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Goodin et al.

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(54) **STIFFENING MEMBER IN A RAPID EXCHANGE DILATION CATHETER**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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(63) Continuation of application No. 09/150,463, filed on Sep. 9, 1998, now Pat. No. 6,066,114.

(51) **Int. Cl.**[7] **A61M 25/00**

(52) **U.S. Cl.** **604/524**; 604/102.02; 604/96.01; 606/194

(58) **Field of Search** 604/96.01, 102.01, 604/102.02, 103, 523, 524; 606/192, 194

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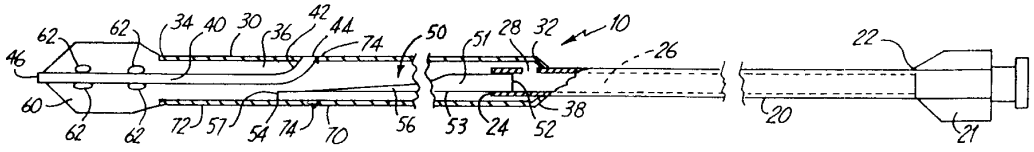
(57) **ABSTRACT**

A dilation catheter having a first shaft section, a second shaft section attached to the first shaft section, and an inflatable balloon attached to the second shaft section. A fluid pathway is defined through the catheter for inflation of the balloon. A guide wire lumen is provided in the second shaft section that can extend between the distal end of the balloon and a point distal of the first shaft section. A stiffening member is provided within the second shaft section of the dilation catheter to provide additional stiffness to the second shaft section. In a preferred embodiment, the stiffening member is attached at the distal end of the first shaft section to occlude the hollow passage of the first shaft section. In this embodiment, the first shaft section farther includes a fluid port that is proximal of the stiffening member and that extends between the hollow passage of the first shaft section and the exterior of the first shaft section. The second shaft section overlaps the first shaft section so that the hollow passage of the second shaft section is in fluid communication with the fluid port of the first shaft section to define the fluid flow pathway. The stiffening member is free from fixed interconnection at its distal end, and includes a linear tapered region along a portion of its length to provide a gradient of stiffness to the second shaft section along the length of the stiffening member.

6 Claims, 2 Drawing Sheets



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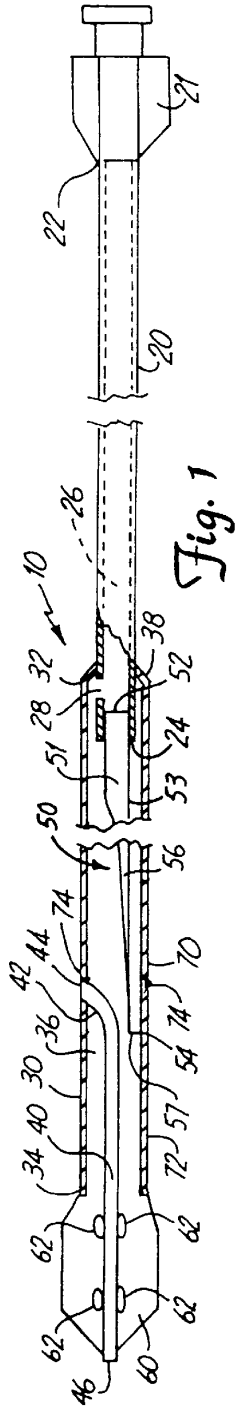

Fig. 1

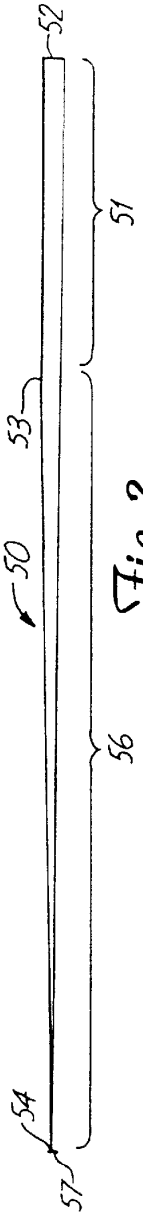

Fig. 2

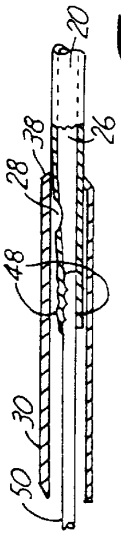

Fig. 3

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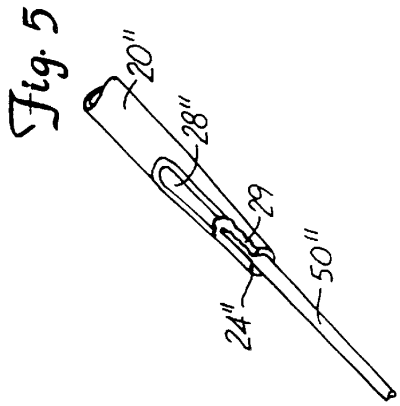

