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(54) Title: GRAFT WITH LEG

(57) Abstract: A prosthesis (1) has a graft sleeve having a first and second ends (9A, 9B) with a lumen therethrough, a main body portion (2) bifurcated at a junction (6) to form a first leg (3) and a second leg (4) such that the lumen of the graft sleeve in main body portion (2) is divided into two smaller lumens. The body portion (2) has two ring stents (7), first leg (3) and second leg (4) each have ring stents (7) which maintain the patency of legs (3, 4) and assist bending of the leg graft without kinking to accommodate the patient's anatomy. The first leg (3) and second leg (4) each include a fenestration (5) in the fabric material forming each leg. Corrugations in first leg (3) and/or second leg (4) allow a degree of twisting to accommodate angular adjustment of the fenestration position.

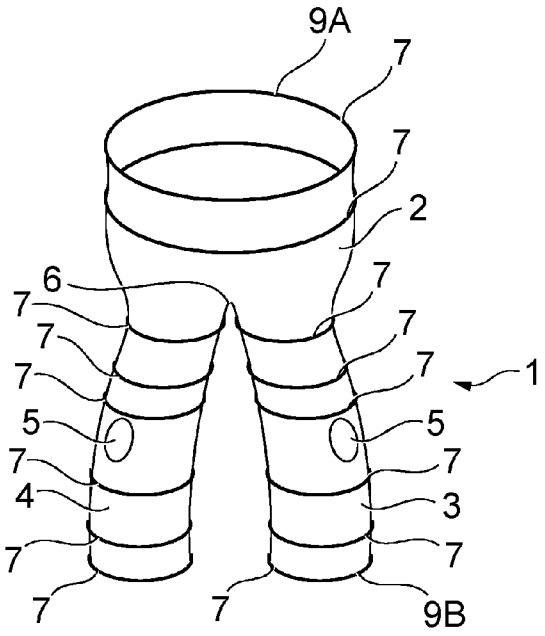

Fig. 1

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GRAFT WITH LEG

The present invention relates to a prosthetic graft and modular stent graft assembly, and in particular to a fenestrated prosthetic graft for deployment by endovascular delivery.

Artificial prostheses consisting of a tubular conduit having an open lumen are well-known and are used in medicine to replace diseased or damaged natural body lumens, such as, for example, blood vessels or other hollow organs for example bile ducts, sections of intestine or the like. The most common use of such artificial prostheses is to replace diseased or damaged blood vessels.

A number of vascular disorders can be treated by use of an artificial prosthesis. One relatively common vascular disorder is an aneurysm. Aneurysm occurs when a section of natural blood vessel wall, typically of the aortic artery, dilates and balloons outwardly. Whilst small aneurysms cause little or no symptoms, larger aneurysms pose significant danger to a patient. Rupture of an aortic aneurysm can occur without warning and is usually fatal, so significant emphasis is placed on early diagnosis and treatment. With an increasingly ageing population, the incidence of aneurysm continues to rise in western societies.

Provided that an aneurysm is diagnosed prior to rupture, surgical treatment to repair the affected vessel wall is effective. Surgical treatment of aneurysm involves the replacement or reinforcement of the aneurismal section of aorta with a synthetic graft or prosthesis under general anaesthesia allowing the patient's abdomen or thorax to be opened (see Parodi et al., Annals of Vascular Surgery (1991) 5:491-499). The patient will then have a normal life expectancy.

Surgical repair of aneurysm is however a major and invasive undertaking and there has been much effort in developing less invasive methods. Currently, aneurysm repair generally involves the delivery by catheter of a fabric or ePTFE graft which is

retained at the required location by deployment of metallic devices (stents). The ability to deliver the stent-graft device by catheter reduces the surgical intervention to a small cut-down to expose the femoral artery and, in suitable circumstances, the device can be deployed percutaneously. Catheter delivery is beneficial since the reduced invasive nature of the procedure allows utilisation of a local anaesthesic and leads to reduced mortality and morbidity, as well as decreased recovery time. For example, endovascular repair is typically used for repair of infra-renal abdominal aortic aneurysms where the graft is placed below the renal arteries. Many different types of devices useful for endovascular repair are now available, for example a resiliently engaging endovascular element described in US 6,635,080 (Vascutek) or a tubular fabric liner having a radially expandable supporting frame and a radiopaque marker element stitched to the liner as disclosed in US 6,203,568 (Medtronic).

However, whilst the endovascular repair of aneurysms is now accepted as the method of choice, the technique has significant limitations and is not suitable for all patients.

Endovascular techniques involve the delivery of the prosthesis by catheter. Since the internal lumen of the catheter defines the maximum dimensions of the prosthesis to be inserted, much effort has been expended in the design of prostheses which can be packaged in a minimal volume, and are easy to deploy once positioned at the required location.

One successful type of prosthesis consists of a stent graft comprising a conduit formed of a flexible sleeve attached to a rigid support or stent. The sleeve will typically be made of a fabric (usually a knitted or woven fabric) of ePTFE, PTFE, polyester (for example DACRON), polyethylene or polypropylene and may optionally be coated to reduce friction; discourage clotting or to deliver a pharmaceutical agent. The fabric will generally be porous on at least one surface to enable cell ingrowth. The stent may be balloon-expandable (eg. a PALMAZ stent made of rigid stainless steel wire), but could also be self-expandable and formed of a

shape memory material, such as nitinol (a nickel-titanium alloy). Numerous different stent designs are known in the art (see for example braided stents described in EP 880949 or wire zig-zag stents described in US 4580568).

The stent grafts are inserted using a delivery catheter and, once correctly located at the site requiring treatment, are deployed by the withdrawal of a delivery sheath of the delivery catheter. Balloon-expandable grafts are then caused to expand in diameter by inflation of a balloon located within the lumen of the graft. Self-expandable grafts radially expand upon release from the delivery sheath. Irrespective of the mode of expansion, once deployed, the stents hold the graft in location by contact with the inner wall of the blood vessel.

