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Heart Valve Prosthesis and Methods of Manufacture and Use

Abstract

A heart valve prosthesis is provided having a self-expanding multi-level frame that supports a valve body comprising a skirt and plurality of coapting leaflets. The frame transitions between a contracted delivery configuration that enables percutaneous transluminal delivery, and an expanded deployed configuration having an asymmetric hourglass shape. The valve body skirt and leaflets are constructed so that the center of coaptation may be selected to reduce horizontal forces applied to the commissures of the valve, and to efficiently distribute and transmit forces along the leaflets and to the frame. Alternatively, the valve body may be used as a surgically implantable replacement valve prosthesis.

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Claims

1. A valve prosthesis comprising: a valve body comprising a plurality of leaflets affixed to a skirt, adjoining leaflets affixed together to form commissures; and a frame supporting the valve body, the frame having a longitudinal axis, wherein the commissures are affixed to the frame along a region of the frame that increases in diameter along the longitudinal axis, wherein the commissures are longitudinally offset from the center of coaptation, and each leaflet has a free edge that is suspended from the leaflet's respective commissures to define coaptation edges and a center of coaptation, and wherein the length of each free edge forms a substantially continuous curve extending downwardly between the respective commissures so that the free edges of the leaflets generally define the shape of catenaries to substantially uniformly distribute loads over the leaflets.

2. The valve prosthesis of claim 1, wherein the catenaries are configured to reduce horizontal loads applied to the commissures.

3. The valve prosthesis of claim 1, wherein each leaflet is individually formed and comprises an enlarged lateral end having a plurality of flaps that are folded over to increase the durability of the commissures.

4. The valve prosthesis of claim 1, wherein the skirt further comprises a plurality of longitudinally-oriented reinforcing tabs.

5. The valve prosthesis of claim 1, wherein the leaflets comprise porcine, bovine, equine or other mammalian pericardial tissue, synthetic material, or polymeric material.

6. The valve prosthesis of claim 1, wherein the frame is self expanding, and wherein the leaflets are affixed to the skirt at joints, and the joints are affixed to the frame to evenly distribute forces through the valve body to the frame.

7. The valve prosthesis of claim 6, wherein the frame further comprises a cell pattern that defines a contour configured to support the joints.

8. The valve prosthesis of claim 4, wherein the frame is self expanding, and wherein and the reinforcing tabs are affixed to the frame.

9. The valve prosthesis of claim 1, wherein the frame is self expanding, and wherein the frame has a contracted delivery configuration and an expanded deployed configuration.

10. The valve prosthesis of claim 9, wherein the frame comprises a cell pattern defined by unequal length zig-zags.

11. The valve prosthesis of claim 9, wherein the commissures are affixed to the frame at a location proximal

of the center of coaptation.

12. The valve prosthesis of claim 9, wherein the frame comprises a cell pattern and the commissures include flaps that span an entire area of at least one cell of the cell pattern.

13. The valve prosthesis of claim 9, wherein the skirt further comprises a plurality of end tabs adapted to be affixed to a proximal-most row of cells of the frame.

14. The valve prosthesis of claim 9, wherein the valve body is deployed superannularly of a patient's aortic annulus when the valve prosthesis is delivered within a patient's aortic valve and the frame is in the expanded deployed configuration.

15. The valve prosthesis of claim 9, wherein the frame is configured to hold a patient's native valve permanently open in the expanded deployed configuration.

16. The valve prosthesis of claim 9, wherein the frame is configured to permit access to a patient's coronary arteries in the expanded deployed configuration.

17. The valve prosthesis of claim 9, wherein the frame has proximal and distal ends and a plurality of cell patterns that vary in size between the proximal and distal ends.

18. The valve prosthesis of claim 9, wherein the frame has, in the expanded deployed configuration, an enlarged outflow section with a first nominal diameter, a conical inflow section having a second nominal diameter and a constriction region having a third fixed diameter smaller than the first and second nominal diameters.

19. The valve prosthesis of claim 18, wherein the conical section has a proximal end and the conical section flares outward towards the proximal end.

20. The valve prosthesis of claim 18, wherein the constriction region comprises a plurality of cell patterns configured to provide a pre-determined radius of curvature for a transition from the constricted region to the outflow section.

21. The valve prosthesis of claim 18, wherein the third fixed diameter is a predetermined diameter.

22. The valve prosthesis of claim 1, wherein, when the valve is in the closed position, the length of each free edge forms a substantially continuous curve extending downwardly between the respective commissures so that the free edges of the leaflets generally define the shape of catenaries to substantially uniformly distribute loads over the leaflets.

23. A valve prosthesis comprising: a valve body comprising three leaflets, wherein adjoining leaflets are sewn together to form commissures; and a self-expanding frame, the frame having an inflow section having a first row of cells, an outflow section having a second row of cells and including an eyelet, and a middle region between the inflow section and the outflow section, wherein the middle region is configured to avoid blocking blood flow to the coronary arteries when the frame is implanted in a body, wherein the area of individual cells in the first row of cells is less than the area of individual cells in the second row of cells, wherein the frame supports the valve body, wherein the frame has a longitudinal axis, wherein the frame has a contracted delivery configuration and an expanded deployed configuration, wherein, when the frame is in the expanded deployed configuration, the outflow section has a larger diameter than the inflow section, wherein a plurality of cells of the frame are positioned between the cells spanned by commissures, wherein

each leaflet has a free edge that is suspended from the leaflet's commissures to define coaptation edges and a center of coaptation, and wherein the length of each free edge forms a substantially continuous curve extending downwardly between the respective commissures so that the free edges of the leaflets generally define the shape of catenaries to substantially uniformly distribute loads over the leaflets.

