A-5

United States Patent

[11] 3,626,949

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[21] Appl. No. 793,369
[22] Filed Jan. 23, 1969
[45] Patented Dec. 14, 1971

[54] CERVICAL DILATOR
2 Claims, 2 Drawing Figs.

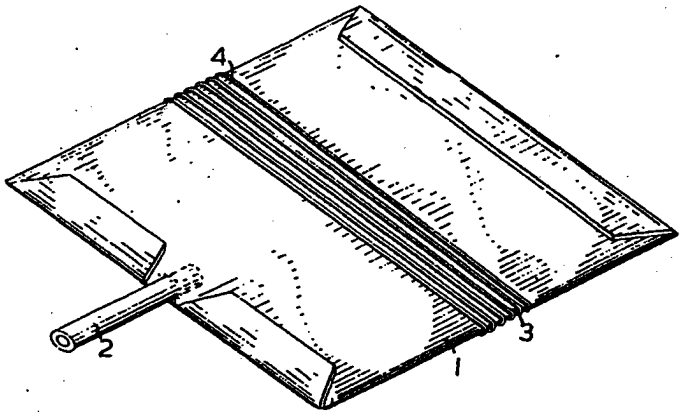
[52] U.S. Cl. 128/344, 128/361
[51] Int. Cl. A61m 29/00, A61b 17/42
[50] Field of Search ..... 128/344, 349 B, 361; 206/DIG. 30

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Primary Examiner—Channing L. Pace
Attorney—Cushman, Darby & Cushman

ABSTRACT: A cervical dilator comprising a fluidtight bag formed from a flexible material and insertable in a collapsed state into the cervical canal, inlet means in said bag for periodically introducing fluid under pressure to alternately inflate said bag whereby the wall of said bag radially expands to directly contact the walls of said canal and to deflate said bag so as to cause dilatation of the cervix and simulate effects of labor contraction, a portion of the wall of said bag intermediate the ends thereof being adapted to be more resistant to radial expansion whereby to form on inflation of said bag a constricted waist portion which accommodates the edges of the cervix.



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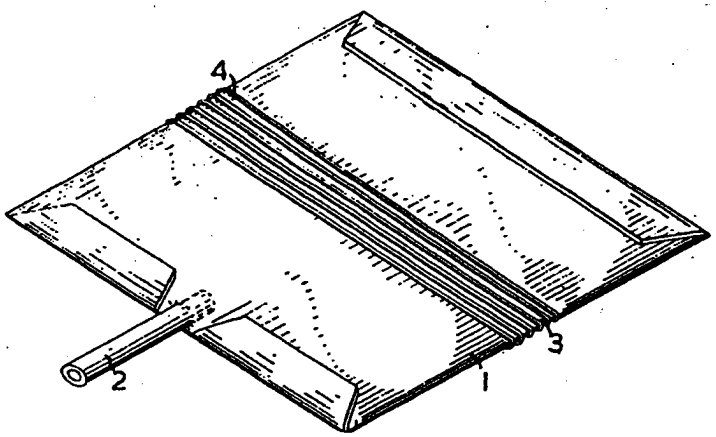


FIG. 1

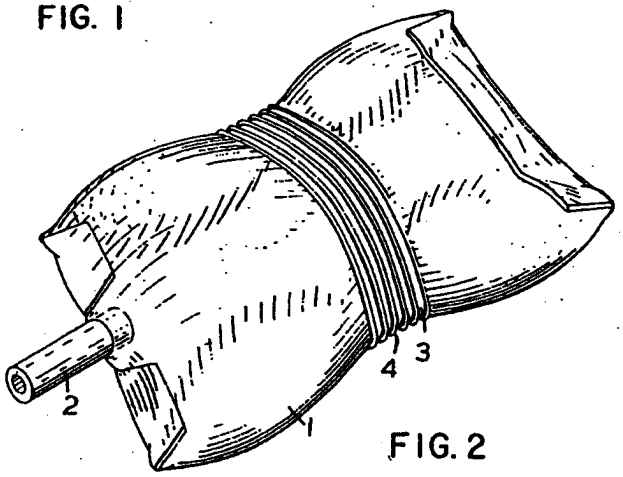


FIG. 2

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ATTORNEYS

CERVICAL DILATOR

The present invention relates to a cervical dilator which is adapted to be inserted into the cervical canal and to cause upon inflation and deflation thereof dilation of the cervix so as to simulate the effect of labor contractions and thus hasten the processes of nature.

During labor, the cervix uteri dilates equally in all directions from a diameter of 0 to 10 centimeters under the pressure of intermittent uterine contractions transmitted through the presenting part (head, breech and/or forebag of water). This dilation permits passage of the baby from the uterine cavity through the pelvis to delivery. Nature however does not produce such labor pains in any regular or standard pattern, since the anatomical and physiological characteristics of all women vary, thus labor can be remarkedly efficient and short or with noneffective contractions extremely protracted. The present invention provides a simple and relatively inexpensive device which will reproduce the effects of labor pains more efficiently and accurately regulating the dilation of the cervix from 0 to 10 centimeters with safety thus hastening the first stage of labor.

In my Canadian application No. 958,955 I have disclosed and claimed such a cervical dilator which comprises a fluidtight container formed from a flexible material and insertable in a collapsed state into the cervical canal, inlet means in said container for intermittently introducing fluid under pressure to alternately inflate said container such that a peripheral radial wall of said container expands radially to directly contact the walls of said canal and deflate said bag so as to cause dilatation of the cervix and simulate the effects of labor contractions, the ends of the container being adapted to limit axial expansion of said container during inflation. In particular, in my copending Canadian application the ends of the container are adapted to substantially prevent axial expansion of the container on inflation thereof, essentially all the expansion of the container during the dilatation being in a radial direction as axial expansion of the container causes expansion of the container into the uterus of the pregnant women, thereby hindering to a substantial extent the delivery of the baby which is undesirable.

Further, the container has a waist portion intermediate the ends thereof and particularly equidistant from the ends thereof which waist portion is of reduced radial dimension for the location of the edges of a cervical os. This allows for the proper positioning of the cervical dilator in the cervical canal when used in simulating the effects of labor contraction.

It has now been found according to the present invention that by adapting the waist portion intermediate the ends of the container or bag so as to be more resistant to radial expansion than the remainder of the walls of the bag, on inflation of the bag the waist portion is constricted and thus at all times accommodates the edges of the cervical os and prevents the bag when under inflation from moving axially into or out of the uterus which is undesirable and thus allows only radial expansion and contraction of the walls of the bag to take place.

According to the present invention therefore there is provided a cervical dilator comprising a fluidtight bag formed from a flexible material and insertable in a collapsed state into the cervical canal, inlet means in said bag for periodically introducing fluid under pressure to alternately inflate said bag whereby the wall of said bag radially expands to directly contact the walls of said canal and deflate said bag so as to cause dilatation of the cervix and simulate effects of labor contraction, a portion of the wall of said bag intermediate the ends thereof being adapted to be more resistant to radial expansion thereby to form on inflation of said bag a constricted waist portion which accommodates the edges of the cervix.

The bag which is suitable made of a relatively heavy gauge plastic material such as polyvinyl chloride suitably has embedded in the waist portion a relatively inextensible fiber such as cotton fiber which provides the necessary resistance to expansion of the waist portion which waist portion is suitably equidistant from the ends of the bag and thus on inflation of the bag the waist portion is constricted to accommodate the edges of the cervix.

As with the cervical dilator of my Canadian application No. 958,955 the ends of the bag are adapted to restrict axial expansion of the bag during inflation and desirably the ends of the bag allow substantially no axial expansion of the bag on inflation thereof.

Inflation and deflation of the bag may suitably be effected by periodically discharging fluid under pressure from a pressure means into said bag through the inlet means, the pressure means being suitably a hydraulic pressure means, the fluid being suitably water. Thus the present invention also provides in combination with the aforesaid cervical dilator of the present invention means for periodically discharging fluid under pressure into said bag through said inlet means to effect inflation or deflation thereof.

The present invention will be further illustrated by way of the accompanying drawings in which

FIG. 1 is a perspective view of a deflated cervical dilator according to a preferred embodiment of the present invention, and

FIG. 2 is a similar view of the cervical dilator of FIG. 1 in the inflated state.

Referring to the accompanying drawings, the cervical dilator comprises a bag 1 formed from a flexible plastic material such as polyvinyl chloride sealed along the top and bottom edges thereof so that there is no appreciable axial expansion of the bag on inflation thereof and having an inlet 2 for the periodic introduction of water under pressure into the bag 1 to effect radial inflation and deflation thereof. The bag 1 has a waist portion 3 which has a continuous thread 4 embedded therein which restricts radial expansion of the waist portion 3 on inflation of the bag 1 (see FIG. 2) thus providing accommodation for the edges of the cervix during expansion of the bag 1 and as such avoiding the tendency of the bag 1 to move axially with respect to the cervix during inflation thereof.

I claim:

1. A cervical dilator comprising a flattenable, closed end, tubular fluidtight bag formed from a flexible plastic material and insertable in a collapsed state into the cervical canal, inlet and outlet means in said bag for allowing intermittent introduction of fluid under pressure to alternately inflate said bag such that the peripheral tubular sidewall of said bag radially expands to directly contact the walls of said canal and deflate said bag so as to cause dilatation of the cervix and simulate effects of labor contraction, a portion of the peripheral wall of said bag intermediate the ends thereof including relatively inextensible reinforcing means which extend circumferentially of the peripheral wall in radially restraining engagement therewith so as to cause said portion of said peripheral wall to be more resistant to radial expansion than the remainder of said peripheral wall whereby to form on inflation of said bag a constricted waist portion having substantially the same girth when said bag is inflated as when said bag is in said collapsed state and which locates and retains the edges of the cervix when said bag is inflated, the ends of said bag defining substantially the extremities of said dilator and being reinforced by being folded transversely and sealed to limit axial expansion of said bag during inflation.

2. The cervical dilator of claim 1 wherein the bag peripheral wall is formed from polyvinyl chloride and relatively inextensible reinforcing means is a continuous textile thread imbedded in said portion of the peripheral wall.

* * * * *

A-6

United States Patent [19]

Grayzel

[11] **Patent Number: 4,878,495**

[45] **Date of Patent: Nov. 7, 1989**

[54] **VALVULOPLASTY DEVICE WITH SATELLITE EXPANSION MEANS**

[76] Inventor: **Joseph Grayzel, 262 Fountain Rd., Englewood, N.J. 07631**

[21] Appl. No.: **50,741**

[22] Filed: **May 15, 1987**

[51] **Int. Cl.**[4] **A61M 25/00**

[52] **U.S. Cl.** **128/344; 128/348.1; 604/101**

[58] **Field of Search** 128/10, 344, 348.1; 604/96–103

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Primary Examiner—Dalton L. Truluck

Attorney, Agent, or Firm—Weingram & Zall

[57] **ABSTRACT**

The present invention provides a valvuloplasty device having a plurality of expandable chambers for valvuloplasty such that the arrangements and disposition of the expandable chambers conforms to the anatomy of the valve to be treated, thereby increasing the likelihood that inflation of the balloons will restore the valve more closely to its original anatomy and function. The expandable chambers can be expanded in various combinations or sequences in order to provide improved results from the treatment. The present invention also provides a method of performing valvuloplasty in which a plurality of expandable chambers having a fixed geometric relationship to each other are positioned within the valve to be treated and the expandable chambers are expanded in combination and/or in sequence to provide improved anatomical structure and function of the valve treated by the method.