Bifurcated stent graft prostheses are known in the art for treatment of abdominal aortic aneurysm at the lower end of the aorta close to its bifurcation into the left and right iliac arteries. The bifurcated stent graft used to treat an aneurysm at this location typically comprises a main body portion located in the aorta which extends across the aneurysm so that it can be fixed in place by expansion of a stent onto healthy aortic wall proximal to the aneurysm. The main portion of the graft divides into two smaller legs, each leg extending down one of the iliac arteries with the distal end of each leg also being fixed by expansion of a stent. For ease of deployment, one leg can be created by use of a separate leg extension with graft assembly occurring *in vivo*. See EP 1063945 and US 5676696.

Depending on the location of an aneurysm, the graft can be adapted to suit the location necessary. For example, where an aneurysm extends down an iliac artery, the graft can include a further arm directed to an internal artery of the iliac artery as described in WO 2007/124053. Alternatively, where the graft is to be located to span across the junction of an intersection (eg. with the renal arteries), the graft can include an opening (fenestration) for alignment with one of the branch vessel(s) (see for example WO 99/29262 or EP 1673038). However, to date such fenestrated grafts must be individually designed for each patient since the anatomy of the vessel branches can vary significantly.

Production of unique, individually designed and manufactured endografts having appropriate branch grafts or fenestrations which match the patient's individual anatomy requires meticulous design based on accurate pre-operative imaging data. The use of patient-specific designed grafts is expensive and requires significant pre-planning so that such grafts are not available in emergency situations. Moreover, the technical difficulties of aligning the fenestration to the branch vessel is significant, requiring precise axial and rotational control of the graft. No adjustments to the graft are possible during deployment, so that any errors in the initial diagnostic imaging or any changes in anatomy from the imaging stages cannot be rectified. An alternative approach requires the deliberate coverage of the branch vessel, which is clearly undesirable.

The desirability of conducting *in vivo* (*in situ*) fenestration of a graft has been also recognised in the art. McWilliams et al., (J. Endovasc Ther (2004) 11:170-174) describe the fenestration of a thoracic graft by passing a guide wire down the branch artery to pierce the fabric of the graft and then expanding the hole formed by inflation of a balloon. However, whilst such techniques require percutaneous retrograde access to the branch vessel for correct location of the fenestration, such access is possible for branches of the aortic arch but not for visceral vessels such as the renal or mesenteric arteries. Moreover, the requirement for retrograde access increases the complexity of the procedure.

There continues to be a need for a graft suitable for deployment at or near a vessel intersection, which is suitable for a range of patient anatomy and which avoids both the requirement for individual design and *in vivo* fenestration.

The requirement for such fenestrated grafts can apply to any vessel intersection, including without limitation, the renal arteries, mesenteric artery, brachiocephalic artery, carotid arteries or left subclarion artery. Graft fenestration design is particularly difficult in locations where two or more intersections are located within the length of the graft.

The present invention provides a prosthesis comprising a graft sleeve having a first end and a second end with a lumen extending therethrough, wherein said graft sleeve is bifurcated at the second end to form a first leg and a second leg, each leg having a lumen in fluid communication with the sleeve lumen, wherein a fenestration is located in at least one of the first leg or the second leg.

The term "fenestration" is defined herein as a hole or opening within a graft or prosthesis (for example in the sidewall of the graft or prosthesis) or to the process of producing such a hole or opening. The fenestration can have any shape including, but not limited to, rectangular, triangular or curvilinear (eg. circular, oval or the like). The fenestration allows fluid communication from the exterior of the graft to the lumen of the graft.

Optionally each fenestration can be bound at its periphery by a strand of resilient material, for example nitinol wire or a strand of PEEK. The strand of resilient material can be sewn around the boundary of the fenestration so that the fenestration is kept open and also so that the edges of the fenestration are prevented from fraying.

Each graft sleeve can be independently formed from any flexible and biocompatible material. The sleeve is usually formed of a woven or knitted fabric. The sleeve will usually be substantially impervious to fluid. Optionally, at least one surface of the sleeve will be sufficiently porous to facilitate cell ingrowth. Suitable materials include polyester, polyurethane, polyethylene, polypropylene, ePTFE, PTFE and the like. Each or any of the sleeves can independently be coated to reduce permeability or to deliver a biological agent. The graft sleeve forms the side walls of the main body portion of the graft (prior to bifurcation), and after bifurcation forms the side walls of the first leg and of the second leg.

For many intended purposes, each or any of the graft sleeve(s) can independently be formed with a constant diameter. However tapered grafts (ie. where the diameter varies along its length) are also possible and are particularly useful for

certain indications. A taper can be useful in assisting adequate docking of a leg graft with the main graft.

In one embodiment, the first leg of the prosthesis has a fenestration in the side wall thereof.

In one embodiment, the second leg of the prosthesis has a fenestration in the side wall thereof.

In one embodiment, the first leg has a fenestration in the side wall thereof and the second leg has a fenestration in the side wall thereof.

In an alternative aspect, the present invention provides a prosthesis comprising a graft sleeve having a first end and a second end with a lumen extending therethrough, wherein said graft sleeve is bifurcated at the second end to form a first leg and a second leg, wherein each of said first and second legs includes a fenestration in the sidewall thereof.

Generally, the prosthesis is inserted so that the fenestrations in either or each of the first and second legs align with an intersection to a branch vessel to allow blood flow thereto. Location of the fenestration(s) in the leg(s) of the prosthesis (as opposed to the main graft portion prior to the bifurcation junction) provides greater flexibility to accommodate a wider range of branch intersection configurations.

