

HEART VALVE WITH DISC OCCLUDERSPECIFICATIONBACKGROUND OF THE INVENTION:1. Field Of The Invention:

The present invention is directed to heart valves. More particularly, the present invention is directed to a heart valve prosthesis including a disc occluder supported intermediate a pair of support struts and restrained by the edge of thickness of a disc being smaller than the gap between the struts.

2. General Background:

For many years, heart valve prostheses have been used in place of defective natural heart valves. Beginning in the early 1960's, heart valve prostheses emerged from a period of experimentation into a period of practical surgical application. These prostheses, like the natural heart valves, are hemo-dynamically operated by the pumping action of the heart. It is essential that in order to operate effectively, such valves must be light in weight but yet very durable and resistant to wear. In addition, the body of the valve must be constructed to evenly distribute forces uniformly across the surfaces of the occluder. In addition, it is essential that the blood flow not be restricted and that the valve function must under all circumstances not be destructive to the blood that is pumped therethrough, or place unnecessary stress on the heart through the valve prosthesis.

Since the emerging of the durable prosthetic heart valves, there has been a voluminous body of literature developed around this area of surgical endeavor. Reference is hereby made to an important body of this literature.

In U.S. Patent No. 4,057,857, issued to Shiley, and U.S. Patent No. 3,284,629, also issued to Shiley, there are disclosed heart valve prosthesis which includes vanes which are essentially supported by a valve structures extended inwardly from the surrounding rings so as to floatingly contain the vane during opening and closing movement in response to the pumping action of the heart.

Although the earlier Shiley valves had met with some success, and did provide excellent results and acceptance in the medical profession, these valves have nevertheless been subject to structural failure of the downstream or outlet strut. It is, of course, desirable to reduce the potential of mechanical failure. In the heart valve described in the above-mentioned Shiley patent, the vane is supported by a pair of twisted wire support rods. The support rods are fabricated as a series of complex bends to create the knuckle-like joint that supports the vane during opening and closing. This arrangement of support rods allows the vane to rotate in a loosely captive arrangement. This provides washing of the vane and evenness of wear.

Also, the earlier Shiley patent describes a prosthesis whereby the disc is fit into a central opening in the housing so that the disc is slightly smaller than the inside diameter of the housing. The resultant gap between the disc and the housing allows for a fixed amount of back flow when the natural cardiac forces hold the disc occluder closed. This amount of back flow represents lost work, as the back flow volume must be compensated by changes in heart power.

The present invention is directed to a heart valve prosthesis which is suited for replacement of the aortic

valve or mitral valve or any of the four valves in the heart. The invention includes a ring body having an elliptical inner wall through which blood flows controlled by a disc occluder supported between proximal and distal support struts having their ends attached to the metallic ring and coinciding with the curvature of the disc. The disc has a thickened outer edge so that the disc allows blood flow through the opening in the ring by rotation and translation of the disc occluder, from a closed position in sealing engagement around the ring body, to an open position wherein the thicker edge of the disc occluder serves as a travel stop for translational movement of the occluder during opening of the valve.

According to one aspect of the present invention, there is provided a heart valve prosthesis comprising:

a) a valve body having a fluid flow bore therethrough;

b) an occluder member comprising a continuous uninterrupted substantially flat or convex upper surface, which extends to an outer extremity to give rise to a thickened peripheral wall portion, which extends wholly below that surface and bounds a lower surface which is substantially flat or concave and which includes a recessed portion when the lower surface is substantially flat, the occluder member

being positioned within the bore of the valve body and movable between open and closed positions in response to fluid flow against the upper and lower surfaces respectively; and

c) means secured to the valve body for allowing rotational and translational movement of the occluder member as the occluder member moves between the open and closed positions.

According to a further aspect of the present invention, there is provided a mechanical heart valve, comprising;

a) a valve body adapted to be mounted within a valve passageway of a heart valve and having a fluid flow channel therethrough;

b) an occluder member, positioned in the fluid flow channel, the occluder member further comprising a continuous uninterrupted substantially flat or convex upper face, and a lower face which is substantially flat or concave and which includes a recessed portion when the lower face is substantially flat, the faces being joined at a thickened peripheral edge, the occluder member being movable between open and closed positions in response to fluid flow through the fluid flow channel; and

c) a first inlet strut contacting the upper face of the occluder member, and a second outlet strut

contacting at least the recessed or concave portion of the lower face of the occluder member, the first and second struts defining means for allowing rotational and translational movement of the occluder member within the channel during fluid flow.

