A HEART VALVE

FIELD OF THE INVENTION

This invention relates to an artificial heart replacement valve.

BACKGROUND TO THE INVENTION

It is known to replace heart valves with artificial valves. One form of heart valve includes a valve located within a collapsible mesh tube or stent. The stent is supplied in a collapsed condition and typically inserted into the body through a vein or artery. Once in position it is expanded using an inflatable balloon. The valve is secured in position by the friction between the native tissue and the stent. After a few weeks the valve becomes more firmly secured through tissue in-growth. Prior to tissue in-growth initial valve migration is however a concern with these type of valves. Heart valves are generally secured within the heart valve annulus within the native valve. In so doing they maintain the native valve open and obviate the need to remove it.

One of the problems typically experienced with such heart valves is that there is limited space for the introduction of the valve in a collapsed or crimped state prior to being expanded by the balloon.

Furthermore, the valve member usually is made up of three flexible leaflets (or cusps as they are sometimes referred to for certain applications but herein referred to as leaflets irrespective of the application) joined along their sides to form a triangular shape. The construction of these leaflets is not always optimal and the materials used to date do not exhibit characteristics

required for extended use, such as wear resistance and resistance to calcification.

It can also be difficult to accurately position such valves as there is no direct visualisation of the site and this has to be done indirectly, often using fluoroscopic imaging.

Still further, there can be leakage of blood between the stent and heart valve annulus or between the stent and artery or vein surface.

OBJECT OF THE INVENTION

It is an object of this invention to create a heart valve which will at least partially alleviate one or more of the abovementioned problems.

SUMMARY OF THE INVENTION

In accordance with this invention there is provided a heart valve which includes a valve member secured within a stent with the valve member including a plurality of valve leaflets secured together, the heart valve being characterised in that the leaflets are made of biological material having a maximum thickness of 0.3 mm.

Further features of the invention provide for the biological material to have a maximum thickness of 0.25 mm; for each leaflet to have an arcuate, preferably generally parabolically shaped side for attachment to the stent; for the stent, in its crimped condition, to have a maximum diameter of 7.5 mm and preferably about 7 mm; for the biological material to be suitably treated kangaroo tissue; and for the kangaroo tissue to be a tissue treated using the ADAPT™ technology of Celxcel Pty Limited (BioMD Limited) of Perth, Western Australia.

The invention also provides for a sleeve made of a porous, biocompatible material to extend about the outer surface of the stent at least partially along its length. The material of the sleeve is preferably selected from porous polyester and expanded polytetraflouroethylene (PTFE), preferably ultrathin porous polyester. The sleeve may extend the length of the stent and the sleeve typically has a thickness of 0.1mm to 0.5mm, preferably 0.2mm. The sleeve may be secured to the stent by stitching typically extending along each end thereof.

The invention also provides a heart valve which includes a valve member secured within an expandable stent having two ends and a central region with the valve member including a plurality of valve leaflets secured together, the heart valve being characterised in that the stent is configured to initially expand at both ends.

Further features of this aspect of the invention provide for the stent to be in the form of a mesh defined by interconnected struts; for the material of the stent to be strengthened in the central region thereof especially by making the struts in that region stronger than the struts in the end regions, typically by making the struts somewhat larger in cross-section; and for the stent to be made of cobalt-chrome (MP25N).

The invention further provides a tool for use in stitching a valve member to a stent comprising a pair of elongate jaws each having a slot extending partway along its length.

Further features of the invention provide for at least one side of each slot to have a series of spaced arcuate notches therein.

In order that the above and other features of the invention may be more fully understood one embodiment thereof will now be described with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:-

Figure 1 is a perspective view of a heart valve;

Figure 2 is a side elevation of the heart valve in Figure 1;

Figure 3 is a perspective view of a stent used in the heart valve of Figure 1;

Figure 4 is a perspective view of a valve member used in the heart valve illustrated in Figure 1;

Figure 5 is a side elevation of a valve leaflet for the valve member illustrated in Figure 4; and

Figure 6 is a side elevation of a second embodiment of a stent for a heart valve.

