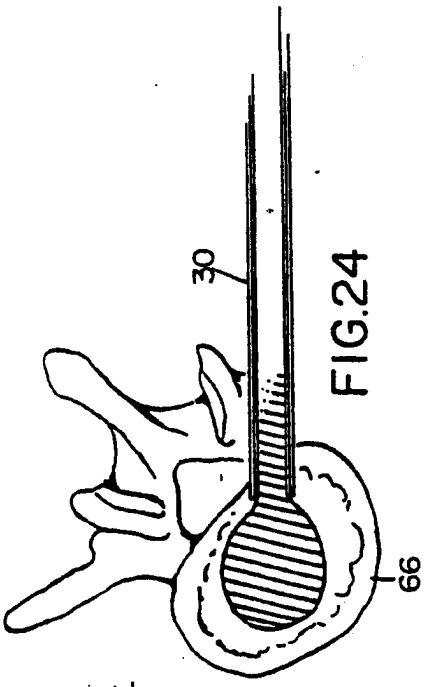


FIG.24

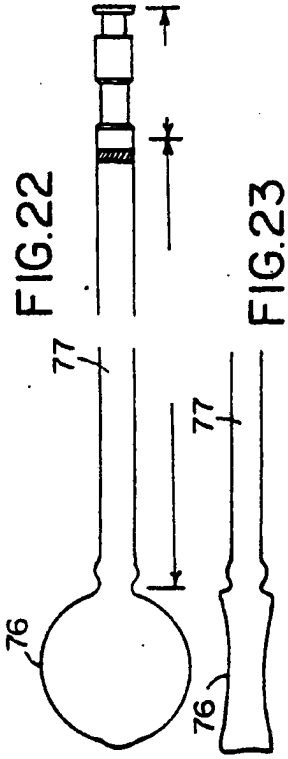


FIG.22 FIG.23

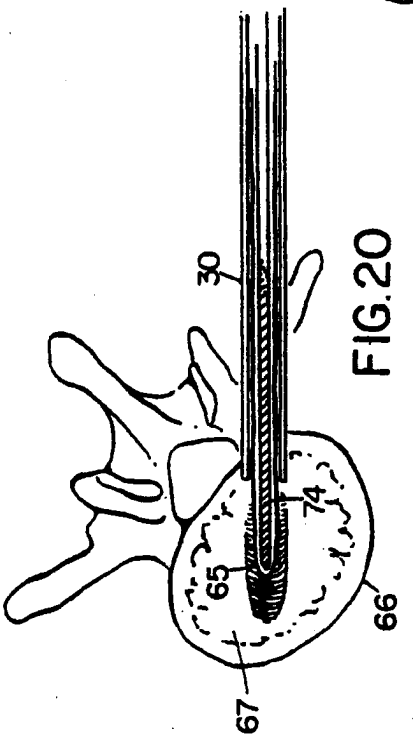


FIG.20

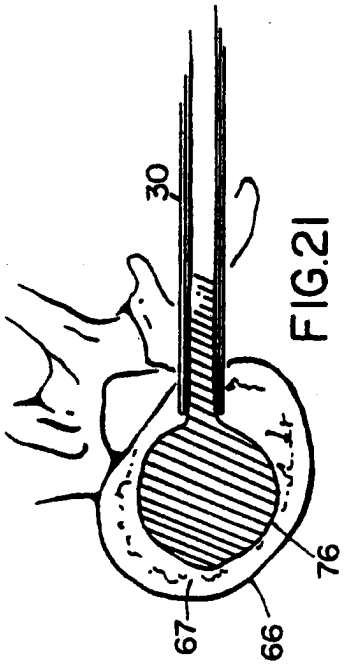


FIG.21

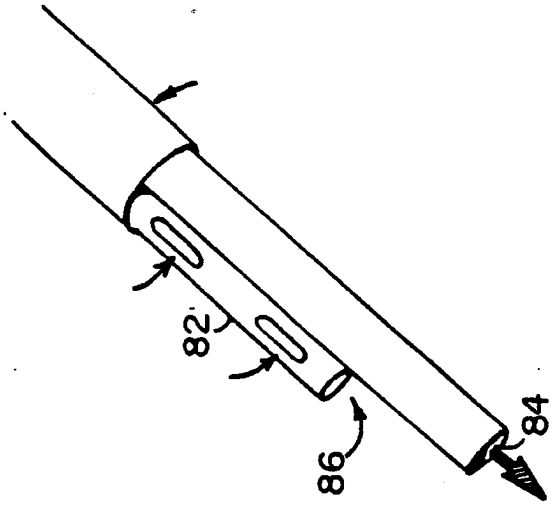


FIG.26

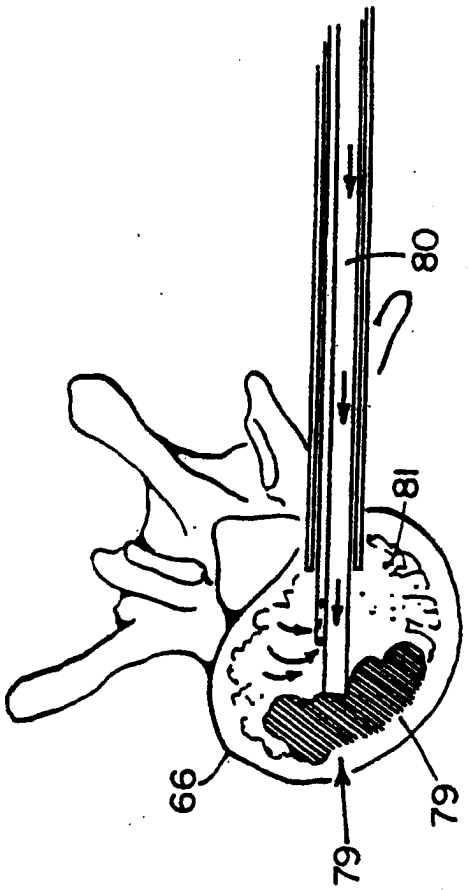


FIG.25

