

STENT DELIVERY AND DEPLOYMENT METHODS AND APPARATUS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority to U.S. Prov. App. 61/819,337 filed May 3, 2013, which is incorporated herein by reference in its entirety.

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FIELD OF THE INVENTION

[0002] The present invention relates generally to stent or scaffold delivery and deployment methods and apparatus. More particularly, the present invention relates to methods and apparatus for providing a smooth transition between a crimped stent and inflation balloon for facilitating intravascular delivery and deployment of the stent or scaffold.

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BACKGROUND OF THE INVENTION

[0003] When a scaffold or stent **12** is crimped upon an inflation balloon **14** for delivery via a catheter **10** within the vasculature, the edges **16** of the scaffold **12** may protrude radially at the balloon-scaffold transition, as shown in the side view of Fig. 1A, and prevent smooth intravascular navigation to the target site.

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[0004] Accordingly, it is desirable to provide for a smooth transition region between the balloon or catheter and the scaffold or stent crimped or otherwise secured upon the balloon.

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SUMMARY OF THE INVENTION

[0005] For scaffolds delivered and deployed intravascularly, one or several configurations may be employed for creating a smoother transition from balloon-to-scaffold. In one variation, a scaffold delivery apparatus may generally comprise a catheter having an inflatable balloon thereupon, an expandable scaffold secured upon the inflatable balloon, and a distal spacer positioned beneath or within the inflatable balloon at a location distal to the scaffold, wherein the distal spacer is tapered to widen from a distal end to a proximal end adjacent to the scaffold.

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[0006] In another variation, the scaffold delivery apparatus may generally comprise an inflatable balloon positioned upon a catheter, and an expandable scaffold secured upon the

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inflatable balloon, wherein a distal portion of the inflatable balloon defines a tapered transition adjacent to a distal end of the scaffold and a proximal portion of the inflatable balloon defines a tapered transition adjacent to the proximal end of the scaffold.

[0007] In another variation, the scaffold delivery apparatus may generally comprise an inflatable balloon positioned upon a catheter, and an expandable scaffold secured upon the inflatable balloon, wherein the scaffold defines at least a distal tapered edge.

[0008] In another variation, the scaffold delivery apparatus may generally comprise a catheter having an inflatable balloon thereupon, an expandable scaffold secured upon the inflatable balloon, a distal spacer positioned beneath or within the inflatable balloon at a location distal to the scaffold, wherein the distal spacer is tapered to widen from a distal end to a proximal end adjacent to the scaffold, and wherein a distal portion of the inflatable balloon defines a tapered transition adjacent to a distal end of the scaffold and a proximal portion of the inflatable balloon defines a tapered transition adjacent to the proximal end of the scaffold.

[0009] In another variation, the scaffold delivery apparatus may generally comprise a catheter having an inflatable balloon thereupon, an expandable scaffold secured upon the inflatable balloon, a distal spacer positioned beneath or within the inflatable balloon at a location distal to the scaffold, wherein the distal spacer is tapered to widen from a distal end to a proximal end adjacent to the scaffold, and wherein the scaffold defines at least a distal tapered edge.

[0010] In another variation, the scaffold delivery apparatus may generally comprise a catheter having an inflatable balloon thereupon, an expandable scaffold secured upon the inflatable balloon, wherein a distal portion of the inflatable balloon defines a tapered transition adjacent to a distal end of the scaffold and a proximal portion of the inflatable balloon defines a tapered transition adjacent to the proximal end of the scaffold, and wherein the scaffold defines at least a distal tapered edge.

[0011] In another variation, the scaffold delivery apparatus may generally comprise a catheter having an inflatable balloon thereupon, an expandable scaffold secured upon the inflatable balloon, a distal spacer positioned beneath or within the inflatable balloon at a location distal to the scaffold, wherein the distal spacer is tapered to widen from a distal end to a proximal end adjacent to the scaffold, wherein a distal portion of the inflatable balloon

defines a tapered transition adjacent to a distal end of the scaffold and a proximal portion of the inflatable balloon defines a tapered transition adjacent to the proximal end of the scaffold, and wherein the scaffold defines at least a distal tapered edge.

[0012] In another variation, the scaffold delivery method may generally comprise providing a catheter having an inflatable balloon thereupon, an expandable scaffold secured upon the inflatable balloon, and a distal spacer positioned beneath or within the inflatable balloon at a location distal to the scaffold, wherein the distal spacer is tapered to widen from a distal end to a proximal end adjacent to the scaffold, and inflating the balloon such that the scaffold is expanded radially beyond the distal spacer.

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BRIEF DESCRIPTION OF THE DRAWINGS

[0013] Fig. 1A shows a side view of a scaffold crimped upon a balloon illustrating the exposed scaffold edges which may hinder navigation of the assembly through the vasculature.

[0014] Figs. 1B and 1C show side views of one variation of an assembly having tapered spacers underneath or within the distal and proximal portions of the inflation balloon which prevent radial exposure of the scaffold edges.