24 Claims, 3 Drawing Sheets

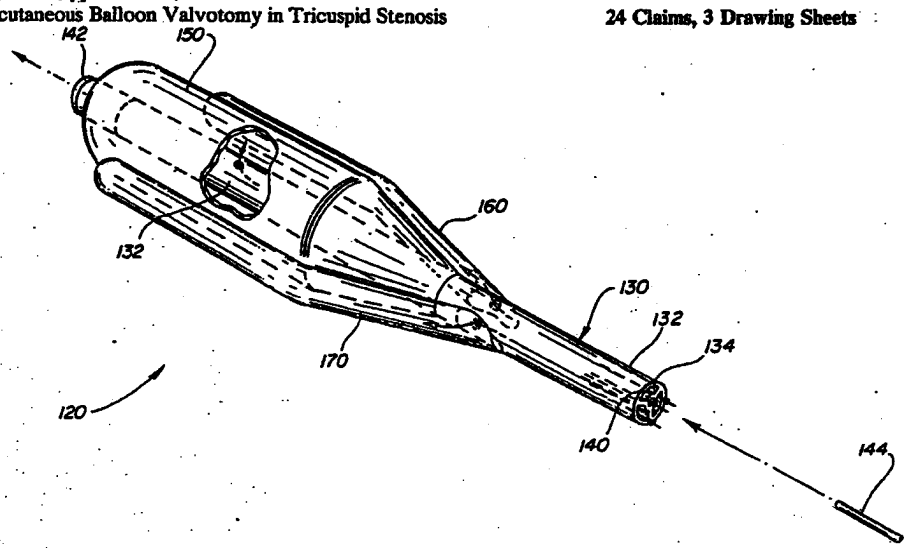


FIG-1

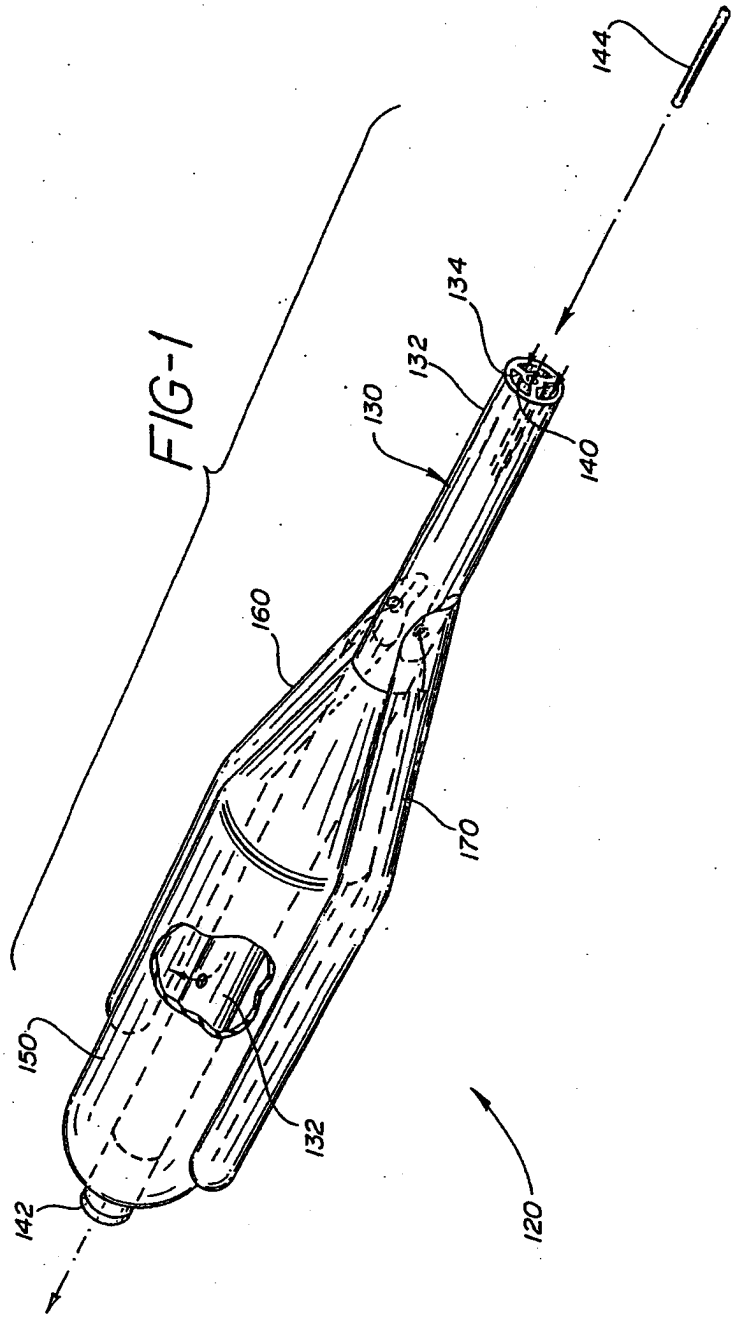


FIG-2

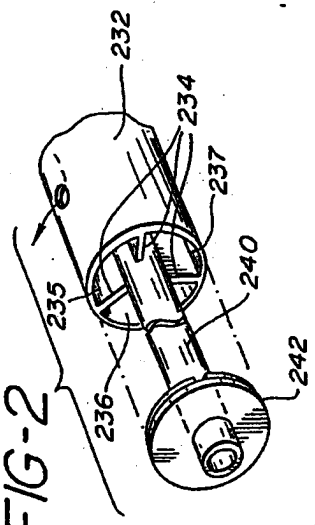

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FIG-3

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FIG-4

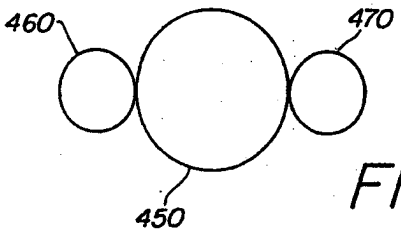


FIG-5

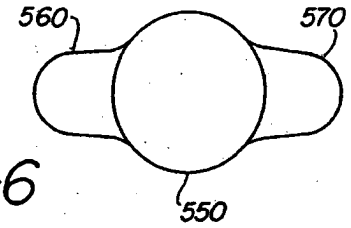


FIG-6

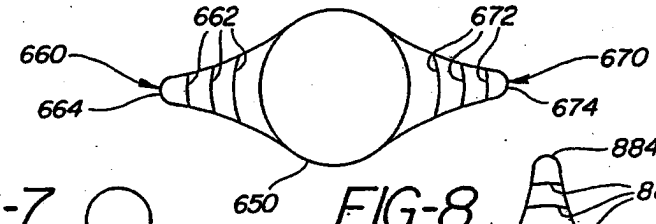


FIG-7

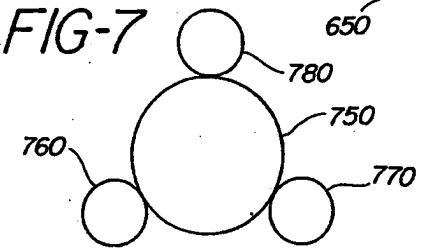


FIG-8

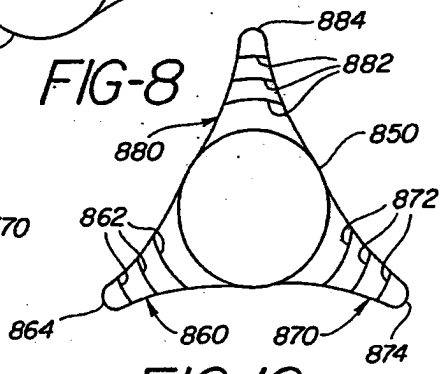


FIG-9

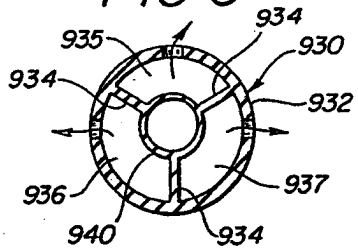


FIG-10

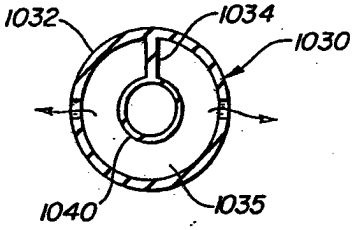


FIG-11

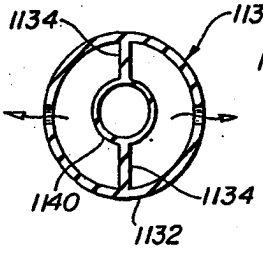


FIG-12

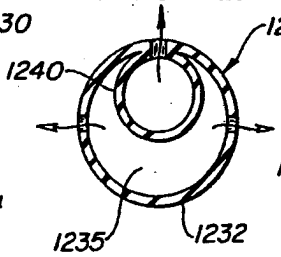
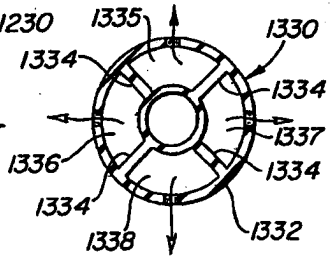


FIG-13



VALVULOPLASTY DEVICE WITH SATELLITE EXPANSION MEANS

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to balloon valvuloplasty and, more particularly, to the method and apparatus for passing an expandable catheter into a valve of the heart and expanding the catheter to effect changes in the valve.

2. Description of the Prior Art

Stenosis, or narrowing of a valve's orifice, is a serious medical condition, generally the result of fusion and immobility of the valve leaflets. Stenosis may be congenital or may be acquired, as for example to sequel to rheumatic fever. In he past, traditional treatments of valvular stenosis have been surgical, employing open heart methods and techniques to either mobilize the existing valve leaflets or, more commonly, to insert a prosthetic valve of a mechanical nature or one derived from animal tissue.

These treatments are less than ideal. Surgery carries risk to life and large expense. Also, persons implanted with a mechanical valve must remain on anticoagulant medication for the remainder of their lifetime. Further, a significant disadvantage to insertion of mechanical valves in the heart is the problem or reliability of the mechanical device. Mechanical valves are subject to failure by fatigue or fracture of the constituent materials. The biologic valves (e.g. porcine or bovine material) are subject to degeneration of the tissues making up the valve.

Because of the shortcomings in the prior mechanical valves and the other difficulties inherent in the open heart methods developed, a relatively new technique of palliative nature has been developed, known as balloon valvuloplasty. In this procedure, a balloon mounted on a plastic tubular catheter is inserted into a blood vessel, passed into the heart and positioned with its deflated balloon member lying within the stenotic valve that is to be treated. The balloon is then inflated quickly with radio-opaque fluid several atmospheres' pressure. Fluoroscopy visualizes the expanding balloon and enables a judgement regarding the degree with which the valve leaflets have been rendered more mobile.

Balloon valvuloplasty has largely been performed with catheters carrying a single, cylindrical balloon of circular cross-section. In a significant proportion of such valvuloplasties, particularly involving the mitral valve whose leaflets present a somewhat elliptical or "fish-mouth" orifice, successful valvuloplasty has required the passage of two such balloon catheters across the mitral orifice side by side, and simultaneous inflation of both balloons. This requirement is made necessary because of the shape of the orifice ideally desired after treatment. Specifically, the mitral valve has only two leaflets and it is therefore necessary to be able to mobilize or "crack" the valve up to the portions of the valve commissures at the periphery of the valve ring, rather than only in the center of the valve.

Needless to say, simultaneous inflation of separate balloon catheters is a reatively difficult procedure requiring coordination of two separate catheters and is therefore more time consuming and riskier because of the difficulty in the simultaneous positioning of the catheters without mutual interference.

Attempts have been made to avoid the difficulties produced in the side-by-side or simultaneous operation of valvuloplasty balloons. An example of this is a "trifoil balloon having three balloons of equal size and shape. The balloons are disposed around the central catheter tube at intervals of 120°. The three balloons are commonly connected to the catheter lumen such that all three balloons inflate simultaneously. While suited for stenotic aortic pulmonic valves which are composed of three mobile semi-lunar leaflets, the "trifoil" balloon arrangement is not suitable for the mitral valve or for a congenitally bicuspid aortic valve. Even for use with stenotic aortic or pulmonic valves, the "trifoil" balloon cannot enter the narrower confines of the valve commissures without significant distortion of the balloon, which is unlikely.

Many patents have issued dealing with different types of expandable catheters. Examples of such patents are those to:

Schultz	4,141,364
Hattler et al.	4,406,656
Van Tassel et al.	4,531,943
Fugua	4,601,713

These patents, however, do not resolve the problems presently discussed.

Schultz, 4,141,364, discloses an expandable endotracheal or urethral tube which contains a number of sections which can be inflated. However, this device is not suited for, nor is it designed to deal with the problems of the specific shaped involved with the valvuloplasty procedure.

Hattler et al., 4,406,656, discloses multi-lumen catheters where fluid flowing in certain lumens causes these lumens to expand, and the absence of fluid-flow in the lumens causes the lumens to contract. As discussed at length in columns 1 and 2 of this patent, a number of prior-art patents relating to multi-lumen catheters are available. However, this patent does not deal with expandable catheters adapted for use in the valvuloplasty field.

Van Tassel et al., 4,531,943, teaches the use of a soft deformable member attached to the distal tip of a catheter. The deformable tip may comprise an inflatable balloon element attached to the distal end of the tip of the catheter. By selectively inflating the balloon tip, the effective area of the tip can be increased to reduce the overall force per unit area at a point of contract between the tip of the catheter and the blood vessel. However, this patent does not deal with the problem of the specialized shapes necessary for valvuloplasty.

Fugua, 4,601,713, deals with catheters applied to urology. the patent indicates that the so-called "Foley" catheter includes a tube with an inflatable cup or balloon at the distal end of the catheter so as to hold the catheter in place. Specifically, the balloon is inflated to retain the catheter in the bladder. However, the patent does not at all deal with catheters that would be suitable for use in valvuloplasty.

SUMMARY AND OBJECTS OF THE INVENTION

The present invention provides a valvuloplasty device having a plurality of balloons for valvuloplasty such that the arrangements and disposition of the balloons conforms to the anatomy of the valve to be

treated, thereby increasing the likelihood that expansion of the balloons will restore the valve more closely to its original anatomy and function. The balloons can be inflated in various combinations or sequences in order to provide improved results from the treatment.

The present invention also provides a method of performing valvuloplasty in which a plurality of balloons having a fixed geometric relationship to each other are positioned within the valve to be treated and the balloons are expanded in combination and/or in sequence to provide improved anatomical structure and function of the valve treated by the method.

Accordingly, it is an object of the present invention to provide a valvuloplasty device having a plurality of balloons which can be inflated to more closely conform to the desired shape to be obtained in a valvuloplasty procedure.