Optionally, at least a portion of each leg is extendable in length. An extendable portion can be provided by the inclusion of annular folds in the graft sleeve and/or by the use of a stretchable fabric (i.e. woven or elasticated). Annular folds (corrugations) can be present in the first leg and/or the second leg. Optionally the annular folds can be produced by heat-setting or crimping the fabric of the legs. Accordingly the distance between the bifurcation junction and the fenestration can be varied independently for each leg. This has the advantage that placement of the main body portion of the graft relative to the branch vessel is not critical at

deployment. Where each leg includes a fenestration, there is also the advantage that two branch vessels which are at different longitudinal locations within a patient can easily be accommodated by the graft of the invention, since the position of each fenestration can be individually adapted as required.

Alternatively or additionally the placement of each leg can be rotationally independent. The fenestration on each leg can thus be angularly adjusted as required for alignment with a branch vessel. The fenestration or a leg can be angularly adjusted, for example, by twisting the excess fabric in the annular folds.

In an alternative embodiment, the first leg of the prosthesis is shorter than the second leg of the prosthesis. In this embodiment, the first leg can either be left in its shortened form or (depending upon the aneurysm to be treated and the anatomy of the patient) can be extended by insertion of a separate tubular extension graft. The first end of the extension graft will be located within the free end of the first leg of the graft of the invention and sealed thereto, typically by expansion of a stent on the extension graft to sealingly engage with the inner luminal surface the first leg. Use of an extension graft to extend a “short trouser leg” in this manner is known in the art, for example as described in US 5676696.

Alternatively the first leg can comprise a short tubular sealing zone and a flange extension. The short tubular zone is equivalent to a short leg as described above. The flange extension is a length of fabric (typically a section of a cylinder) which forms an extended docking zone able to overlap an extension graft. Optionally a loop can be present at the end of the flange extension so that it can be held during deployment.

The fenestrated leg of the extension graft can be docked into the first leg at any rotational angle, allowing alignment of the fenestration to a branch vessel independently to that of a fenestration in the second leg.

Generally, the prosthesis is inserted so that the fenestrations in either or each of the second leg and in the extension graft attached to the first leg align with an intersection to a branch vessel to allow blood flow thereto. Location of the fenestration(s) in the second leg of the prosthesis and/or in the extension graft (as opposed to the main graft portion of the graft prior to the bifurcation junction) provides greater flexibility to accommodate a wider range of branch intersection configurations.

Optionally at least a portion of the second leg is extendable in length, for example by including annular folds. Optionally, at least a portion of the extension graft is extendable in length, for example by including annular folds. Annular folds (corrugations) can be present in the second leg and/or extension graft. Optionally the annular folds can be produced by heat setting or crimping the fabric. Accordingly the length of the second leg and/or extension graft can be independently varied. This has the advantage that placement of the main body portion of the graft relative to the branch vessel is not critical at deployment. Where each leg includes a fenestration, there is also the advantage that two branch vessels which are at different longitudinal locations and/or different rotational locations within a patient can easily be accommodated by the graft of the invention, since the position of each fenestration can be individually adapted as required.

In any embodiment of the graft of the present invention the bifurcation is to be located proximal of the vessel intersection. Thus, the location of the graft in the main vessel is adjusted to allow alignment of the fenestration(s) with the branch intersection(s). Use of a separate, optionally fenestrated, tubular extension graft to extend the first leg of the graft provides an ability to separately accommodate two branch intersections which vary from each other in longitudinal location, size and/or angular (rotational) location.

Generally, the prosthesis will also comprise at least one stent attached to the first end of the graft sleeve. The first end will usually be the proximal end of the graft sleeve (ie. located closer to the heart). After deployment, the stent attached to the

first end of the graft sleeve will expand against the luminal surface of the body vessel into which the prosthesis is deployed. The stent can be formed from any resilient biocompatible material, as known in the art. The stent can be balloon expandable or self-expandable. Suitable materials include metals (eg. stainless steel, nitinol) and polymers, particularly engineering high modulus polymers such as polyether ether ketone (PEEK). PEEK polymers with shape memory behaviour can be used. Exemplary stent configurations are known in the art and include wire mesh stents, helices, coils, rings and other suitable configurations; see US 4735645, US 6635080 and US 6203568.

Each stent can be independently formed of any suitable biocompatible material having the necessary resilience to fold inwardly into a first folded configuration (ie. for packaging) and to adapt a second open configuration (ie. after deployment).

Optionally, one or more ring stents can be attached to the first end of the graft sleeve. The ring stents can each be formed from nitinol wire and will typically include multiple windings of nitinol wire. Each stent can be attached to the external surface of the sleeve or to the internal (luminal) surface of the sleeve. Generally, it is more convenient to attach the stents to the external (non-luminal) surface of the sleeve.

In one embodiment, the first end of the graft sleeve comprises a pair of ring stents which, after deployment, together hold the graft sleeve in position within the body vessel. Optionally, the two stents can be formed of nitinol wire. The ring stent closest to the first end of the graft sleeve can be of a shallow sinusoidal configuration, with the second ring stent (further along the graft sleeve) being of sinusoidal or circular configuration. Optionally, a stabilising stent member (or a pair of such members) as described in PCT/GB2012/051236 or GB 2491481 can be located between the two ring stents.

The number of strands of wire in a ring stent can be varied according to the diameter of wire utilised and the size of graft. The number of strands wound can vary from 2 to 120 or even more, but would typically have 10 to 30 strands forming

the ring stent. Any diameter wire which maintains the required resilience can be used. Suitable diameters for the wire can be selected from a range of 0.1 mm to 2 mm, for example 0.5 mm to 1 mm.

Each stent can conveniently be positioned externally of the sleeve of the prosthesis.

Conveniently, each stent is attached to the graft sleeve by sewing, but any other suitable means of attachment to the sleeve (eg. adhesive or heat bonding) could alternatively be used.

