Title: STENT DELIVERY AND DEPLOYMENT METHODS AND APPARATUS

Abstract: For scaffolds delivered and deployed intravascularly, one or several configurations may be employed for creating a smoother transition from balloon-to-scaffold. For instance, one or more spacers may be positioned in proximity to the scaffold. Alternatively, portions of the inflatable balloon may be configured to provide a smooth transition. In another alternative, the stent edges may be shaped to provide a smooth transition. In yet other variations, any number of different combinations of such features may be employed.
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.

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.

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.

[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.

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.

[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
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.

[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.

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
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 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.

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, 20, as shown in the side view of Fig. 1C.

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 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.

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 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.

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 variation.
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 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.

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 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:
   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.

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.

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.

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.

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.

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

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.

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 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:
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.

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
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.

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,

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. 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

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;
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.

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 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.
Exposed scaffold edge may hinder navigation

FIG. 1A

Spacers underneath the balloon prevent scaffold edges protruding

FIG. 1B

Balloon inflated

FIG. 1C
Stent edges shaped to smooth transition

Balloon inflated

FIG. 3A

FIG. 3B
### INTERNATIONAL SEARCH REPORT

**International application No.**

PCT/US14/34038

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### A. CLASSIFICATION OF SUBJECT MATTER

**IPC(8) -** A61F 2/00, 2/95; A61M 25/10 (2014.01)

**CPC -** A61F 2/00, 2002/0022: A61M25/00, 25/10

According to International Patent Classification (IPC) or to both national classification and IPC

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### B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

**IPC(8) -** A61F 2/00, 2/02, 2/82, 2/95; A61M 25/10, 25/04 (2014.01)


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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)


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### C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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<tr>
<td>X</td>
<td>US 8152819 B2 (EUTENEUER CL et al.) April 10, 2012; abstract; figures 1-5; column 3, lines 37-50; column 4, lines 1-12, 61-67; column 5, lines 12-18; claims 1-2, 9</td>
<td>1-6, 12, 13, 17; 7-11, 14-16</td>
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<tr>
<td>Y</td>
<td>US 8,057,526 B2 (PACETTI SD) November 15, 2011; figure 7; column 11, lines 45-50</td>
<td>7-11, 14-16</td>
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<tr>
<td>A</td>
<td>US 5639274 A (FISCHELL RE et al.) June 17, 1997; entire document</td>
<td>1</td>
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<td>A</td>
<td>US 6,106530 A (HARADA K) August 22, 2000; entire document</td>
<td>1</td>
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<tr>
<td>A</td>
<td>US 6,585,747 B1 (LIMON TA et al.) July 1, 2003; entire document</td>
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Further documents are listed in the continuation of Box C.

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* Special categories of cited documents:
  - "A" - document defining the general state of the art which is not considered to be of particular relevance
  - "E" - earlier application or patent published on or after the international filing date
  - "L" - document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason as specified
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  - "P" - document published prior to the international filing date but later than the priority date claimed
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  - "&" - document member of the same patent family

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**Date of the actual completion of the international search**

30 August 2014 (30.08.2014)

**Date of mailing of the international search report**

23 SEP 2014

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**Name and mailing address of the ISA/US**

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Form PCT/ISA/210 (second sheet) (July 2009)