Still another object of the present invention is to provide a valvuloplasty device having a plurality of balloons which enables the balloons to be inflated independently of each other during a valvuloplasty procedure.

Another object of the present invention is to provide a valvuloplasty device having a plurality of balloons in which the ballons can be independently expanded from separate pressure sources.

Yet another object of the present invention is to provide a valvuloplasty device having a plurality of balloons in which the end of the balloons can cover the end of the device.

A still further object of the present invention is to provide a valvuloplasty device having a plurality of balloons in which the device can extend beyond the end of the balloons to allow the device to be positioned along a predisposed spring guide.

Another object of the present invention is to provide a valvuloplasty device having a plurality of balloons in which the device includes a central large balloon and a plurality of satellite balloons to enable the device, when all balloons are expanded, to more closely resemble the shape that is desired for the particular valvular anatomy of the valve being treated by the valvuloplasty procedure.

Yet another object of the present invention is to provide a valvuloplasty device having a plurality of balloons in which the catheter is capable of exerting a greater force on the immobile leaflets of a stenotic valve and to direct such forces as to favor division of fused leaflets along the original commissural lines of separation.

A still further object of the present invention is to provide a valvuloplasty device having a plurality of balloons which balloon elements can be selectively directed at the valve commissures, into the remnant region of such commissures, and direct a specific force at the commissural line until disecting into the periphery of the valve ring.

Another object of the present invention is to provide a valvuloplasty device having a plurality of balloons which provides a centrally located balloon that inflates to enlarge the valvular orifice centrally while driving a plurality of satellite balloons in an outward direction.

A further object of the present invention is to provide a valvuloplasty device having a plurality of balloons which possesses a relatively large outer perimeter made up from a plurality of smaller individual balloons to enable higher inflation pressures for relatively thin wall-thicknesses of the balloon.

Yet another object of the present invention is to provide a valvuloplasty device having a plurality of balloons which includes a bulbous end at the end of a balloon to prevent expulsion of the balloon from the valve orifice by the cyclical blood pressures within the beating heart.

Still another object of the present invention is to provide a valvuloplasty devices having a plurality of balloons which can be used on bicuspid and tricuspid heart valves.

A further object of the present invention is to provide a valvuloplasty device having a plurality of balloons which can provide improved control and effectiveness in balloon valvuloplasty.

Another object of the present invention is to provide a valvuloplasty device having a plurality of balloons which includes a separate channel for a guide member to enable use with the Seldinger percutaneous technique or other like techniques.

It is yet another object of the present invention to provide a method of valvuloplasty employing a valvuloplasty device having a plurality of balloons in which method the balloons can be inflated separately to achieve different anatomical shape as desired during the valvuloplasty procedure.

Another object of the present invention is to provide a method of valvuloplasty employing a valvuloplasty device having a large central balloon and satellite balloons to enable separate dilation of the commissural regions and the central valvular orifice.

A still further object of the present invention is to provide a method of valvuloplasty including a multiple balloon valvuloplasty device which can be used in accordance with the Seldinger technique for insertion and guidance through the vascular channel.

Other objects and advantages will be apparent from the following description of the invention, the novel features being particularly pointed out hereinafter in the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view, partially broken away, of a valvuloplasty device in the inflated state built in accordance with the teachings of the present invention;

FIG. 2 is a partial perspective view of the end portion of the central core of the device shown in FIG. 3;

FIG. 3 is a side view, partially in section, of a device similar to the device shown in FIG. 1, in the inflated state;

FIGS. 4–8 are schematic view of the cross-section of various balloons for valvuloplasty device built in accordance with the teachings of the present invention; and

FIGS. 9–13 are various cross-sections of catheters for valvuloplasty device built in accordance with the teachings of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

As shown in FIG. 1, a valvuloplasty device generally indicated at 120 has a catheter portion 130 with an inner tubular core 140. A plurality of balloons consisting of a central balloon 150 and two sattelite balloons 160 and 170 which are fastened to the catheter portion.

FIGS. 2 and 3 show a modified embodiment of the invention, though similar with respect to many features. These similarities and distinctions will be apparent from the following discussion. In discussing the various fig-

ures, elements common to more than one figure may be referred to by the last two digits of the member.

As seen in FIGS. 1, 2, 3 and 9, the central member of the valvuloplasty device has a cylindrical tubular cross-section with an outer skin or wall 32 and a plurality of dividers 34, which dividers 34 divide the tubular section into three separate passages 35, 36 and 37. A hole or aperture in the top of passage 35 communicates the passage with the large central balloon 50 while other holes or apertures in passages 36 and 37 communicate the passage with the left and right satellite balloons 60 and 70, respectively. The passages 35, 36 and 37 can be connected to separate or single souces of pressurized liquid, such as isotonic saline, by any of the convenient conventional means presently known, to expnd the balloons. Additionally, various non-toxic radio-opaque dyes can be mixed with the pressurizing liquid to expand the balloons so that the position of the catheter can be easily seen by means of fluoroscopy during the valvuloplasty procedure.

The inner tubular core 40 of the catheter extends the length of the catheter and, as seen in FIGS. 2 and 3, extends beyond the end of the outer circumferentially disposed passages 35, 36, 37. A closure plate 42 seals the end of the circumferential fluid passages. The tubular extending core 40 allows for mounting or placing of the catheter core a guide wire which has previously been positioned within the vessel prior to introduction of the catheter.

As shown in FIG. 3, the end of the large central balloon is enlarged so that when the balloon is expanded, by introduction of a pressure fluid, the enlarged end of the balloon 352 expands beyond the dimensions of the adjoining satellite balloons 360 and 370 to act as a means for securing the position of the valvuloplasty device with respect to the valve that is being treated. The variation of pressures in the heart would tend to force the catheter back out of the valve. By having an end which is larger than the dimension of the valve being treated, it is assured that the catheter will be properly positioned during the valvuloplasty procedure and will not move.

It should be noted that the bulbous end of the valvuloplasty device is always to be positioned in the higher pressure side of the valve. In that position, surface 35 of the bulbous end will abut the ring of the valve to hold the valvuloplasty device in position.

As can be noted from examination of FIG. 1, the catheter portion of the valvuloplasty device 30 extends beyond the end of the central balloon. The entire end could be caped off, or the central core member 40 may remain open to allow for a guide wire, generally indicated at 44, to extend beyond the front of the catheter. Alternatively, as shown in FIG. 3, the fluid passages can be terminated within or before the end of the balloon portion of the valvuloplasty device with the catheter portion extending beyond the end of the balloon. Needless to say, it is also possible for the entire catheter portion including the core section 40 to terminate before the end of the balloon section.

In operation, the valvuloplasty device is directed into the orifice of the valve to be treated either by means of a pre-positioned guide wire or without such a guide. Such positioning is usually done with the aid of fluoroscopy.

Once the valvuloplasty device is in place, the valvuloplasty procedure can be undertaken with relative ease. Because there is a main balloon and one or more satellite balloons, which can be independently connected to the fluid passages in the catheter portion, a variety of shapes can be produced by selective expansion of the separate balloons.

As shown in FIGS. 4, 5 and 6, it is possible to produce valvuloplasty device of many configurations. FIG. 4 schematically shows a central balloon 450 having satellite ballons 460 and 470 which can be separate balloons fastened to the central balloon 450 or the outer wall of the catheter portion by any convenient fastening means. The central balloon 450 can be left unexpanded while the satellite balloons 460 and 470 can be first expanded to provide a relatively broad cross-section to allow for alignment and positioning of the catheter in bicuspid or "fish mouth" type valves. The central balloon 450 can then be explained which would tend to drive the satellites into the commissures of the valve to produce the heightened effect at the edges of the valve and thereby provide greater effectiveness of the valvuloplasty proceeding.

As shown in FIG. 5, another cross-section for a twin-satellite balloon valvuloplasty device has a central balloon 550 with sattelites 560 and 570. This configuration, however, would have a one-piece or continuous outer skin and therefore present a smoother, more continuous contacting surface during the valvuloplasty proceeding.

The configuration shown in FIG. 6 again has a large central balloon 650 with satellite balloons generally indicated at 660 and 670. However the satellite balloons include a plurality of ribs or partitions 662 and 672 respectively which partitions serve primarily for purposes of shaping the satellite balloons so that the balloons can have an oblong shape with relatively narrow edges 674 and 664 respectively. Such a shape facilitates access to the narrowest region of the valve for which the valvuloplasty proceeding is occurring. The balloons 660 and 670 could be independently inflated, if desired. Additionally, the partition sections 662 and 672 could be constructed to separate the satellite balloons into distinct segments, or sections, to enable the distinct sections of the satellite balloon to be separately expanded.

FIG. 9 was described somewhat in the discussions of FIGS. 1-3. FIGS. 9-13 are cross-sectional views of various central tubular catheter portions of the valvuloplasty devices. The views are schematic in nature in that the pathways from all passages are shown in FIGS. 9-13 in the same plane although they may not actually be so aligned. In FIG. 9, the central portin 930 has an outer cylindrical wall 932 which is divided by dividers 934 into three passages 935, 936 and 937. Each of the passages has one or more holes or apertures which communicate with the adjacent balloon to allow for the passage of the expanding liquid for that balloon.

As mentioned previously, the central core 940 provides a tubular section through which a guide could be inserted, or it could be used as another passage for pressure liquid.

FIG. 10 shows another variation of the catheter portion 1030 having an outer cylindrical section 1032 and an inner cross section 1040. A single divider 1034 positions the central core member from the outer wall 1032. Two apertures are positioned on opposite sides of the outer peripheral chamber 1035 and could be connected to two balloons to simultaneously expand the balloons. Of course, an additional aperture can also be formed so that three balloons can be inflated simultaneously. The inner chamber core 1040 can be used as a guide passage

or could be used to expand a central balloon, depending on whether or not the catheter portion 1030 had a configuration similar to that shown in FIG. 3 with the core portion extending beyond the outer portions of the catheter portion.

FIG. 11 is similar to that of FIG. 10 with the addition of a second divider 1134 to divide the outer fluid carrying section into two distinct sections. The central core member 1140 can serve the same purpose as mentioned for the embodiment shown in FIGS. 9 and 10.

The embodiment of the central section shown in FIG. 12 is again similar in function to those of the outer embodiments shown in FIGS. 9–13, particularly FIG. 10 in that it only has two channels. The catheter portion 1230 has an outer cylindrical wall 1232 and in inner core section 1240. There are no dividers but there is only a single outer fluid passage 1235 with apertures on opposite sides to connect with the satellite balloons. The central core portion 1240 can have separate apertures for connecting to a central balloon. Alternatively, an additional set of apertures can be provided from flowpath 1234 to a central balloon, and core 1240 can be used for guide purposes.

FIG. 13 shows another embodiment of the catheter portion generally indicated at 1330 having an outer wall 1332 and a plurality of dividers 1334 which separate the section into an upper passage 1335, left and right side passages 1336 and 1337, and bottom passage 1338. The central core portion 1340 serves the function, in this case, of acting as a guide only since there are four separate flow passages which would be sufficient to separately inflate a central balloon member and three satellite balloons.

Referring to FIGS. 7 and 8, we see a schematic representation of the cross-section of a three-satellite balloon embodiment of the invention. FIG. 7 is substantially similar to FIG. 4 in that is has a central balloon 750 and satellites having circular cross-sections. The satellites consist of lower left and lower right satellite balloons 760 and 770 and a top, or dorsal, balloon 780 is also present. The three baloons can operate in much the same manner as the two balloon configuration previously shown. These three balloon embodiments are, of course, adapted for use with valvuloplasty procedures for tricuspid valves.

FIG. 8 is a tri-satellite ballon configuration similar to FIG. 6 in that the satellite portions are partitioned. A central balloon 850 has three satellite balloons; a top satellite 880, a lower left and lower right satellite balloon 860 and 870 respectively. Each segment has a plurality of separator or partition members 862, 872 and 882 respectively, which members are primarily for the shaping of the satellites to enable a desirable tapered shape having relatively narrow ends 864, 874 and 884, respectively, which will allow for positioning of the balloons into the narrowest portion of the valve. As with the embodiment shown in FIG. 6, the partition members 862, 872 and 882 could also be used to separate the satellite balloons into separate sections which could be separately expanded.

The method of performing the valvuloplasty procedure using the apparatus described is straightforward. The first step is to position the valvuloplasty device within the valve to be treated. The positioning can be done either with or without the aid of a guide wire which has first been inserted through the area to be treated.

Once the valvuloplasty device is in place, any combination or sequence of expansion can be produced with the plurality of balloons that comprise the embodiment of the invention. The central balloon can be expanded at a relatively low pressure so that the enlarged end of the balloon will expand sufficiently greater than the area of the valve being treated to ensure that the catheter will be securely positioned. The sattelite balloons can then be partially inflated to provide a non-circular or irregular profile or cross-section that will facilitate proper positioning of the balloons within the irregular orifice of the valve to be treated to obtain a maximum beneficial effects from the valvuloplasty procedure. The satellite balloons can then be expanded to maximum pressure to produce the desired cross-sectional configuration and forces to drive the satellite into the commissures of the valve. After expansion of the satellites, the central balloon can be expanded to further drive the edges of the satellite balloons into the commissures of the valve.