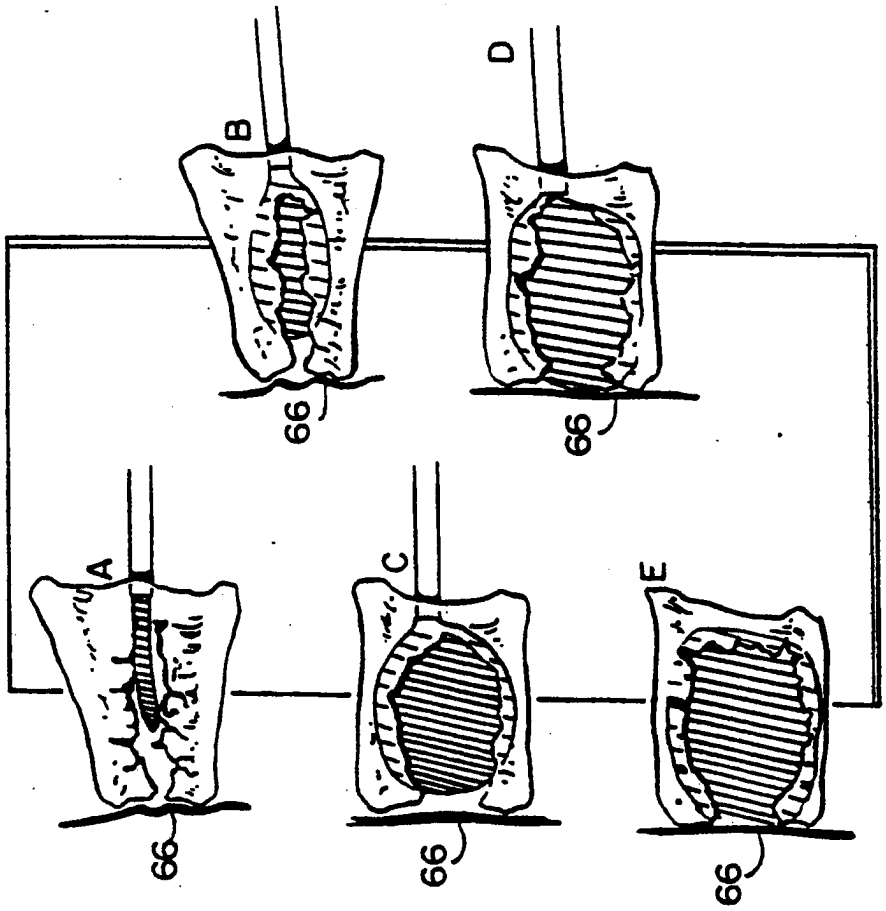


FIG.28

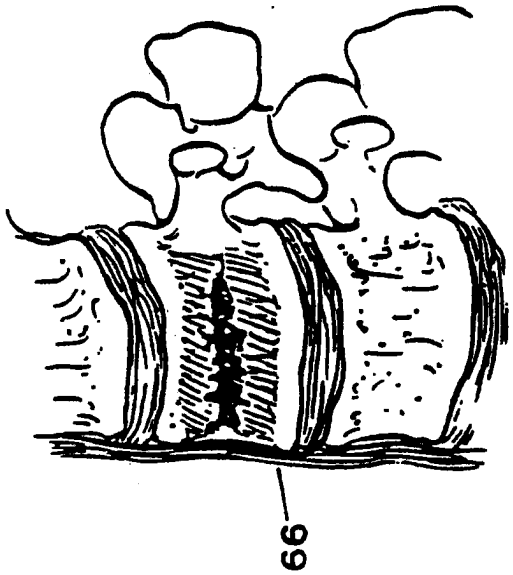


FIG.27

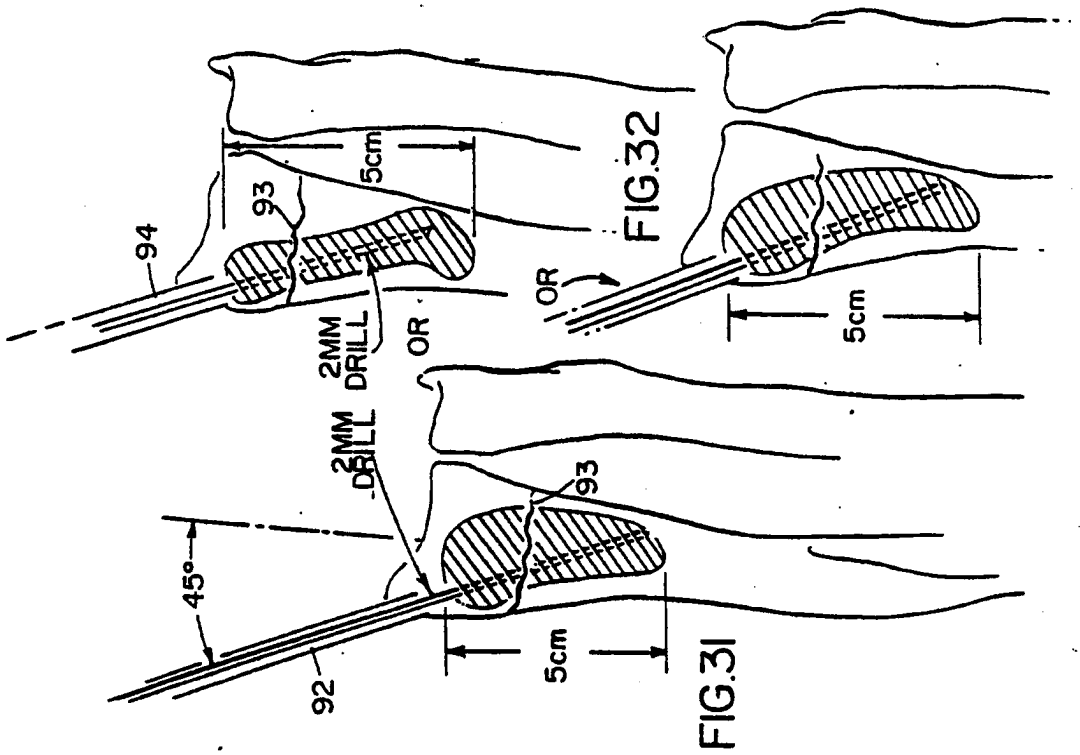


FIG.32

FIG.31

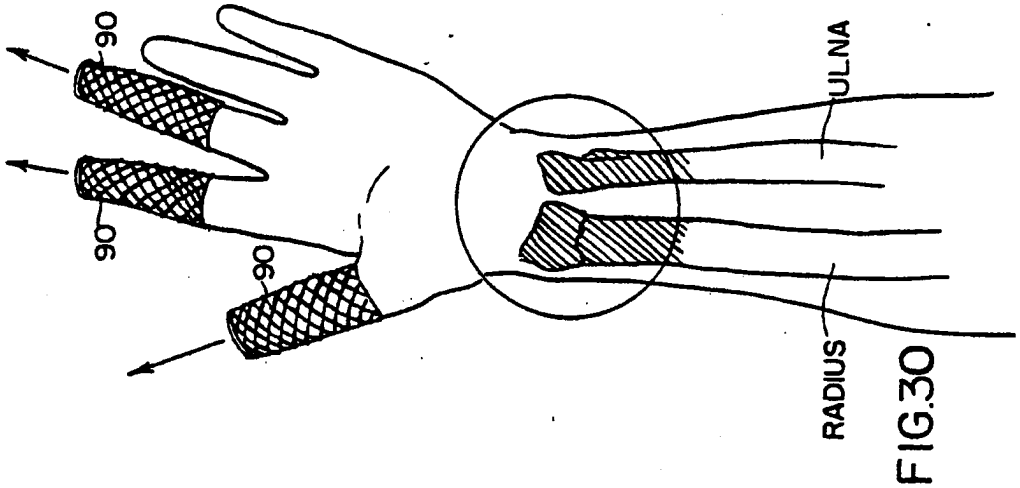


FIG.30

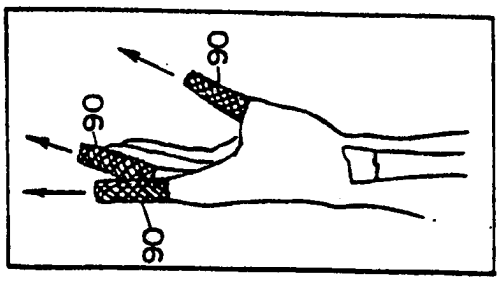


FIG.29

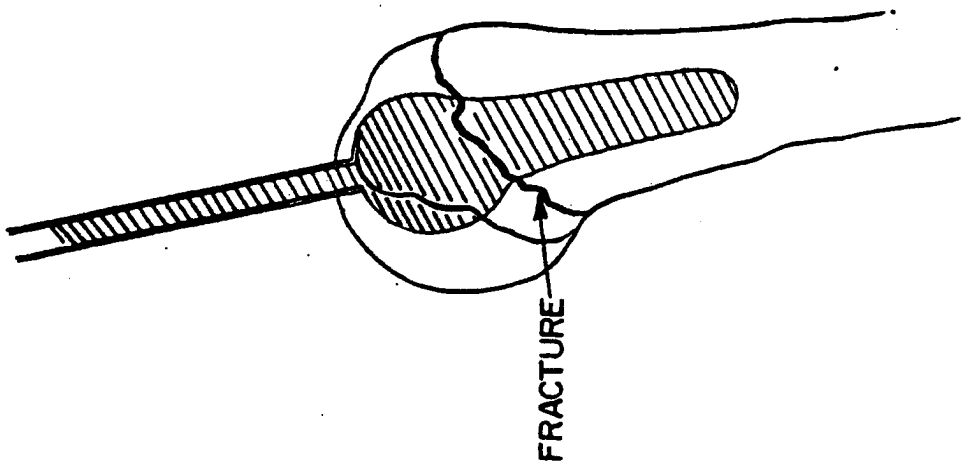


FIG.34

