**Abstract:** A method of and system for assembling a stent graft (20) includes temporary diameter reduction arrangements to enable partial release of a stent graft to assist with positioning before complete release. The diameter reduction arrangement includes a release wire (72) and flexible threads (74, 80) extending to struts (76) of a self-expanding stent (70) either side of the release wire and being pulled tight. Removal of the release wire enables full expansion of the self-expanding stent.

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Description

Technical Field

This invention relates to a medical device and more particularly to a stent graft for mounting onto a deployment device for endovascular introduction.

Background of the Invention

Throughout this specification the term distal with respect to a portion of the aorta, a deployment device or a prosthesis is the end of the aorta, deployment device or prosthesis further away in the direction of blood flow away from the heart and the term proximal means the portion of the aorta, deployment device or end of the prosthesis nearer to the heart. When applied to other vessels similar terms such as caudal and cranial should be understood.

This teachings herein are particularly discussed in relation to stent grafts for placement into the thoracoabdominal aorta for the treatment of aneurysms and more specifically in relation to juxtarenal placement. These teachings are not, however, so restricted and may be applied to stent grafts for placement in any lumen of the human or animal body.

The segment of aorta between the celiac and renal arteries is the best endowed with adventitial elastin, the most stable and the last to dilate. Aneurysms of this area are associated with aneurysms of less stable areas in the descending thoracic aorta, infrarenal aorta or both. Surgical repair of the thoracoabdominal aorta often involves wide exposure through long, multi-cavity incisions, followed by periods of visceral ischemia. Despite advances in surgical techniques and perioperative care, the mortality and morbidity rates remain high, especially in patients who are old, sick or have already undergone open surgical repair of an adjacent segment of the aorta. In such cases, an endovascular alternative would be welcome, yet endovascular methods of thoracoabdominal and pararenal aortic repair have been slow to develop. The challenge has been to exclude the aortic aneurysm while maintaining flow to its visceral branches.
It is roughly 4 years since two distinctly different approaches to this problem were reported. The two devices were: a bifurcated abdominal aortic stent-graft with fenestrations for the renal and superior mesenteric arteries, and a thoracoabdominal stent-graft with branches for the celiac, superior mesenteric and renal arteries. In recent years, the distinctions between fenestrated and multi-branched stent-grafts have been blurred by the emergence of many hybrid devices with features such as Nitinol ringed fenestrations, externally cuffed fenestrations, internally cuffed fenestrations, external spiral cuffs and axially-oriented cuffs or branches, both external and internal. Each element has advantages and disadvantages and each combination has a different role, as described below.

There now exists a family of devices, which share several key features. In each of them, a barbed uncovered Z-stent anchors the proximal end, and a single proximal orifice attaches to a non-dilated segment of aorta (or previously inserted prosthesis). They all distribute blood through multiple branches, cuffs or holes (fenestrations) and they have series of Z-stents and Nitinol rings, providing support from one end of the stent-graft to the other.

In cases of juxtarenal AAA, the rim of non-dilated infrarenal aorta is too short for secure haemostatic implantation of an unfenestrated stent-graft. There is only enough room in the neck for the proximal end of the proximal stent; the rest of this covered stent expands into the aneurysm, assuming a conical shape. Under these circumstances, there is insufficient apposition between the stent-graft and the aorta to achieve a reliable seal. Properly positioned fenestrations (holes) provide a route for flow through the stent-graft into the renal arteries, thereby allowing the proximal end of the stent-graft to be placed higher in the non-dilated pararenal aorta where it assumes a cylindrical shape. The dual goals of renal perfusion and aneurysm exclusion are achieved only when the fenestration is positioned precisely over the renal orifices, and the outer surface of the stent-graft around the fenestration is brought into close apposition with the inner surface of the aorta around the renal orifice. Typical fenestrated technique uses a bridging catheter, sheath or balloon to guide each fenestration to the
corresponding renal orifice, and a bridging stent to hold it there. Stent-graft deployment has five main stages: extrusion of the half-open stent-graft, trans-graft renal artery catheterization, complete stent-graft expansion, renal stenting, and completion of the aortic exclusion with bifurcated extension into the iliac arteries.