The balloons are not intended to remain expanded for a significant period of time since, when expanded, they tend to occlude the blood flow through the valve and disrupt the functioning of the heart. Therefore,, it is envisioned that the expansion of the balloons will be of relatively short duration and/or a series of pulses sequenced in some way with the beating of the heart.

In certain circumstances, it may be desirable to first expand the central balloon of the catheter rather than one satellite balloons to thereby determine if sufficient function can be obtained from the valve by merely treating the central portion of the valve as distinguished from the edge portions.

Additionally, it may be beneficial to sequence the expansion of the central balloon before the expansion of the satellite balloons in order to partially spread the commissures thereby facilitating entry of the satellites to the commissures.

From the above detailed description of the invention, it should be noted that the present invention provides a more effective method of valvuloplasty in which it is possible for the valvuloplasty device to conform to the detailed anatomy of the valve to be treated. The previous valvuloplasty devices are relatively unsuitable for access to the commissures of the valve so that treatment occurred primarily in the central area of the valve. By being able to work at the peripheral edges of the valves, far superior valvuloplasty results should be obtainable. Additionally, the use of the guide in collaboration with a bulbous end on the central balloon stabilizes the position of the valvuloplasty device during the course of the procedure thereby enhancing the accuracy of the valvuloplasty procedure. Not only is the axial positioning of the valvuloplasty device enhanced by means of a guide wire and an enlarged bulbous end, but, in addition, the ability to separately expand satellite balloons will ensure enhanced radial positioning of the valvuloplasty device for the valvuloplasty procedure.

It should be pointed out that, while the embodiments shown have a cylindrical catheter portion, the catheter portion need not be cylindrical but could be composed of separate tubes of cylinders joined together in a variety of patterns, either as a ribbon of passageways or by various other means.

While several embodiments of the invention have been illustrated and described, it is apparent that many other variations may be made in the particular design and configuration without departing from the scope of the invention as set forth in the appended claims.

I claim:

1. A balloon catheter for valvuloplasty comprising:

a catheter portion having a plurality of flow passages therein;

primary expandable means coupled to a source of pressurized liquid;

auxiliary expandable means coupled to a source of pressurized liquid;

said auxiliary expandable means mounted circumferentially adjacent said primary expandable means with the axis of said primary and auxiliary expandable being displaced and capable of being expanded under control of said liquid supply separately and independently of the expansion of said primary expandable means and in substantially parallel relation to the primary expandable means said auxiliary expandable means being displaced laterally from the axis of said primary expandable means upon expansion of said primary expandable means.

2. The device of claim 1 wherein each of said expandable means communicates with separate fluid paths in said catheter portion of said catheter.

3. The device of claim 1 wherein said auxiliary expandable means consisting of at least one separately expandable chamber.

4. The device of claim 1 wherein said auxiliary expandable means consisting of two separately expandable chambers.

5. The device of claim 1 wherein said auxiliary expandable means consisting of three separately expandable chambers.

6. The device of claim 1 wherein said first expandable means further comprises a large expansible end portion adapted to expand to an area greater than the area of the remaining portion of the first expandable means to act as a retaining means for the device when properly positioned for valvuloplasty.

7. The device of claim 1 wherein said auxiliary expandable means comprise partition means within said expandable means to shape said auxiliary expandable means when in the expanded state.

8. The device of claim 7 wherein said partition means shape said auxiliary expandable means to produce a relatively narrow rounded edge of said auxiliary exandable means.

9. The device of claim 7 wherein said partition means separate said auxiliary expandable means into separate and distinct compartments which can be independently expanded.

10. The device of claim 1 further comprising guide means extending through one of said expandable means to enable said device to be moved along said guide means to position said device.

11. The device of claim 10 wherein said guide means extend through said first expandable means.

12. A balloon catheter valvuloplasty device comprising:

a central catheter portion;

a plurality of liquid glow paths in said central section;

a guide passage in said central catheter portion;

first expandable means connected to said central catheter portion and communicating with one of said liquid flow paths to expand upon introduction of pressurized liquid therein;

auxiliary expandable means comprising a plurality of separately expandable chambers mounted circumferentially adjacent to and in substantially parallel relation to the primary expandable means;

each of said separately expandable chambers communicating with a separate fluid path in said central section;

said first expandable means including an enlarged end section adapted to expand larger than the area of a valve to be treated to position and anchor the device during a valvuloplasty proceeding;

at least one of said separately expandable chambers comprising a plurality of partition means;

said partition means shaping said separately expandable chamber to produce a relatively narrow rounded edge thereof; and

guide means extending through said central means and through said first expandable means for housing a guide wire for positioning of said catheter.

13. A balloon catheter valvuloplasty device comprising:

a primary expandable chamber;

at least one satellite expandable chamber circumferentially adjacent and in substantially parallel relation to the primary expandable means with the axis of said primry and auxiliary expandable means being displaced;

a central catheter portion having flow passage means therein;

said flow passage means communication with a source of pressurized fluid for expanding said primary and satellite expandable chambers;

said primary and satellite expandable chambers communicating with said flow passage means;

said primary and satellite expandable means in fixed position with relation to each other; and

said auxiliary expandable means being displaced laterally from the axis of said primary expandable means upon expansion of said primary expandable means.

14. The device of claim 13 wherein said flow passage means communicating with a source of pressurized fluid for expanding said primary and satellite expandable chambers consisting of a single flow passage communicating with the primary and satellite expandable chamber means.

15. The device of claim 1, 12 or 13 wherein said first expandable means is centrally located.

16. A method of performing valvuloplasty on a valve associated with the heart comprising the steps of:

placing a valvuloplasty device adjacent a valve to be treated by valvuloplasty said valvuloplasty device having a primary expandable chamber and at least one auxiliary expandable chamber mounted circumferentially adjacent to said primary expandable chamber and adapted to expand parallel to the primary expandable chamber;

a positoning the valvuloplasty device across the plane of the valve;

expanding expandable chamber and at least one auxiliary expandable chamber associated with said valvuloplasty device of flex or open the segments of the valve to be treated;

contracting the expandable chambers; and

removing the valvuloplasty device from the valve.

17. The method of valvuloplasty according to the method of claim 16 wherein the step of placing a valvuloplasty device adjacent a valve to be treated by valvuloplasty includes the stept of guiding the valvuloplasty device along a guide passing through the valve to be treated.

18. The method of valvuloplasty according to the method of claim 16 wherein said valvuloplasty device

includes an enlarged forward section and further comprising after the step of positoning the valvuloplasty device, the step of securing the valvuloplasty device by expanding the enlarged forward section of an expandable chamber associated with the valvuloplasty device beyond the valve.

19. The method of valvuloplasty according to the method of claim 16 wherein the step of positioning the valvuloplasty device includes the step of auxiliary positioning the valvuloplasty device by means of inflating an enlarged forward section of the main expansion balloon.

20. The method of valvuloplasty according to the method of claim 16 wherein the step of positioning the valvuloplasty device includes the step of rotationally positioning the valvuloplasty device by inflating an auxilary expandable chamber before inflating the primary expandable chamber.

21. The method of valvuloplasty according to the method of claim 16 wherein the step of expanding the main expandable chamber and at least one auxiliary expandable chamber includes the steps of sequentially expanding the auxiliary expandable chamber prior to expansion of the primary expansion chamber so that expansion of the primary chamber will drive the auxiliary expansion chamber into the commissures or narrow portions of the valve to be expanded.

22. The method valvuloplasty according to the method of claim 16 wherein the step of expanding the main expandable chamber and at least one auxiliary chamber includes the step of expanding auxiliary and primary expansion chambers together.

23. The method valvuloplasty according to the method of claim 16 wherein the step of expanding the main expandable chamber and at least one auxilariy chamber includes the step of expanding the primary expansion chamber before the auxiliary expansion chamber.

24. A method of performing valvuloplasty on a valve associated with the heart comprising the steps of:

placing a valvuloplasty device adjacent a valve to be treated by valvuloplasty by guiding the valvuloplasty device along a guide passing through the valve to be treated said valvuloplasty device having a plurality expandable chamber and at least one auxiliary expandable chamber mounted circumferentially adjacent said primary expandable chamber and adapted to expand parallel to the primary expandable chamber;

axially positioning the valvuloplasty device across the plane of the valve by means of inflating an enlarged forward section of the primary expansion chamber;

rotationally positioning the valvuloplasty device within the plane of the valve by at least partially expanding an auxiliary expandable chamber before inflating the primary expandable chamber; and

expanding the primary and auxiliary expandable chamber in sequence to flex or open the segments of the valve to be treated by sequentially expanding one of the auxiliary expandable chambers or the primary chamber prior to the other chamber to drive the auxiliary expandable chamber into the commissures or narrow portions of the valve to be expanded when both primary and auxiliary balloons are expanded.

* * * * *

A-7

United States Patent [19]

Goldberger

[11] **Patent Number: 4,909,252**

[45] **Date of Patent: Mar. 20, 1990**

[54] **PERFUSION BALLOON CATHETER**

[75] Inventor: **Jeffrey Goldberger, San Francisco, Calif.**

[73] Assignee: **The Regents of the Univ. of California, Oakland, Calif.**

[21] Appl. No.: **199,128**

[22] Filed: **May 26, 1988**

[51] **Int. Cl.**[4] **A61M 29/02**

[52] **U.S. Cl.** **606/194; 604/96**

[58] **Field of Search** 604/96–103; 128/325, 344, 348.1

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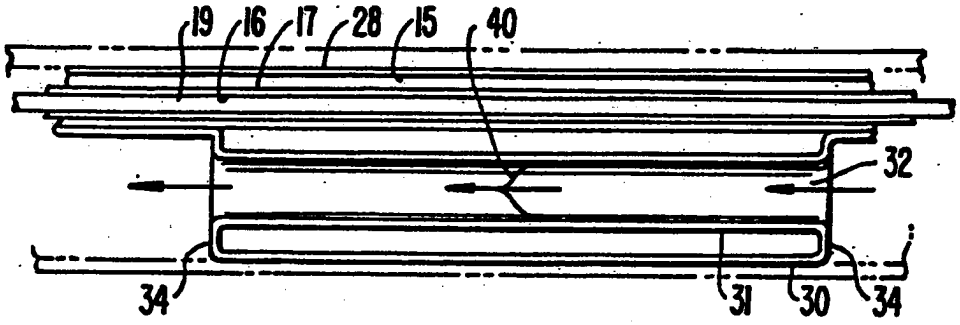
Primary Examiner—Dalton L. Truluck

Attorney, Agent, or Firm—Majestic, Parsons, Siebert & Hsue

[57] **ABSTRACT**

A balloon catheter utilizing a perfusion balloon at one end thereof is described. The perfusion balloon has a donut shaped cross section having a central opening formed therethrough. The central opening provides a blood flow passage even when the balloon is fully inflated. When inflated, the perfusion balloon is used to dilate a stenotic region of a blood vessel or heart valve to restore blood flow. After deflation, if the blood vessel collapses, the balloon catheter of the present invention can be reinflated and kept in place while the patient is prepared for surgery. In this manner, acceptable blood flow is provided regardless of the length of time required for surgical preparation. In an alternate embodiment, a one-way valve is formed integrally with the perfusion balloon so that the present invention may be better applied to valvuloplasty. In this application, the balloon is inflated at a stenotic region of a heart valve to expand the valve and restore acceptable blood flow. The one-way valve of the perfusion balloon takes the place of the coronary valve so that normal operation of the heart can be maintained during the valvuloplasty process.

