A medical device, specifically a stenting device for use in vascular surgery and in particular, for use with bifurcated blood vessels. The device comprising an expandable stent, having a proximal region and a distal region, and a balloon catheter comprising a balloon having a proximal section with a first diameter and a distal section with a second diameter characterised in that the proximal and distal sections of the balloon, when expanded, form an eccentric shape.

**Figure 1A**

1. Proximal section 
2. Distal section 
3. Expansion of balloon 
4. Stent 
5. Stent deployment

**Abstract:**

A medical device, specifically a stenting device for use in vascular surgery and in particular, for use with bifurcated blood vessels. The device comprising an expandable stent, having a proximal region and a distal region, and a balloon catheter comprising a balloon having a proximal section with a first diameter and a distal section with a second diameter characterised in that the proximal and distal sections of the balloon, when expanded, form an eccentric shape.
STENTING DEVICE COMPRISING A BALLOON WITH AN ECCENTRIC SHAPE

Field of Invention

[0001] The invention relates to a medical device, specifically a stenting device for use in vascular surgery and in particular, for use with bifurcated blood vessels.

Background

[0002] Many existing stent technologies exist in order to ensure the proper flowing of blood through narrowing blood vessels. A number of surgical techniques have been developed over the years to introduce various types of stents into different vascular structures. Blockages around bifurcated blood vessels pose a particular problem for stenting technology in that the stent needs to hold open three separate sections of vasculature. Surgical techniques for doing so include "crush" stenting techniques and "T" stenting techniques. One particular technique, the mini-culotte technique, involves introducing a first stent into the typically smaller of the two branched vessels at the bifurcation (herein referred to as the "side branch"), followed by the introduction of a second overlapping stent into the other typically larger branch (herein referred to as the "main branch"). Various shortcomings exist with this technique and the stents adapted for this purpose. In particular, the struts of the stent introduced into the side branch can hinder the insertion and expansion of a second stent (introduced after insertion of the first stent) in the main branch. Further, having two overlapping stents in a vessel increases the risk of complications such as stent thrombosis or in-stent restenosis.

[0003] Furthermore, many stents adapted for bifurcated vasculature are difficult to use. Most dedicated bifurcation stents require a complex delivery system based on the simultaneous use of two wires and two balloons and/or the presence of several markers on the delivery system for a precise deployment which make the procedure very complex and requires high levels of training.

[0004] Where balloons of one common diameter are used, it is either the case that, when the balloon is expanded, the stent in the main vessel is under expanded or the stent in the side branch is over expanded. Various "bottle-shaped" stents have been used in the past (i.e.
wherein the balloon and/or the stent tapers to a reduced diameter in the distal portion wherein both the proximal and distal sections are concentrically aligned) but these do not provide effective deployment. The stent or portions thereof will not be adequately pressed up against the vessel wall at the corner of the bifurcation.

[0005] Accordingly, what is required is a device which is able to provide optimal support to the bifurcated blood vessel, whilst at the same time providing an easier to use stenting system which does not suffer from the above-mentioned shortcomings. The invention is intended to overcome or at least ameliorate some of these problems.

**Summary of Invention**

[0006] There is provided in the first aspect of the invention, a stenting device for vascular surgery, comprising an expandable stent, having a proximal region and a distal region; a balloon catheter, the balloon catheter comprising a balloon having a proximal section with a first diameter and a distal section with a second diameter, characterised in that the proximal and distal sections of the balloon forms an eccentric shape. The inventors have found that using a balloon catheter, wherein the proximal and distal sections of the balloon have an eccentric shape, ensures that that expansion of the stent into a branch of a bifurcated blood vessel occurs more effectively.

[0007] The eccentric arrangement ensures excellent expansion of the distal stent region including at the junction between the main vessel and the side branch. This not only ensures a good result and optimal stent apposition to the vessel wall in the side branch and main vessel but also improves the ease with which a second stent can be incorporated into the main branch via the gap between the proximal and distal regions of the stent.