The three forms of fenestration in common use are the large fenestration, the scallop and the small fenestration. A large fenestration is used only when the target artery is well away from the aneurysm. No bridging stent is required, or even feasible, since one or more stent struts cross the orifice of a large fenestration. A scallop is essentially a large open-topped fenestration. In many cases, the presence of a scallop for the superior mesenteric artery allows sufficient separation (> 15mm) between proximal margin of the stent-graft and the middle of the renal orifices. Small fenestrations are commonly placed over both renal arteries and held there by bridging stents. Stent struts cannot cross the orifice of a small fenestration. Small fenestrations are therefore confined to the lower halves of the triangular spaces between adjacent stent-struts.

Localized juxtarenal aneurysms or pseudoaneurysms require no more than a single cylindrical fenestrated stent-graft, but most cases of infrarenal aneurysms extend to the aortic bifurcation and require bilateral iliac outflow through a bifurcated stent-graft. The combination of a fenestrated proximal component with a bifurcated distal component is called a composite stent graft. Dividing the stent-graft into two components separates the two halves of the procedure. The operator need not be concerned about the position or orientation of the bifurcation while inserting the fenestrated proximal component, or about the position and location of the fenestrations while inserting the bifurcated distal component. The composite arrangement also separates the fenestrated proximal component from the large caudally directed hemodynamic forces that act mainly upon the bifurcation of the distal component. A small amount of slippage between the two is preferable to any proximal component migration, where even a few millimetres of movement would occlude both renal arteries. Indeed, the low rate of renal
artery loss is testimony to the accuracy of stent-graft deployment and the stability of stent-graft attachment.

The positioning of the fenestration is therefore very important to avoid renal occlusion.

Positioning is further complicated because the diameter of a stent graft is deliberately made larger than the diameter into which it is to be placed to allow for accurate sealing against the vessel wall, possible errors in sizing and subsequent relaxation of the vessel wall. Hence, once released a stent graft with self-expanding stents will take up apposition against the vessel wall and it will be difficult if not impossible to reposition it.

Summary of the Invention

In the preferred embodiments the invention is able to provide a system for reducing the diameter of the stent graft during deployment, wherein temporary diameter reducing ties are applied to at least a portion of the stent graft.

The can also allow positioning after initial release of a stent graft from a deployment device.

According to an aspect of the present invention, there is provided a temporary diameter reduction constraint arrangement for a stent graft as specified in claim 1.

The stents are preferably zigzag stents comprising struts and bends therebetween and the engagement of the threads with respective struts is intermediate the ends of the struts.

There can be two release wires and a circumferential thread extending circumferentially in each direction from each of the release wires at a plurality of positions along the release wires to hold the stent graft at a reduced diameter of the stent graft along the length of the stent graft. Preferably the positions along the length of the release wires corresponds with a middle portion of the struts of the self-expanding stents along the length of the stent graft.

According to another aspect of the present invention, there is provided a method of temporarily reducing the diameter of at least a portion of a self-expanding stent graft as specified in claim 6.
The method can include the steps of applying a plurality of flexible threads in each circumferential direction from each release wire at a plurality of positions along the release wires to temporarily reduce the diameter of the stent graft along the length of the stent graft. Preferably the engagement of the threads with the respective struts of the stent grafts is intermediate the ends of the struts.

**Brief Description of the Drawing**

Embodiments of the present invention are described below, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 shows a schematic view of an aneurysed aorta with a bifurcated and fenestrated stent graft deployed into it;

Figure 2A and 2B show schematically how one arrangement of a diameter reducing ties are applied to a stent graft;

Figure 3A and 3B show an alternative embodiment of diameter reducing ties intended for use with a stent graft; and

Figures 4A, 4B and 4C show a stent graft in various stages of application and release of double diameter reducing ties on a stent graft.