19 Claims, 2 Drawing Sheets



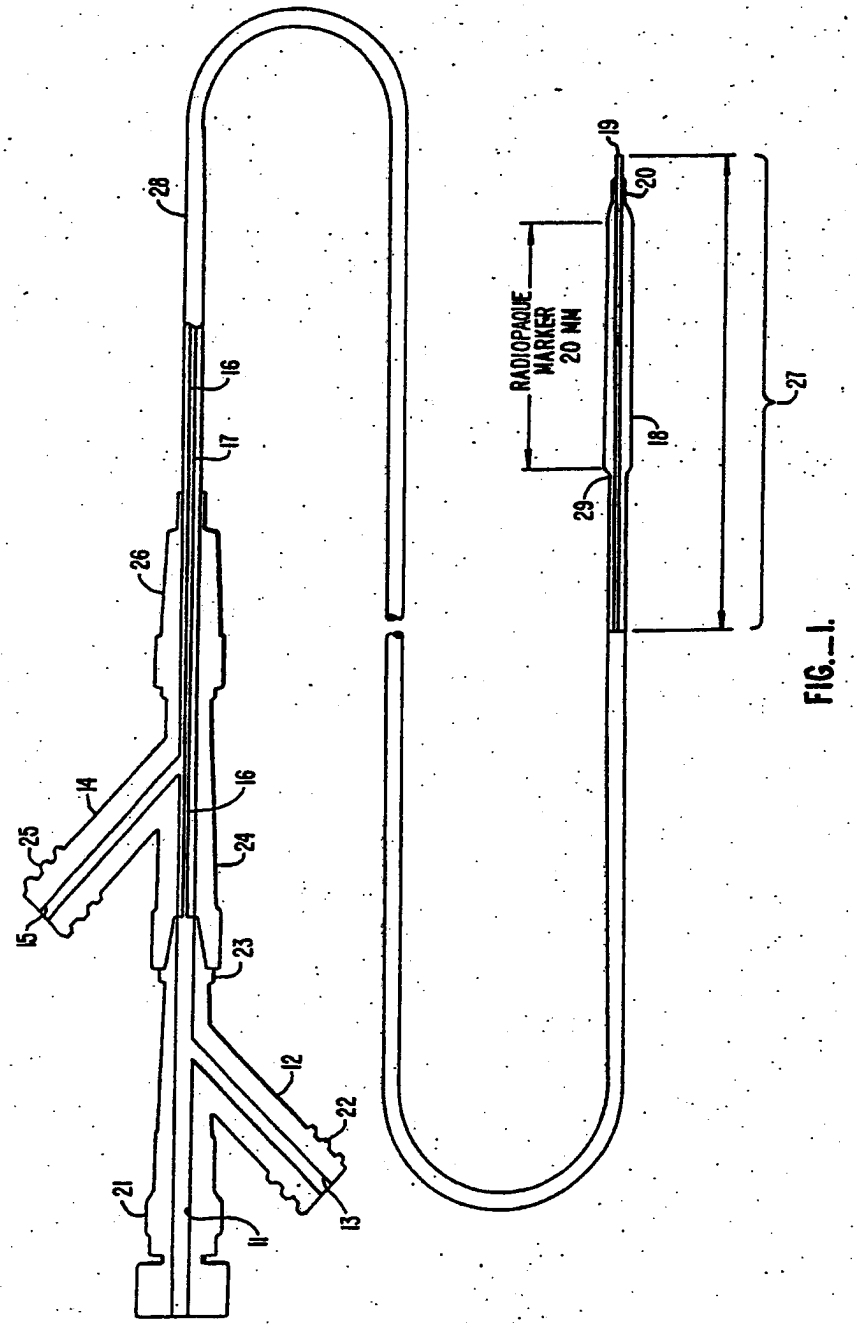

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RADIOPAQUE MARKER 20 MM
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FIG. 1.

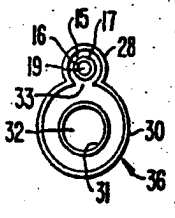


FIG._3a.

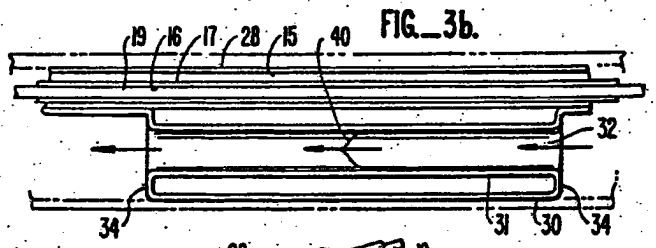


FIG._3b.

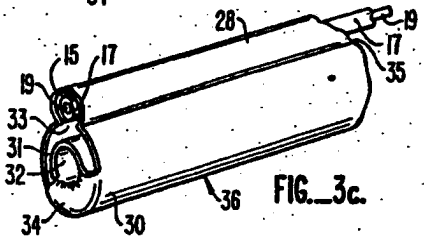


FIG._3c.

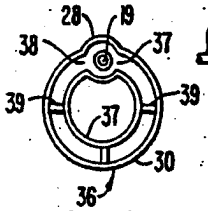


FIG._4a.

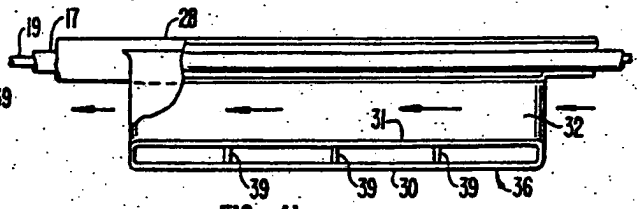


FIG._4b.

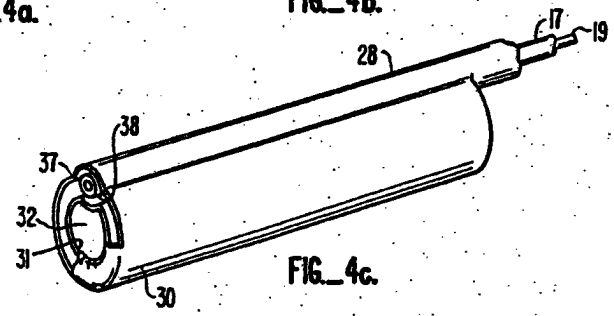


FIG._4c.

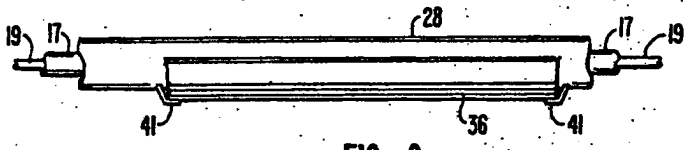


FIG._2.

PERFUSION BALLOON CATHETER

BACKGROUND OF THE PRESENT INVENTION

1. Field of the Invention

This invention relates to the field of catheters and in particular to coronary dilation catheter assemblies utilizing a perfusion balloon at one end thereof.

2. Background Art

A blood vessel of a circulatory system can often become narrow to the point where the flow of blood is limited or severely restricted. This narrowing of the blood vessel region is called a "stenosis" and is caused by the growth or development of a mass or lesion on the inner walls of the blood vesse. The stenosis must be removed, compressed, or bypassed to restore maximum blood flow capability to the blood vessel. Presently, the methods for treating stenosis of a blood vessel comprise either a surgical procedure or angioplasty.

The method known as angioplasty involves the insertion of a balloon catheter into a blood vessel at the stenotic region. The balloon is then inflated to compress the lesion material comprising the stenosis back against the walls of the blood vessel and ideally, permanently compressing the lesion material to increase the diameter of the blood vessel and hence blood flow rate of the blood vessel.

Prior art angioplasty catheters comprise a guide wire designed as either part of an angioplasty catheter or to fit inside one which is inserted through a guiding catheter into the circulatory system at some location and advanced through the blood vessel to a point past the stenosis. A balloon catheter comprising a balloon fastened around the exterior of a hollow catheter tube is inserted about the wire and slid over the guide wire until it is at the point of the stenosis.

Once in place, the balloon is inflated with a suitable fluid to dilate the lesion causing the stenosis. The balloon is then deflated and the stenotic region is observed to see if blood flow is restored. This may involved completely removing the catheter assembly and measuring the rate of blood flow through the blood vessel. If the stenosis is not compressed and springs back into place, closing the vessel, or if the blood vessel completely collapses, the patient may need to undergo surgery if the blood vessel cannot be maintained open by further dilatations. This must be done as soon as possible because a blood vessel cannot be blocked for more than a short period of time without damaging the tissue that it supplies. Therefore, while the catheter procedure can often prevent the need for surgery, it is still necessary to have the surgeons and operating room on standby during the procedure, tus incurring the expense of preparing completely for surgery during the procedure.

One disadvantage of such prior art balloon catheters is the complete occlusion of the vessel during the angioplasty process. Typically, the balloon can only remain inflated for a few secons before it must be deflated to permit blood flow to continue. Further, the catheter often must be completely removed from the blood vessel to determine if the procedure was successful.

Therefore, it is desirable to provide an angioplasty catheter in which a blood flow path is provided past the stenotic region of a blood vessel receiving the angioplasty treatment. It is also desirable to provide a catheter assembly which can be left in place while the effectiveness of treatment is determined. One prior art attempt to provide such a catheter is described in U.S. Pat. No. 4,581,017 to Sahota. There, small orifices are provided in the proximal end of the balloon catheter adjacent to the balloon and at the distal end of the catheter adjacent to the balloon. These orifices provide a flow path for blood during the angioplasty process. The orifices are designed to provide blood flow while the balloon remains inflated and if, after the balloon is deflated, the blood vessel collapses. However, the device of Sahota still results in insufficient cross sectional flow area in the blood vessel.

It is also desired to provide a balloon catheter which can be used for valvuloplasty procedures. At the present tme, when a valvuloplasty balloon dilatation cathether is inflated across a stenotic heart valve, the heart continues to pump against a completely obstructed valve apparatus, placing severe stress on the heart muscle.

Therefore, it is an object of the present invention to provide a balloon catheter which permits blood flow while the balloon is inflated.

It is a further object of the present invention to provide a balloon catheter which can be kept in place and inflated while the patient is prepared for surgery.

It is still another object of the present invention to provide a balloon catheter which can be utilized for valvuloplasty.

SUMMARY OF THE PRESENT INVENTION

A balloon catheter utilizing a perfusion balloon at one end thereof is described. The perfusion balloon has a donut shaped cross section having a central opening formed therethrough. The central opening provides a blood flow passage even when the balloon is fully inflated. When inflated, the perfusion balloon is used to dilate a stenotic region of a blood vessel or a heart valve to restore blood flow. After deflation, if the blood vessel collapses, the balloon catheter of the present invention can be reinflated and kept in place while the patient is prepared for surgery. In this manner, acceptable blood flow is provided regardless of the length of time required for surgical preparation. In an alternate embodiment, a one-way valve is formed integrally with the perfusion balloon so that the present invention may be applied to valvuloplasty. In this application, the balloon is inflated at a stenotic region of a heart valve to expand the valve and restore acceptable blood fow. The one-way valve of the perfusion balloon takes the place of the heart valve so that normal operation of the heart can be maintained during the valvuloplasty process.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cross sectional view of a balloon catheter assembly.

FIG. 2 is a side view of an alternate embodiment of the present invention.

FIG. 3*a* is an end view of the preferred embodiment of the present invention.

FIG. 3*b* is a cross sectional view of the preferred embodiment of FIG. 3*a*.

FIG. 3*c* is a perspective view of the embodiment of FIG. 3*a*.

FIG. 4*a* is an end view of an alternate embodiment of the present invention.

FIG. 4*b* is a cross sectional view of the embodiment of FIG. 4*a*.

FIG. 4*c* is a perspective view of the embodiment of FIG. 4*a*.

DETAILED DESCRIPTION OF THE PRESENT INVENTION

A catheter utilizing a perfusion balloon on one end thereof is described. In the following description numerous specific details, such as catheter diameter, balloon diameter, etc. are set forth in order to provide a more thorough understanding of the present invention. It will be apparent, however, to one skilled in the art, that the present invention may be practiced without these specific details. In other instances, well known features have not been described in detail in order not to unnecessarily obscure the present invention.

The present invention comprises an angioplasty catheter having a perfusion balloon disposed at the distal end for expanding a stenotic blood vessel. The catheter consists of a main lumen, or passage, a minor lumen, a catheter tube and a guide wire. The main lumen permits the passage of a guide wire for steering the catheter into place. The minor lumen provides a fluid path for inflating the perfusion balloon such as with a dye to allow viewing of the stenotic region via x-rays. The perfusion balloon itself is a cylindrical balloon which is substantially donut shaped in cross section. In other words, when inflated, the balloon has a central opening therethrough to permit the flow of blood or other fluids through the blood vessel.

The balloon is a double walled bladder such that when the balloon is inflated, it comprises a hollow shell which in cross section has a central opening therethrough. Prior art balloon catheters having openings in the catheter wall for blood flow around the balloon can leave up to a 92 percent obstruction of the blood vessel cross section. The present invention, even when inflated, provides a passage which is 35 to 60 percent of the original vessel size.

Referring to FIG. 1, a cross sectional view of a typical catheter is illustrated. The catheter assembly consists of a proximal lumen 12 and distal lumen 14. The proximal lumen 12 is a "Y" connector having input ports 21 and 22 and output port 23. Input port 21 includes a central passage 11 for introduction of a guide wire through the catheter assembly. Input port 22 has an opening 13 therethrough which intersects the central opening 11 and is used for the inroduction of medication, if desired, through the catheter.

The distal lumen 14 has ports 24 and 25 and output port 26. The output port 23 of the proximal lumen 12 is coupled to the input port 24 of the distal lumen 14. The distal lumen 14 includes an inner channel 16 therethrough for receiving the guide wire from channel 11 of the proximal lumen. Port 25 includes channel 15 which leads to and surrounds channel 16 and is used for an introduction of inflating fluid and/or radiopaque fluid to the balloon at the catheter tip. Coupled to the output port 26 of the distal lumen 14 is the coaxial catheter assembly consisting of an inner catheter tube 17, an outer "sleeve" catheter tube 28, the balloon 18 and the guide wire 19. The channel 15 between the inner catheter and the sleeve catheter is used for introduction of inflating fluid to the balloon at the catheter tip.

Referring now to distal end 27 of the catheter assembly, the outer sleeve 28 has a constant diameter or may taper to the point of attachment of the balloon 18. The balloon 18 is substantially a widening of the diameter of the outer catheter 28 at the point 29. At point 20, the catheter diameter narrows again. The guide wire 19 exits the balloon and inner catheter at the distal end of the entire catheter assembly.