According to a further aspect of the present invention there is provided a heart valve prosthesis, comprising:

a) a valve body having a fluid flow bore therethrough;

b) an occluder member, positioned in the fluid flow bore, further having a continuous substantially flat upper face, and a lower face including a recessed surface portion, both faces being joined at a thickened peripheral edge, the occluder member being movable between open and closed positions in response to fluid flow against the upper and lower surfaces respectively of the occluder member; and

c) strut means secured to the valve body, and spanning across a portion of the fluid flow bore, for allowing rotational and translational movement of the occluder member as the occluder member moves between open and closed positions in response to fluid flow through the flow bore.

According to a further aspect of the present invention there is provided a heart valve prosthesis comprising:

a) a valve body having a fluid flow bore therethrough;

b) an occluder member comprising a continuous uninterrupted flat upper surface, and a thickened peripheral wall portion, and further defining a lower surface which includes a recessed portion, the occluder member being positioned within the bore of the valve body and movable between open and closed positions in response to fluid flow against the upper and lower surfaces respectively; and

c) a first inlet strut and a second inlet strut in spaced relation across the flow bore for housing the occluder member therebetween, the first and second inlet struts each straddling the bore of the valve body between points less than 180° apart.

These and other features of the heart valve prosthesis of this invention will become more readily apparent in view of the detailed discussion taken with the attached drawings wherein:

Fig. 1 is a partial cut-away perspective view of a heart with the prosthetic valve of the invention mounted in the mitral position and aortic position;

Fig. 2 is a cross-sectional view of the preferred embodiment of a heart valve prosthesis in accordance with the present invention;

Fig. 3 is an overall side view of the preferred embodiment of a heart valve prosthesis in accordance with the present invention;

Fig. 4 is a top plane view of the preferred embodiment of a heart valve prosthesis in accordance with the present invention;

Fig. 5 is a cross-sectional view of an alternate embodiment of a heart valve prosthesis in accordance with the present invention shown in a closed position;

Fig. 6 is a cross-sectional view of the alternate embodiment of a heart valve prosthesis in accordance with the present invention shown in an open position;
and

FIGURE 7 is a top plane view of a portion of the alternate embodiment of a heart valve prosthesis in accordance with the present invention.

DETAILED DESCRIPTION OF THE INVENTION:

5 The preferred embodiment of the heart valve prosthesis of the present invention is illustrated in FIGURES 1 - 4 by the numeral 10. As seen in FIGURE 1, prosthetic heart valve 10 would be positioned within a human heart 12 which comprises left and right atria 14 and
10 16 respectively, left and right ventricles 18 and 20, respectively, with aorta 22 receiving the outflow of blood from left ventricle 20, that outflow regulated by aortic valve 24 and the flow of blood from atrium 14 to ventricle 18 regulated by a mitral valve 26.

15 For purposes of discussion, FIGURE 1 illustrates the present invention mounted both in replacement of the natural aortic valve 24 and the mitral valve 26.

Turning now to the structure of valve 10, reference is made to FIGURES 2 - 4. In FIGURE 2, there is
20 illustrated a cross-sectional view of valve 10 mounted in replacement of a natural heart valve. As seen in FIGURE 2, valve 10 includes a metallic ring 30 having an inner blood flow bore 32 through which blood flows during operation of the valve. As illustrated clearly in FIGURE
25 2, metallic ring 30 would comprise a ring body 31 having an upper annular shoulder portion 34 and a lower annular shoulder portion 36, shoulder portions 34 and 36 securing a typical suture ring 33 therebetween. Suture ring 33 would then be positioned onto annular tissue shelf 38
30 which is a natural tissue remaining after the natural heart valve has been removed. Suture ring 33 would be sutured to tissue shelf 38 for securing valve 10 in position within the natural valve opening.

As further illustrated in the FIGURES 2-4, metallic
35 ring 30 has an elliptically shaped inner wall 39 serving as the wall of flow bore 32 through which blood flows during operation of the valve.

The flow of blood through flow bore 32 is controlled by a blood flow control means mounted within ring body 30. This control means would further comprise a tilting disc occluder 40, having a lenticular design, with the annular edge 42 being thicker than the center portion 44 of occluder disc 40 as seen in cross-section in FIGURE 2. This disc occluder 40 is radially symmetrical about an axis perpendicular to the centerline of the outlet throat 45 of valve 10. The disc occluder 40 would further comprise a convex blood inlet surface 46 and a concave outlet surface 48.

Disc occluder 40 is supported in operation by upper and lower supporting strut members 50 and 52, termed as inlet and outlet struts respectively, with each inlet and outlet strut 50 and 52 having their ends attached to metallic ring 30 at points 53 and 55, preferably the means of attachment being an integral attachment, with the ring and strut members formed out of a single piece of metal.