Optionally each leg or extension graft can include a series of ring stents. Such stents can typically be formed of multiple windings of nitinol wire. Optionally the stents can be attached to the exterior of the graft sleeve, by stitching, in a sinusoidal (saddle-shaped) configuration. Use of ring stent(s) on each leg or extension graft is beneficial since the lumen is held in an open configuration whilst retaining the ability of the leg/extension graft to be folded or concertinaed to allow adjustment of length.

A stent which is ring-shaped (annular) will have an inner circumference substantially identical to (preferably identical to) the outer circumference of the graft sleeve (the tubular graft). By "substantially identical to" we refer to a circumference which is equal to or up to 5% greater than the outer circumference of the graft sleeve, preferably which is equal to or up to 2% greater than the outer circumference of the graft sleeve and more preferably equal to or up to 1% greater than the outer circumference of the graft sleeve.

A stent which is sinusoidal or “saddle shaped” refers to a circular ring stent formed of a material which is sufficiently resilient to be distorted so that a first pair of diametrically opposed points on the circumference of the ring are displaced in one axial direction whilst a second pair of diametrically opposed points, centrally located on the circumference between the first pair, are displaced in the opposing axial direction to form a symmetrical saddle shape. For convenience, the first pair of

points can be described as “peaks”, with the second pair of points described as “valleys”. The degree of axial displacement between the first pair of points and the second pair of points (which axial displacement is also termed the “saddle height”), is a function of the original circumference of the ring stent prior to its distortion, relative to the final circumference of a circle within which the distorted (saddle shaped) configuration can be located. Thus, the ratio of final circumference: original circumference provides a simplistic notation of the axial displacement. Generally the final circumference will be the outer circumference of the graft sleeve to which the stent is to be attached. The percentage oversize of the undistorted inner circumference of the circular stent relative to the outer circumference of the graft sleeve also gives a convenient measure of the saddle shape adopted, and can be calculated as:

$$\text{Oversize \%} = \frac{[\text{Stent inner diameter - Graft sleeve outer diameter}]}{\text{Graft sleeve outer diameter}} \times 100\%$$

Optionally the first end of the graft sleeve can comprise two stents: first stent being a saddle-shaped stent and a second stent being a ring stent or saddle-shaped stent. Thus, in one embodiment the first end of the graft sleeve can comprise two saddle shaped stents. The terminal first stent can be formed of a continuous loop of resilient material (nitinol or PEEK or the like) having a sinusoidal (saddle) shape as described above. This first saddle shaped stent can have a saddle height of 4 to 8 mm and is conveniently located at one end of the graft sleeve. A second stent formed in a continuous loop and either in circular form with an inner circumference substantially identical to the outer circumference of the graft sleeve or in a sinusoidal shape (as described above for the first stent) is also present and is adjacent the first stent. The second stent can also be formed from resilient material (nitinol or PEEK or the like). The resilient material can be formed as an elongate strand and wound into a loop. Conveniently these two stents are spaced 5 to 13 mm apart (for example 5 to 8 mm at the closest point) and provide good sealing of the graft prosthesis against the luminal wall of the blood vessel.

Each of the first and second legs, or the extension graft can comprise 2, 3, 4 or 5 separate saddle shaped stents. Optionally the size of the valleys and peaks in the saddle shaped stents can increase monotonically between the stents. Optionally saddle shaped stents with two different saddle heights can be present, differentiated by their saddle height. For example one saddle shaped stent type can have a saddle height of 4 to 8 mm, and a further saddle shaped stent type can have a saddle height of 8 to 15 mm. The stents can be placed 12 to 25 mm apart. One or more stents of each saddle shape can be present.

Conveniently the spacing of each stent in the first leg, second leg and/or extension graft is such that the peak of one stent is traversely aligned with the valley of its immediate neighbour. Optionally, the peaks and valleys of each stent element is longitudinally aligned with the peaks and valleys, respectively, of its immediate neighbour. This arrangement provides increased axial and tensional stiffness.

Conveniently, the second leg and/or the first leg of the prosthesis can also include at least one stent at its end, which stent is able to seal against the luminal surface of the body vessel.

Additionally or alternatively the distal end of each or either leg(s) can include a "locking ring" and/or a taper to provide a docking zone for a further leg extension.

The stent graft prosthesis can be inserted into the patient using a delivery catheter and, once correctly located at the site requiring treatment, is deployed by the withdrawal of a delivery sheath of the delivery catheter. Balloon-expandable grafts are then caused to expand in diameter by inflation of a balloon located within the lumen of the graft. Self-expandable grafts radially expand upon release from the outer tube. Irrespective of the mode of expansion, once deployed, the stents hold the graft in location by contact with the inner walls of the blood vessel.

Since the stent graft prosthesis will need to be compressed for loading into the catheter and during delivery, in general terms, each stent is formed from the

minimum amount of material possible. Thus, for stents located in the middle portion of the body and/or on the legs are formed from the minimum material able to maintain the patency of the sleeve lumen at the required diameter. Likewise stents forming part of the fixing means (at the first end of the prosthesis) are formed from the minimum amount of material able to provide the stent with adequate radial force for sealing and/or migration resistance.

In one embodiment, the prosthesis remains attached to its catheter after the sheath is retracted. A suitable graft of this type is the ANACONDA® graft of Vascutek Ltd., UK (see US 6,635,080).

In one embodiment, where the graft is to be inserted in a blood vessel, the method of the invention employs a graft which can be at least partially collapsed to allow blood flow between the outer surface of the graft and the inner lumen of the blood vessel until correction location has been achieved. Such perfusion avoids the risk of ischemia and consequent damage to tissue.

In one aspect, the present invention provides a modular endovascular stent graft assembly comprising:

a) a main graft sleeve having a first end and a second end with a lumen extending therethrough,
b) a first leg and a second leg formed by bifurcation of the main graft sleeve;
c) wherein said first leg is shorter than said second leg;
d) a fenestration located in a side wall of the second leg; and
e) an extension graft having a first end and a second end, said first end having a fixing means to sealingly engage with said first leg, said extension graft optionally having a fenestration located between said first end and said second end thereof.

