FLEXIBLE STENT FOR HEART VALVE

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References Cited

UNITED STATES PATENTS
3,570,014 3/1971 Hancock
3,197,788 8/1965 Segger

OTHER PUBLICATIONS


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ABSTRACT

An arrangement for heart valves that includes a stent having apexes interconnected by arms, the apexes being deflectable inwardly upon hemodynamic loading of the heart valve for reducing the stress in the valve tissue, the stent being covered by a cloth sleeve which may have an integral bead or flap for attachment to the heart, padding being provided beneath portions of the sleeve for protection, and a reinforcing ring extending around the assembly over the marginal portions of the heart valve, with sutures extending through the reinforcing ring and tissue of the heart valve for forming an attachment to the stent.

27 Claims, 12 Drawing Figures
FLEXIBLE STENT FOR HEART VALVE

BACKGROUND OF THE INVENTION

1. Field of the Invention
This invention relates to a supporting framework, or stent, for a natural or synthetic heart valve.

2. Description of Prior Art
It has been established that a stent is a useful arrangement for supporting a natural or synthetic heart valve for implantation in the human heart. The design shown in U.S. Pat. No. 3,570,014 offers advantages in properly supporting the valve and permitting its advance preparation for storage until the requirement for use arises. There has remained, however, room for improvement, particularly in assuring the reliability of the valve and its proper functioning over a long period of time. Malfunctioning of the valve may be caused by overstressing the valve tissue by the hemodynamic pressure imposed upon it when in use. Further areas of continued problems involve the fixing of the valve in the heart so as to provide a bed for ingrowth or attachment of tissue and a hemodynamic seal while avoiding clotting.

SUMMARY OF THE INVENTION

The present invention provides an improved arrangement for supporting a natural or synthetic heart valve in which the reliability of the valve is significantly improved. The invention contemplates the use of a stent which may bear a resemblance in appearance to that of the aforementioned U.S. Pat. No. 3,570,014. It includes three spaced apexes to support the valve commissures, with arms interconnecting the apexes. However, unlike the stent of that patent and other previous designs, the stent of the present invention is resilient. This allows deflection of the three apexes of the stent when the valve is subject to hemodynamic pressure during diastole. As the apexes are resiliently bent inwardly toward the axis of the stent, the stress in the tissue of the heart valve is correspondingly reduced. The result is a major improvement in the reliability of the valve, with an attendant reduction in danger to the life of the patient. The stent returns to its normal full diameter when the pressure is relieved, so that there is no undue restriction when the valve is in the open position.

The stent is arranged so that the arms remote from the apexes act as torsion bars as the deflection takes place, while the apexes themselves experience little distortion. Various arrangements may be included to stiffen the bars as may be required to obtain the proper degree of resiliency in the stent. The stiffening arrangements may include additional elements interconnecting the upper and lower bars of the stent.

A noncorrosive metal, such as stainless steel, may be used in constructing the stent, or it may be made of plastic. In either event, it is preferable that it be possible to deflect the arms permanently in order to vary the lateral dimensions of the stent so that it can be adjusted to fit a particular heart valve to be applied to it. This may be accomplished by exceeding the yield point of the metal stent, or through the use of heat or solvents in bending the plastic. In either event, however, the stent retains its resilience after the adjustment.

For a plastic stent, a reinforcing ring may be provided at the exterior of the end of the stent remote from the apexes, the ring being fitted loosely in a notch having a frustoconical inner wall which assures that the ring does not interfere with the flexing of the stent from the pressures on the heart valve.

Improved means also may be included for more readily attaching the tissue to the stent and providing a matrix for ingrowth and subsequent fixation of the donor valve by the host tissue. This may include a cloth sleeve around the stent entirely covering it, together with an annular ring of cloth or sponge on the exterior of the unit at the end of the apexes extending over the marginal edge of the heart valve. The sutures for attaching the heart valve to the stent pass through the cloth ring as well, which reinforces the loops of the sutures so that they do not tend to cut through the tissue of the valve. Felt packing is included at apexes beneath the cloth sleeve to protect the cloth and sutures from abrading through contact with the stent.