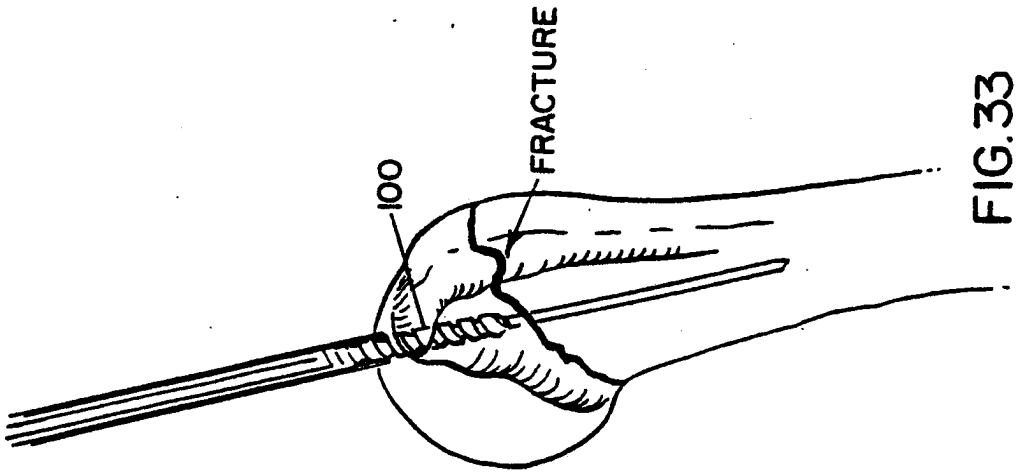


FIG.33

SURGICAL PROTOCOL FOR FIXATION OF BONE USING INFLATABLE DEVICE

This is a continuation-in-part application of application Ser. No. 07/308,724, filed Feb. 9, 1989, entitled "Surgical Protocol for Fixation of Osteoporotic Bone Using Inflatable Device," now U.S. Pat. No. 4,969,888.