DETAILED DESCRIPTION WITH REFERENCE TO THE DRAWINGS

A heart valve (1) is shown in Figures 1 and 2 and includes a tubular stent (2) having a valve member (4) secured internally thereof and an external sleeve (6). Referring also to Figure 3, the stent (2) is cylindrical and is formed by laser cutting a plurality of concentric diamond-shaped holes in a length of cobalt-chrome (MP35N) tubing. The stent (2) thus has a diamond mesh appearance with each of its ends (8, 9) being serrated.

The stent (2) is shown in its expanded condition in which it has a length of between 20 and 22mm and a diameter of between 23 and 26mm. However, in the manufacture of the stent (2) a cobalt-chrome tube of 10mm diameter is

used. The tube is expanded after cutting and the valve member (4) and sleeve (6) secured thereto. The assembled heart valve (1) is then crimped over a balloon catheter (not shown) in conventional manner.

Referring especially to Figures 4 and 5, the valve member is formed from three valve leaflets, each cut from a sheet of kangaroo tissue which has been treated using the ADAPT™ technology of Celxcel Pty Limited. Each leaflet (12) has a straight outlet side (14) with normally extending sides (16) at each end, each approximately a third of the length of the outlet side (14). An arcuate inlet side (18) extends between the sides (16) opposite the outlet side (14). In this embodiment, the inlet side (18) has a parabolic shape.

The leaflets (12) are secured together along their sides (16) to form a triangular shape by a row of stitching (20) which tapers slightly inwardly from the start of the abutting inlet sides (18) towards the outlet sides (14).

The valve member (4) is subsequently secured within the stent (2) by stitching along the sides (16, 18) as indicated in Figure 5 by the dots (22). It will be appreciated that the parabolic shape of the inlet side (18) of each leaflet (12) corresponds to the shape of an inclined section through the stent (2) along which each leaflet (12) is secured thereto.

The use of the treated kangaroo tissue has a number of advantages. Firstly, the tissue is flexible and resistant to wear. Secondly, it resists calcification and thus retains its flexibility for extended periods. Thirdly, it is relatively tough and can consequently be thinner than many other materials used in this application. In this embodiment, the leaflets each have a maximum thickness of 0.22mm. This characteristic of treated kangaroo tissue is especially important as it enables the entire heart valve in its crimped state in which it is ready for introduction into the human body to be appreciably smaller in diameter than in the instance of other heart valves presently used. The use of the kangaroo tissue enables the crimped heart valve to have a

diameter of 6.7 mm [20 French] whereas the conventional prior art crimped heart valve has a diameter of 8.0 mm [24 French]. This is a significant reduction in size and it is envisaged that it will greatly facilitate initial placement of the crimped heart valve.

Another important feature of the heart valve (1) is the sleeve (6) provided about the outer surface of the stent (2). The sleeve is made of a porous, bio-compatible material, in this embodiment ultra-thin porous polyester having a thickness of 0.2 mm. The ends of the sleeve (6) conform to those (8, 9) of the stent (2) and stitching (24, 26) along each of the ends (8, 9) secures the sleeve (6) to the stent (2). The sleeve (6) is further secured in position by the stitching securing the valve member (4) to the stent, the stitching extending about both the stent and the corresponding portion of the sleeve (6).

The sleeve (6) has two major functions. The first is to provide a porous surface for tissue in-growth which assists in securing the heart valve (1) in position after implantation. The second function is to provide increased resistance between the heart valve and the arterial wall and to so prevent migration of the device after implantation. Critically, the sleeve also assists in preventing blood leakage between the heart valve (1) and arterial wall. This greatly increases the effectiveness of the heart valve.

It will be appreciated, however, that many other embodiments of a heart valve exist which fall within the scope of the invention. For example, any suitable material can be used for the sleeve including expanded PTFE. In this embodiment, Corex sutures are used for all the stitching, but any other suitable material can be used. Also, the valve member can have any suitable shape. The stent too can be made of any suitable material and can have any suitable shape.

Referring to Figure 6, the stent could be made so that the material at the ends (8, 9) is thinner than that at the centre (30). This will result in the end

regions expanding initially during inflation to give the stent a waisted shape as illustrated by the broken lines. This shape will ensure that the heart valve becomes easily centralised within the valve annulus where it can be secured in position before inflating the balloon further to give the stent a more uniform cylindrical shape. This can easily be achieved by making the central bands of struts defining the mesh structure approximately 10% thicker than those at the ends.