The cloth sleeve around the stent may be provided with a bead intermediate the upper and lower arms, which also facilitates attachment to the heart and the ingrowth of tissue. When used in the mitral position, there is a projecting flat ring of cloth provided at the end of the stent opposite the apexes. This provides a means for suturing the valve assembly in the heart, resulting in a hemodynamic seal and a suitable bed over which tissue can be affixed or ingrown upon the grafting of the heart valve assembly.

BRIEF DESCRIPTION OF THE DRAWINGS:

FIG. 1 is a perspective view, partially broken away, illustrating a heart valve mounted on a stent in accordance with this invention;

FIG. 2 is an enlarged perspective view of the stent;

FIG. 3 is a side elevational view of the stent, illustrating the manner in which the stent deflects under load;

FIG. 4 is a top plan view of the arrangement of FIG. 3;

FIG. 5 is an enlarged fragmentary perspective view showing the attachment of the heart valve and cloth elements to the stent;

FIG. 6 is a perspective view of a stent having additional members for controlling the deflection of the upper arms;

FIG. 7 is a perspective view of a stent having a different arrangement of the members to control the deflection of the upper arms;

FIG. 8 is a perspective view of a modified form of the stent also controlling the deflection of the upper arms;

FIG. 9 is an enlarged fragmentary sectional view illustrating the arrangement for reinforcing the base of the stent when made from plastic;

FIG. 10 is a view similar to FIG. 5, but with a different arrangement of the cloth covering elements;

FIG. 11 is a view similar to Figs. 5 and 10, but with the addition of a flap at the base of the stent for attachment to the heart; and

FIG. 12 is a perspective view of a stent of a different configuration.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The stent 10 illustrated in Figs. 1-4 is of a basic shape for use in the aortic, mitral, tricuspid or pulmonary location. The stent 10 is an annular framework, circular in plan, made of a material which is both noncorrosive and resilient. Suitably, it may be constructed of a stainless steel, such as that marketed under the
3,755,823

trademark "Elgiloy" by Elgiloy Company, 853 Dundee Ave., Elgin, Ill. 60120. A resilient plastic, such as polypropylene, also may be used for the stent 10.

The stent 10 includes three apical portions 11, 12 and 13 at one end of the annular framework, which are of generally oval shape so that they present rounded upper surfaces. Openings 14, 15 and 16 may be provided through the apical portions 11, 12 and 13. The apical portions 11, 12 and 13 are for supporting the commissures of a heart valve 18, which may be from a human or from an animal. Particularly when the stent is intended to receive an animal valve, the apical portions are not distributed equally around the perimeter of the stent 10. In the example shown, there is equal angular spacing between the apical portions 11 and 12 and between the apexes 11 and 13. However, the spacing between the apical portions 12 and 13 is approximately 17–33 percent under the spacing of the other apexes, preferably around 20–25 percent less. This is in order that the stent will conform to the spacing of the commissures of the valve 18 to be applied to it, which for animals is very close to this proportioning. Alternative spacing of the apexes is such that, if one space between adjacent apexes is a reference, a second is around 4–10 percent less than the reference space, and the third is about 17–33 percent less than the reference space.

Extending between the lower portions of the apical parts 11, 12 and 13 of the stent 10 are support arms 19, 20 and 21. These arms are scalloped, being curved away from the apical portions 11, 12 and 13 so that they are concave toward the end of the stent where the apexes are located. Immediately beneath the apexes 11, 12 and 13 are short depending posts 22, 23 and 24, respectively, which are approximately parallel to the axis of the stent 10. Lower support arms 25, 26 and 27 interconnect the bottom ends of the posts 22, 23 and 24. The arms 25, 26 and 27 may fall substantially in a radial plane through the stent, collectively forming a ring, or they may be scalloped generally as are the arms 19, 20 and 21. However, when scalloped, the lower arms 25, 26 and 27 are not scalloped as deeply as are the upper arms. The lower arms 25, 26 and 27 are substantially the same distance from the axis of the stent as are the upper arms 19, 20 and 21.