[0008] The term "eccentric shape" is intended to mean that the distal and proximal sections of the balloon are substantially parallel with one another but are not concentrically located. Typically the eccentric shape is an eccentric reducer-like shape. This is advantageous as a side branch of the bifurcated blood vessel is typically narrower in diameter than the main vessel from which it branches off.
The term "eccentric reducer-like shape" is intended to mean that the balloon, in its inflated form, takes on a shape similar to that of an eccentric reducer, such as the type used in conventional water plumbing systems. For example, it is typically the case that the first diameter (of the proximal section) is greater than the second diameter (of the distal section). This creates a step down in diameter between the proximal section and the distal section of the balloon. In other words, both the distal and proximal sections are not concentrically located. It is typically the case that the proximal section and the distal section are joined so that they form one common, straight wall along substantially the entire length of the balloon (i.e. bridging both the proximal and distal sections of the balloon) such as is shown in FIGURE 1A. The common wall need not be exactly parallel and uniformly spaced from the central axis of the proximal or distal sections of the balloon.

It is typically the case that the stent is for use with bifurcated blood vessels and furthermore is typically adapted to introduce a stent into the side branch of a bifurcated vessel. The bifurcated vessels may be peripheral or main vessel (arteries or veins), and are typically peripheral arteries. Often, the device is adapted to deliver the stent into the main vessel and side branch only i.e. the bifurcated vessel is stented via only one of the branches. It is also the case that the balloon of the balloon catheter typically comprises one proximal section and one distal section. Further, the stent used with the stenting device of the invention also typically has one proximal region and one distal region. The stenting device typically comprises one balloon catheter and each balloon catheter typically comprises one balloon. Furthermore, each balloon catheter typically comprises one guidewire.

It is typically the case that the proximal and distal sections of the balloon have a generally cylindrical shape (i.e. a cross section of the balloon in its inflated configuration perpendicular to the axis of the guidewire is generally circular). It is also typically the case that the stent has a generally cylindrical shape. However, other possible configurations are envisaged, such as stents having a star shaped cross-section or polygonal cross-section and there is no particular limitation on the specific shape of the cross-section provided that the stent is capable of expanding and holding its structure in order to maintain a conduit in an open configuration.

It is typically the case that the proximal region of the stent and the distal region of the stent are connected to one another by one or more linkers. The stent for use with the
invention is typically a balloon expandable stent but may in some instances be a self-expanding stent. Typically, the number of linkers is in the range one to ten, preferably less than four. In one embodiment of the invention, two linkers are provided between the proximal region and distal region of the stent. Embodiments comprising only one linker are also provided. The linker(s) connect the proximal and distal regions of the stent so that each region may pivot with respect to one another. The linkers are typically strands of flexible material and they may be made from the same material as the proximal and/or distal regions of the stent. The linker(s) may function as a hinge between the proximal and distal regions of the stent.

[0013] Linking the proximal region and distal regions together by means of one or more linkers ensures that when the stent is positioned in the bifurcated vessel (with the distal region entering into the side branch and the proximal region in the main vessel) a gap in the stent is present in order to allow blood (or other materials, such as another stent) to pass through into the main branch via the main vessel. This is illustrated in FIGURE 2B. This arrangement is particularly favourable when combined with the generally eccentric reducer-like shaped balloon described above, as the balloon ensures that the distal portion of the stent firmly contacts the wall of the side branch.

[0014] It is also typically the case that the device is equipped with one or more radiopaque markers. These markers allow the position of the device to be monitored within a patient so that the device can be accurately located at the site of bifurcation. Typically, the radiopaque markers are associated with one or more of the linkers. This is usually the case as the device is intended to be positioned so that the linkers line up with the junction between the main vessel and the side branch of the bifurcation.

[0015] The radiopaque markers are not limited to any particular material provided they can be observed during a procedure. The skilled person would appreciate that a number of different radiopaque markers can be used in order for the position of the stent to be tracked as it passes through the body. The radiopaque materials typically comprise materials such as platinum and iridium.

[0016] The diameter of the proximal region of the stent is typically greater than the diameter of the distal region of the stent. Typically, the diameter of the proximal region is in the range
3.0mm to 5.0mm. Furthermore, the diameter of the distal region of the stent is typically in the range 2.0mm to 3.0mm.