In an alternative aspect, the present invention provides a modular endovascular stent graft assembly comprising:

a) a main graft sleeve having a first end and a second end with a lumen extending therethrough,

b) a first leg and a second leg formed by bifurcation of the main graft sleeve;

c) wherein said first leg is shorter than said second leg;

d) an extension graft having a first end and a second end, said first end having a fixing means to sealingly engage with said first leg, said extension graft having a fenestration located between said first end and said second end thereof; and

e) optionally said second leg has a fenestration in a side wall thereof.

In a further aspect, the present invention provides an implantable prosthesis comprising:

i) a compliant and substantially fluid impervious tubular sleeve having a proximal end and a distal end with a conduit therethrough;

ii) a first ring stent formed from multiple windings of wire of a shape memory material, attached to said sleeve at said proximal end;

iii) a bifurcation of said sleeve, so that said sleeve forms a first leg and a second leg at its distal end;

iv) a fenestration in said first leg and/or said second leg; and

v) a second ring stent formed from multiple windings of wire of a shape memory material, attached to said second leg at the distal end thereof.

In a further aspect, the present invention provides a method of treating a target site proximate to a branch vessel intersection, said method comprising inserting a prosthesis according to the present invention so that a fenestration in said first or second leg is aligned with said branch vessel.

In a further aspect, the present invention provides a method of treating a target site proximate to first and second branch vessel intersections, said method comprising inserting a prosthesis according to the present invention so that a fenestration in the first leg is aligned with said first branch vessel and a fenestration in the secondly is aligned with said second branch vessel.

In each of the aspects described above for treatment of a target site, the target site can include an aneurysm which is treated through deployment of the prosthesis. Optionally the aneurysm is a thoracic aortic aneurysm.

In each of the aspects described above for treatment of a target site, the prosthesis according to the present invention can be inserted so that the bifurcation junction is proximal to the branch vessel intersections. Where two branch vessel intersections are present but are not located 180° to each other (due to the patient's natural anatomy), the modular assembly described above can be used to accommodate the angular alignment of the fenestrations as required.

Additionally, the prosthesis is desirably inserted using endovascular techniques.

Preferred or alternative features of each aspect or embodiment of the invention apply *mutatis mutandis* to each other aspect or embodiment of the invention, unless context demands otherwise.

The present invention will now be further described by reference to the following figures in which:

Figure 1 is a schematic illustration of a first embodiment of a prosthesis according to the invention;

Figure 2 is a schematic illustration of a second embodiment of a prosthesis according to the present invention;

Figure 3 is a schematic illustration of an extension graft forming part of a stent graft assembly according to the present invention;

Figure 4 is a schematic illustration of the assembled grafts of Figures 2 and 3;

Figure 5 shows the anterior (A) and posterior (B) views of a graft according to the first embodiment of the present invention; and

Figure 6 illustrates an alternative embodiment of the prosthesis according to the present invention.

In more detail, Figure 1 illustrates a bifurcated stent graft prosthesis (1) according to the present invention. The prosthesis (1) consists of a graft sleeve having a first end (9A) and a second end (9B) with a lumen therethrough. The graft sleeve comprises a main body portion (2) which is bifurcated at a junction (6) to form a first leg (3) and a second leg (4). Thus the lumen of the graft sleeve in main body portion (2) is divided into two smaller lumens (of each leg (3), (4)) after the bifurcation junction (6). The stent graft prosthesis (1) includes a number of ring stents (7) formed by multiple windings of nitinol wire. As illustrated, body portion (2) has two ring stents (7), first leg (3) has 6 ring stents (7) and second leg (4) also has 6 ring stents (7). Optionally one or more ring stents (7) can be located on the graft sleeve in a sinusoidal or saddle shaped form. The graft sleeve forming the main body portion (2), first leg (3) and second leg (4) can be formed from any suitable knitted or woven fabric, for example woven polyester. The stents (7) can be attached to the exterior surface of the sleeve by any suitable means, but can conveniently be attached by sewing using a suitable biocompatible thread, for example suture thread. The bifurcated graft can be woven in a one piece format, for example as described in WO 02/27085.

The main portion (2) of prosthesis (1) has a lumen which is in fluid communication with the lumen of first leg (3) and second leg (4). As illustrated, first leg (3) includes a fenestration or aperture (5) in the fabric material forming first leg (3). As illustrated, second leg (4) includes a fenestration or aperture (5) in the fabric material forming second leg (4). It is of course also possible for either first leg (3) or second leg (4) to be formed without the fenestration (5) shown in Figure 1. Optionally, each fenestration (5) can be bounded by nitinol wire to hold the aperture open and to prevent fraying of the aperture edges.

As illustrated, each of first leg (3) and second leg (4) include 6 ring stents (7) along its length. Depending on the length of each leg (3), (4) the number of ring stents (7) can be varied. These rings stents (7) may be of sinusoidal (saddle shaped) form or may be circular. The ring stents (7) maintain the patency of legs (3), (4) and assist bending of the leg graft without kinking to accommodate the patient's anatomy. The ring stents (7) may be formed from multiple windings of nitinol wire and attached to the exterior surface of legs (3), (4), for example by stitching. The fabric material may itself be corrugated or crimped. For example, the fabric material forming first leg (3) and/or second leg (4) can be corrugated by heat setting into crimps prior to attachment of the ring stents (7). In use both the ring stents (7) and the corrugations in first leg (3) and/or second leg (4) mean that it is possible for the length of leg between junction (6) and fenestration (5) to be shortened by partly folding or bunching the fabric in order to align fenestration (5) with the target branch vessel. The corrugations in first leg (3) and/or second leg (4) also allow a degree of twisting to accommodate angular adjustment of the fenestration position.