This invention relates to improvements in the surgical treatment of bone conditions of the human and other animal body systems and, more particularly, to a method and apparatus for use in correcting such conditions.

BACKGROUND OF THE INVENTION

Every year in the United States there occurs over 1.2 million bone fractures of osteoporotic bone. Over nine hundred thousand (900,000) of those fractures occur in bones which can be treated with the percutaneous balloon technology of the present invention which includes instant fixation by methyl methacrylate cement or with liquid artificial bone substitutes. Those fractures which can be treated by the method and apparatus of the present invention are distal radius fractures, the proximal humerus fractures, the vertebral body compression fractures, and fractures of other long bones.

Osteoporotic and non-osteoporotic vertebral body compression fractures are currently treated with bed rest, analgesics, and intravenous hydration during the first week after onset of the problem. These steps are followed by the prescription of a soft or firm spinal corset, depending upon the physician's preference. In most cases, the corset is not worn because the patient suffers much discomfort and oftentimes greater discomfort than that due to the fracture of the vertebral body. The fracture pain lasts from two to eight months. In many cases, patients with vertebral body collapse fractures require about one week in an acute care hospital and two to three weeks in an extended care facility until they are able to move about independently and with only moderate pain. Current treatment does not substantially alter the conditions of the vertebral body.

The current management of shoulder fractures includes either long term immobilization in a sling, followed by lengthy physical therapy. If the fracture is in three or four parts, the fracture is treated with a shoulder hemiarthroplasty. Long term stiffness is the rule, following either treatment due to long term immobilization and/or extensive wound healing.

Colles' fractures of the wrist in the elderly are currently treated in three different ways: 1) they are treated with closed reduction and application of a short arm cast for one or more weeks; 2) they can be treated with a short arm cast without reduction; and 3) they may be treated with closed reduction and pins and plaster immobilization for eight weeks. All treatment modalities result in considerable stiffness and have frequent malunions of the fractures.

Because of the problems associated with the treatment of vertebral body fractures, Colles' fractures, shoulder fractures and other bone conditions similar thereto, a need has existed for a method and apparatus to improve on the protocol for treating such fractures such as shortening the time in which a patient suffers pain due to such fracture. The present invention provides apparatus and a method of percutaneous fracture fixation which satisfies this need.

SUMMARY OF THE INVENTION

This invention relates to a method and apparatus for the fixation of fractures of osteoporotic and non-osteoporotic bones. The invention is especially suitable for use in the fixation of osteoporotic vertebral body compression fractures, Colles' fractures and fractures of the proximal humerus. The method of the present invention includes a series of steps including forming an incision in the body and penetrating the bone having the fracture with instruments including a guide pin and a cannula, drilling the bone marrow of the bone to enlarge the cavity or passage to be treated, following which an inflatable device, such as an expandable balloon, is inserted in the cavity and inflated. The expansion of the balloon causes a compacting of the bone marrow against the inner surface of the outer cortical wall of the bone to be treated to further enlarge the cavity. Then, a flowable synthetic bone material or methyl methacrylate cement is directed into the cavity and allowed to set to a hardened condition. Following this, the instruments are removed and the incision in the skin is covered with a bandage.

In the fixation of vertebral body fractures, an elliptical inflatable device is first used, if needed, to initiate the compacting of the bone marrow and to commence the formation of a cavity or passage in the bone marrow, following which a larger inflatable device is inserted into the cavity to further compact the bone marrow in all directions. In the fixation of Colles' fractures and proximal humerus fractures, a gourd-shaped inflatable device is used to compact the bone marrow.

It is the intention of the present invention to provide, in each case of a fracture of osteoporotic or non-osteoporotic bone, an inflatable device that has a shape of or the ability to conform to the internal surface configuration of the cortical bone in which the device is used. Thus, the inner surface configuration of the cortical bone of a vertebral body is disk-shaped or checker-shaped, the cortical bone of distal radius is gourd-shaped and the cortical bone of the proximal humerus is also gourd-shaped.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a patient about to undergo the surgical treatment of vertebral body fixation in accordance with the method of the present invention, the patient lying prone on a U-shaped holder;

FIG. 2 is a front elevational view of the patient on the holder;

FIG. 3 is a side elevational view of the patient, showing hyperextension of the spine of the patient;

FIG. 4 is a perspective view of the rear portion of the patient showing the patient lying between the sides of the holder;

FIG. 5 is a stabilizer bracket for a guide pin and a cannula forming parts of the apparatus for carrying out the method of the present invention;

FIG. 6 is a perspective view of the patient holder shown in FIGS. 1, 2 and 4;

FIG. 7 is another perspective view of the holder of FIG. 6 looking upwardly from the bottom thereof;

FIG. 8 is a top plan view of the portion of the patient showing several vertebral bodies of the patient and the way in which the a guide pin enters a patient for carrying out the method of the present invention;

FIG. 9 is a schematic front elevational view of the patient and a vertebral body of the patient showing the

entry angles of the guide pin of the apparatus of the present invention;

FIG. 10 is a side elevational view of the vertebrae, showing a guide pin inserted into one of the vertebral bodies;

FIG. 11 is a top plan view of the guide pin inserted into the vertebral body;