As shown in Figure 7, a tool is also provided which assists in suturing the valve member in position on the stent. The tool (40) includes a pair of narrow elongated jaws (42) each extending from a handle (44), the handles being secured together at one end (46). The jaws (42) and handles (44) are made of a stainless steel and are shaped to be biased apart at the end (46). Corresponding slots (48) extend centrally along each jaw (42) from the free end (50) thereof, with the slots (48) each having a series of spaced apart arcuate notches (52) therein. The notches (52) are shaped to receive a sewing needle.

In use, the joined sides (16) of leaflets (12) are held against the side of the stent by between the jaws (42) whereafter they are stitched in position, the notches (52) acting as a template to ensure uniformity.

The tool is fairly simple to make but greatly facilitates manufacture of the stent as it permits both the valve member to be held in position and to be secured by a stitching whilst being so held. It will be appreciated that other embodiments of a tool exist which fall within the scope of the invention especially as regards the shape of the jaws and the slot therein.

CLAIMS:

1. A heart valve (1) which includes a valve member secured within a stent (2) with the valve member including a plurality of valve leaflets (12) secured together, the heart valve being characterised in that the leaflets are made of biological material having a maximum thickness of 0.3 mm.

2. A heart valve has claimed in claim 1 in which the biological material has a maximum thickness of 0.25 mm.

3. A heart valve has claimed in either one of claims 1 or 2 in which each leaflet has an arcuate shaped side (18) for attachment to the stent.

4. A heart valve has claimed in any one of the preceding claims in which the stent, in its crimped condition, has a maximum diameter of about 7.5 mm.

5. A heart valve has claimed in claim 4 in which the stent, in its crimped condition, has a maximum diameter of about 7.0 mm.

6. A heart valve has claimed in any one of the preceding claims in which the biological material is suitably treated kangaroo tissue

7. A heart valve as claimed in claim 6 in which the kangaroo tissue is a tissue treated using the ADAPT™ technology of Celxcel Pty Limited (BioMD Limited) of Perth, Western Australia.

8. A heart valve as claimed in any one of the preceding claims in which a sleeve (6) made of a porous, biocompatible material extends about the outer surface of the stent, at least partially along its length.

9. A heart valve has claimed in claim 8 in which the material of the sleeve is selected from porous polyester and expanded polytetraflouroethylene (PTFE).

10. A heart valve has claimed in either one of claims 8 or 9 in which the sleeve extends the full length of the stent.

11. A heart valve has claimed in any one of claims 8 to 10 in which sleeve is secured to the stent by stitching (22) typically extending along each end thereof.

12. A heart valve has claimed in any one of the preceding claims in which the stent is configured to initially expand at both ends (8, 9).

13. A heart valve has claimed in claim 12 in which the stent is in the form of a mesh defined by interconnected struts with the material of the stent being strengthened in a central region thereof by making the struts in that region stronger than the struts in the end regions.

ABSTRACT

A heart valve (1) is provided in which a valve member including a plurality of valve leaflets (12) secured together is secured within a stent (2). The leaflets are made of a biologic material that has a maximum thickness of 0.3 mm. Suitably treated kangaroo tissue such as that treated using the ADAPT™ technology is considered appropriate. Each leaflet preferably has an arcuate shaped side (18) for attachment to the stent. The resultant crimped stent may have a maximum diameter of about 7.5 or even 7.0 mm. Preferably, a sleeve (6) made of a porous, biocompatible material extends about the outer surface of the stent, along at least a part, and typically all of its length. Preferably, the stent is configured to initially expand at both ends (8, 9), this being conveniently achieved by using a stent in the form of a mesh defined by interconnected struts with the struts in a central region being stronger than the struts in the end regions.