Fig. 5

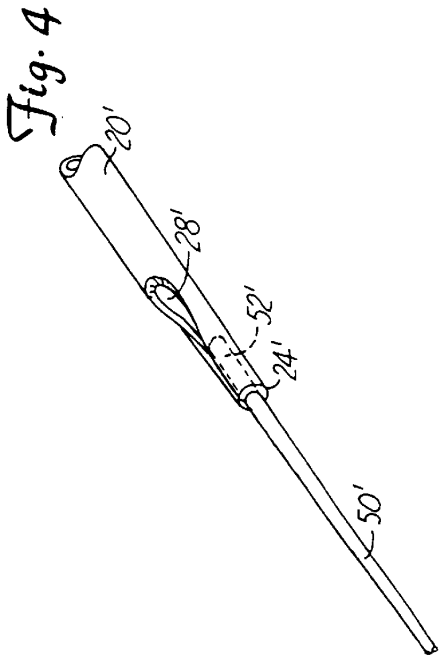

Fig. 4

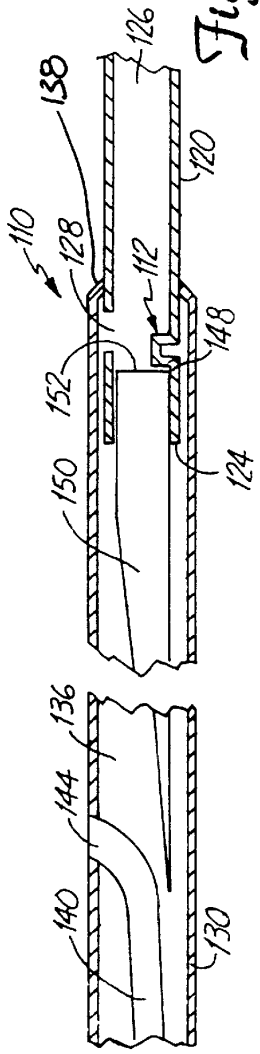

Fig. 6

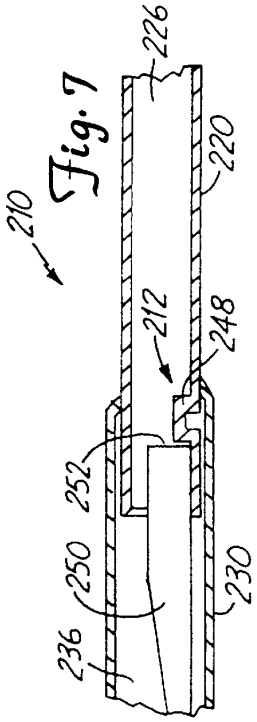

Fig. 7

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STIFFENING MEMBER IN A RAPID EXCHANGE DILATION CATHETER

REFERENCE TO RELATED APPLICATION

This application is a continuation of application Ser. No. 09/150,463 filed on Sep. 9, 1998, now U.S. Pat. No. 6,066,114, and which is hereby incorporated by reference in its entirety.

TECHNICAL FIELD

The present invention relates generally to medical devices for insertion and advancement through a body lumen. In particular, the present invention is a balloon catheter having a stiffening member for use in intravascular catheterization therapies.

BACKGROUND OF THE INVENTION

Intravascular catheters are presently in wide clinical use for a variety of diagnostic and therapeutic purposes. Intravascular catheterization therapies, such as percutaneous transluminal coronary angioplasty ("PTCA"), have been developed as alternatives to bypass surgery for treating vascular diseases or other conditions that occlude or reduce the lumen size of portions of a patient's vascular system. In particular, balloon angioplasty has proven to be a useful, and in many circumstances preferred, treatment for obstructive coronary diseases.

In a typical PTCA procedure, a guide catheter is introduced into a peripheral artery of a patient, such as a femoral artery through an incision at the groin. The guide catheter is advanced through the femoral or other peripheral artery to a desired coronary site. Typically, the guide catheter is advanced through the aorta until the distal end of the guide catheter is positioned adjacent to the coronary ostium for the coronary artery to be treated. A guide wire is introduced through the guide catheter, and a balloon dilation catheter is then introduced over the guide wire. More particularly, the guide wire is advanced past the distal end of the guide catheter within the lumen of the diseased vessel and manipulated across the region of stenosis. The balloon dilation catheter is then advanced past the distal end of the guide catheter over the guide wire until the balloon is positioned across the region of stenosis. The balloon is then inflated by supplying a fluid under pressure to the balloon through an inflation lumen in the balloon dilation catheter, which stretches the diseased vessel to re-establish acceptable blood flow through the vessel. Intravascular therapeutic and diagnostic procedures utilizing dilation catheters, such as PTCA, have achieved wide acceptance because of their effectiveness and because they involve a relatively minor surgical procedure as compared to coronary bypass surgery.