FIG. 12 is a perspective view of the guide pin placed within the vertebral body and a tissue expander sliding on the guide pin to the vertebral body;

FIG. 13 is a side elevational view of the tissue expander over the guide pin;

FIG. 14 is a view similar to FIG. 12 but showing a cannula carried by the tissue expander toward the vertebral body;

FIG. 15 is a view similar to FIG. 13 but showing teeth of the cannula embedded in the outer wall of the vertebral body;

FIG. 16 is a view similar to FIG. 14 but showing another view of the cannula embedded in the cortical wall of the vertebral body;

FIG. 17 is a view similar to FIG. 15 but showing the withdrawal of the tissue expander through the cannula;

FIG. 18 is a view similar to FIG. 11 but showing a drill guided into the vertebral body by the guide pin through the cannula;

FIG. 19 is an enlarged perspective view of the drill of FIG. 18;

FIG. 20 is a view similar to FIG. 18 but showing an elliptical inflatable device inserted into the vertebral body to expand the bone marrow in the vertebral body;

FIG. 21 is a checker-shaped inflatable device in the vertebral body to complete the expansion of the bone marrow in the vertebral body;

FIG. 22 is a top plan view of the checker-shaped inflatable device of FIG. 21;

FIG. 23 is a side elevational view of the checker-shaped inflatable device of FIG. 22;

FIG. 24 is a view similar to FIGS. 20 and 21 but showing the insertion of the inflatable device of FIG. 22 into a vertebral body;

FIG. 25 is a view similar to FIG. 24 but showing the insertion of a liquid artificial bone or methyl methacrylate cement into the vertebral body to replace the bone marrow;

FIG. 26 is an enlarged, fragmentary perspective view for directing liquid bone or methyl methacrylate cement into the vertebral body;

FIG. 27 is a side elevational view of the vertebral body after the liquid bone has been injected into the interior thereof;

FIG. 28A is a schematic side view of a vertebral body showing the initial insertion of an elliptical inflatable device in the vertebral body and before inflation of the device;

FIG. 28B is a view similar to FIG. 28A but showing partial inflation of the inflatable device of FIG. 28A to initiate a cavity or passage in the bone marrow of the vertebral body;

FIG. 28C is a view similar to FIG. 28B but showing a checker-shaped inflatable device in the vertebral body to further compact the bone marrow in the vertebral body;

FIG. 28D is a view similar to FIG. 28C but showing the initial injection stage in which liquid bone or methyl methacrylate cement is injected into the vertebral body;

FIG. 28E is a view similar to FIG. 28D but showing the vertebral body after the liquid bone or methyl methacrylate cement has set to a hardened condition;

FIG. 29 is a schematic top plan view of a distal radius fracture of the wrist, the fracture at the end of the radius being aligned with Chinese finger traps;

FIG. 30 is a view similar to FIG. 29 but looking in a different direction at the hand but illustrating the fracture;

FIG. 31 is a view of the fracture with the guide pin being inserted through the interface of the fracture;

FIG. 32 is a view similar to FIG. 31 but showing a drill in the radius, and the area to be filled with liquid bone or methyl methacrylate cement;

FIG. 33 is a side elevational view of a shoulder showing a fracture therein; and

FIG. 34 is a view similar to FIG. 33 but showing the bone fracture and cavity to be filled with liquid bone or methyl methacrylate cement.

DETAILED DESCRIPTION OF THE DRAWINGS

Percutaneous vertebral body fixation is indicated for all causes of spontaneous osteoporotic or non-osteoporotic vertebral body collapse fractures except those due to infection or neoplasia. The etiology of the bone marrow should be diagnosed prior to fixation. Concomitant endocrine therapy, chemotherapy or radiation is not contraindicated with percutaneous vertebral fracture fixation.

Impending vertebral body collapse as determined by the presence of previous collapse fractures and increased uptake on technetium-99 bone scan in a non-collapsed vertebral body. Various CT density values may eventually correlate with impending vertebral body collapse and be utilized to predict impending vertebral body fractures.

Contradictions of such fixation are as follows:

Presence of pyogenic infection;

Presence of tuberculous infection;

Presence of neoplasia;

Presence of sepsis;

High velocity spinal fractures;

Fractures above the level of T-6; and

Fractures which demonstrated widened pedicles on AP spine x-rays.

To illustrate the teachings of the present invention, the following specification will be described with respect to treatment of fractures relating to osteoporotic bone, but it is to be understood that the invention applies also to treatment of fractures relating to non-osteoporotic bone.

In carrying out the teachings of the method of the present invention as to osteoporotic vertebral fixation, a patient 10 is placed on a generally U-shaped holder 12 so that the patient lies above the central part 14 of holder 12 and between a pair of spaced sides 16 and 18 as shown in FIGS. 1, 2 and 4. Holder 12 can be of any suitable construction, such as metal or plastic and is constructed to render the patient generally immovable when the patient is prone as shown in FIGS. 1-4. The length of sides 16 and 18 is preferably sufficient to achieve the aim of rendering the patient generally immovable.

Typically, the length of sides 16 and 18 is approximately 12 to 15 inches. For the comfort of the patient, a cushion 20 is provided above central part 14 as shown in FIG. 2. The central part 14 has holes 22 therethrough

(FIGS. 6 and 7) and the holes are for the purpose of receiving circular portions of the cushion 20 formed due to the weight of the patients to anchor the cushion in place and to prevent it from moving relative to holder 12 when the patient's body is on the cushion as shown in FIG. 2. This assures that the cushion will not contribute to the movement of the patient relative to the holder. Pads 24 and 26 are placed at the chest and hip regions of the patient for the comfort of the patient and to extend the spine.

FIG. 5 shows a support bracket 28 adjustably mounted on the sides 16 and 18 of holder 12. The purpose of bracket 28 is to support a cannula 30 and guide pin 70 forming part of the apparatus of the present invention. Cannula 30 will be described hereinafter in more detail.