**Detailed Description**

Referring to Figure 1 it can be seen that there is schematically shown an aorta 2 extending down to an aortic bifurcation at 3 and into two iliac arteries 5 and 7. An aneurysm 9 defined by a bulge in the aorta wall 11 extends from near to the aortic bifurcation 3 nearly to the renal arteries 13 and 15. There is insufficient non-aneurysed length of the aorta distally of the renal arteries and hence to place a stent graft to bypass the aneurysm it is necessary to place some of the stent graft proximally of the renal arteries.

This embodiment is discussed in relation to a bifurcated stent graft having a longer leg for extending into one iliac artery and a shorter leg into which a leg extension may be deployed for the contralateral iliac artery but the teachings herein are not so limited and may also be used for a composite stent graft in which the fenestrations are in a proximal tubular portion of the composite stent graft and if necessary a further bifurcated portion of stent graft is used to extend down to the iliac arteries.
The stent graft 20 has a bifurcation 24 and a long leg 27 extending down iliac artery 7 and a short leg 26 directed towards iliac artery 5. A leg extension 28 is connected into the short leg 26 and extends down the iliac artery 5. The stent graft 20 has a proximal internal stent 36 and a plurality of external stents 38 along the length of its tubular body. At the renal arteries 13 and 15 there are fenestrations 30 and 32 respectively for allowing access to the renal arteries and it is to the placement of these renal fenestrations on the stent graft so that they match up with the renal arteries when the stent graft is deployed into the aorta that the teachings herein are directed. Methods of deployment of such a stent graft are described in WO-98/53761, which features and other features disclosed could be used with the system taught herein.

Although the renal arteries in Figure 1 are depicted as extending laterally either side of the aorta, in fact the position of the renal arteries is very variable and are sometimes closer together towards the anterior surface of the aorta and can be positioned more or less apart longitudinally.

Figures 2A and 2B show schematically one embodiment of diameter reducing tie. In this drawing the graft material of a stent graft is not shown and only a portion of a self-expanding stent is shown stretched out flat.

As can be seen in Figure 2A, a self-expanding stent 70 which would extend around the tubular body of a stent graft and be stitched to the stent graft is shown. A release wire 72 is stitched longitudinally along the stent graft, shown in more detail in Figure 4A, with a stitch 72a of the release wire being exposed to the outside of the stent graft in the region of the self-expanding stent 70.

A first suture thread 74 of a flexible material is passed around the release wire 72 and extended out to one side of the release wire over the struts 76 of the stent graft to pass over three struts and to be looped around a fourth strut and into the graft material. The suture thread 74 is then pulled tight and knotted, as shown in Figure 2B, with a knot 78 so that the struts between the release wire 72 and the knot 78 are pulled closer together against the resilient force of the self-expanding stent.

A similar action is carried out to the other side of the release wire with a
second suture thread 80 of a flexible material. In this case the thread 80 can either pass around the release wire 72 or is passed underneath the two strands of the thread 74 and over the release wire 72. Then it can be passed over three struts and looped around a fourth strut and into the graft material, pulled tight and knotted at 82.

The reduction in distance between the release wire 72 and the knot 78 may be from 50 to 75 percent. For instance, if the distance x in Figure 2A is 15 millimetres around the circumference of the stent graft from the release wire 72 to the strut at which the knot 78 is placed, then this can be reduced to 5 millimetres as shown by the dimension y in Figure 2B. With two diameter reducing ties, one to each side of the release wire 72, a total circumference reduction of 20 millimetres can be achieved, which will change the diameter of a 36 millimetre stent graft to approximately 28 millimetres. This can be less than the diameter of the aorta in that region, which means that the stent graft will still be manoeuvrable within the aorta while still mounted onto the deployment device but partially freed by the withdrawal of a containing sheath.

Where a greater amount of diameter reduction is desirable, double diameter reducing ties may be used as depicted in Figures 3A and 3B. In this embodiment, two release wires 90 and 92 are used parallel to each other and spaced by 6 or 7 struts of a self-expanding stent 91. The two release wires 90 and 92 are stitched longitudinally along the stent graft, as can be seen in more detail in Figure 4A, with stitches 90a and 92a being exposed to the outside of the stent graft in the region of the self-expanding stent 91. A first suture 93 extends from one side of the release wire 90 and a second suture 94 extends to the other side of the release wire 90, being knotted off at 95 and 96. Similarly, sutures 97 and 98 are extended either side of the release wire 92 and are knotted off at 99 and 100. Generally the knots 96 and 99 go on either side of the same strut.