24. The valve prosthesis of claim 23, wherein the leaflets comprise porcine, bovine, equine or other mammalian pericardial tissue, synthetic material, or polymeric material.

25. The valve prosthesis of claim 23, wherein the leaflets are sewn to a skirt at joints, wherein the skirt is sewn to the inflow section of the frame, and wherein the joints are affixed to the frame to evenly distribute forces through the valve body to the frame.

26. The valve prosthesis of claim 25, wherein the frame further comprises a cell pattern that defines a contour configured to support the joints.

27. The valve prosthesis of claim 23, wherein the frame comprises a cell pattern defined by unequal length zig-zags.

28. The valve prosthesis of claim 23, wherein the commissures are affixed to the frame at a location proximal of the center of coaptation.

29. The valve prosthesis of claim 23, wherein the commissures include flaps that span an entire area a cell.

30. The valve prosthesis of claim 23, wherein the frame is configured to permit access to a patients coronary arteries in the expanded deployed configuration.

31. The valve prosthesis of claim 23, wherein at least one cell in the outflow section is larger than at least one cell in the inflow section.

32. The valve prosthesis of claim 23, wherein a cell in the outflow section has a first area, wherein a cell in the inflow section has a second area, and wherein the first area is larger than the second area.

33. The valve prosthesis of claim 23, wherein the inflow section includes a first row of cells, wherein the outflow section includes a second row of cells, and wherein the number of cells in the first row of cells is equal to the number of cells in the second row of cells.

34. The valve prosthesis of claim 23, wherein the middle region and the outflow section comprise a cell pattern that provides a pre-determined radius of curvature for a transition from the middle region to the outflow section when the frame is in the expanded deployed configuration.

35. The valve prosthesis of claim 23, wherein the diameter of the constriction region is less than the diameter of the inflow section.

36. The valve prosthesis of claim 23, wherein the outflow section includes exactly three eyelets.

37. The valve prosthesis of claim 23, wherein the frame includes four rows of cells.

38. A valve prosthesis comprising: a valve body comprising three leaflets, wherein adjoining leaflets are sewn together to form commissures; and a self-expanding frame comprising a plurality of cells, the frame having an inflow section, an outflow section, and a middle region between the inflow section and the outflow

section, wherein the middle region is configured to avoid blocking blood flow to the coronary arteries when the frame is implanted in a body, wherein the frame supports the valve body, wherein the frame has a longitudinal axis, wherein the frame has a contracted delivery configuration and an expanded deployed configuration, wherein, when the frame is in the expanded deployed configuration, the outflow section has a larger diameter than the inflow section, wherein each commissure is configured to span a cell of the frame to distribute force within the commissures and to the frame, and wherein a plurality of cells of the frame are positioned between the cells spanned by commissures, wherein each leaflet has a free edge that is suspended from the leaflet's commissures to define coaptation edges and a center of coaptation, and wherein the length of each free edge forms a substantially continuous curve extending downwardly between the respective commissures so that the free edges of the leaflets generally define the shape of catenaries to substantially uniformly distribute loads over the leaflets.

Description

BACKGROUND OF THE INVENTION

[0001] 1. Field of the Invention

[0002] The present invention relates to replacement valves for improving the cardiac function of a patient suffering from cardiac valve dysfunction, such as aortic valve regurgitation or aortic stenosis. More particularly, the present invention relates to heart valve prostheses that provide improved durability and are particularly well-suited for percutaneous delivery.

[0003] 2. Background of the Invention

[0004] Heart valve replacement has become a routine surgical procedure for patients suffering from valve regurgitation or stenotic calcification of the leaflets. While certain procedures may be performed using minimally-invasive techniques (so-called "keyhole" techniques), the vast majority of valve replacements entail full sternotomy and placing the patient on cardiopulmonary bypass. Traditional open surgery inflicts significant patient trauma and discomfort, requires extensive recuperation times and may result in life-threatening complications.

[0005] To address these concerns, within the last decade efforts have been made to perform cardiac valve replacements using minimally-invasive techniques. In these methods, laparascopic instruments are employed to make small openings through the patient's ribs to provide access to the heart. While considerable effort has been devoted to such techniques, widespread acceptance has been limited by the clinician's ability to access only certain regions of the heart using laparoscopic instruments.

[0006] Still other efforts have been focused on percutaneous transluminal delivery of replacement cardiac valves to solve the problems presented by traditional open surgery and minimally-invasive surgical methods. In such methods; a valve prosthesis is compacted for delivery in a catheter and then advanced, for example, through an opening in the femoral artery and through the descending aorta to the heart, where the prosthesis then is deployed in the aortic valve annulus. Although transluminal techniques have attained widespread acceptance with respect to delivery of stents to restore vessel patency, only mixed results have been obtained with respect to percutaneous delivery of relatively more complicated valve prostheses.

[0007] One such example of a previously-known device heart valve prosthesis is described in U.S. Pat. No. 6,454,799 to Schreck. The prosthesis described in that patent comprises a fabric-based heart valve disposed

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