The disc support inlet strut 50 and outlet strut 52 are further comprised of sections of revolution described by the intersection of two spheres of radius identical to the radius of the disc face 46 or 48 that contacts each of said strut members respectively. The origin of such radii are described by the opening angle of the disc occluder 40, and will vary as the openings angle varies. The connection between strut members 50 and 52 onto metal ring 30 are such that the connection points 53 and 55 are less than 180° apart, in their support function and the center point of curvature 57 is less than half the radius of opening 32. In addition, strut members 50 and 52 are positioned a distance apart, so as to provide a travel space for free-floating disc occluder 40 to undertake both rotational movement in the direction of Arrow 59, the limit of the rotation defined by the angle of the surfaces of strut members 50 and 52 contacting faces 46 and 48 of disc occluder 40 during rotation. In addition, due to the lenticular shape of disc occluder 40, with the edges 42

being thicker than center 44, disc occluder 40 is allowed to undergo translational movement between struts 50 and 52 as illustrated by Arrows 58 and 61 during operation of the valve. This translational movement over a occluder 40 is restricted up to the point that the thickness of the occluder 40 as it increases towards outer edge 42 will serve as a stop for further movement of occluder 40 during operation of the valve, that stopping point defined by the distance of the space between struts 50 and 52 wedging the body 40 therebetween and thus restricting any further movement during use.

FIGURE 2 illustrates disc occluder 40 as it is in the open position as blood flow is moving in the direction of Arrow 60. There is further illustrated, in phantom view, disc occluder 40 having returned to the closed fluid sealing position as seen in the FIGURE. In that position, disc occluder 40 has returned to a position substantially in horizontal alignment with ring 30, with the thickened end portion 42 resting on an interior shelf portion 35 of ring 30, and in sealing engagement therebetween. As seen in FIGURE 4, shelf portion 35 runs slightly less than 180° around the opening of bore 32. This contact between disc occluder 40 and shelf 35 results in a partial fluid seal around that portion of bore 32 to limit back flow during periods of valve closure. As seen in FIGURE 4, shelf portion 35 would generally extend in its approximately 180° structure around that portion of the ring 30 which does not house the contact points between struts 50 and 52 and the body of ring 30. In the preferred embodiment, shelf portion 35 lies in the center of metallic ring 30, although a slight shift to accommodate a taller or flatter disc 40 could be accommodated.

It should be noted as seen in FIGURE 2 at that point where shelf portion 30 terminates, there is provided a flat inner wall 37 of ring 30, where the very edge 43 of occluder 40 does not make contact. Therefore, there is provided a small fluid flow space 41 between the inner

wall 37 and the edge 43 so that there may be provided accommodation for a small amount of back flow between disc 40 and metallic ring 30.

In operation, valve 10 operates in response to the natural fluid pressures of blood generating by the pumping of the heart, wherein the disc 40 would cam between open and closed positions as seen particularly in FIGURE 2. This camming motion is governed by the design and location of the inlet support strut 50 and the outlet support strut 52. Beginning from the closed position as seen in phantom view in FIGURE 2, the disc 40 is maintained in the closed position by a greater force of fluid pressure in the direction of Arrow 62 on the outlet surface 48 of disc occluder 40. In that position occluder 40 is forced to seal its outer body portion against the shelf 35, and against the contact surface of inlet support strut 50. However, as the fluid pressure becomes greater on the inlet side 46 of disc occluder 40 than on the outlet side 48, disc occluder 40 rotates generally about the center 51 of outlet support struts 52. This rotation is illustrated by Arrow 59 as the fluid flow is moving in the direction of Arrow 60. As the disc occluder 40 rotates to an intermediate position between fully open and fully closed, fluid drag on surface 46 disc occluder 40 translates the disc 40 slightly in the direction of outlet side 66 a distance as seen by Arrow 68. This translational movement of disc 40 occurs as the result of disc 40 being unconnected to either the inlet support strut 50 or the outlet support strut 52, and generally free floating therebetween for rotational and translational movement.

As the fluid would continue to flow around and pass disc occluder 40, the disc is translated further downstream toward the outlet side 66 until the thickness of the disc edge 42 exceeds the gap between the inlet support struts 50 and the outlet support strut 52. At this point, disc 40 is restrained from opening any further, and the valve is fully opened. This opening angle of occluder 40

in relation to valve body 30 is controlled both by the position of the inlet support strut 50 and outlet support strut 52 and the relation between the contact surfaces of inlet struts 50 and outlet struts 52.