Bracket 28 includes a pair of clamps 31 and 32 for releasably connecting the bracket to respective sides 16 and 18 of holder 12 by means of thumb screws 34. Bracket 28 further includes a pair of legs 38 and 40 which are made up of connectable extensions as shown in FIG. 5. Legs 38 and 40 are releasably connected to respective clamps 31 and 32 by thumb screws 42 and 44. A rod 46 is connected by thumb screws 48 and 50 to end sleeves 52 and 54 on the upper ends of respective legs 38 and 40. Rod 46 can be rotated in the sleeves 52 and 54 to thereby rotate a clamp 56 coupled to the rod 46 and having a leg 58 on which cannula 30 and guide pin 70 are adjustably mounted. Thus, the cannula can be moved toward or away from legs 38 and 40 and can rotate about the longitudinal axis of rod 46. In this way, the cannula can be adjusted as to the distance from the patient to rod 46 as well adjust the position of the bracket 28 by means of shifting clamps 31 and 32 along the sides of holder 12.

The teachings of the method of the present invention will be hereinafter described with respect to treatment of a person with osteoporotic spine disease. The presence of such disease is evidenced by a plain film spinal x-rays and either CAT-scan evidence of impending fracture or plain film x-ray evidence of vertebral body collapse. In obtaining such evidence, both sagittal and coronal CAT-scans should be obtained before the performance of the method of the present invention. The coronal scan is also needed to determine the width of the vertebral body which is to be treated and also to rule out the presence of posterior displacement of the colon which can interfere with the posterolateral approach which generally occurs in four percent of the patients. If the colon is noted, the approach must be altered to the other side of the body.

The sagittal CAT-scan is needed to determine the height of the vertebral body to be treated. If an acute compression fracture is present, then the appropriate height is determined by the height of the vertebral body located superior to the fracture. If the patient has an acute fracture of a vertebral body, the patient is to be placed prone in the manner shown in FIGS. 1–4.

Attempts to reconstitute the height of the vertebral body should be made by hyperextending the patient's spine as shown in FIG. 3. If the patient has an impending fracture of a vertebral body, then the patient can be positioned either prone as shown in FIGS. 1–4 or on his side depending upon the surgeon's preference. If on the side, the patient is rendered immovable by suitable structure for holding the patient in one position during the time that the method of the present invention is being performed.

The posterolateral approach is used whether the patient is prone (FIGS. 1–4) or in the lateral position. Then the entry point on the skin is determined radiologically and is located approximately 10 cm from the midline and just inferior to a rib if present at that level as shown in FIG. 8.

FIG. 8 shows the entry points of the instruments for carrying out the method of the present invention for two vertebral bodies spaced from each other. The instrument shown in FIG. 8 is a guide pin 70 which enters the patient at an incision 62 (FIG. 8). A choice of angle of entry of the guide pin 70 can be 30° to 45° as shown in FIG. 9. The vertebral body to be injected is located fluoroscopically. The skin, underlying soft tissue and lateral cortex of the vertebral body are injected with a long spinal needle. General anesthesia is not advisable.

The surgical procedure for treating a vertebral body is as follows:

The vertebral body 66 to be treated (FIGS. 10 and 11) is penetrated by the pointed end 68 of quide pin 70 which enters the vertebral body between the inferior and superior end plates of the body 66 and into the posterior quarter of the vertebral body. Pedioles are to be ignored. The quide pin penetrates to a depth in the range of 60 to 80% across vertebral body 66 as shown in FIG. 11. Placement of the pin is fluoroscopically monitored. Any further penetration beyond 70% runs the risk of perforation of the vertebral body and an adjacent major vessel or lung.

With the guide pin penetrating the vertebral body 66 as shown in FIGS. 10 and 11, a soft tissue expander 71, which is a tubular member as shown in FIGS. 12 and 13, is inserted over the guide pin until the end of the expander makes contact with the vertebral body as shown in FIG. 13. Expander 71 then forms a guide for cannula 30 to guide the cannula toward the vertebral body to be treated.

When the cannula makes contact with the wall of the vertebral body, the cannula is rotated clockwise under pressure to force the teeth 31 of the cannula into the wall of the vertebral body 66 as shown in FIG. 15. This locks the cannula into the wall as shown in FIG. 16 so that the cannula can be coupled to bracket 28 (FIG. 5) for stabilization thereby. Then, the expander 71 can be removed from the interior of cannula 30 as shown in FIG. 17.

Once the cannula is stabilized, a drill stop is formed to prevent penetration of the far cortex of the vertebral body by drill 72 (FIGS. 18 and 19). The drill stop is formed by a shoulder 67 on pin 70 (FIG. 19) which is engageable with shoulder 69 on drill 72 and holding pin 70 with bracket 28.

Vertebral body 66 is drilled by a 4 mm drill 72. The drilling depth is monitored by fluoroscopy to the end of the guide 10. The drill is tubular and is guided by the guide pin 70 as shown in FIG. 19.

The next step to be performed in carrying out the method of the present invention is to withdraw the pointed guide pin 70 and replace it with a deflated elliptical or chambered bladder device 65. The elliptical balloon 65 is monitored fluoroscopically. This is achieved by inflating the elliptical balloon 65 to a pressure in the range of 50 to 300 psi with a radio-opaque contrast medium by an injector as shown in FIG. 24. The purpose of the elliptical balloon 65 is to center a second, checker-shaped inflatable device or balloon 76 (FIGS. 21–23) in the interior of vertebral body 66. After the elliptical balloon 65 is deflated and removed, check-

er-shaped or cylindrically shaped device or balloon **76** is inserted into the cannula and directed into the interior of vertebral body **66** as shown in FIG. **21**.