[0017] It is typically the case that the length of the distal region of the stent is greater than the length of the proximal region of the stent. Typically the distal region has a length in the range 10.0mm to 30.0mm, often in the range 15.0 to 20.0mm. It is also typical that the proximal region has a length in the range 2.0mm to 10.0mm, and often in the range 4.0mm to 6.0mm. The skilled person would appreciate that different ranges of diameters, for both the stent and the balloon, could be employed depending on the particular type of vessel or vessels in the body for which the stent is intended (such as coronary arteries, peripheral arteries and veins).

[0018] Further, it is often the case that the proximal region of the stent has a greater number of struts than the distal region of the stent in particular where the distal region has a reduced diameter with respect to the proximal region. Typically, the proximal region of the stent has six to ten struts, whereas the distal region typically has four to eight struts. The inventors have found that having struts within these particular ranges ensures good contact between the stent and the vasculature and ensures an even material to artery ratio. This ensures a consistent radial strength for both the proximal and distal regions of the stent. If the metal to vessel ratio is too high it is more likely that stent thrombosis or in-stent resterosis will occur.

[0019] The stent is typically mounted on the balloon of the balloon catheter and is typically cramped to the balloon of the balloon catheter. It is typically the case that the stent is mounted onto the balloon such that the radiopaque markers are positioned at the transition point between the distal section and proximal section of the balloon. The term "transition point" is not intended to refer to a single fixed point and depends to a large extent on the shape of the balloon. For instance, the reduction in size between the proximal section and the distal section of the balloon could occur over a very short length (less than 0.5mm) or could occur over longer lengths, such as 1mm to 5mm. The skilled person would appreciate that this would vary depending on the size and shape of the bifurcated vessels to be treated. The skilled person would appreciate that the markers are located in order to best assist a surgeon in positioning the stent in the bifurcated vessel. Often, a radiopaque marker will be positioned on each of the proximal end, distal end and transition point of the stent. Alternatively, only two markers may be used at the proximal and distal ends of the stent.
Further, it is typically the case that the radiopaque markers are located against the edge of the balloon which, in use, abuts against the junction between the main vessel and the side branch. See for instance common wall 11 in Figure 1a which forms one of the walls of the distal and proximal sections of the balloon where there is no reduction or "step down" in the spacing of this wall from the guidewire at the transition between the distal section and the proximal section of the balloon. This ensures that when the balloon is expanded, the radiopaque markers are located at the junction between the main vessel and the side branch ensuring that the markers become pressed into the vessel wall.

The material from which the stent is made can be any biologically suitable material. Any conventional stent materials are envisaged provided it is biocompatible and it is preferable for the stent material to be suitable for use as a balloon expanding stent. Typically, the material from which the stent is made has no elastic memory as it is desired for the stent to remain in a deployed configuration after the balloon has been deflated and removed. The stent materials may have elastic memory in some situations where such materials are arranged to bias the stent into a deployed configuration. However, in such embodiments the stent would typically need to be restrained when introduced into the target vessels to prevent premature deployment. Typical materials from which the stent may be made include metals and alloys of metals, bioabsorbable materials or combinations thereof. Typical metals include stainless steel, shape memory alloys such as Nitinol, cobalt-chromium or combinations thereof. Examples of typical bioabsorbable materials suitable for use in the invention include poly-L-lactide, magnesium or combinations thereof.

It is also the case that the stent may further comprise a coating material. Suitable coatings for use in the invention include polymers, drugs, anti-restenotic agents or combinations thereof generally known in the art. In one example, the core of struts or filaments from which the stent is comprised will be a metal, typically magnesium, and the coating will be a bio-reabsorbable material, typically poly-L-lactide.

There is also provided in the second aspect of the invention, a method of stenting a bifurcated blood vessel having a main vessel and a side branch comprising the steps of:

(i) introducing the device according to the first aspect of the invention into the bifurcated blood vessel so that the proximal region is positioned at the main vessel and the distal region is positioned in the side branch;
(ii) inflating the balloon catheter in order to deploy the stent;
(iii) deflating the balloon catheter; and
(iv) extracting the balloon catheter.