Prior to attaching the valve 18 to the stent 10, a felt packing or jacket 28 is applied around each of the apexes 11, 12 and 13, extending downwardly also to encompass the support posts 22, 23 and 24 and the immediately adjacent portions of the lower arms 25, 26 and 27. The felt jackets 28 cover both the inner and outer surfaces of the stent. After this, a sleeve 29, which may be of woven material or felt, or of sponge, is applied to the stent 10. The cloth sleeve 29 is annular and contoured so that it fits over the apical portions 11, 12 and 13 and the felt packing 28, providing inner and outer layers along the inner and outer surfaces of the stent. The outer layer of the cloth sleeve 29 is stitched together around the perimeter of the stent to provide a bead 30. A ring 31 of felt or sponge may be received within the bead 30. The bead 30 and ring 31 provide a location for suturing when the valve is grafted in the heart, enabling a hemodynamic seal to be obtained.

When applying the cloth sleeve 29 to the stent 10, the valve 18 is positioned on the stent, with the valve commissures at the apexes 11, 12 and 13, while the margins of the cusps conform to the scalloped configuration of the support arms 19, 20 and 21. The presence of the various apexes and support arms assures that there is a portion of the stent conforming to the shape of the valve 18 available for secure attachment of all peripheral parts of the valve. The arcuate upper configuration of the apexes 11, 12 and 13 allows angular latitude in the positioning of the valve commissures. There are some dimensional differences among all natural valves, so that the spacing of the commissures may vary to a degree. With the upper portions of the apexes 11, 12 and 13 being arcuate, valves of different proportions may be accommodated and allowed to assume their natural contour while still being afforded ready and appropriate locations for attachment.

While being made of resilient material, the stent 10 may be given a permanent deflection, which is important in adapting the stent to conform to the contour of the particular heart valve being applied to it. The permanent deflection for a metal stent is achieved by manually deforming the arms 19, 20 and 21 beyond the yield point, while, for plastic stents, the application of heat or solvents may be necessary. Because of the scalloped configuration, bending of the support arms 19, 20 and 21 upwardly as the stent is shown causes an increase in the effective diameter of the stent. This is indicated in phantom in the left-hand portion of FIG. 3. Conversely, downward deflection of the support arms reduces the stent diameter. Permanent deflection of the arms 19, 20 and 21, therefore, allows the shape of the stent to be adjusted as needed. The resilience of the stent 10, however, is retained, irrespective of whether or not the arms 19, 20 and 21 are given a permanent deflection.

After the valve 18 has been applied to the stent 10, an additional annular reinforcing ring of cloth or sponge 33 is applied to the scalloped end of the stent 10, extending entirely around the perimeter of the stent. The outer margin of the ring 33 is tucked under the upper edge of the outer layer of the sleeve 29.

Sutures 34 extend through the cloth ring 33, the edge of the outer layer of the sleeve 29 and the tissue of the valve 18, holding the assembly on the stent 10. The cloth ring 33 acts as a reinforcement for the suture line, distributing the load on the sutures. Without the cloth ring 33, there is some tendency for the loops of the sutures to pull through the tissue of the valve 18. However, the loops of the sutures 34 bear against the reinforcing ring 33 and will not cut the valve tissue.

The felt packing around the apexes 11, 12 and 13 provides a soft bed and padding that protects the sutures and the cloth 29 as well. Otherwise, there can be some abrasion of the sutures and the cloth on the relatively hard stent surface.

This completes the preparation of the heart valve, which may be stored at this point, ready for implantation. With the stent 10 being entirely covered by cloth, there is no exposure of the metal or plastic of the stent in the portions of the heart where clotting is a problem. Only tissue is exposed in the critical areas, so any tendency to clot is minimized.