5 Following the opening of the valve to the fully open position as seen in FIGURE 2, fluid pressure would return to the outlet side 66 in the direction of Arrow 62. At that point, disc 40 is translated towards the inlet side 64 as the fluid on that side becomes smaller than the
10 fluid pressure on the outlet side 66. As the fluid flow increases, the disc is translated back towards the inlet side 64 by fluid drag. The translational movement of disc occluder 40 is occurring through the force of fluid flow in the direction of Arrow 62 and while simultaneously disc
15 40 is rotating about a point away from the center line of the opening 32 in metallic ring 30. This action continues until disc 40 would make contact after rotation and translation with metal ring 30. When the edge 43 of disc 40 has made contact with the inner wall 37 of ring 30,
20 further translation towards the inlet side is precluded. At this point, the fluid flow causes disc 40 to begin to rotate generally about the point of contact with wall 37. This disc rotation continues until the surface 46 of occluder 40 is contacted against the face of inlet strut
25 50 and the thickened edge 42 is forced into partial sealing engagement against shelf 35. Again, it should be noted that while in the sealing position, a small amount of fluid back flow is allowed at gap 41 between disc occluder 40 and the inner wall 37 of metallic ring 30.
30 The disc 40 would remain in the closed position until the fluid pressures reverts between the inlet and outlet sides of the valve, and the valve rotation and translation cycle would begin once more.

35 Returning now to FIGURE 1, it should be noted that in the FIGURE there is included a valve 10 secured within the mitral valve 26 between atrium 16 and ventricle 20, and in the aortic valve 24 which is between the aorta 22 and

ventricle 20. As seen in the FIGURE, the aortic valve 24 is in the open position due to the pressure of fluid from the inlet side 64 to the outlet side 66 as blood is being coursed into aorta 22. However, while blood is being
5 coursed therethrough, the mitral valve 26 is in the closed position since the blood flow on the outlet side 66 is greater than the blood flow on the inlet side 64. When the fluid pressure would increase within atrium 16, the valve 10 of mitral valve 26 would return to the open
10 position to allow fluid flow into ventricle 20, while the valve in aortic valve 24 would revert to the sealing closed position while ventricle 20 is receiving blood from atrium 16.

With reference to FIGURES 5, 6 and 7, an alternate
15 embodiment of the heart valve prosthesis in accordance with the present invention is shown. As indicated, the valve includes a metallic ring 30' with a ring body 31' having an upper annular shoulder portion 34' and a lower annular shoulder portion 36'. The alternate embodiment
20 includes a disc occluder 40' which is supported in operation by upper and lower supporting strut members 50' and 52', again termed as inlet and outlet struts respectively. As indicated above with respect to the preferred embodiment, each inlet and outlet strut has ends
25 which are attached to the metal ring 30' preferably being of an integral nature with the ring and strut members formed of a single piece of metal. Also, the connection between the strut members 50' and 52' onto the metal ring 30' are such that the connection points are less than
30 180° apart.

As indicated above with respect to the preferred embodiment, the strut members 50' and 52' are positioned a distance apart so as to provide a travel space for the free-floating disc occluder 40' to undertake both
35 rotational movement in the direction of Arrow 59' and translational movement in the direction of Arrow 58'. The limit of the rotation (Arrow 59') is defined by the angle

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of the surfaces of strut members 50' and 52' contacting faces 46' and 48'. FIGURE 5 illustrates the heart valve in a closed or sealed position while FIGURE 6 illustrates the valve with the occluder 40' in an initially open position (solid lines). Once rotated as indicated by Arrow 59', the occluder 40' is permitted to undergo translational movement between struts 50' and 52' as illustrated by Arrow 58'. This results in a final location of the occluder 40' as indicated by phantom lines in FIGURE 6. Translational movement is terminated when shoulder 101 of occluder 40' engages the top surface of strut 52'. When in a closed position as shown in FIGURE 5, the thickened end portion 42' of occluder 40' contacts interior shelf portion 35' of ring 30'. The thickened end portion 42' of occluder 40' extends annularly around the occluder disc 40'.

Except for the structural differences as illustrated in FIGURES 5, 6 and 7, the alternate embodiment performs the same function and operates in the same manner as the preferred embodiment illustrated in FIGURES 2, 3 and 4. Accordingly, the description of the operation of the preferred embodiment and the flow of fluid in each direction through the annular ring during the operation of the preferred embodiment is equally applicable with respect to the operation of the alternate embodiment.

FIGURE 7 is a top plane view of the alternate embodiment but with the occluder 40' removed. The shapes of the strut members 50' and 52' are shown which permits free-flowing rotational and translational movement of the disc occluder 40' which has a flat surface 46' for the interior portion of the occluder rather than convex 46/concave 48 surfaces as disclosed for the preferred embodiment.