Advancing a catheter to position a balloon across a stenotic lesion can be a difficult and time consuming task due to the tortuous passages through which the catheter must be navigated by a physician. The efficacy of such procedures relies upon the balloon being precisely positioned at the desired location. Furthermore, catheters must be able to traverse tortuous pathways in a patient's vasculature in a manner as atraumatic to the patient as possible. To satisfy these requirements, catheters must balance a number of competing design criteria. Specifically, catheters should have a small profile to permit navigation through small body lumens. The catheter must be axially strong along its longitudinal length to give the catheter "pushability" for transmitting a longitudinal force along the catheter so a physician can push the catheter through the vascular system to the stenosis. At the same time, however, the catheter must be flexible so that the catheter has good "trackability" so as to be able to navigate the tortuous passages of a patient's vascular system.

To satisfy these competing design criteria, catheters typically have a stiff proximal portion and a flexible distal portion to which the inflation balloon is attached. The stiff proximal portion gives the catheter sufficient axial and longitudinal strength to give the catheter pushability, while the flexible distal portion permits the catheter to pass through tortuous, tight curvatures of the vasculature.

One type of balloon dilation catheter, commonly referred to as an "over-the-wire" catheter, typically includes a single lumen shaft that extends from the proximal end of the catheter to the distal end of the balloon. A guide wire is inserted into and extends along the length of the single lumen shaft. The guide wire is used to steer the catheter through the patient's vasculature by advancing the catheter over the previously inserted wire until the balloon is positioned at a desired treatment location. In this catheter, the guide wire must be inserted into and through the entire length of the dilation catheter prior to the catheter being inserted into a patient's vasculature. As such, the guide wire must protrude from the patient's body by a length greater than the length of the dilation catheter. Moreover, because the guide wire extends through the length of the catheter there is relatively large friction between the guide wire and the catheter. As a result, manipulation of an over-the-wire dilation catheter can be difficult.

A catheter design that alleviates these shortcomings is referred to as a "rapid-exchange" catheter. An example of a rapid-exchange catheter is described in United States Patent Reexamination Certificate B1 4,762,129 to Bonzel, the entire disclosure of which is hereby incorporated by reference for all purposes.

While catheters of the rapid-exchange type have been highly successful in PTCA procedures, the flexible distal portion of such catheters may kink and/or buckle when the catheter is subjected to high axial loads. A region of the catheter where such kinking and buckling can occur is the interface between the stiff proximal portion and the flexible distal portion of the catheter due to the change in stiffness at this interface. Attempts have been made to provide a structure that resists kinking and buckling in this region. Such structures are described in U.S. Pat. No. 5,156,594 to Keith, U.S. Pat. No. 5,658,251 to Ressemann et al, and U.S. Pat. No. 4,748,982 to Horzewski et al.

There is a continuing need for improved catheters, however. In particular, a rapid-exchange catheter having a stiffening member that provides a gradually varying stiffness at the interface between a stiff proximal portion and a flexible distal portion of the catheter is highly desirable. Such a stiffening member should be efficient to manufacture and use, and should be effective in providing sufficient stiffness to the interface between the proximal and distal portions of the catheter, while not unduly influencing the flexibility of the catheter.

SUMMARY OF THE INVENTION

The present invention is a dilation catheter for insertion into and advancement through a body lumen. In a first embodiment, the dilation catheter comprises a first shaft section having a proximal end, a distal end, and a first stiffness. The first shaft section also includes a hollow passage along a length of the first shaft section and a fluid

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port proximal of the distal end of the first shaft section. The fluid port extends between the hollow passage and the exterior surface of the first shaft section. In this manner the hollow passage and the fluid port permit fluid flow through a length of the first shaft section. A second shaft section has a proximal end which is attached to the first shaft section at a region adjacent the distal end of the first shaft section. The second shaft section further includes a distal portion and has a second stiffness that is less than the first stiffness of the first shaft section. The second shaft section includes a hollow passage along a length of the second shaft section that is in fluid communication with the fluid port of the first passage to define a fluid pathway between the length of the first shaft section and the length of the second shaft section. A dilation member is attached to the distal portion of the second shaft section and is fluidly coupled to the hollow passage of the length of the second shaft section. In this manner, the dilation member receives fluid.