The diameter of balloon **76** is determined by the pre-operative CAT-scan results. The diameter is in the range of 1.0 cm to 3.5 cm. The axial height of the balloon (FIG. **23**) is determined by the intra-operative reduction height of the vertebral body fracture. The height is in the range of 0.5 cm to 4.0 cm. If the balloon placement is somewhat eccentric, a smaller balloon may be needed. The balloon **76** has a neck **77**, and the outer configuration of the balloon **76** is substantially the same as that of the inner surface of the cortical wall of the vertebral body **66**.

The progress of balloon inflation is monitored fluoroscopically to ensure proper insertion of the balloon **76**. The balloon is injected, gradually, with contrast as in the case of the elliptical balloon to a maximum height. This may require pressure as great as 300 psi to accomplish. The balloon's inflation should be monitored on the lateral fluoroscopic view of the spine. Posterior displacement of the bone into the spinal canal or full expansion of balloon **76** signals the termination of the chamber preparation. Further expansion of the balloon at this point could result in spinal cord or root injury.

As balloon **76** is inflated, it forces the osteoporotic bone marrow **67** laterally and outwardly of the wall of the vertebral body **66**. This compacts the bone marrow and leaves a void in the interior of the vertebral body to be treated. The compacted bone marrow forms a dam to block any fracture of the vertebral body. Thus, when liquid synthetic bone or methyl methacrylate cement is forced into the void, the compacted bone marrow will substantially prevent flow through the fracture.

After the balloon **76** has been deflated it is removed from the cannula **30**. An irrigation nozzle (not shown) is then inserted into the vertebral body **66**. Irrigation is performed with normal saline solution. Irrigation should be performed until the effluent is reasonably clear.

After the vertebral body has been irrigated, the artificial bone substitute, which may include a synthetic bone or methyl methacrylate cement, is injected into the void left by the inflation of balloon **76**. A double barrel injection gun nozzle aspirates constantly through the short barrel. Such injection gun nozzle is shown in FIGS. **25** and **26** and includes a material delivery tube **80** and an aspirating tube **82**, both of which have open ends **84** and **86**, respectively. Injection of synthetic bone material is monitored using lateral fluoroscopy. Leakage posteriorly into the canal of tube **82** requires an abrupt stopping of the injection. Leakage anteriorly is exceedingly rare since the anterior longitudinal ligament is intact with these fractures.

The volume of injection ranges between 3 and 5 cc's. A larger volume is injected than one would predict from the size of the chamber formed with balloon **76** even in those patients injected prophylactically.

The injection gun nozzle shown in FIG. **26** is slowly removed as the vertebral body is injected with artificial bone or cement. At the entry hole into the vertebral body the tip of the injection nozzle is twisted as the cement sets up. At that time, the injection gun nozzle should be removed. FIGS. **28A** and **28B** show the sequence of the expansion of elliptical balloon **65**. FIGS. **28C** and **28D** show checker-shaped balloon **76** in the vertebral body **66**. FIG. **28E** shows the vertebral body after the mass **81** of artificial bone or methyl methacrylate cement has set to a hardened condition.

After the proper volume of artificial bone or cement has been inserted into the void of the vertebral body, cannula **30** is removed and the skin is dressed with a bandage.

Surgical protocol for Colles' fractures are described as follows with reference to FIGS. **29–32**.

The current treatment for distal radius fractures of the wrist in osteoporotic patients includes: (1) closed reduction and application of a short arm cast with the wrist in a flexed position for six weeks; (2) application of a short arm cast without reduction of the fracture; and (3) closed reductions of the fracture with Chinese finger traps and application of pins and plaster. All three techniques require cast immobilization for 6 to 8 weeks and result in considerable stiffness for many months. In the case of the second treatment described, the wrist is also malpositioned.

The treatment of the present invention involves the reduction of the fracture with Chinese finger traps and the subsequent use of a balloon to create a chamber followed by the injection of either methyl methacrylate cement or a flowable bone substitute into the chamber to fix the fracture. Immobilization would only be a removable splint for two to four weeks. The wrist would be exercised daily to prevent the subsequent stiffness which usually follows wrist fracture.

The steps involved in this procedure are the same as those listed for the percutaneous fixation of vertebral body fractures. The Colles' fracture is positioned this time using finger traps **90** as shown in FIGS. **29** and **30**. Local anesthesia is injected. The hand and forearm are prepped in the usually sterile fashion. A smooth guide pin **92** (FIG. **31**) is inserted from the tip of the styloid at a 45° angle across the fracture **93**. This is followed by a soft tissue expander and then a 2 mm cannula **91**. A 2 mm drill **94** (FIG. **32**) is then used to drill a canal or passage across the fracture using fluoroscopic control. The drill and guide pin are removed and a gourd-shaped distal radius balloon **95** is introduced into the fracture region through the cannula. The balloon **95** has a configuration substantially the same as that of the inner surface of the cortical bone. The deflated diameter of a globe-shaped part **95*a*** of balloon **95** is in the range of 7 to 10 mm, the overall length L is in the range of 4 to 7 cm, and cylindrical part **95*b*** has a length in the range of 5 to 8 mm.

The balloon **95** is expanded with contrast liquid using x-ray control. Expansion of the balloon **95** causes compacting of the osteoporotic bone marrow against the inner surface of the cortical wall. The balloon is then deflated and the cavity is then injected with a mass **97** of either methyl methacrylate cement or liquid bone substitute. A splint is used for two to four weeks.

Surgical protocol for the percutaneous fixation of proximal humerus fractures is as follows, with reference to FIGS. **33** and **34**:

Percutaneous intra-osseous balloon fixation is indicated for all one-part shoulder fractures (i.e. non-displaced shoulder fractures), all two-part shoulder fractures except greater tuberosity fractures, and all three-part fractures that do not include a prominent elevation of the greater tuberosity or could be better treated with a hemiarthroplasty. It is not now indicated for four-part fractures.