The balloon of the preferred embodiment of the present invention is illustrated in FIGS. 3*a*–3*c*. Referring first to FIG. 3*c*, a perspective view of the preferred embodiment shows the balloon 36 coupled to one side of the outer sleeve catheter 28. The perfusion balloon of the present invention is essentially a double walled bladder having an outer wall 30 and an inner wall 31. The outer wall 30 connects to the catheter sleeve 28 along line 35. The outer wall continues in a curved path to the inner wall 31. This curved connecting material may be thought of as side wall 34. A gap 33 in the outer catheter 28 provides fluid connection to the interior of the bladder between walls 30 and 31 and to channel 15. When inflating fluid is provides in channel 15, it fills the balloon 36, expanding the balloon into the shape of FIG. 3*c*.

The perfusion balloon of the present invention, when inflated, takes the shape of an elongated hollow tube. The balloon has a central opening 32 extending coincide with the longitudinal axis of the balloon. This opening 32 has an area which, in the preferred embodiment, is approximately 35–60% of the blood vessel cross sectional area. Referring to FIG. 3*a*, the cross section of the perfusion balloon is substantially ring shaped, like a doughnut or tire tube. In the preferred embodiment, the perfusion balloon is disposed on one side of the outer catheter 28. However, the outside catheter 28 may be disposed at any orientation and/or or location with respect to the perfusion balloon such as, for example, inside, outside, or in the center.

A typical blood vessel subject to the angioplasty process has a diameter of approximately 2.5 to 3.5 millimeters, resulting in a cross sectional blood flow area of approximately 4.9 to 9.6 square millimeters. The prior art perfusion catheters which provide orifices in the catheter tube for blood flow are limited in cross sectional area to the area of the catheter itself. In other words, when a prior art balloon perfusion catheter is inflated, the only available blood flow path is the catheter tube itself, which is substantially smaller than the blood vessel.

A typical prior art catheter has a diameter of approximately 0.7 mm. Therefore, the cross sectional area of the catheter is 0.38 mm^2. This means that at best, only about 8% of the normal cross sectional area is available for blood flow. In other words, the prior art catheter results in a 92% obstruction of the blood vessel when and if the entire cross section of the catheter is available for blood flow. However, some of the cross sectional area of the catheter is taken up by the guide wire, the balloon inflation lumen, and the catheter walls. Therefore, the available cross sectional area generally is less, on the order of 3–4% of the normal blood vessel.

In the preferred embodiment of the present invention, the gap between the inner wall 31 and outer wall 30 of the perfusion balloon, (see FIG. 3*a*) is approximately 0.5 mm. When inflated, the diameter of the outer wall is coincident with the wall of the blood vessel, or approximately 3 mm. Thus, the diameter of the opening 32 is approximately 2 mm. The cross sectional area of the perfusion balloon available for blood flow is thus 3.14 mm^2. The cross sectional area of a 3 mm blood vessel is approximately 7 mm^2, so that the present invention provides a blood flow path which is approximately 44% of the maximum available area when inflated. The blood flow area when the balloon is inflated is actually

greater than the flow area of a stenotic blood vesse. In a typical stenotic blood vessel, less than 30% of the flow area is available. When the balloon is inflated, approximately half the ideal flow area is available.

For a 3.5 mm blood vessel, assuming a 0.5 mm gap between the inner and outer walls, the perfusion balloon of the present invention provides 4.9 mm^2 blood flow area. This translates to 51% of the maximum available area of 9.6 mm^2 in such a blood vessel.

Referring to FIG. 3*b*, the perfusion balloon **36** is disposed substantially below the outer catheter tube **28**. The guide wire **19** extends through inner catheter **17**, with channel **16** surrounding the wire for the introduction of fluid to the distal end of the catheter region. The inner catheter **17** is coaxial with outer catheter sleeve **28**, with the space between defining channel **15**, for introduction of inflating fluid to the balloon **36**.

An alternate embodiment of the present invention is illustrated in FIGS. 4*a*–4*c*. In this embodiment, the outer catheter **28** is disposed essentially within the circumference of the perfusion balloon **36**. Referring to FIG. 4*a*, the outer wall **30** of the perfusion balloon **36** extends from the walls of the outer catheter **28**. Openings **37** and **38** in the side walls of outer catheter **28** provide fluid connection to channel **15** for the introduction of inflating fluid to the balloon **36**. As in the previously discussed embodiment, the inner **31** and outer **30** walls of the balloon are connected by side wall **34** to create a double walled bladder. When inflated, the balloon provides an open central passage **32** for the flow of blood in the blood vessel being treated.

Referring now to FIG. 4*b*, the profile of this embodiment is lower than the profile of the embodiment of FIG. 3*b* by the approximate circumference of the outer catheter **28**. This results in additional blood flow area because the outer catheter is disposed substantially between the inner and outer walls of the balloon **36**.

To insure that the spacing between the inner and outer walls of the balloon remains consistent, it may be necessary to provide ribbed members between the walls as spacers. These ribs **39** are shown in FIGS. 4*a* and 4*b* and are disposed radially about the center of the balloon. The radial spacing insures complete fluid connectivity to the channel **15** while maintaining the desired 0.5 mm gap between the inner and outer walls of the balloon.

When the catheter assembly is inserted into the blood vessel, it is desired to provide a very low profile so that trauma to vessel walls is minimized. In addition, a low profile may be needed to enable the assembly to be inserted into stenotic regions which have become nearly closed off. The balloon itself is deflated during insertion and positioning of the catheter assembly. In an embodiment of the present invention illustrated in FIG. 2, retaining clips **41** are provided to hold the deflated and folded balloon **36** in place against the outer catheter **28** prior to inflating. The clips **41** are hingedly connected to the outer catheter **28** and "break away" due to the pressure of the balloon when the balloon is inflated. However, although the clips **41** move out away from the balloon **36**, they remain attached to the outer catheter **28** so as to be removed from the vessel when the catheter is removed. This perfusion balloon catheter can be similarly used for angioplasty of other arteries of the body.

The present invention may also be utilized for valvuloplasty procedures. If there is a stenosis in one of the heart valves, it is desirable to remove the stenosis or to open up the valve. Generally, the stenosis is such that the valve can close but can only open very slightly. In the past, surgery has been required to correct a valve stenosis. At present, valvuloplasty is being explored as a non-surgical option for correcting these stenoses. If a prior art catheter assembly is utilized, blood flow is cut off completely across the valve, so that the heart is pumping against a completely obstructed outlet, which can lead to damage. This limits the application of prior art catheters to only a few seconds of inflation after which the catheter must be removed. If the balloon can be inflated for longer periods without risk, the valvuloplasty may be more effective.

In an alternate embodiment of the present invention, a one way valve is provided integrally with the perfusion balloon, permitting it to be used in a valvuloplasty procedure. Referring to FIG. 3*b*, a one way valve **40** is provided within the central passage **32** of the balloon **36**. The valve **40** consists of a number of vanes which are coupled at one end to the walls of the passage **32** and curve away from the wall in a downstream direction. When blood is pumped through the valve (from right to left in FIG. 3*b*) the vanes are urged open, allowing passage of the blood. If blood flows in the other direction, the fluid pressure urges the vanes to come together, preventing flow of blood. It is not necessary that the one way valve be completely fluid tight when off, because even normal heart valves themselves may have some leakage. Further, if the leakage is temporary, no permanent damage results. Thus, the perfusion balloon of the present invention may temporarily take the place of a valve, permitting the use of the present invention in a valvuloplasty procedure.

The perfusion balloon of the present invention is comprised of a flexible plastic material such as polyvinyl chloride (pvc) or any suitable material which can be sterilized for internal applications. The length of the ballon depends on the application but is generally within the range of 2 to 3 cm. for coronary artery angioplasty and 3–6 cm. for valvuloplasty. The diameter of the catheter assembly is approximately 0.3 to 0.8 mm for angioplasty procedures and 2 to 3 mm for valvuloplasty procedures.

As a further alternate embodiment of the present invention, the catheter **28** is disposed within the channel **32** of the balloon. An opening in the catheter **28** communicates with the balloon through inner wall **31** of the balloon. This provides a more rounded cross-section when inflated.

Thus, a perfusion balloon catheter which permits the flow of blood when the balloon is inflated has been described.

I claim:

1. A balloon for use with a catheter assembly comprising:

a first cylindrical outer wall;

a second cylindrical inner wall disposed within and coupled to said first outer wall such that a cavity is defined between said first and second walls and an open central passage is defined interiorly of said second wall;

said first wall having an opening therein for fluid connection to a first channel,

said first wall being coupled to a first catheter tube,

said first catheter tube disposed about a second catheter tube, space between said first and second catheter tubes defining said first channel, and

wherein said first and second catheter tubes are disposed so as to leave said central passage free of obstructions and permit free flow through said passage.

2. The balloon of claim 1 wherein said first channel is coupled to a fluid source for inflating said balloon.

3. The balloon of claim 1 further including a plurality of ribs coupled to, and disposed between, said first and second walls for defining said cavity between said first and second walls.

4. The balloon of claim 1 further including a one way valve coupled to said balloon for limiting fluid flow in a first direction and permitting fluid flow in a second direction.

5. The invention of claim 1 further including a guide wire extending through said first inner catheter tube.

6. The invention of claim 1 wherein said catheter tubes extend at least partly through said balloon.

7. The invention of claim 6 wherein said catheter tubes extend all the way through said balloon.

8. The invention of claim 1 wherein said first catheter is disposed outward of said inner wall.

9. The invention of claim 8 wherein said second catheter is disposed outward of said inner wall.

10. A catheter assembly comprising:

a first inner catheter coupled to a first lumen;

a guide wire extending through said first inner catheter;

a second outer catheter surrounding and coaxial with said first inner catheter, said second outer catheter coupled to a second lumen;

a balloon coupled to said second catheter, said balloon comprising a first cylindrical outer wall and a second cylindrical inner wall disposed within and coupled to said first outer wall such that a cavity is defined between aid first and second walls and an open central passage is defined interiorly of said second wall, said first outer wall having an opening therein for fluid connection to said second lumen through said second outer catheter;

said second lumen for providing inflating fluid to said balloon through said opening in said first outer wall, and

wherein said first and second catheters are disposed so as to leave said central passage free of obstructions and permit free flow through said passage.

11. The catheter assembly of claim 10 further including a plurality of ribs coupled to, and disposed between, said first and second walls for defining said cavity between said first and second walls.

12. The catheter assembly of claim 10 further including a one way valve coupled to said balloon for limiting fluid flow in a first direction and permitting fluid flow in a second direction.

13. The invention of claim 10 wherein said catheter tubes extend at least partly through said balloon.

14. The invention of claim 13 wherein said catheter tubes extend all the way through said balloon.

15. The invention of claim 10 wherein said first catheter is disposed outward of said inner wall.

16. The invention of claim 15 wherein said second catheter is disposed outward of said inner wall.

17. A method of producing blood flow in a stenotic region of a blood vessel comprising the steps of:

inserting a catheter assembly into said blood vessel, said catheter assembly having a first inner catheter coupled to a first lumen, a guide wire extending through said first inner catheter, and a second outer catheter surrounding and coaxial with said first inner catheter, said second outer catheter coupled to a second lumen;

inflating at said stenotic region a balloon coupled to said second outer catheter to compress said stenotic region, said balloon comprising a first cylindrical outer wall and a second cylindrical inner wall disposed within and coupled to said first outer wall such that a cavity is defined between said first and second walls;

channeling blood flow through said balloon at a flow channel defined within said second cylindrical inner wall when said balloon is inflated, said first and second catheters being disposed so as to leave said flow channel free of obstructions;

whereby blood flow is maintained when said balloon is inflated.

18. The method of claim 17 wherein said said first outer wall of said balloon has an opening formed therein for fluid connection to said second lumen through said second outer catheter.

19. The method of claim 18 wherein said balloon further includes a one way valve coupled to said balloon for limiting fluid flow in a first direction and permitting fluid flow in a second direction.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 4,909,252
DATED : MARCH 20, 1990
INVENTOR(S) : JEFFREY GOLDBERGER

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

Column 7, line 37, in Claim 10: replace "aid" with --said--

Signed and Sealed this

Sixteenth Day of April, 1991

Attest:

Attesting Officer

HARRY F. MANBECK, JR.

Commissioner of Patents and Trademarks

[redacted]

A-8

United States Patent [19]

Shaffer et al.

