SYSTEMS AND METHODS FOR SIZING AND IMPLANTING PROSTHETIC HEART VALVES

FIELD

[001] The present disclosure concerns embodiments of a prosthetic heart valve, as well as systems and methods relating to such.

BACKGROUND

[002] The human heart can suffer from various valvular diseases. These valvular diseases can result in significant malfunctioning of the heart and ultimately require replacement of the native valve with an artificial valve. There are a number of known artificial valves and a number of known methods of implanting these artificial valves in humans.

[003] Various surgical techniques may be used to replace or repair a diseased or damaged valve. Due to stenosis and other heart valve diseases, thousands of patients undergo surgery each year wherein the defective native heart valve is replaced by a prosthetic valve. Another less drastic method for treating defective valves is through repair or reconstruction, which is typically used on minimally calcified valves. The problem with surgical therapy is the significant risk it imposes on these chronically ill patients with high morbidity and mortality rates associated with surgical repair.

[004] When the native valve is replaced, surgical implantation of the prosthetic valve typically requires an open-chest surgery during which the heart is stopped and patient placed on cardiopulmonary bypass (a so-called “heart-lung machine”). In one common surgical procedure, the diseased native valve leaflets are excised and a prosthetic valve is sutured to the surrounding tissue at the valve annulus. Because of the trauma associated with the procedure and the attendant duration of extracorporeal blood circulation, some patients do not survive the surgical procedure or die shortly thereafter. It is well known that the risk to the patient increases with the amount of time required on extracorporeal circulation. Due to these risks, a substantial number of patients with defective native valves are deemed inoperable because their condition is too frail to withstand the procedure. By some estimates, more than 50% of the subjects suffering from valve stenosis who are older than 80 years cannot be operated on for valve replacement.

[005] Because of the drawbacks associated with conventional open-heart surgery, percutaneous and minimally-invasive surgical approaches are garnering intense attention. In one technique, a prosthetic valve is configured to be implanted in a much less invasive procedure by way of catheterization. For instance, U.S. Patent Nos. 5,411,522 and 6,730,118 describe collapsible transcatheter heart valves that can be percutaneously introduced in a compressed state on a catheter and expanded in the desired position by balloon inflation or by utilization of a self-expanding frame or stent.

[006] An important design parameter of a transcatheter heart valve is the diameter of the folded or crimped profile. The diameter of the crimped profile is important because it directly influences the physician's ability to advance the transcatheter heart valve through the femoral artery or vein. More particularly, a smaller profile allows for treatment of a wider population of patients, with enhanced safety. Another important design parameter is control of perivalvular leakage around the valve, which can occur for a period of time following initial implantation.

[007] Selecting the size of transcatheter heart valve to implant in a patient is yet another important consideration.

SUMMARY

[008] Described herein are embodiments of prosthetic heart valves that, among other things, have a small crimp profile, control perivalvular leakage, and can be implanted in a wide range of native annulus sizes.

[009] In one representative embodiment, a prosthetic heart valve comprises a frame comprising an inflow end and an outflow end and being radially collapsible and expandable between a radially collapsed configuration and a radially expanded configuration, wherein the frame comprises a plurality of struts defining openings. The prosthetic heart valve can further comprise a valvular structure mounted within the frame and comprising a plurality of leaflets that regulate the flow of blood through the frame, wherein each leaflet comprises an inflow surface, an outflow surface, and a cusp edge portion that is fixed relative to the frame. The prosthetic heart valve can also comprise a sealing member mounted on the frame and comprising an inner layer and an outer layer. At least the outer layer is mounted on the outside of the frame, and the inner layer covers at least the openings in the frame between adjacent cusp portions of adjacent leaflets and the inner layer does not cover one or more openings in the frame at locations facing the outflow surfaces of the leaflets to permit

retrograde blood to flow through the one or more uncovered openings in the frame and into space between the outer layer and the frame.

[010] Also described herein are systems and methods for sizing and deploying a prosthetic heart valve. These systems and methods can, for example, improve blood flow characteristics ("hemodynamics") through a native valve or other area in which the prosthetic heart valve is implanted.

[011] In one representative embodiment, a method of selecting a prosthetic heart valve is provided. The method can include determining a native annulus area of a native heart valve by taking an image of the native annulus and measuring the image, determining which prosthetic heart valves of a plurality of prosthetic heart valves covers the determined native annulus area, analyzing hemodynamic data of each prosthetic heart valve of the plurality of prosthetic heart valves, and selecting a desired prosthetic heart valve of the plurality of prosthetic heart valves based on the analyzed hemodynamic data.