By using these double diameter reducing ties, for instance, a reduction in circumference of up to 40 millimetres may be obtained for a 36 millimetre diameter stent graft which will give a final diameter of approximately 24
millimetres. Once again, with such reduction in diameter movement of the stent graft for final positioning can be easily achieved.

Figures 4A, 4B and 4C show a stent graft with various stages of fitting and release of diameter reducing ties.

Figure 4A shows a more proximal portion of a composite stent graft for mounting into the aorta. The stent graft includes a tubular body 120 with an internal zigzag self-expanding stent 122 at its proximal end and an exposed proximally extending stent 124 mounted to the proximal end of the tubular body 120. Further external self-expanding stents 126 are supplied along the length of the body towards the distal end 128. It will be noted the tubular body 120 tapers at 130 so that it has a first selected diameter at the proximal end and a slightly smaller diameter further down the length of the tubular body.

This embodiment will be discussed particularly in relation to installation of double diameter reducing ties. The first stage is the placement of release wires 132 and 134 which extend longitudinally along the tubular body and are stitched in and out of the tubular body. Stitches can be seen on the exterior of the tubular body in regions coinciding with the intermediate region of the struts of each of the exposed stents. In the region designated as 130, for instance, a suture is placed around the release wire and extended across about three struts of the zigzag stent 126 to strut 136, where it is passed around the strut 136 and into the graft material of the tubular body 120, then being pulled tight as shown at 138 in Figure 4B. Similarly, a suture 140 extended from the other direction from the release wire 132 for about three struts, is passed around a strut and into the graft material of the tubular body 120, then being pulled tight.

A similar extension of sutures in each direction from release wire 134 is installed to compress the other side. The suture 142 which extends back towards the release wire 132 is joined to the same strut 136 as the suture 138. The suture 144 extends in the opposite direction from the release wire 134.

This process is repeated with the other exposed stents 126 and the internal stent 122. In the case of the internal stent 122, the sutures are inserted through the material of the tubular body 120 to go around the stents, where they are
knotted but otherwise remain outside of the tubular body. This gives the result as shown in Figure 4B, where the diameter of the stent graft is considerably reduced. Diameter reducing ties may be either placed along the entire length of the stent graft so that the stent graft remains manoeuvrable after its partial release or can be confined to only the parts of the stent graft that are larger in diameter than the vessel lumen into which it is to be placed.

Figure 4B shows the stent graft mounted onto a deployment device with a pusher catheter 150 at one end and a nose cone capsule 152 into which the proximally extending stent 124 is received at the other end. At this stage a containing sheath has been withdrawn onto the pusher catheter so that the stent graft has partially expanded under the influence of self-expanding stents but complete expansion has been prevented by the diameter reducing ties 138, 140, 142 and 144.

Figure 4C shows the stent graft still mounted onto the deployment device so that the exposed stent 124 is still received in the capsule 152 but the release wires 132 and 134 have been withdrawn so that the diameter reducing ties are released. It will be noted that the sutures 140, 138, 142, and 144 remain on the outside of the stent graft. This is not a problem as they do not interfere with blood flow and may assist with adhesion of the stent graft onto the wall of the aorta.

In another arrangement, where space permits, two sets of double diameter reducing ties may be used with one set of double diameter reducing ties and trigger wire placed anterior to the renal arteries and another set of double diameter reducing ties and trigger wire placed posterior to the renal arteries. Throughout this specification and the claims that follow unless the context requires otherwise, the words 'comprise' and 'include' and variations such as 'comprising' and 'including' will be understood to imply the inclusion of a stated integer or group of integers but not the exclusion of any other integer or group of integers.
Claims

1. A temporary diameter reduction constraint arrangement for a stent graft (20), the stent graft comprising a biocompatible graft material tube of a selected diameter and a plurality of self-expanding stents (38) fastened thereto, the constraint arrangement including at least one release wire (72) extending longitudinally along the graft material tube and at least one circumferential thread (74-98) engaged around the release wire (72) and a portion of the stent graft circumferentially spaced a selected distance from the release wire (72) and drawn tight and tied to reduce the circumference and hence the overall diameter of the stent graft.

