BRIEF SUMMARY OF THE INVENTION

[0004] Embodiments of the present invention provide an elastomeric distal tip for an adjustable length angioplasty balloon catheter sheath. The distal tip provides the unexpected advantage of returning to its original shape, or substantially its original shape, after balloon expansion and deflation, which helps prevent trauma to the vessel when the sheath is repositioned in the vessel.

[0005] In one embodiment, the elastomeric distal tip is attached to the distal end of an axially moveable retractable sheath that covers an inflatable balloon located at a distal end portion of the catheter. In some embodiments, the distal tip comprises an elastomeric plastic having a tensile strength of about 41 MPa to 50 MPa (megapascals), and a flexural modulus of between about 0.04 and 0.10 GPa (gigapascals). In some embodiments, the distal tip has a wall thickness of about 140 microns to about 191 microns. The distal portion of the retractable sheath is positioned concentrically around the inflatable balloon, such that the sheath surrounds the circumference of the folded (uninflated) balloon.

[0006] In one aspect, an angioplasty balloon catheter is provided, the catheter comprising an axially moveable retractable sheath and a distal tip attached to a distal end of the sheath, where the distal portion of the retractable sheath is positioned concentrically around an inflatable balloon. The distal tip of the sheath comprises an elastomeric plastic having a tensile strength of 41 MPa to 50 MPa, a flexural modulus of between 0.04-0.10 GPa (gigapascals) and a thickness of 140 microns to 191 microns.

[0007] In some embodiments, the distal tip is an elastomeric plastic comprising a copolymer of polyether and polyamide. In some cases, the distal tip is about 1.0 to 1.5 mm in axial length. The distal tip can be frustroconical in shape, having a greater diameter proximal end and a smaller diameter distal end. In some embodiments, the distal tip tapers in a distal direction (e.g., from the greater diameter proximal end to the smaller diameter distal end). In some embodiments, the distal tip comprises a lumen extending in a longitudinal direction from the proximal end to the distal end.

[0008] In some cases, the distal tip comprises an annular marker band disposed or located at the proximal end of the tip. The marker band typically has an inside diameter that is greater than the uninflated (folded) diameter of the balloon that is located on the distal end portion of the catheter. One function of the marker band is to help prevent the inflatable balloon from opening

prematurely, for example, prior to balloon expansion by a cardiologist. The marker band can also be configured to help prevent the distal tip from over-expanding during balloon inflation. In some embodiments, the marker band is about 0.04 inches in axial length. In some embodiments, the lumen of the distal tip has an axial (or inside) diameter that is at least 0.01 inches less than the inside diameter of the marker band.

[0009] Disclosed herein is a method for treating a vessel in a subject in need of treatment is provided. In some embodiments, the method comprises:

(a) positioning a balloon catheter in a vessel of the subject;

(b) extending an inflatable balloon or a portion thereof through a lumen of the distal tip;

(c) expanding the balloon or portion thereof to come in contact with a vessel wall;

(d) deflating the balloon; and

(e) retracting the deflated balloon through the lumen of the distal tip;

wherein the distal tip returns to its original shape after deflation of the balloon.

[0010] If the vessel has more than one lesion that needs treatment, the catheter can be repositioned at the appropriate location in the vessel without retracting the catheter from the subject, and steps (b) – (e) above are repeated. The distal tip returns to substantially its original shape after each deflation of the balloon. Thus, embodiments of the present invention provide a distal tip having unexpected advantages over the art.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Figure 1 illustrates one embodiment of a distal tip described herein. Fig. 1(A) shows an isometric view; Fig. 1(B) shows a side view; and Fig. 1(C) shows a section (A-A) view.

[0012] Figure 2 illustrates one embodiment of a retractable sheath assembly described herein.

[0013] Figure 3 illustrates one embodiment of a balloon catheter assembly described herein.

DEFINITIONS

[0014] Unless defined otherwise, technical and scientific terms used herein have the same meaning as commonly understood by a person of ordinary skill in the art. The term "a" or "an" is intended to mean "one or more." The term "comprise" and variations thereof such as "comprises" and "comprising," when preceding the recitation of a step or an element, are

11. The catheter of claim 7, wherein the marker band is about 0.04 inches in axial length.

12. The catheter of claim 7, wherein the lumen of the distal tip has an axial diameter that is at least 0.010 inches less than the inside diameter of the marker band.