The fracture is reduced with the patient sitting upright. The fracture is injected with local anesthesia as is

the area just posterior to the greater tuberosity where a guide pin will be introduced. The fracture is reduced with traction and held by an assistant. A guide pin is introduced through the head of the humerus just posteriorly to the greater tuberosity and followed fluoroscopically across the fracture to approximately 8 cm below the fracture. The soft tissue expander is introduced followed by the 3 mm cannula. A canal is drilled over the guide pin with a 3 mm drill **100** and the drill and guide pin are removed.

A gourd-shaped proximal humerus inflatable device or balloon is introduced into the cavity and inflated using contrast and fluoroscopic control. The balloon is then removed and then the cavity is injected with a mass **101** of either methyl methacrylate cement or a liquid artificial bone substitute as shown in FIG. **34**. The fracture is held until the injected substance hardens. The entry site on the top of the shoulder is dressed with a steri-strip and the patient is given a sling for 2 to 4 weeks. During those weeks, the patient should remove the sling several hours a day but perform no heavy lifting.

The gourd-shaped proximal humerus balloon has a configuration substantially the same as that of balloon **95** (FIGS. **31** and **32**). The diameter of the globe-shaped part of the proximal humerus balloon is in the range of 14 to 20 mm. The diameter of the cylindrical part is in the range of 6 to 8 mm, and its length is in the range of 8 to 14 cm.

We claim:

1. A method of fixation of a fracture or impending fracture of a bone having bone marrow therein comprising:

forming a passage in the bone marrow;

compacting the bone marrow to increase the volume of said passage; and

filling the passage with a flowable material capable of setting to a hardened condition.

2. A method as set forth in claim **1**, wherein said compacting step includes forcing the bone marrow outwardly and against the site of the fracture or impending fracture.

3. A method as set forth in claim **1**, wherein said compacting step includes forcing the bone marrow outwardly of the central portion of the bone.

4. A method as set forth in claim **3**, wherein said forcing step includes directing the bone marrow against an inner surface of the bone within the fracture or impending fracture.

5. A method as set forth in claim **1**, wherein said compacting step includes inflating an inflatable device in said passage to urge the bone marrow therein.

6. A method as set forth in claim **5**, wherein is included the step of inserting the device in the passage before the inflating step.

7. A method as set forth in claim **1**, wherein is included the step of inserting an inflatable device in said passage, said increasing step including inflating the device to force the bone marrow outwardly of said passage.

8. A method as set forth in claim **1**, wherein said forming step includes drilling said bone marrow to form said passage.

9. A method as set forth in claim **8**, wherein said drilling step includes guiding a drill through and into the proximate cortical bone marrow.

10. A method as set forth in claim **8**, wherein said forming step includes drilling the bone marrow to a predetermined depth.

11. A method as set forth in claim **10**, wherein said depth is in the range of approximately 60 to 80% of the maximum oblique dimension of the bone containing the bone marrow.

12. A method as set forth in claim **1**, wherein the fracture is a fracture of a vertebral body of the human spine.

13. A method as set forth in claim **1**, wherein said fracture is a Colles' fracture of the distal radius.

14. A method as set forth in claim **1**, wherein said fracture is a fracture of the proximal humerus.

15. A method as set forth in claim **1**, wherein said flowable material is selected from the group consisting of liquid synthetic bone and methyl methacrylate cement.

16. A method of fixation of a fracture of a bone containing bone marrow therein comprising:

drilling said bone to form a recess therein;

inserting an inflatable device in said recess;

inflating the device in the recess to increase the volume thereof and to force the bone marrow outwardly of the recess to form a void in the bone; and

filling the void in the bone with a flowable material capable of setting to a hardened condition.

17. A method as set forth in claim **16**, wherein said inflating step includes inflating a chambered bladder device having an elliptical configuration.

18. A method as set forth in claim **16**, wherein said inflating step includes inflating a chambered bladder device having generally cylindrical configuration.

19. A method as set forth in claim **16**, wherein is included the step of guiding a drill into the bone.

20. A method as set forth in claim **16**, wherein said inflating step includes inflating the device with a radiopaque material.

21. A method as set forth in claim **16**, wherein said inflating step includes compacting the bone marrow in the bone.

22. A method as set forth in claim **16**, wherein said inflating step includes forcing the bone marrow outwardly of the central portion of the bone.

23. A method as set forth in claim **22**, wherein said inflating step includes compacting the bone marrow against an inner surface of the bone.

24. A method as set forth in claim **16**, wherein said drilling step includes guiding a drill into the bone, and rotating the drill about its longitudinal axis.

25. A method as set forth in claim **24**, wherein said drilling step includes drilling the bone marrow to a predetermined depth.

26. A method as set forth in claim **25**, wherein said depth is in the range of approximately 60 to 80% of the maximum oblique dimension of the bone.

27. A method as set forth in claim **16**, wherein the fracture is a fracture of a vertebral body of the human spine.

28. A method as set forth in claim **16**, wherein said fracture is a Colles' fracture of the distal radius.

29. A method as set forth in claim **16**, wherein said fracture is a fracture of the proximal humerus.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

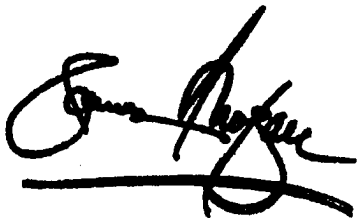
PATENT NO. : 5,108,404
DATED : April 28, 1992
INVENTOR(S) : Arie Scholten and Mark A. Reiley

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title page,
Item [*] Notice:, substitute the following Terminal Disclaimer information:
-- The portion of the term of this patent subsequent to February 9, 2009 has been disclaimed. --

Signed and Sealed this

Second Day of December, 2003



JAMES E. ROGAN
Director of the United States Patent and Trademark Office