2. A constraint arrangement as in claim 1, including a circumferential thread (74-98) extending circumferentially in each direction from the release wire (72).

3. A constraint arrangement as in claim 1 or 2, wherein the stents (38) are zigzag stents including struts and bends therebetween, the engagement of the flexible thread into the graft material including the engagement of the thread around a strut of the self-expanding stent.

4. A constraint arrangement as in any preceding claim, wherein the selected distance is reduced by from 50 to 75%.

5. A constraint arrangement as in any preceding claim, including first and second release wires (90,92) extending longitudinally along the graft material tube and circumferential threads (93-98) extending circumferentially in each direction from each of the release wires (90, 92).

6. A method of reducing temporarily the diameter of at least a portion of a self-expanding stent graft, the stent graft (20) comprising a tubular body of a biocompatible graft material and a plurality of self-expanding stents (38), the method including the steps of:
   a) extending a release wire (72) longitudinally along the stent graft and stitching the release wire into the graft material tube;
   b) looping a first flexible thread (74) around the release wire (72) and extending the first flexible thread laterally around the circumference of the stent graft to a position a selected distance from the release wire;
c) engaging the first flexible thread into the graft material, and

d) drawing the ends of the thread together and tying ends of the thread,
whereby the selected distance is temporarily reduced thereby reducing the overall diameter of the stent graft.

7. A method as in claim 6, wherein the stents are zigzag stents including struts and bends therebetween, the method including the step of engaging the first flexible thread (74) into the graft material including engaging the thread around a strut of a self-expanding stent.

8. A method as in claim 6 or 7, including the steps of:

e) passing a second flexible thread (80) around the release wire (72) or the around the first flexible thread (74) and extending the second flexible thread laterally around the circumference of the stent graft in the opposite direction to the first flexible thread to a position a selected distance from the release wire;

f) engaging the second flexible thread into the graft material, and

g) drawing the ends of the second thread together and tying ends of the thread,
whereby the selected distance is reduced thereby reducing the overall diameter of the stent graft.

9. A method as in any one of claims 6 to 8, wherein the selected distance is reduced by from 50 to 75%.

10. A method as in any one of claims 6 to 9, including applying a plurality of flexible threads to reduce the diameter along the length of the stent graft.

11. A method as in any one of claims 6 to 10, including the steps of;

j) extending a second release wire (92) longitudinally along the stent graft parallel to and spaced from the first release wire (90);

k) looping a third flexible thread (97) around the second release wire and extending the third flexible thread laterally around the circumference of the stent graft to a position a selected distance from the second release wire;

l) engaging the third flexible thread into the graft material, and

m) drawing the ends of the thread together and tying ends of the thread,
n) passing a fourth flexible thread (98) around the third flexible thread and extending the fourth flexible thread laterally around the circumference of the stent graft in the opposite direction to the third flexible thread to a position a selected distance from the second release wire;

o) engaging the fourth flexible thread into the graft material, and

p) drawing the ends of the fourth thread together and tying ends of the thread,

whereby the selected distance is reduced thereby reducing the overall diameter of the stent graft.

12. A method as in claim 11, including the step of applying a plurality of flexible threads (93-98) in each circumferential direction from each release wire at a plurality of positions along the release wires to reduce the diameter of the stent graft along the length of the stent graft.
# INTERNATIONAL SEARCH REPORT

## A. CLASSIFICATION OF SUBJECT MATTER

| INV. | A61F2/06 |

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

## B. FIELDS SEARCHED

| Minimum documentation searched (classification system followed by classification symbols) | A81F |

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 practical, search terms used) EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

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