[0024] This approach is very similar to conventional stent application techniques and thus makes the device easier to install than many existing bifurcation specific. This reduces the level of training required by medical professionals.

[0025] In addition, unless otherwise stated, all numerical indices provided in the specification are intended to be modified by the term "about". Further, unless stated to the contrary, the disclosure of alternative values for the upper and lower ends of the permitted range of a parameter, is to be construed as an implied statement that each intermediate value of said parameter, lying between the smaller and greater of the alternatives, is itself also disclosed as a possible value for the parameter. Unless otherwise stated, each of the integers described herein may be used in combination with any other integers as would be understood by the skilled person. Further, although all aspects of the invention preferably "comprise" the described features in relation to that aspect, it is specifically envisaged that they may "consist" or "consist essentially" of those features outlined in the description and claims. Unless otherwise stated, all terms are to be construed according to their commonly understood meaning in the art.

**Description of Figures**

[0026] The invention will now be described with reference to the accompanying figures;

FIGURE 1A shows a cross-section (BB) of the balloon catheter along the length of the catheter wherein the balloon catheter is in its inflated configuration.
FIGURE 1B shows an end-on view of the balloon catheter from the distal end of the balloon catheter when the balloon catheter is in its inflated configuration.
FIGURE 2A shows the layout of the stent in its unfurled configuration.
FIGURE 2B shows the stent in its deployed configuration within a bifurcated blood vessel.
FIGURE 3A and 3B show cross-sections of the portion of the linkers between the proximal and distal regions of the stent containing a radiopaque marker.
FIGURE 4 shows a side view of a linker between the proximal and distal regions of the stent.
Specific Description

[0027] FIGURE 1A shows a cross-section (BB) of the balloon catheter 10 in its inflated configuration. The balloon catheter comprises a guidewire 1 to which is attached a balloon 2 having a first proximal section 3, a transitional section 5 and a distal section 7. The diameter of the distal section 7 is less than the diameter of the proximal section 3 and there is a gradual transition in diameter along the length of the transitional section 5. This results in an overall eccentric reducer-like shape. Accordingly, when the balloon 2 is inflated, a common wall 11 is formed along the full length of the balloon 2 in each of the proximal section 3, transitional section 5 and distal section 7. The opposing wall to common wall 11 is composed of a first wall section 9 in the proximal section 3, a second wall section 13 in the distal section 7 separated by the transitional section 5 of the balloon catheter 10. Whilst the first and second wall portions 9, 13 are parallel with one another, they are spaced differently with respect to the guidewire 1.

[0028] FIGURE 1B shows the end-on view from the distal section of the balloon catheter. The proximal and distal sections of the balloon of the balloon catheter have a generally circular cross-section (AA).

[0029] FIGURE 2A shows an expanded form of the stent 20 of the invention. The stent comprises a first proximal region 21 and a longer distal region 23 which are linked together by means of two linkers 29 each containing a radiopaque marker 31. The length of the proximal region 21 is about 3.5mm in length and the length of the distal region 23 is about 23.0mm in length. The proximal region 21 of the stent has an eight cell configuration whereas the distal region 23 has a six cell configuration. The circumference 25 of the stent 20 is also shown and in the expanded form the diameter of the distal region 23 is either 2.5mm 2.75mm or 3.0mm when the proximal section 21 is 3.5mm, 3.75mm and 4.0mm. The proximal region may also have a larger diameter of 4.25 mm or 4.50 mm.

[0030] FIGURE 2B shows the stent in a deployed configuration in a bifurcated blood vessel 30. The bifurcated blood vessel has a main vessel 4 which splits into two sub-branches. A side branch 6 and the continuation of the main vessel, herein referred to as the main branch 8. The stent 20 is deployed so that the proximal region 21 of the stent 20 is located within the
main branch 4 and the distal region 23 of the stent 20 is located within the side branch 6. The stent, in use, is positioned so that the linker 29 and radiopaque markers 31 are positioned against the vessel wall at the junction between the main vessel 4 and the side branch 6. If necessary, a further stent can be introduced through lumen 12 in order to insert a stent into the main branch 8 through the main vessel 4 via the opening created between the proximal region 2 1 and the distal region 23.