Figure 2 illustrates an alternative embodiment of a stent graft prosthesis (11) according to the invention. In this embodiment the prosthesis (11) comprises a main body portion (12) which bifurcates at junction (16) to form a first leg (13) and a second leg (14). First leg (13) is longer than second leg (14) and this configuration can be of assistance in deployment of the prosthesis (11) by endovascular techniques. First leg (13) is commonly termed a "short trouser leg" in the art. Second leg (14) includes a fenestration (5) which allows communication from outside second leg (14) to the lumen thereof. The material of the graft sleeve and stents (17) and the presence of corrugations can be as described above for the graft of Figure 1.

Figure 3 illustrates a separate extension graft (13A) for use with the stent graft prosthesis (11) of Figure 2. Graft (13A) has first end (10A) and a second end (10B). Extension graft (13A) is formed from any suitable biocompatible flexible material, for example woven polyester. Graft (13A) will usually also include a number of

stents (17) which may be of annular or sinusoidal (saddle shaped) configuration. The stents (17) can be formed from multiple windings of nitinol wire and can be attached by any suitable means, including stitching. Whilst extension graft (13A) is illustrated as having 5 stents (17) the number of stents required can be varied depending on the length and circumference of the graft (13A). However, the presence of a stent (17) at first end (10A) is required for sealing engagement. Thus stent (17) at end (10A) acts as a fixing means for graft (13A). In use extension graft (13A) is inserted into the lumen of first leg (13) of the graft (11) of Figure 2 and sealed thereto, for example, by expansion of stent (17) located at end (10A). The stent or pair of stents located at the first end (10A) of the extension graft (13A) of Figure 3 form a sealing zone able to dock with first leg (13) of Figure 2 and seal thereto. However, other forms of sealing engagement are possible, for example the use of a balloon expandable Z-stent or other stent type. The extension graft (13A) is shown with a fenestration (15A) so that the assembled combination of the stent graft (11) of Figure 2 together with the extension graft (13A) of Figure 3 is equivalent to the integrated stent graft prosthesis (1) shown in Figure 1. The assembled graft (11) is shown in Figure 4 and shows the sealing zone (20) achieved by overlapping first end (10A) within the lumen of leg (13). In an alternative embodiment fenestration (15A) need not be present in the extension graft (13A). Alternatively the fenestration (5) can be omitted from second leg (14) of the prosthesis (11).

Figure 5 shows a schematic illustration of an embodiment similar to that illustrated in Figure 1. In this embodiment the first and second legs (3), (4) are formed integrally with the main graft body (2). Anchoring hooks (8), for example as described in PCT/GB2012/051248, may be present to ensure that the prosthesis is firmly anchored to the luminal surface of the target vessel and to avoid migration of the prosthesis after deployment. Stents (7) are shown in a saddle shaped configuration.

Figure 6 illustrates an alternative embodiment of a prosthesis (21), in which the “short trouser leg” (23) includes a short tubular docking zone (31) and an extended

docking zone formed by a fabric flange (30). An extension graft, such as that illustrated in Figure 3, can be located into the docking zone (31) so that the flange (30) lies along one side of the extension graft (13A) (not shown). The first end (10A) of the extension graft (13A) will still be inserted into the lumen of the tubular docking zone (31), with stent(s) (17) at first end (10A) of extension graft (13A) expanded against the lumen of docking zone (31) to sealingly engage with the docking zone (31). Stents are present above the flange (30) and provide a suitable area for sealing engagement of the extension graft (13A). Second leg (24) is illustrated with a fenestration (25). Stents (27) are shown in a saddle shaped configuration.

Fabric flange (30) ensures that the docking zone (31) can be held securely during insertion of extension graft (13A), thus avoiding unintentional and undesirable inversion of docking zone (31) during graft assembly. During insertion of extension graft (13A), flange (30) can be held under gentle tension in extended form by engagement of loop (33) by the delivery system. Once extension graft (13A) has been deployed within docking zone (31) and stent (17) at first end (10A) expanded to engage sealingly with zone (31), loop (33) is released.

Claims

1. A prosthesis comprising a graft sleeve having a first end and a second end with a lumen extending therethrough, wherein said graft sleeve is bifurcated at the second end to form a first leg and a second leg, each of the first and second legs having a lumen in fluid communication with the lumen of the graft sleeve, wherein a fenestration is located in at least one of the first leg or the second leg.

2. A prosthesis as claimed in claim 1, wherein the fenestration has a periphery bound by a strand of resilient material.

3. A prosthesis according to claim 1 or claim 2, wherein the graft sleeve is a tapered graft sleeve.

4. A prosthesis according to any one of the preceding claims, wherein the first leg of the prostheses has a side wall and a fenestration in the side wall.

5. A prosthesis according to any one of the preceding claims, wherein the second leg of the prostheses has a side wall and has a fenestration in the side wall.

6. A prostheses according to any of the preceding claims 1 to 3, wherein the first leg has a side wall and a fenestration in the first leg side wall, and the second leg has a side wall and a fenestration in the second leg side wall.

7. A prosthesis according to any one of the preceding claims 1 to 3, wherein the graft has a first leg and a second leg, each one of which has a fenestration.

8. A prosthesis comprising a graft sleeve having a first end and a second end with a lumen extending therethrough, wherein said graft sleeve is bifurcated at the second end to form a first leg and a second leg, wherein each of said first and second legs has a side wall and each side wall of said first and second legs includes a fenestration.

9. A prosthesis according to any one of the preceding claims, wherein the graft sleeve has a leg a portion of which is extendable in length.

10. A prosthesis according to claim 9, wherein the extendable length leg portion is formed by inclusion of annular folds in the graft sleeve.