An important advantage is realized from the resilience of the stent 10. Because of this, the stent 10 can deflect in response to hemodynamic pressure on the valve 18 during diastole after grafting in the heart of a patient. This, in turn, significantly reduces the tensile stress in the valve commissures, as a result of which the valve is more reliable and the risk to the patient is mini-
mized. The nature of the deflection experienced by the stent is indicated in phantom in the right-hand portion of FIG. 3, as well as being shown in FIG. 4. The apexes 11, 12 and 13 are deflected inwardly by the forces imposed on the stent, pivoting about their lower portions as the movement takes place. During this deflection, the lower support arms 25, 26 and 27 act as torsion bars, twisting to allow the deflection of the apexes to occur. As the lower arms twist and the apexes bend inwardly, the upper arms also experience deflection. The apexes themselves are relatively rigid so that they do not bend appreciably, with the support arms being proportioned so that they will experience practically all of the distortion which takes place. The inward deflection of the apexes 11, 12 and 13 reduces their spacing from the central axis of the stent, giving the stent a shape such that less tensile stress is imposed on the valve cusps. This is because the supports for the valve cusps are moved closer together by the deflection, which can be shown mathematically to result in reduced loading on the cusps. With the apexes 11, 12 and 13 deflected inwardly, the cusps can assume a more natural and relaxed position during diastole. Also, energy is absorbed in deflecting the apexes, resulting in a damping effect that reduces the tensile stress in the valve tissue. While relieving the stress in the valve, the resilience of the stent also allows the apexes to return to their normal positions when the pressure is relieved. Consequently, the apexes do not remain in their inward positions where they extend into the valve passageway, and the valve can assume a full-open position without imposing an obstruction to the flow through it.

Experiments have established that, if the apexes are permitted to deflect approximately two millimeters in an average size human valve, the tensile stress in the commissures of the valve at the margin of attachment is reduced by approximately 20 percent compared with that experienced on a rigid stent. This is a significant factor in assuring the proper functioning of the valve over a long period of time. Of course, the stent must be proportioned so that the proper amount of deflection will occur under the hemodynamic pressure exerted, which typically is around 2.3 psi.

The stent may be modified as indicated in FIG. 6 by the inclusion of a pair of diagonal bars 36 and 37 positioned on one or the other side of each of the support posts 22, 23 and 24. These diagonal bars stiffen the upper arms 19, 20 and 21 for controlling their deflection during preparation of the stent. This is to avoid bending the arms when the cloth sleeve 29 is attached so that the upper and lower arms are not brought into interengagement.

The stent of FIG. 7 is similar to that of FIGS. 1-4, but with the addition of intermediate posts 38, 39 and 40 between the upper arms 19, 20 and 21 and the lower arms 25, 26 and 27, respectively. The intermediate posts 38, 39 and 40 connect at the centers of the upper arms, stiffening them when it is desired to reduce the amount of deflection permitted.

In FIG. 8 of FIG. 8, the straight posts beneath the apical portions are eliminated. Instead, the stent is provided with diagonal bars 43 and 44 beneath each of the apexes 45, 46 and 47. The latter elements are integral with the upper arms 48, 49 and 50, and open at their bottom ends because of the absence of the vertical posts beneath them. The diagonal posts 43 and 44 not only connect the upper arms 48, 49 and 50 with the lower arms 51, 52 and 53, but also serve to control the deflection of the upper arms.

FIG. 9 illustrates a fragmentary section of a plastic stent provided with an annular recess at its lower corner, which receives a metal reinforcing ring 55. The recess is defined by a radial upper wall 56 and a frustoconical inner wall 57, which tapers toward the end of the stent remote from the apexes. The ring 55, fitting loosely in the recess in the bottom end of the stent, stiffens and reinforces the plastic stent at that location. The surface 57 is tapered so that there will be no interference to inward deflection of the post 58 when the stent deflects under load. Therefore, the ring 55 will not interfere with full flexing of the stent. It will, however, keep the adjacent portion of the stent in a circular shape when the deflection takes place, so that the stent does not become unduly distorted.