Because many varying and different embodiments may be made within the scope of the inventive concept herein taught, and because many modifications may be made in the embodiments herein detailed in accordance with the

descriptive requirement of the law, it is to be understood that the details herein are to be interpreted as illustrative and not in a limiting sense.

What is claimed as invention is:



CLAIMS

1. A heart valve prosthesis comprising:

a) a valve body having a fluid flow bore therethrough;

b) an occluder member comprising a continuous uninterrupted substantially flat or convex upper surface, which extends to an outer extremity to give rise to a thickened peripheral wall portion, which extends wholly below that surface and bounds a lower surface which is substantially flat or concave and which includes a recessed portion when the lower surface is substantially flat, the occluder member being positioned within the bore of the valve body and movable between open and closed positions in response to fluid flow against the upper and lower surfaces respectively; and

c) means secured to the valve body for allowing rotational and translational movement of the occluder member as the occluder member moves between the open and closed positions.

2. A valve prosthesis as claimed in claim 1, wherein the means secured to the valve body for providing rotational and translational movement of the occluder further comprises a first inlet strut and a second outlet strut in spaced relation across the flow bore for housing the occluder member therebetween.



-13-

3. A valve prosthesis as claimed in claim 2, wherein the inlet strut and the outlet strut are curved along a radius substantially equal to the radius of curvature of the occluder body.

4. A valve prosthesis as claimed in any of the preceding claims wherein the lower surface of the occluder member is a concave surface and the upper surface is a convex surface.

5. A valve prosthesis as claimed in any of the preceding claims wherein there further comprises means on the occluder member to restrict the rotational and translational movement of the occluder member in response to fluid flow.

6. A mechanical heart valve, comprising;

a) a valve body adapted to be mounted within a valve passageway of a heart valve and having a fluid flow channel therethrough;

b) an occluder member, positioned in the fluid flow channel, the occluder member further comprising a continuous uninterrupted substantially flat or convex upper face, and a lower face which is substantially flat or concave and which includes a recessed portion when the lower face is substantially flat, the faces being joined at a thickened peripheral edge, the

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-14-

occluder member being movable between open and closed positions in response to fluid flow through the fluid flow channel; and

c) a first inlet strut contacting the upper face of the occluder member, and a second outlet strut contacting at least the recessed or concave portion of the lower face of the occluder member, the first and second struts defining means for allowing rotational and translational movement of the occluder member within the channel during fluid flow.

7. A heart valve as claimed in claim 6, wherein the upper and lower faces of the occluder member are curved along a radius equal to the radius of curvature of the strut members.

8. A heart valve as claimed in claim 6 or 7, wherein the strut members further provide means for supporting the occluder member in the sealed position against the flow of blood.

9. A heart valve as claimed in claim 6, 7 or 8, wherein there is further provided means to allow fluid back flow through the fluid flow channel during closure of the occluder member against the valve body.

10. A heart valve prosthesis, comprising:

a) a valve body having a fluid flow bore therethrough;



b) an occluder member, positioned in the fluid flow bore, further having a continuous substantially flat upper face, and a lower face including a recessed surface portion, both faces being joined at a thickened peripheral edge, the occluder member being movable between open and closed positions in response to fluid flow against the upper and lower surfaces respectively, of the occluder member; and

c) strut means secured to the valve body, and spanning across a portion of the fluid flow bore, for allowing rotational and translational movement of the occluder member as the occluder member moves between open and closed positions in response to fluid flow through the flow bore.

11. A heart valve as claimed in claim 10 wherein the strut means comprises inlet and outlet struts which straddle the bore of the valve body between points less than 180° apart.

12. A heart valve as claimed in any of claims 10 to 11 wherein there is further provided means for allowing a restricted amount of back flow through the flow bore when the valve is in the closed position.

13. The heart valve as claimed in any of claims 10 to 12, wherein the valve may be positioned to replace either an aortic valve or a mitral heart valve.



-16-

14. A heart valve prosthesis comprising:

- a) a valve body having a fluid flow bore therethrough;
 - b) an occluder member comprising a continuous uninterrupted flat upper surface, and a thickened peripheral wall portion, and further defining a lower surface which includes a recessed portion, the occluder member being positioned within the bore of the valve body and movable between open and closed positions in response to fluid flow against the upper and lower surfaces respectively; and
 - c) a first inlet strut and a second outlet strut in spaced relation across the flow bore for housing the occluder member therebetween, the first and second struts each straddling the bore of the valve body between points less than 180° apart.
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