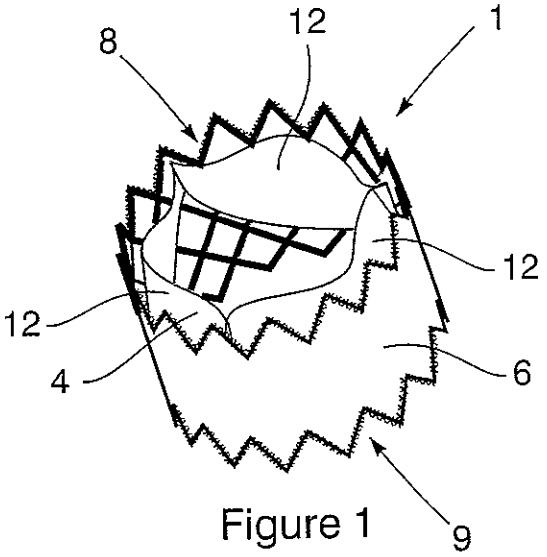

Figure 1

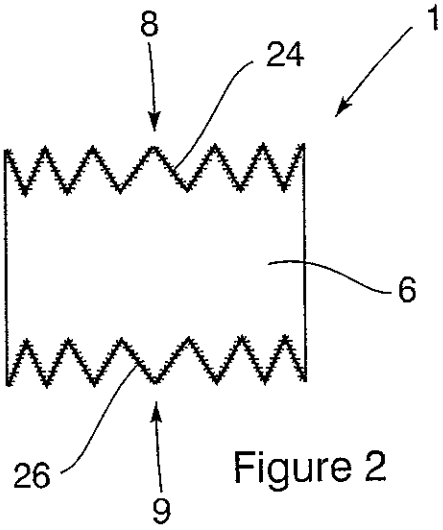

Figure 2

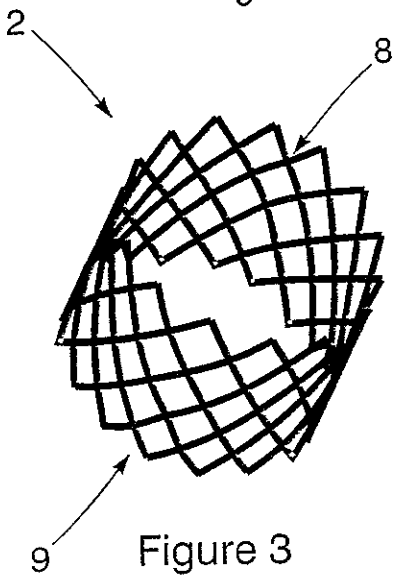

Figure 3

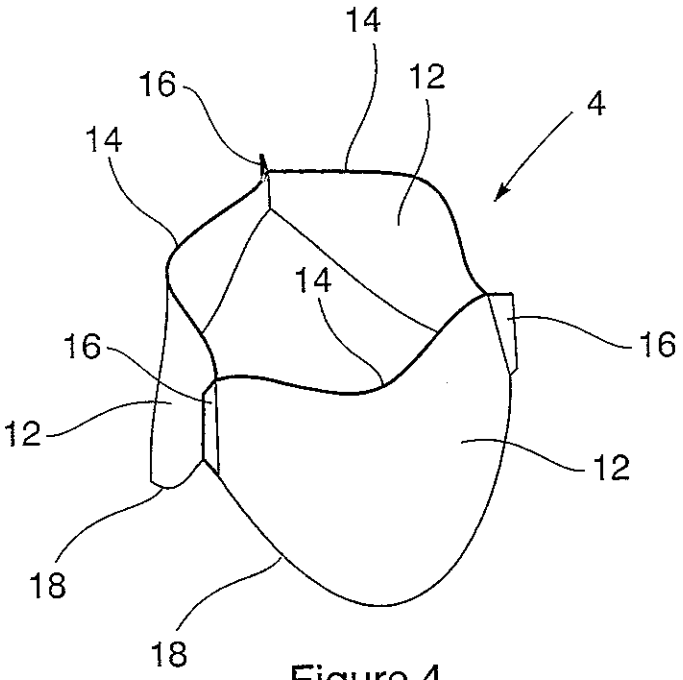