The arrangement of FIG. 10 is similar to that of FIG. 5, but illustrates a variation in the attachment of the reinforcing ring at the scalloped end of the stent. Here, the annular member 60 of cloth or sponge extends over the upper edge of the cloth sleeve 29, rather than being tucked under the outer layer of the sleeve 29. The edges of the reinforcing ring 60 are doublet under so that the ring 60 is in two layers with no exposed edges. Again, the elements attached to the stent 10 are held in place by sutures. The overlapping of the annular ring 60 over the outside layer of the sleeve 29 provides the assembly with a smoother and neater appearance.

Another variation is shown in FIG. 11 in which the cloth sleeve 61 is similar to the cloth sleeve 29 described above. In addition, however, the sleeve 61 is provided with a flat, doubled-over, annular extension or flap 62 around the exterior of the stent adjacent the lower arms 25, 26 and 27. The cloth extension 62 provides a hemodynamic seal when grafted in the heart, as well as a suitable bed over which tissue can be affixed or ingrown. This version is for use in the mitral position. No rigid reinforcement is included with the annular element 62, although felt or sponge may be provided between its layers.

The stent 64 of FIG. 12 preferably is made of plastic for full flexibility of its apexes 65, 66 and 67. The base ring 68 serves as the means to connect the apexes, as well as acting as a torsion bar and annular stiffener. Cloth may be used to cover the stent 64, generally as described above, and the heart valve 18 may be sutured to the cloth when mounted on the stent. Instead of an animal or human heart valve, however, other tissue, such as fascia lata or pericardium, may be affixed to the stent to create valve cusps. For such purposes, the apexes 65, 66 and 67 may be equally spaced. A stiffener ring 55 may be employed with the stent 64 to reinforce the base ring 68.

The foregoing detailed description is to be clearly understood as given by way of illustration and example only, the spirit and scope of this invention being limited only by the appended claims.

What is claimed is:

1. A stent for a heart valve comprising a framework of annular configuration, said framework including spaced apical portions extending around the longitudinal axis thereof and arms interconnecting said apical portions, for thereby providing an attachment for the commissures and cusps of a heart valve,
said framework including means for permitting substantial resilient deflection of said apical portions inwardly toward said longitudinal axis of said framework such that there is an apical portion so deflected a distance of at least approximately 2 millimeters in response to predetermined loading on said apical portions, which loading is that produced by hemodynamic pressure of approximately 2.3 psi when a heart valve is mounted on said framework and grafted in the heart of a human, and return of said apical portions to the original positions thereof upon the removal of said predetermined loading.

2. A device as recited in claim 1 in which, for said means for permitting said resilient deflection of said apical portions, said arms are twistable as torsion bars upon the application of said predetermined loading to said apical portions.

3. A device as recited in claim 2 in which said apical portions are relatively rigid so as to be substantially undistorted upon the application of said predetermined loading to said apical portions.

4. A device as recited in claim 2 in which said framework includes additional arms collectively of annular shape, said additional arms being spaced axially from said first-mentioned arms and relatively closer to said apical portions.

5. A device as recited in claim 4 in which said additional arms incline axially away from said apical portions intermediate said apical portions.

6. A device as recited in claim 5 in which said additional arms are deflectable to take a permanent set while retaining the resilience thereof for varying the distances thereof from the axis of said framework.

7. A device as recited in claim 6 including in addition means interconnecting said first-mentioned arms and said additional arms for stiffening said additional arms.

8. A device as recited in claim 7 in which said means interconnecting said first-mentioned arms and said additional arms includes members connecting to said additional arms at locations angularly spaced from said apical portions.

9. A device as recited in claim 8 in which said members are in pairs, positioned one on either side of each of said apical portions.

