APPARATUS AND METHODS FOR TREATING OBSTRUCTIONS WITHIN BODY LUMENS

FIELD OF THE INVENTION

The present invention relates generally to apparatus for treating obstructive material and/or other obstructions within a body lumen of a patient, e.g., within a tubular graft, aorto-venous fistula, blood vessel, and the like. More particularly, the present invention relates to apparatus, e.g., balloon catheters, for infusing fluids into a body lumen, for removing or otherwise capturing thrombus or other obstructive material within a body lumen, and/or for dilating a body lumen, and to methods for making and using such apparatus.

BACKGROUND

Flow within a blood vessel or other body lumen within a patient's vasculature may become constricted or ultimately interrupted for a variety of reasons. For example, a vessel may gradually narrow due to inflammation and/or cell proliferation. In addition, thrombus may form due to such narrowing or other flow problems within a vessel.

For example, an aorto-venous graft may be implanted in an arm of a patient experiencing kidney failure, e.g., to facilitate dialysis treatment. Such grafts may be a fistula formed directly in the patient's body, e.g., through tissue between an adjacent artery and vein or other vessels, may be a xenograft implanted between two vessels, or may be a synthetic graft. Such grafts only have a limited life cycle due to inflammation, thrombus formation, and the like. Once such a graft becomes sufficiently occluded or otherwise deteriorates, a new graft must be implanted at a new location for subsequent treatment.

Accordingly, apparatus and methods for removing material from aorto-venous grafts, blood vessels, or other body lumens and/or otherwise treating body lumens would be useful.

SUMMARY

The present disclosure~~invention~~ is directed to apparatus for treating a body lumen of a patient, e.g., a tubular graft, aorto-venous fistula, blood vessel, and the like. More particularly, the present disclosure~~invention~~ is directed to apparatus for infusing fluids into a body lumen, for

compared to the distal end of the balloon such that, when the sealing member is directed proximally into the distal tip, the distal tip may expand and conform to the shape of the sealing member. When the sealing member is directed distally to open the outlet, the distal tip may resiliently return to its original size and/or shape.

In addition or alternatively, the elongate inner member may include a "J" or otherwise curved distal tip, e.g., extending distally from the sealing member or otherwise distally from the distal end of the inner member. The distal tip may be sufficiently flexible such that, when a guidewire or other instrument is advanced through the elongate member into the distal tip, the distal tip may be substantially straightened, which may facilitate advancing the apparatus over the guidewire. When the guidewire is withdrawn from the distal tip, the distal tip may resiliently return to its curved shape, which may facilitate locating and/or advancing the apparatus into a branch from a main vessel or other body lumen.

Optionally, any of the apparatus herein may include a helical member including a first end coupled to the tubular member distal end and a second end coupled to the elongate member distal end, the helical member extending helically around the elongate member within the balloon interior. The elongate member may be movable to a third position in which the elongate member distal end is directed towards the tubular member distal end to cause the helical member to compress axially and expand radially outwardly, thereby expanding the balloon to an expanded helical shape.

In accordance with still another embodiment, an apparatus is provided for treating a body lumen that includes an outer member including a proximal end, a distal end sized for introduction into a body lumen, and a first lumen extending between the proximal and distal ends; and an expandable balloon including a proximal end secured to the outer member distal end, and a distal end comprising an outlet, the balloon including an interior communicating with the first lumen and the balloon outlet. An inner member is slidably disposed within the first lumen, the inner member including a proximal end adjacent the outer member proximal end, a distal end extending from the balloon outlet, and a sealing member on the inner member distal end. The inner member may be movable between a first position wherein the sealing member is spaced from the balloon outlet such that fluid introduced through the first lumen passes through the balloon interior and out the balloon outlet, and ~~biased to~~ a second position wherein the sealing member substantially seals the balloon outlet such that fluid introduced through the first lumen enters the balloon interior

The helical member may be expanded and collapsed independent of movement of the inner member between the first and second positions. For example, a source of inflation media may be coupled to the apparatus for expanding the balloon before activating the second actuator to expand the helical member such that the helical member expands substantially unimpeded within the balloon interior. In addition or alternatively, a source of vacuum may communicate with the first lumen for collapsing the balloon after expanding the helical member such that the balloon conforms substantially to the shape of the helical member to adopt an expanded helical shape. In an exemplary embodiment, both the source of inflation media and the source of vacuum may be a single syringe for delivering fluid into and removing fluid from the balloon interior to expand and collapse the balloon.

In accordance with still another embodiment, an apparatus is provided for treating a body lumen that includes an outer member including a proximal end, a distal end sized for introduction into a body lumen, and a first lumen extending between the proximal end and an outlet in the distal end. An inner member may be slidably disposed within the first lumen that includes a proximal end adjacent the outer member proximal end, and a distal end adjacent the outer member distal end. The apparatus may also include an expandable balloon including proximal and distal ends secured to the outer member distal end, and an interior communicating with the first lumen via one or more openings in the outer member distal end.