11. A prosthesis according to claim 9, wherein the extendable portion comprises a stretchable fabric.

12. A prosthesis according to claim 11, wherein the stretchable fabric is woven or elasticated.

13. A prosthesis according to claim9, wherein the extendable length leg portion comprises a corrugated leg portion.

14. A method of forming an extendable leg portion in a graft sleeve comprising heat setting or crimping the fabric of a selected portion of the graft sleeve to provide a leg portion with an extendable length.

15. A prosthesis comprising a graft sleeve having a first end and a second end with a lumen extending therethrough wherein said graft sleeve is bifurcated at the second end to form a first leg and second leg, wherein the first leg is shorter than the second leg.

16. A prosthesis comprising a graft sleeve having a first end and a second end with a lumen extending therethrough wherein said graft sleeve is bifurcated at the second end to form a first leg and second leg, wherein the first leg comprises a short tubular sealing zone and flange extension.

17. A modular endovascular stent graft assembly comprising

a) a main graft sleeve having a first end and a second end with a lumen extending therethrough,

b) a first leg and a second leg formed by bifurcation of the main graft sleeve;

c) wherein said first leg is shorter than said second leg;

d) a fenestration located in a side wall of the second leg;

e) an extension graft having a first end and second end said first end having a fixing means to sealingly and engage with said first leg said extension graft,

optionally having a fenestration located between said first end and said second end thereof.

18. A modular endovascular stent graft assembly comprising:

a) a main graft sleeve having a first end and second end with a lumen extending therethrough;

b) a first leg and second leg formed by bifurcation of the main graft sleeve;

c) wherein said first leg is shorter than said second leg;

d) an extension graft having a first end and a second end, said first end having a fixing means to sealingly engage with said first leg, said extension graft having a fenestration located between said first end and said second end thereof; and

e) optionally said second leg has a fenestration in a side wall thereof.

19. An implantable prosthesis comprising:

i) a compliant and substantially fluid impervious tubular sleeve having a proximal end and a distal end with a conduit therethrough;

ii) a first ring stent formed from multiple windings of wire of a shape memory material, attached to said sleeve at said proximal end;

iii) a bifurcation of said sleeve, so that said sleeve forms a first leg and a second leg at its distal end;

iv) a fenestration in said first leg and/or said second leg; and

v) a second ring stent formed from multiple windings of wire of a shape memory material attached to said second leg at the distal end thereof.

20. A method of treating a target site proximate to a branch vessel intersection, said method comprising inserting a prosthesis according to any other preceding claims so that a fenestration in said first or second leg is aligned with said branch vessel of said branch vessel intersection.

21. A method of treating a target site proximate to first and second branch vessel intersections, said method comprising inserting a prosthesis according to any one of the preceding claims 1-19, so that a fenestration in the first leg is aligned with said first branch vessel of said branch vessel intersection and a fenestration in the second leg is aligned with said second branch vessel of said second branch vessel intersection.

22. A method according to claim 20 or claim 21, wherein the prosthesis is insertable such that a junction at the bifurcation is proximal to the branch vessel intersections.

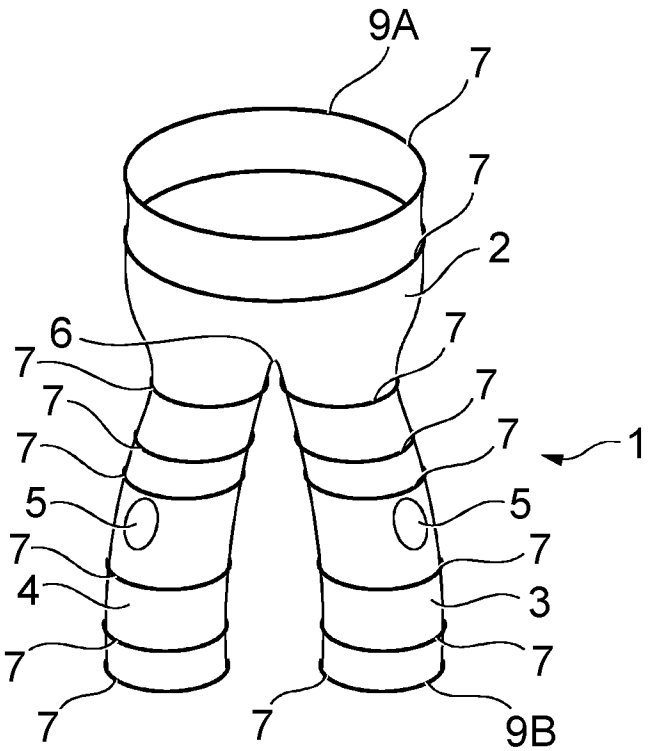
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Fig. 1

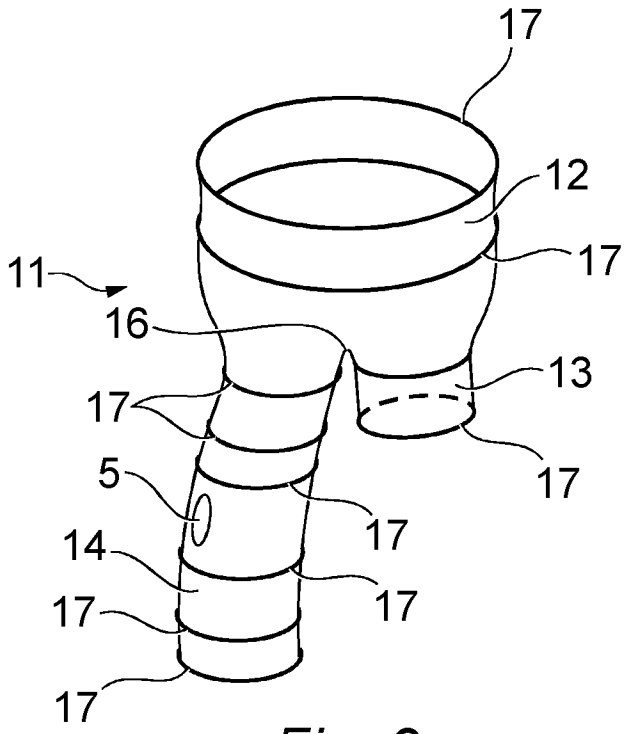
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Fig. 2