[11] **Patent Number: 5,049,132**

[45] **Date of Patent: Sep. 17, 1991**

[54] **BALLOON CATHETER FOR DELIVERING THERAPEUTIC AGENTS**

[75] Inventors: **Maureen A. Shaffer; James E. Leone, both of Miami, Fla.**

[73] Assignee: **Cordis Corporation, Miami Lakes, Fla.**

[21] Appl. No.: **461,648**

[22] Filed: **Jan. 8, 1990**

[51] **Int. Cl.**[5] **A61M 29/00**

[52] **U.S. Cl.** **604/101; 604/96; 606/194**

[58] **Field of Search** **604/96, 101, 280; 128/207.15; 606/192, 194**

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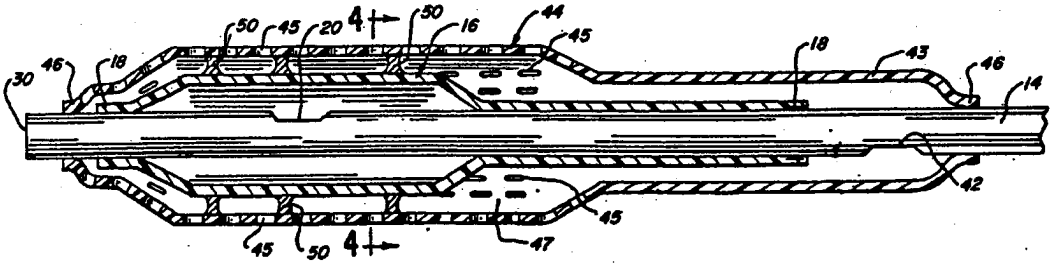
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Primary Examiner—John D. Yasko
Assistant Examiner—Anthony Gutowski
Attorney, Agent, or Firm—Gerstman & Ellis, Ltd.

[57] **ABSTRACT**

A balloon catheter comprises a catheter shaft which typically defines a first inflation lumen and a first, inflatable balloon mounted on the shaft in communication with the first inflation lumen. By this invention a second inflation lumen is typically provided, spaced from the first lumen and defined by the catheter shaft. A second balloon is mounted on the shaft in communication with the second inflation lumen. The second balloon defines apertures which are sized to permit liquid flow outwardly through the balloon. Thus, medication may be delivered in a controlled manner. Alternatively, the second balloon for medication administration may be the only balloon present on the catheter.

13 Claims, 1 Drawing Sheet



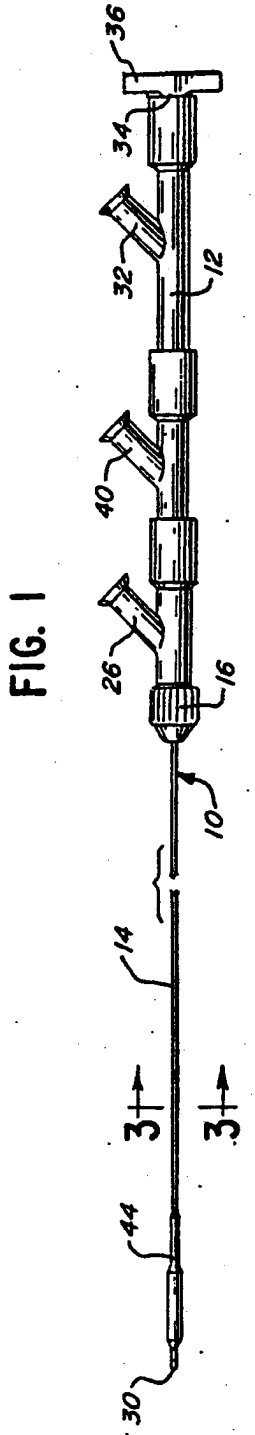


FIG. 1

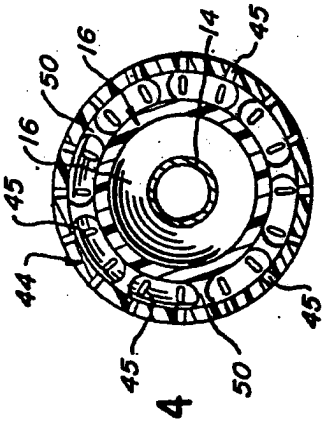


FIG. 4

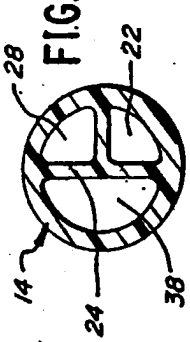


FIG. 3

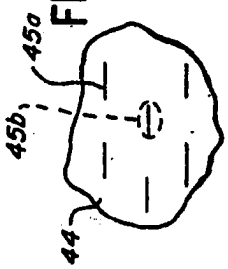


FIG. 5

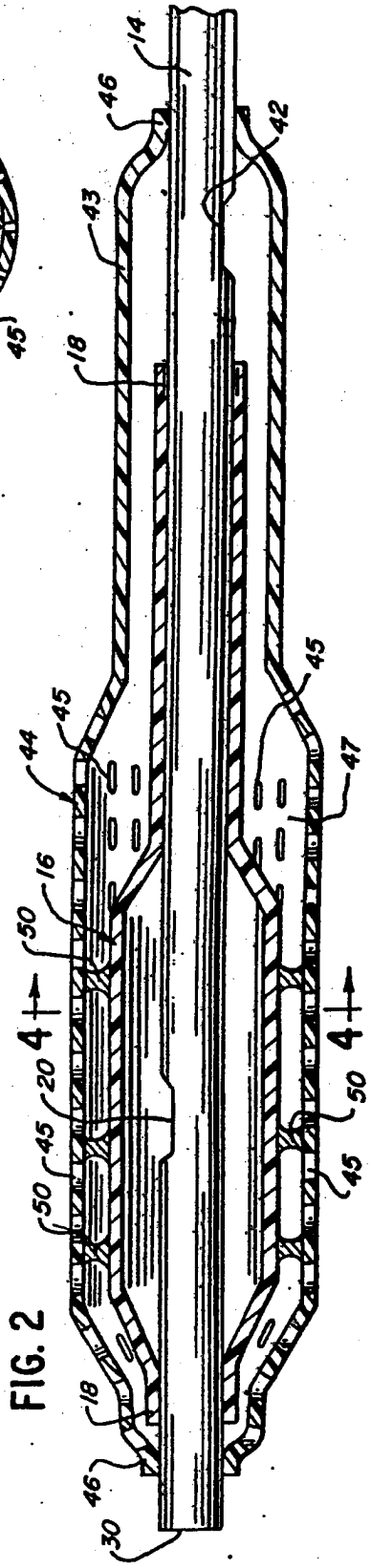


FIG. 2

BALLOON CATHETER FOR DELIVERING THERAPEUTIC AGENTS

BACKGROUND OF THE INVENTION

As described in Wolinsky U.S Pat. No. 4,824,436, the process of treating coronary artery disease with an balloon (typically the PTCA procedure) results in at least a temporary, forcible expansion of a coronary artery cross section which is narrowed by an atherosclerotic lesion or stenosis. However, following such rough, physical balloon expansion of such a stenosis, often a restenosis takes place in which the artery again closes up. To counter this, heparin is given to the patient. For example, it is the current custom in a PTCA procedure to deliver by injection up to about 10,000 units of heparin as a bolus during or immediately after the procedure, with hourly, additional doses of heparin being administered up to 24 hours after the PTCA procedure. This, however, has known disadvantages in that some patients such as ulcer patients or patients with high blood pressure are contraindicated for the administration of such large amounts of heparin.

As another approach to the problem of restenosis, the previously cited Wolinsky patent teaches the administration of heparin by means of a special catheter to the stenosis area after a PTCA procedure or the like. However, this requires the insertion of a second catheter into the patient's arterial system, to accomplish this special application of heparin

In Rowe pending U.S. Pat. Application No. 322,929, filed Mar. 14, 1989 and entitled Method and Apparatus for Delivery of Therapeutic Agent, a balloon catheter is described, being, if desired, of a type useful for a PTCA or related procedure. However, as an improvement, a coating of heparin or other medication is carried on the surface of the balloon. Accordingly, heparin or other medication is forced into the stenosis site by the pressure of the expanding balloon, so that the heparin is applied in a single step as the stenosis area is physically expanded by the balloon. However, there may be a need for larger quantities of medication than can be provided by such an expansion balloon surface as described in the above-mentioned patent application. Additionally, there may be a need for a sequence of medications, to be applied one after the other, and this also is not readily accomplished in the cited patent application with a single catheter insertion. Additionally, it may be desired to apply the medication without the application of substantial pressure, and this also is not done with ease in the above-described invention. Also, there is a need for a system in which the medication does not leak out of the system until the catheter is positioned at exactly the desired location, and where the choice of medication may change with a late decision by the physician after the catheter has been emplaced.

By the invention of this application, any or all of the above objectives may be accomplished, to provide greater flexibility and effectiveness to catheters for delivering therapeutic agents.

DESCRIPTION OF THE INVENTION

In this invention, a balloon catheter is provided which comprises a catheter shaft and an inflation balloon carried thereon in communication with an inflation lumen extending through the catheter. By this invention, the inflation balloon defines aperture means extending through its wall, said aperture means being

sized to permit pressurized flow of medication outwardly through the balloon wall. Thus, after proper emplacement of the catheter, the desired medication may be applied to the appropriate site in the body by being forced through the inflation lumen to the interior of the catheter balloon. From there, the medication, typically under at least gentle pressure, migrates through the aperture means of the balloon wall into the desired area for medical treatment.

Specifically, such a balloon catheter may be used for PTCA or other, similar procedures for enlarging arteries and the like, but it may be used for any other purpose as well, such as in a Foley Catheter for the bladder For example, antibiotics may be administered, or anestetic prior to catheter removal. The preferred plurality of apertures on the balloon may be proportioned to be small enough so that the balloon may be pressure-inflated despite the presence of the apertures, while medication flows out of the apertures. Thus, the medication may be forcefully administered by pressure in the expanding balloon, to provide pressure administration of heparin or the like to a stenosis site, for example. In this circumstance, the medication itself serves as the balloon inflation fluid, being administered in a volume and at a pressure so that the balloon is expanded at a desired pressure despite the leakage of medication through the apertures in the balloon wall.

Preferably, the balloon catheter of this invention comprises a catheter shaft which defines a first inflation lumen and carries a first, inflatable balloon which is typically aperture-free. The inflatable balloon is mounted on the catheter shaft in communication with the first inflation lumen.

In accordance with this invention, a second lumen, spaced from the first inflation lumen, is defined by the catheter shaft as well. A second balloon is mounted on the catheter shaft in communication with the second lumen defined in the shaft, this being the balloon which defines the aperture means through its wall as described above. Such apertures of the aperture means are sized to permit liquid flow outwardly through the balloon. Optionally, when the apertures are holes having a diameter of about 0.002 inch or less, many liquid medications will not flow through the apertures except under substantial pressure, which facilitates the inflation of the second balloon with such medication and the administration of controlled quantities thereof at desired pressures. Otherwise, the apertures may preferably have diameters of about 0.01 to 0.05 inch or more for essentially spontaneous medication flow therethrough.

As a further preferred feature of this invention, the second balloon is positioned generally radially outwardly about the first balloon in telescoping relation therewith. Accordingly, pressure from the first balloon can be used to outwardly expand the second balloon, and to help provide pressure administration of the medication, which may flow into the region between the first and second balloons and outwardly through the apertures in the second balloon wall. Accordingly, such a catheter may be used in a PTCA procedure to provide a conventional high pressure expansion of the stenosis site with the first balloon, after the catheter has been properly emplaced. This may be followed by deflation of the first balloon to any desired degree, and the addition of medication such as heparin solution to the area between the first and second balloons through the second lumen, from where the heparin flows outwardly

through the apertures, while any desired pressure is administered by any combination of pressurization of the medication itself and the first balloon.

Thus, by means of a single balloon catheter insertion, a PTCA or other balloon expansion procedure may be performed, followed by the immediate administration of any desired medication. The choice of medication may be delayed by the physician until the outcome of the PTCA procedure has been determined. Then, the desired medication solution or combination of solutions may be administered through the proximal end of the catheter through the second lumen into the space between the two balloons, followed by dispersion of the medication at the desired site, under any desired pressure. Alternatively, the balloon catheter for delivering therapeutic agents may be used subsequent to any conventional PTCA or similar procedure to infuse such therapeutic agent without the use of this device to effect dilation of the vessel, or even in cases in which there is no vessel dilation

The second, outer balloon may, if desired, not completely overlap the first, inner balloon. For example, when the second balloon has at least a small, proximal section which does not overlap the second balloon, that may serve as a place where the second lumen can communicate with the space within the second balloon and outside of the first balloon.

It may also be desirable for the second balloon to be spot-sealed to the first balloon in a plurality of spaced areas. This facilitates the collapsing of the second balloon, along with the first balloon, by a conventional vacuum suction process for packaging of the catheter. Otherwise, the presence of the apertures in the second balloon makes the suction collapsing of the second balloon to remove all possible air a more difficult process.

The catheter of this invention may also carry a guide wire in its own added lumen, to facilitate the insertion of the catheter of this invention in a manner which is conventional to the clinical catheter art, particularly angiographic and angioplastic catheters.

It may also be desired for the apertures of the second balloon to comprise slits in the second balloon wall having abutting sides in their normal, unstretched configuration, rather than holes with sides that do not normally abut. This limits fluid communication inwardly or outwardly through the wall of the second balloon as the second balloon is collapsed for packaging and then advanced to a desired site in a patient. However, upon even low pressurization, the slit-type apertures open by stretching for the easy delivery of medication to the exterior of the second balloon, and they close again when the pressure ceases.