Figure 4

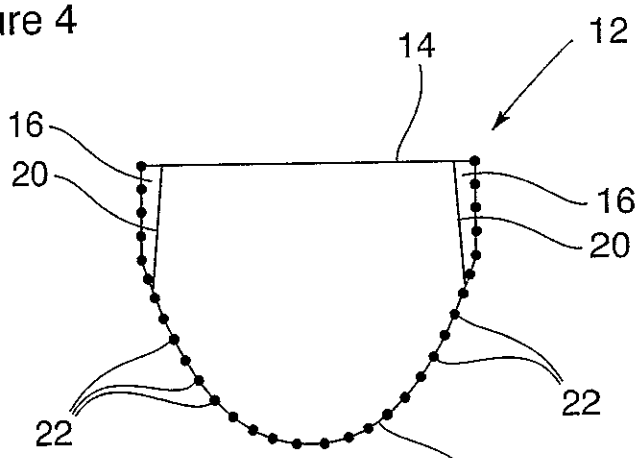

Figure 5

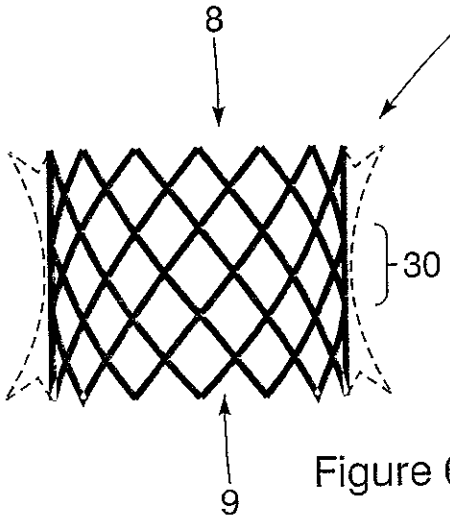

Figure 6

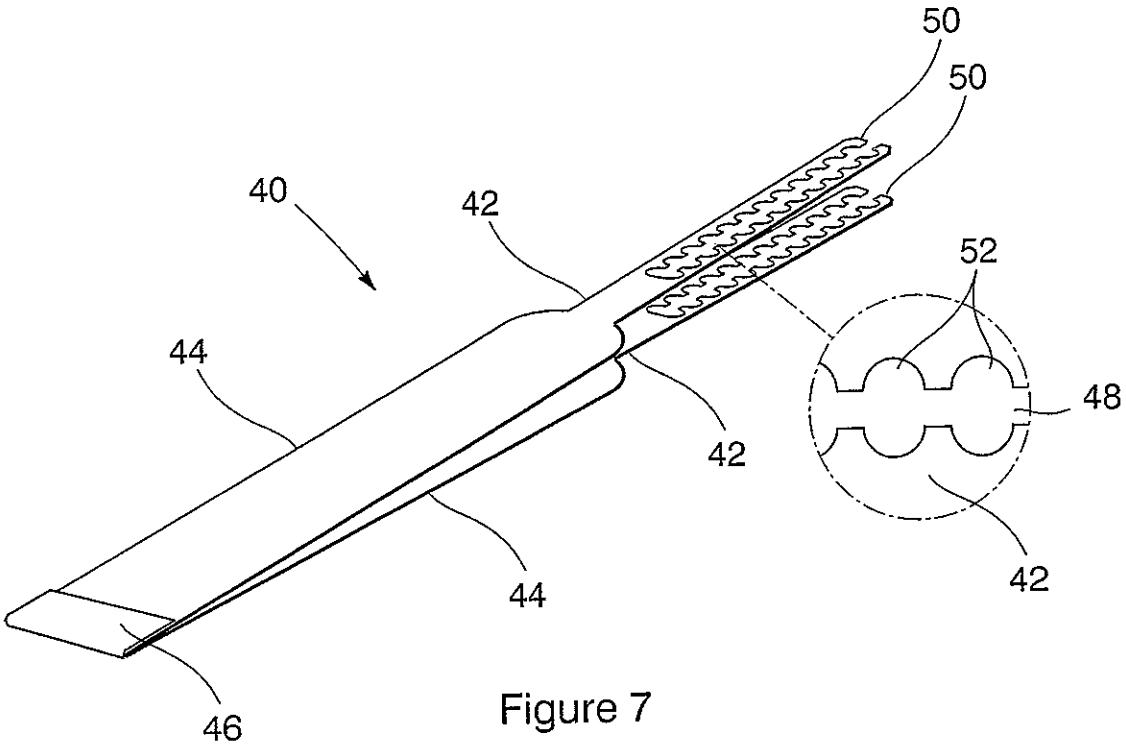

Figure 7