A sealing member may be provided on the inner member distal end, and the inner member may be movable between a first position wherein the sealing member is spaced from the outlet such that fluid introduced through the first lumen exits the outlet, and a second position wherein the sealing member substantially seals the outlet such that fluid introduced through the first lumen enters the balloon interior to expand the balloon. Optionally, the inner member may be biased towards one of the first and second positions. For example, a spring element may be coupled between a spring stop in the balloon distal end and the inner member distal end for enhancing a seal between the sealing member and the outlet and/or for biasing the inner member towards the second position, e.g., to automatically seal the outlet with the sealing member.

In accordance with yet another embodiment, there is provided an apparatus for treating a body lumen, comprising: an outer member including a proximal end, a distal end sized for introduction into a body lumen, and a first lumen extending between the proximal and distal ends; an expandable balloon comprising a proximal end secured to the outer member distal end, and a distal end comprising an outlet, the balloon comprising an interior communicating with the first lumen and the balloon outlet; an inner member slidably disposed within the first lumen, the inner member comprising a proximal end adjacent the outer member proximal end, and a distal end extending from the balloon outlet; a sealing member on the inner member distal end, the inner member being movable between a first position wherein the sealing member is spaced from the balloon outlet such that the fluid introduced through the first lumen passes through the balloon interior and out the balloon outlet, and a second position wherein the sealing member substantially seals the balloon outlet such that fluid introduced through the first lumen enters the balloon interior to expand the balloon; a spring element comprising an intermediate portion fixed to the inner member within the balloon, a proximal portion extending proximally from the intermediate portion, and a distal portion extending distally from the intermediate portion, the distal portion coupled to the balloon distal end, thereby biasing the inner member towards the second position; and a helical member comprising a first end coupled to the other member distal end and a second end coupled to the proximal portion of the spring element, the helical member extending helically around the inner member within the balloon interior, the inner member movable to a third position in which the inner member distal end is directed towards the outer member distal end to cause the helical member to expand radially outwardly, the balloon overlying the helical member to define an expanded helical shape.

In accordance with still another embodiment, there is provided an apparatus for treating a body lumen, comprising: an elongate outer member including a proximal end, a distal end sized for introduction into a body lumen, and a first lumen extending between the proximal end and an outlet in the distal end; an inner member slidably disposed within the first lumen and having a cross-section smaller than the first lumen such that an annular lumen is defined between the outer and inner members between the outer member proximal end and the outlet, the inner member comprising a proximal end adjacent the outer member proximal end, and a distal end adjacent the outer member distal end; an expandable balloon comprising a proximal end secured to the outer member distal end and a distal end secured to the outer member distal end distal to the proximal end, the balloon comprising an interior communicating with the first lumen via one or more openings in the outer member distal end; a sealing member on the inner member distal end, the inner member being movable between a first position wherein the sealing member is spaced from the outlet such that fluid introduced through the first lumen exits the outlet, and a second position wherein the sealing member substantially seals the outlet such that fluid introduced through the first lumen enters the balloon interior to expand the balloon; and a spring element between a spring stop in the balloon distal end and the inner member distal end for biasing the inner member towards the second position.

In accordance with yet another embodiment, an apparatus is provided for treating a body lumen that includes an outer member including a proximal end, a distal end sized for introduction into a body lumen, and a first lumen extending between the proximal and distal ends, and an expandable balloon including a proximal end secured to the outer member

The inner member may be directed to a distal position, e.g., using an actuator on a proximal end of the outer member, consequently directing the sealing member away from and opening the outlet. Fluid may be delivered through the first lumen such that the fluid passes through the outlet into the body lumen. Optionally, the inner member may be directed to an intermediate position wherein some of the fluid is delivered into the body lumen and some of the fluid passes through one or more passages in the sealing member into the balloon interior to at least partially expand the balloon.

If desired, the inner member may be directed towards the proximal position to substantially seal the outlet with the sealing member, and fluid may be delivered through the first lumen with the outlet substantially sealed, thereby delivering the fluid through the one or more passages in the sealing member to expand the balloon from the contracted condition to an enlarged condition. The balloon may be used to dilate or otherwise treat a body lumen. After sufficient treatment, the fluid may be aspirated from the interior of the balloon through the one or more passages and first lumen to return the balloon to the contracted condition.

Other aspects and features of the present disclosure~~invention~~ will become apparent from consideration of the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

It will be appreciated that the exemplary apparatus shown in the drawings are not necessarily drawn to scale, with emphasis instead being placed on illustrating the various aspects and features of the illustrated embodiments.

FIG. 1 is a side view of a first exemplary embodiment of an apparatus including a balloon for treating a body lumen, the apparatus operable in a first mode for minimizing a profile of the apparatus for introduction into the body lumen, a second mode for infusing fluid into the body lumen, and a third mode for removing material within the body lumen.

FIG. 2A is a side view of the apparatus of FIG. 1 in the first mode for minimizing a profile of the apparatus for introduction into a body lumen.

FIG. 2B is a side view of the apparatus of FIG. 1 in the second mode for infusing fluid into a body lumen.

FIG. 2C is a side view of the apparatus of FIG. 1 in the third mode in which the balloon is expanded for removing material within a body lumen.