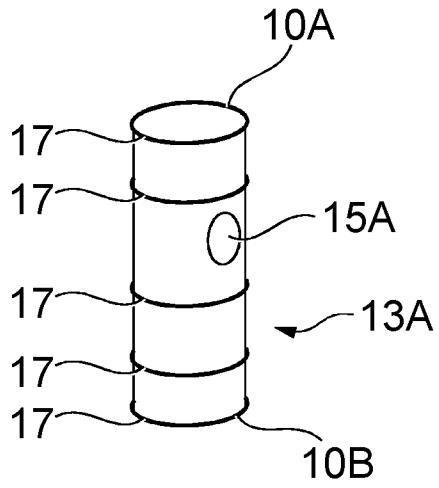

Fig. 3

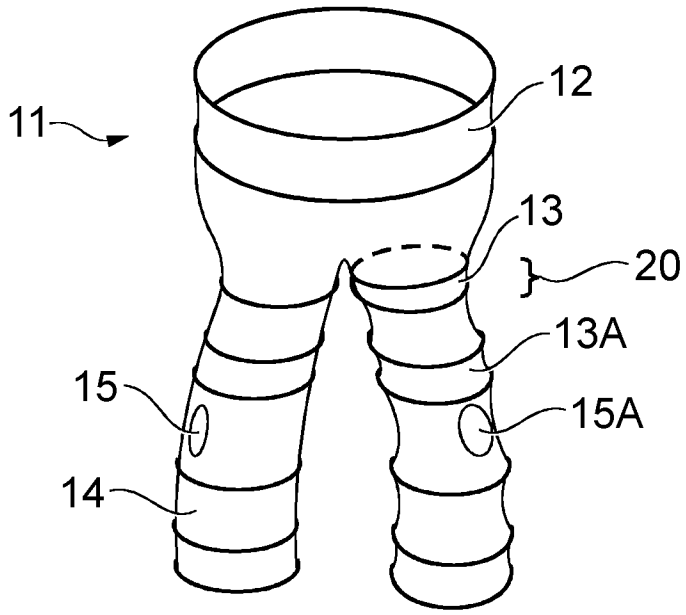

Fig. 4

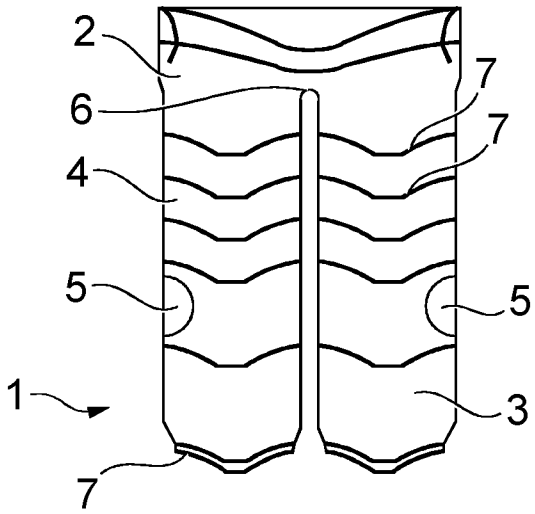

Fig. 5A

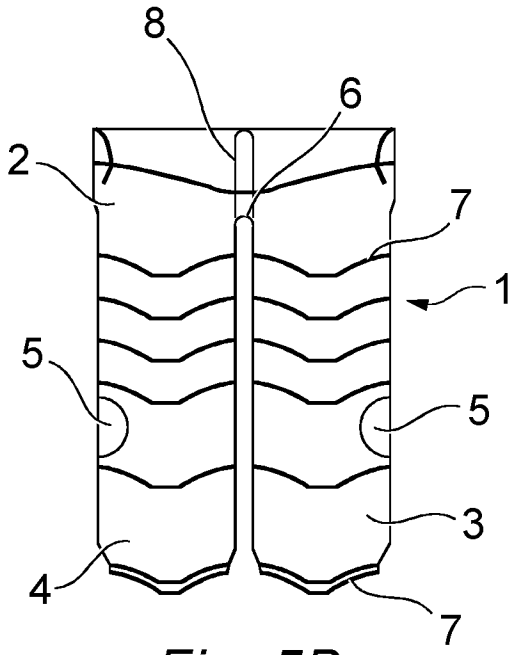

Fig. 5B

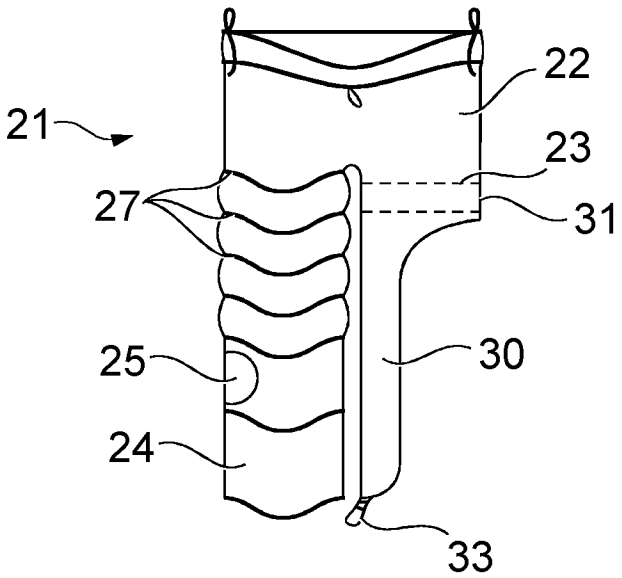

Fig. 6