The dilation catheter further includes a guide wire lumen in at least a portion of the second shaft section. The guide wire lumen includes a proximal end that extends through the second shaft section at a location distal of the first shaft section. The guide wire lumen permits the insertion of a guide wire into the lumen. A stiffening member is further provided in the dilation catheter. The stiffening member includes a proximal end that is attached to the distal end of the first shaft section so as to occlude the hollow passage of the first shaft section at a location distal of the first shaft section fluid port. The stiffening member extends into the hollow passage of the second shaft section to provide additional stiffness to the second shaft section of the dilation catheter at a region along the length of the stiffening member. The stiffening member preferably includes a tapered region having a gradient of stiffness along its length to provide a gradient of stiffness to the second shaft section.

In a second embodiment, the stiffening member of the dilation catheter is a "floating" member that is free from fixed interconnection with the first shaft section and the second shaft section. The first shaft section includes the features of the first shaft section of the first embodiment described above, and further includes an axial stop member that projects into the hollow passage of the length of the first shaft section to arrest the axial motion of the stiffening member in the proximal direction as the catheter is advanced in the body lumen. The stiffening member can have substantially the same cross sectional shape and area as the hollow passage of the length of the first shaft section to occlude the hollow passage when it engages the axial stop member. In this embodiment, the fluid pathway is defined by the hollow passage and fluid port of the first shaft section, and by the hollow passage of the length of the second shaft section.

In a third embodiment of the present invention, a balloon dilation catheter can include a stiffening member that has a cross sectional area that is less than the cross sectional area of the hollow passage of a first shaft section. In such an embodiment, the fluid flow pathway through the dilation catheter is preferably substantially linear between the first and second shaft sections, and the first shaft section need not include a fluid port.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a side view of a dilation catheter in accordance with the present invention shown partially in section to illustrate a stiffening member in a second shaft section for providing additional stiffness to the second shaft section as the catheter is advanced in a body lumen.

FIG. **2** is a side view of the stiffening member of the dilation catheter of FIG. **1**.

FIG. **3** is a detailed side view of a portion of the catheter of FIG. **1** shown in section to illustrate a first structure for attachment of the stiffening member to the first shaft section.

FIG. **4** is an isometric view of a portion of a first shaft section and a stiffening member in accordance with the present invention showing a second structure for attaching the stiffening member to the first shaft section.

FIG. **5** is an isometric view of a portion of a first shaft section and a stiffening member in accordance with the present invention showing a third structure for attaching the stiffening member to the first shaft section.

FIG. **6** is a sectional view of a portion of a second embodiment of a dilation catheter in accordance with the present invention shown in section to illustrate a floating stiffening member in a second shaft section that is free from fixed attachment to a first shaft section.

FIG. **7** is a side sectional view of a portion of a third embodiment of a dilation catheter in accordance with the present invention having a floating stiffening member.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

With reference to the Figures, and more specifically to FIGS. **1–3**, a dilation catheter **10** in accordance with the present invention is shown. Dilation catheter **10** is comprised of a first shaft section **20**, a second shaft section **30** that is attached to the first shaft section, such as hypotube **20**, and a dilation member, such as inflatable balloon **60**, attached to the second shaft section **30**. Dilation catheter **10** is adapted to be inserted into and advanced through a body lumen to position balloon **60** at a desired treatment site within a patient. Balloon **60** receives a fluid flow through catheter **10** for inflation of balloon **60** when positioned at the desired treatment location. In this manner, dilation catheter **10** can be used to treat arterial and coronary diseases by re-establishing acceptable blood flow through a partially occluded body lumen in a patient's vasculature.

Hypotube **20** of dilation catheter **10** includes a proximal end **22** and a distal end **24**. Proximal end **22** is attached to a hub **21** in a conventional manner. Hypotube **20** includes a hollow passage, such as lumen **26** (shown partially in phantom), along its length that is fluidly coupled to hub **21**. Hub **21** can be attached to an external source of fluid flow (not shown) to permit fluid flow into lumen **26** of hypotube **20**.

The second shaft section **30** includes a proximal end **32** that is attached to hypotube **20** at a region adjacent to the distal end **24**. Second shaft section **30** also includes a hollow passage, such as lumen **36**, along its length that is in fluid communication with the lumen **26** of the hypotube **20**. A distal end **34** of second shaft section **30** is sealingly attached to balloon **60** in such a manner that the lumen **36** of second shaft section **30** is fluidly coupled to balloon **60**. In this manner, balloon **60** can receive fluid through the catheter **10** for inflation of the balloon **60** at the desired treatment site within a patient's vasculature.

In order to provide pushability to dilation catheter **10**, a hypotube **20** is preferably used as the first shaft section in a known manner. Hypotube **20** is an elongated, thin walled metal tube, typically constructed of stainless steel, having lumen **26** along its length. Because of its thin walled construction, hypotube **20** provides a small diameter shaft section to permit passage of catheter **10** through a small

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