10. A device as recited in claim 9 in which said members of each pair are divergent toward said additional arms.

11. A device as recited in claim 10 in which said framework includes a post interconnecting each of said apical portions and said first-mentioned arms, each of said posts being positioned between said members of each of said pairs.

12. A device as recited in claim 11 in which said framework includes a post interconnecting each of said apical portions and said first-mentioned arms, each of said posts being positioned between said members of each of said pairs.

13. A device as recited in claim 2 in which said framework includes a post interconnecting each of said apical portions and said first-mentioned arms, each of said posts being positioned between said members of each of said pairs.

14. A device as recited in claim 2 in which said framework is constructed of a resilient stainless steel material.

15. A device as recited in claim 2 in which said framework is constructed of a resilient plastic material.

16. A device as recited in claim 2 in which said framework includes an annular groove receiving said ring, said groove having an inner surface tapering away from said apical portions so that said ring will not restrict said resilient deflection of said apical portions.

17. A heart valve assembly comprising a stent, said stent including a generally tubular framework having spaced apaxes at one end and arms interconnecting said apaxes, said apaxes being normally spaced a predetermined distance from the longitudinal axis of said framework, a heart valve on said framework, said heart valve having commissures substantially at said apaxes and cusps having marginal portions adjacent said arms, and means for attaching said heart valve to said framework, said framework including means for permitting substantial resilient deflection of said apaxes inwardly toward said axis a distance of at least approximately 2 millimeters in response to hemodynamic pressure of approximately 2.3 psi on said heart valve upon grafting of said heart valve in a heart, and return of said apaxes to said predetermined distance from said axis upon removal of said hemodynamic pressure.

18. A device as recited in claim 17 in which, for said means for permitting said resilient deflection of said apical portions, said arms are twistable as torsion bars upon the application of said predetermined loading to said apical portions.

19. A device as recited in claim 18 in which said apical portions are relatively rigid so as to be substantially undistorted upon the application of said predetermined loading to said apical portions.

20. A device as recited in claim 17 including in addition a material selected from the group consisting of cloth or sponge means entirely covering said framework.

21. A device as recited in claim 17 including in addition a first material selected from the group consisting of cloth or sponge means, said material including an annular element extending over the marginal edge portion of said heart valve at said one end, said means for attaching said heart valve to said framework including sutures, said sutures extending through said material and said heart valve with loop portions of said sutures engaging said material for thereby preventing said sutures from pulling through the tissue of said heart valve.

22. A device as recited in claim 21 in which said material includes a sleeve entirely receiving said framework so as to provide an inner layer and an outer layer, and including an annular bead on the exterior of said outer layer intermediate the ends thereof for providing a means for attachment to a heart.

23. A device as recited in claim 22 in which said bead is integral with said outer layer, and including a ring of a second material selected from the group consisting of sponge or felt received in said bead.

24. A device as recited in claim 23 in which said first material includes padding between said layers at the lo-
cations of said apexes for protecting said sutures and said layers from being abraded by said framework.

25. A device as recited in claim 24 in which said padding includes a layer of felt on both sides of each of said apexes.

26. A device as recited in claim 17 including in addition a material selected from the group consisting of:

said material including an uninterrupted sleeve entirely receiving said framework so as to provide an inner layer and an outer layer, and an integral generally flat uninterrupted annular flap at the end of said stent opposite from said one end for providing a means for attachment to a heart.

27. A heart valve assembly comprising a stent, said stent including a generally tubular framework having spaced apexes at one end and arms inter-

10 connecting said apexes, said arms being inclined away from said apexes at locations intermediate said apexes, a heart valve on said framework, said heart valve having commissures substantially at said apexes and cusps having marginal portions adjacent said arms, an annular member of material selected from the group consisting of cloth or sponge material overlying the marginal edge portion of said heart valve at said one end, and sutures extending through said annular member and said marginal edge portions for attaching said heart valve to said framework, said sutures having loop portions engaging said annular member for thereby protecting said heart valve from damage by said sutures.