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[0015] Figs. 2A and 2B show side views of another variation of an assembly where the distal and proximal portions of the inflation balloon abutting the scaffold may be specially shaped in a tapered manner to prevent radial exposure of the scaffold edges.

[0016] Figs. 3A and 3B show side views of yet another variation of an assembly where the distal and proximal portions of the scaffold may be shaped or tapered to present a smooth transition between the catheter, inflation balloon, and scaffold.

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DETAILED DESCRIPTION OF THE INVENTION

[0017] For scaffolds **12** with wall thicknesses greater than 50 μm , it is possible to improve intravascular navigation by creating a smoother transition from balloon-to-scaffold. One method of creating this smooth transition is to place spacers underneath or within the balloon **14** that will increase the diameter of balloon **14** just prior and/or just after the scaffold, as shown in the side view of Fig. 1B. A distal spacer **18** which is tapered to widen radially from its distal end to its proximal end may be positioned distal to the scaffold **12**. A similar proximal spacer **20** which is tapered to narrow radially from its distal end to its proximal end

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may be positioned proximal to the scaffold **12** as well. The widened ends of the spacers **18**, **20** may have a diameter which is similar or the same as the diameter of the crimped scaffold **12** secured upon the balloon **14** to prevent the scaffold edges **16** from protruding beyond the spacers **18**, **20** during intravascular delivery. Alternatively, depending on the crimped
5 diameter of the scaffold **12** the diameter of the crimped balloon **14** at the spacer regions can range from one wall thickness less than the crimped diameter of the scaffold **12** to two wall thickness greater than crimped diameter of the scaffold **12**.

[0018] When the scaffold **12** is to be deployed, the inflation balloon **14** may be simply expanded as normally done to expand the scaffold **12** beyond the diameter of the spacers **18**,
10 **20**, as shown in the side view of Fig. 1C.

[0019] Another variation is illustrated in the side views of Figs. 2A and 2B which show an inflation balloon **14** which is specially configured to define a step **30**, **32** in the balloon **14** to accommodate the diameter change due to scaffold wall thickness. The distal step **30** may be defined by the balloon **14** distal to the scaffold **12** and the proximal step **32**
15 may be defined by the balloon **14** proximal to the scaffold **12** such that the steps **30**, **32** abut the scaffold **12** in a tapered manner to present a smooth balloon-scaffold transition. The balloon **14** may be inflated normally for deployment into the body lumen.

[0020] Figs. 3A and 3B show side views of yet another variation where the distal **40** and proximal edges **42** of the scaffold **12** may be tapered. The transitioning scaffold edges
20 **40**, **42** can be created using methods including, e.g., angled laser beam, profile machining, control depth profile machining, using laser beam or other mechanisms, injection molding process, abrasive or material removal process, as well as other material removal/deposit processes. The balloon **14** may be simply inflated as normal for stent deployment, as shown in Fig. 3B.

[0021] Lastly, the stent **14** can also be made thinner to smooth the balloon-scaffold transition. The thinned stent **14** as well as each of the transition features described herein may be used in any number of combinations. For example, the spacers **18**, **20** may be used in combination with the tapered balloon edges **30**, **32** in a single assembly. Alternatively, these features may also be used in combination with the tapered scaffold edges **40**, **42** in any
30 variation.

[0022] Moreover, the transition features described herein may be used with any number of scaffolds or stent structures and particularly with polymeric substrate and stent assemblies as described in U.S. Pat. Apps. 10/867,617 filed June 15, 2004 (U.S. Pub. 2005/0021131); 13/476,853 filed May 21, 2012 (U.S. Pub. 2012/0232643); 13/476,858 filed
5 May 21, 2012 (U.S. Pub. 2012/0232644); 12/541,095 filed August 13, 2009 (U.S. Pub. 2010/0042202); U.S. Pats. 8,206,635; 8,206,636; and 8,309,023. Each of these references is incorporated herein by reference in its entirety for any purpose.

[0023] Modification of the above-described methods and devices for carrying out the invention, and variations of aspects of the invention that are obvious to those of skill in the
10 arts are intended to be within the scope of this disclosure. Moreover, various combinations of aspects between examples are also contemplated and are considered to be within the scope of this disclosure as well.

CLAIMS

What is claimed is:

1. A scaffold delivery apparatus, comprising:

5 a catheter having an inflatable balloon thereupon;

an expandable scaffold secured upon the inflatable balloon; and

a distal spacer positioned beneath or within the inflatable balloon at a location distal to the scaffold,

wherein the distal spacer is tapered to widen from a distal end to a proximal end

10 adjacent to the scaffold.

2. The apparatus of claim 1 further comprising a proximal spacer positioned beneath or within the inflatable balloon at a location proximal to the scaffold.

15 3. The apparatus of claim 2 wherein the proximal spacer is tapered to narrow from a distal end adjacent to the scaffold to a proximal end.

4. The apparatus of claim 1 wherein a widened end of the distal spacer defines a diameter which is similar to a diameter of the scaffold when crimped upon the balloon to prevent scaffold edges from protruding beyond the spacer.

20 5. The apparatus of claim 4 wherein expansion of the scaffold for deployment expands the scaffold to a second diameter which is larger than the diameter of the spacer.