[0031] FIGURES 3A AND 3B show cross-sections along the length of the linker 29 and across the linker 29 respectively at the position of the radiopaque marker 31. The radiopaque marker 31 is a platinum iridium marker and has a diameter of approximately 0.08mm.

[0032] FIGURE 4 shows a close-up image of the linker 29 and radiopaque marker 31 wherein the radiopaque marker 31 is located along the length of linker 29.

[0033] It should be appreciated that the stent of the invention and the method of treating a bifurcating blood vessel described herein are capable of being implemented in a number of ways, only a few of which have been illustrated and described herein.
Claims

1. A stenting device for vascular surgery comprising:
an expandable stent having a proximal region and a distal region; and
a balloon catheter comprising a balloon having a proximal section with a first
diameter and a distal section with a second diameter characterised in that the proximal
and distal sections of the balloon, when expanded, form an eccentric shape.

2. A device according to claim 1, wherein the eccentric shape is an eccentric reducer-
like shape.

3. A device according to claim 1 or 2, wherein the proximal region and the distal region
of the stent are connected by one or more linkers.

4. A device according to claim 1 to 3, wherein the device comprises one or more
radiopaque markers.

5. A device according to claim 4, wherein the one or more radiopaque markers are
associated with the one or more linkers.

6. A device according to any preceding claim, wherein the diameter of the proximal
region of the stent is greater than the diameter of the distal region of the stent.

7. A device according to any preceding claim, wherein the diameter of the proximal
region of the stent is in the range 3.0mm to 5.0mm.

8. A device according to any preceding claim, wherein the diameter of the distal region
of the stent is in the range 2.0mm to 3.0mm.

9. A device according to any preceding claim, wherein the length of the distal region of
the stent is greater than the length of the proximal region of the stent.

10. A device according to any preceding claim, wherein the proximal region of the stent
has 6 to 10 struts.

11. A device according to any preceding claim, wherein the distal region of the stent has 4
to 8 struts.

12. A device according to any preceding claim, wherein the stent is crimped to the
balloon catheter.

13. A device according to any preceding claim, wherein the stent is made from a material
selected from: metals, bio-absorbable materials, shape memory materials or
combinations thereof.

14. A device according to claim 13, wherein the metal is selected from: stainless steel,
Nitinol, cobalt-chromium or combinations thereof.
15. A device according to claim 13 or 14, wherein the bio-absorbable materials are selected from: poly-L-lactide, magnesium or combinations thereof.

16. A device according to any preceding claim, wherein the stent further comprises a coating.

17. A device according to claim 16, wherein the coating is polymers, drugs, anti-restenotic agents or combinations thereof.

18. A method of stenting a bifurcated blood vessel having a main vessel and a side branch comprising the steps of:

(i) introducing the device according to any preceding claim into the bifurcated blood vessel so that the proximal region is positioned in the main vessel and the distal region is positioned in the side branch;

(ii) inflating the balloon catheter in order to deploy the stent;

(iii) deflating the balloon catheter; and

(iv) extracting the balloon catheter.

19. A device as described in the accompanying description and drawings.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F2/954
A61F2/958
A61F2/82
A61F2/915

ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

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

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

EPO-internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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"A" document member of the same patent family

Date of the actual completion of the international search

15 April 2016

Date of mailing of the international search report

22/04/2016

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016

Authorized officer

Mary, Celine
## DOCUMENTS CONSIDERED TO BE RELEVANT

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### Box No. II  Observations where certain claims were found unsearable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. **X** Claims Nos.: 10, because they relate to subject matter not required to be searched by this Authority, namely:

   **Rule 39.1(iv) PCT** - Method for treatment of the human or animal body by surgery

2. **☐** Claims Nos.:

   because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. **☐** Claims Nos.:

   because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box No. III  Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. **☐** As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. **☐** As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. **☐** As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos. :

4. **☐** No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos. :

**Remark on Protest**

- **☐** The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

- **☐** The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

- **☐** No protest accompanied the payment of additional search fees.