Examples of medications that may be administered may include any medication or therapeutic agent which would be desirably applied locally to a specific, internal tissue site which is accessible by the catheter.

Specific examples of such medications or therapeutic agents include anti-thrombogenic agents or other agents for suppressing stenosis or late restenosis such as heparin, streptokinase, urokinase, tissue plasminogen activator, anti-thromboxane B^2 agents, anti-B-thromboglobulin, prostaglandin E, aspirin, dipyridimol, anti-thromboxane A_2 agents, murine monoclonal antibody 7E3, triazolopyrimidine, ciprostene, hirudin, ticlopidine, nicorandil, and the like. Anti-platelet derived growth factor may be used as a therapeutic agent to suppress subintimal fibromuscular hyperplasia at an arterial stenosis site, or any other inhibitor of cell growth at the stenosis site may be used.

The therapeutic agent also may comprise a vasodilator to counteract vasospasm, for example an antispasmodic agent such as papaverine. The therapeutic agents may be vasoactive agents generally such as calcium antagonists, or alpha and beta adrenergic agonists or antagonists. Additionally, the therapeutic agent may include a biological adhesive such as medical grade cyanoacrylate adhesive or fibrin glue, for example to adhere an occluding flap of tissue in a coronary artery to the wall, or for a similar purpose.

Also, the balloon catheter of this invention may be expanded to apply a stent to the coronary artery or elsewhere. With the application of the stent, an anti-thrombogenic agent may be applied to its internal tissue site for preferably long term suppression of thrombogenic activity in the vicinity of the stent.

Additionally, the therapeutic agent in accordance with this invention may be an anti-neoplastic agent such as 5-fluorouracil or any known anti-neoplastic agent, preferably mixed with a controlled release carrier for the agent, for the application of a persistent, controlled release anti-neoplastic agent to a tumor site.

The therapeutic agent may be an antibiotic which may be applied by this invention, preferably in conjunction with a controlled release carrier for persistence, to an infected stent or any other source of localized infection within the body. Similarly, the therapeutic agent may comprise steroids for the purpose of suppressing inflammation or for other reasons in a localized tissue site.

The therapeutic agent may constitute any desired mixture of individual pharmaceuticals of the like, for the application of combinations of active agents.

Additionally, glucocorticosteroids or omega-3 fatty acids may be applied, particularly to stenosis sites to obtain clinical benefit thereby. Any of the above medications may include controlled release agents to prolong the persistence of the medication.

Thus, by this invention, medications may be applied in conjunction with a pressure-applying balloon expansion process, where the dosage, the pressure of application, and the selection of the medication may be independently made apart from the balloon expansion process.

DESCRIPTION OF THE DRAWINGS

In the drawings, FIG. 1 is a plan view of the catheter of this invention;

FIG. 2 is an enlarged, fragmentary, longitudinal sectional view of the distal tip of the catheter of FIG. 1;

FIG. 3 is a sectional view taken along line 3—3 of FIG. 1;

FIG. 4 is a sectional view taken along line 4—4 of FIG. 2; and

FIG. 5 is an enlarged, fragmentary plan view of a portion of the outer balloon of the catheter of FIG. 1, showing slit-type apertures as an alternate embodiment.

DESCRIPTION OF SPECIFIC EMBODIMENTS

Referring to the drawings, a balloon-type catheter is disclosed, being similar in purpose and construction to a commercially available PTCA dilatation catheter except as otherwise shown.

As is conventional, proximal catheter hub 12 is provided, being typically made of a rigid polycarbonate material. At the distal end of hub 12 is attached catheter

tubing 14 which may be made of nylon, for example, being attached to hub 12 by manifold 16 of conventional design.

At the distal end of catheter tube 14 is positioned a pair of catheter balloons in generally telescoping relation with each other. A first inner balloon 16 is a conventional PTCA inflation balloon made of nylon, heat sealed at its respective ends 18 to the outside of catheter tubing 14. One or more inflation ports 20 pass through the wall of catheter body 14 to provide communication between the interior of first balloon 16 and a catheter lumen 22, shown in cross section in FIG. 3 as being defined by an integral, T-shaped interior wall 24 of catheter 14. Lumen 22 communicates with inflation port 20 at the distal end and with inflation port 26 near the proximal end of the catheter. Inflation port 26 provides temporary sealing communication with a syringe or any other desired source of compressed fluid in a manner conventional for balloon catheters.

Another lumen 28 is provided within catheter body 14. Lumen 28 extends completely through the catheter, forming an open aperture at the distal end 30 at one end and communicating with lateral injection port 32 close to the proximal end 34. Additionally, lumen 28 communicates axially completely through hub 12 to extend through the proximal end 34 of the catheter as well. A conventional hemostasis screw 36 may be threadedly attached to the proximal end 34 of the catheter, to close off and seal the proximal end of lumen 28.

Thus, a guide wire may be inserted through the entire length of lumen 28 of the catheter, to assist in catheter insertion in conventional manner. Then, after the catheter has been inserted to the desired position, the guide wire may be removed, and the hemostasis screw 36 applied. At this point, X-ray contrast or other desired solution may be administered through port 32, from where it is conveyed through the catheter and out of distal end 30.

In accordance with this invention, another lumen 38 is provided to catheter body 14, identified as the "second lumen" herein. Lumen 38 communicates at its proximal end with lateral connection port 40, and at its distal end with one or more lateral ports 42 positioned in catheter body 14 typically proximally to balloon 16. A second balloon 44 is carried by catheter body 14, the second balloon being positioned generally radially outwardly about first balloon 16 in telescoping relation therewith. However, in this embodiment, a portion 43 of second balloon 44 is positioned proximally of first balloon 16 to provide for communication of port 42 with the space 47 between the first and second balloons 44, 16. Second balloon 44 may be made, for example, of poly(ethylene terephthalate) or nylon.

As previously described, second balloon 44 defines aperture means in the form of holes 45, typically in the form of pores or perforations, of dimensions and types described above. Typically, second balloon 44 will be made of the same material as catheter body 14 to facilitate good heat seals 46 between second balloon 44 and catheter body 14. The distal heat seal 46 may be placed on top of heat seal 18, if desired.

It is preferred for a large plurality of spaced apertures 45 to be distributed about substantially the entire surface of second balloon 44 to maximize the uniformity of distribution of whatever medication passes outwardly through the wall of second balloon 44.

Such balloons 44 may be made by a variety of processes, for example by laser punching of holes in a preformed plastic balloon, or by punching with multiple needles on a platen or jig, or making use of a slitting machine to form a multiplicity of slits about the surface area of the balloon. Alternatively, porous plastic tubing may be extruded by means of a variety of processes involving a two component system homogenous liquid is cooled to form a two phase, immiscible liquid system, following which the extruded mixture is quickly cooled to form a two phase solid matrix. Following this, one of the phases is washed out of the system, leaving a porous tube. Such processes are well-known to the art.

Accordingly, the catheter of this invention, after insertion into a body cavity such as a coronary artery, may be used by inflating the first balloon 16 in a conventional PTCA process to enlarge the lumen of an artery which is partially blocked by a stenosis. The pressurized fluid for this process is provided to first balloon 16 through inflation port 26 and lumen 22.

Also, either before, during, or after the process of inflating balloon 16, medications such as heparin solution or any other desired medication or mixtures thereof may be administered through port 40 and lumen 38 into the space 47 between balloons 16 and 44. Pressure may be applied as necessary, either directly through port 40 or indirectly by the inflation of balloon 16, causing the medication to migrate outwardly through the wall of the balloon 44 to the surrounding tissue.

It can be seen that the catheter of this invention provides great versatility in that pressure without medication can be applied, or medication can be applied with pressure, and also medication can be applied without significant pressure, with sequential administrations of different kinds of medication being available, and last minute choices may be made as to the medication to be administered. All of this is possible with the insertion of a single catheter. Likewise, medication which is incompatible in some way with the fluid used to inflate balloon 16 may be provided in a separated manner, and also the medication may be kept relatively separate, at least until delivery, from X-ray contrast media or the like administered to lumen 28 through port 32.

It may also be desirable to connect the respective balloon 16, 44 with thin, spaced spot seals 50 so that balloon 44 is retracted as balloon 16 is retracted, but a substantial space 47 still remains between the two balloons to receive medication. The thickness of spot seals 50 and the spacing between balloon 16, 44 is exaggerated in FIG. 2 for purposes of clear illustration.

An advantage of spot seals 50 comes particularly in the preparation of the catheter for insertion into the body. Typically, balloon catheters have their balloons completely collapsed by application of a suction pressure to their lumen, so that the balloon initially assumes the smallest possible cross-sectional dimension. However, because of the presence of apertures 45 in second balloon 44, it is not easily collapsed by suction, particularly when many apertures are present as may be desirable, or the apertures have a dimension larger than 0.0005 inch or so. Accordingly, the presence of spot seals 50 causes second balloon 44 to collapse with first balloon 16. Further collapse of balloon 44 may be achieved to a certain extent with a substantial suction that can take air out of the balloon faster than it enters through apertures 45. Additionally, if desired, outer balloon may be wrapped in an impermeable wrapping to assist in the suction collapse.

Referring to FIG. 5, a section of outer balloon 44 is shown as an alternate embodiment in which the aper-

tures 45*a* are of a slit-type, normally having abutting sides. However, under pressure the slits open as shown at dotted line reference numeral 45*b*, for flow communication.

The above has been offered for illustrative purposes only, and is not intended to limit the scope of the invention of this application, which is as defined in the claims below.

That which is claimed is:

1. In a balloon catheter which comprises a catheter shaft which defines a first inflation lumen and a first, inflatable balloon mounted on said shaft in communication with said first inflation lumen, the improvement comprising, in combination:

a second inflation lumen, spaced from said first lumen, defined by said catheter shaft, and a second balloon mounted on said shaft in communication with said second inflation lumen, said second balloon defining aperture means sized to permit liquid flow outwardly through said second balloon, whereby medication may be delivered in controlled manner, said second balloon being spot-sealed to said first balloon in a plurality of spaced areas which are spaced from the ends of said balloons.

2. The balloon catheter of claim 1 in which said aperture means comprises slits in the second balloon wall having abutting sides in their normal, unstretched configuration.

3. The catheter of claim 3 in which said second balloon is positioned generally radially outwardly about said first balloon in telescoping relation therewith.

4. The catheter of claim 1 in which said catheter shaft defines a third lumen for receiving a guide wire.

5. The balloon catheter of claim 1 in which said aperture means comprises holes having a diameter of 0.01 to 0.05 inch.

6. The balloon catheter of claim 1 in which said second balloon is made of poly(ethylene terephthalate) or nylon.

7. In a balloon catheter which comprises a catheter shaft which defines a first inflation lumen and a first, inflatable balloon mounted on said shaft in communication with said first inflation lumen, the improvement comprising, in combination:

a second inflation lumen spaced from said first lumen, defined by said catheter shaft, and a second balloon mounted on said shaft in communication with said second inflation lumen, said second balloon defining apertures sized to permit liquid flow outwardly through said second balloon, said second balloon being positioned generally radially outwardly about said first balloon in telescoping relation therewith, said apertures comprising slits in said second balloon wall having abutting sides in their normal, unstretched configuration, whereby medication may be delivered in controlled manner, said second balloon being spot-sealed to said first balloon in a plurality of spaced areas which are spaced from the ends of said balloons.

8. The catheter of claim 7 in which said catheter shaft defines a third lumen for receiving a guide wire.

9. The balloon catheter of claim 8 in which said second balloon is made of poly(ethylene terephthalate) or nylon.

10. In the method of expanding a partially occluded artery which comprises inserting a catheter shaft having an inner balloon carried thereon into said artery and inflating said balloon to expand the lumen of said artery, the improvement comprising, in combination:

a second, outer balloon being positioned about said inner balloon and spot-sealed to said inner balloon in a plurality of spaced areas which are spaced from the ends of said balloons, and including the steps of, prior to inserting said catheter shaft and inner and second balloons into said artery, applying suction to the interior of said inner balloon to collapse both it and the second balloon spot-sealed thereto, and, after inserting said catheter shaft and inner and second balloons into said artery, pressurizing said inner balloon to expand the lumen of said artery, and conveying medication through a catheter lumen to a space between the exterior of said inner balloon and said second, outer balloon positioned bout said inner balloon, and thereafter passing said medication through aperture means in said second outer balloon to provide medication to a site of stenosis in the artery in a manner correlated with the process of expanding the lumen of said artery.

11. The method of claim 10 in which the inner balloon is pressurized to expand the lumen of said artery simultaneously with the step of providing medication to the space between the inner and outer balloon, whereby said medication passes through the apertures of said outer balloon under pressure, to be forced into said stenosis site.

12. The method of claim 10 in which the pressure applied to said inner balloon is released, followed by administration of said medication to the space between the inner and outer balloons, whereby medication passes to said stenosis site through said apertures.

13. The method of claim 12 in which said inner balloon is again pressurized as said medication reaches the stenosis site, to force said medication into the stenosis site by expansion of said balloons.

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