25 6. The apparatus of claim 1 wherein a distal portion of the inflatable balloon defines a tapered transition adjacent to a distal end of the scaffold and a proximal portion of the inflatable balloon defines a tapered transition adjacent to the proximal end of the scaffold.

7. The apparatus of claim 1 wherein the scaffold defines at least a distal tapered edge.

30 8. A scaffold delivery apparatus, comprising:

an inflatable balloon positioned upon a catheter; and

an expandable scaffold secured upon the inflatable balloon,

wherein the scaffold defines at least a distal tapered edge.

9. The apparatus of claim 8 further comprising a distal spacer positioned beneath or within the inflatable balloon at a location distal to the scaffold, wherein the distal spacer is tapered to widen from a distal end to a proximal end adjacent to the scaffold, and

5 10. The apparatus of claim 8 wherein a distal portion of the inflatable balloon defines a tapered transition adjacent to a distal end of the scaffold and a proximal portion of the inflatable balloon defines a tapered transition adjacent to the proximal end of the scaffold, and wherein the scaffold defines at least a distal tapered edge.

10 11. The apparatus of claim 8 further comprising a distal spacer positioned beneath or within the inflatable balloon at a location distal to the scaffold,

 wherein the distal spacer is tapered to widen from a distal end to a proximal end adjacent to the scaffold,

 wherein a distal portion of the inflatable balloon defines a tapered transition adjacent
15 to a distal end of the scaffold and a proximal portion of the inflatable balloon defines a tapered transition adjacent to the proximal end of the scaffold, and
 wherein the scaffold defines at least a distal tapered edge.

 12. A scaffold delivery apparatus, comprising:
20 an inflatable balloon positioned upon a catheter; and
 an expandable scaffold secured upon the inflatable balloon,
 wherein a distal portion of the inflatable balloon defines a tapered transition adjacent to a distal end of the scaffold and a proximal portion of the inflatable balloon defines a tapered transition adjacent to the proximal end of the scaffold.

25 13. A scaffold delivery apparatus, comprising:
 a catheter having an inflatable balloon thereupon;
 an expandable scaffold secured upon the inflatable balloon;
 a distal spacer positioned beneath or within the inflatable balloon at a location distal to
30 the scaffold,
 wherein the distal spacer is tapered to widen from a distal end to a proximal end adjacent to the scaffold, and

wherein a distal portion of the inflatable balloon defines a tapered transition adjacent to a distal end of the scaffold and a proximal portion of the inflatable balloon defines a tapered transition adjacent to the proximal end of the scaffold.

5 14. A scaffold delivery apparatus, comprising:
a catheter having an inflatable balloon thereupon;
an expandable scaffold secured upon the inflatable balloon;
a distal spacer positioned beneath or within the inflatable balloon at a location distal to the scaffold,

10 wherein the distal spacer is tapered to widen from a distal end to a proximal end adjacent to the scaffold, and
wherein the scaffold defines at least a distal tapered edge.

15 15. A scaffold delivery apparatus, comprising:
a catheter having an inflatable balloon thereupon;
an expandable scaffold secured upon the inflatable balloon;
wherein a distal portion of the inflatable balloon defines a tapered transition adjacent to a distal end of the scaffold and a proximal portion of the inflatable balloon defines a tapered transition adjacent to the proximal end of the scaffold, and
20 wherein the scaffold defines at least a distal tapered edge.

16. A scaffold delivery apparatus, comprising:
a catheter having an inflatable balloon thereupon;
an expandable scaffold secured upon the inflatable balloon;
25 a distal spacer positioned beneath or within the inflatable balloon at a location distal to the scaffold,
wherein the distal spacer is tapered to widen from a distal end to a proximal end adjacent to the scaffold,
wherein a distal portion of the inflatable balloon defines a tapered transition adjacent
30 to a distal end of the scaffold and a proximal portion of the inflatable balloon defines a tapered transition adjacent to the proximal end of the scaffold, and
wherein the scaffold defines at least a distal tapered edge.

17. A method of delivery a scaffold, comprising:

providing a catheter having an inflatable balloon thereupon, an expandable scaffold secured upon the inflatable balloon, and a distal spacer positioned beneath or within the inflatable balloon at a location distal to the scaffold, wherein the distal spacer is tapered to

5 widen from a distal end to a proximal end adjacent to the scaffold; and,

inflating the balloon such that the scaffold is expanded radially beyond the distal spacer.

18. The apparatus of claim 15 wherein the catheter comprises an intravascular

10 catheter.

19. The apparatus of claim 15 wherein the expandable scaffold has a wall thickness greater than 50 μm .

15 20. The apparatus of claim 15 wherein the expandable scaffold is crimped upon the inflatable balloon which is deflated.

21. The apparatus of claim 15 wherein the distal portion and the proximal portion of the inflatable balloon each define a step in the inflatable balloon to accommodate a diameter
20 change due to a wall thickness of the scaffold.

22. The apparatus of claim 21 wherein the steps abut the scaffold in a tapered manner to present a smooth balloon-scaffold transition.