[012] In some embodiments, the hemodynamic data includes a pressure gradient across the prosthetic heart valve. The pressure gradient is blood pressure at an outflow end of the prosthetic heart valve divided by blood pressure at an inflow end of the prosthetic heart valve.

[013] In some embodiments, the selected prosthetic heart valve has the lowest pressure gradient of the prosthetic heart valves covering the determined native annulus area.

[014] In some embodiments, the selected prosthetic heart valve has the largest nominal diameter of the prosthetic heart valves covering the determined native annulus area.

[015] In some embodiments, the selected prosthetic heart valve has the largest expanded diameter of the prosthetic heart valves covering the determined native annulus area.

[016] In some embodiments, the method further comprises determining a diameter of the native annulus. The selected prosthetic heart valve has an expanded diameter that is less than the determined diameter of the native annulus.

[017] In some embodiments, the expanded diameter is within a range of 0-10% less than the determined diameter of the native annulus.

[018] In some embodiments, the expanded diameter is within a range of 0-5% less than the determined diameter of the native annulus.

[019] In some embodiments, the method further comprises determining a diameter of the native annulus, wherein the selected prosthetic heart valve has an expanded diameter that is greater than the determined diameter of the native annulus.

[020] In some embodiments, the expanded diameter is within a range of 0-40% greater than the determined diameter of the native annulus.

[021] In some embodiments, the expanded diameter is within a range of 0-20% greater than the determined diameter of the native annulus.

[022] In some embodiments, the prosthetic heart valve is balloon expandable.

[023] In some embodiments, the method is executed as an application on a computing device.

[024] In some embodiments, the method further comprises implanting the selected prosthetic heart valve in the native annulus.

[025] In one representative embodiment, a method of selecting a prosthetic heart valve is provided. The method can include determining a diameter of a native heart valve annulus, advancing a prosthetic heart valve through a patient's vasculature to the native heart valve annulus. The prosthetic heart valve is in a radially collapsed configuration. The prosthetic heart valve comprises, a frame comprising an inflow end and an outflow end and being radially collapsible and expandable between the radially collapsed configuration and a radially expanded configuration, and a valvular structure mounted within the frame and comprising a plurality of leaflets that regulate flow of blood through the frame. Each leaflet comprises opposing upper tabs on opposite sides of the leaflet, opposing lower tabs on opposite sides of the leaflets below the upper tabs, a cusp edge portion extending between the lower tabs, the cusp edge portion being fixed relative to the frame. Each upper tab is paired with an adjacent upper tab of an adjacent leaflet to form a plurality of commissures that are fixed relative to the frame, and each lower tab is folded to form at least one fold layer along the cusp edge portion of the respective leaflet, and the method further comprises expanding the prosthetic heart valve from the radially collapsed configuration to the radially expanded configuration, wherein in the radially expanded configuration, the prosthetic heart valve has an outer diameter that is larger than the determined diameter of the native heart valve annulus.

[026] In some embodiments, the outer diameter of the prosthetic heart valve in the radially expanded configuration is within a range of 5-40% larger than the determined diameter of the native heart valve annulus.

[027] In some embodiments, the outer diameter of the prosthetic heart valve in the radially expanded configuration is within a range of 10-20% larger than the determined diameter of the native heart valve annulus.

[028] In some embodiments, the outer diameter of the prosthetic heart valve in the radially expanded configuration is less than a nominal diameter of the prosthetic heart valve.

[029] In another representative embodiment, a method of implanting a prosthetic heart valve is provided. The method comprises: determining a native annulus area and a native annulus diameter of a native annulus of a native heart valve by taking an image of the native annulus, obtaining measurements of the native annulus from the image, and calculating the area and the diameter of the native annulus based on the measurements; determining which prosthetic heart valves of a plurality of prosthetic heart valves covers the determined native annulus area; analyzing hemodynamic data of each prosthetic heart valve of the plurality of prosthetic heart valves; selecting a prosthetic heart valve of the plurality of prosthetic heart valves based on the analyzed hemodynamic data, wherein the selected prosthetic heart valve has a nominal diameter that is greater than the determined native annulus diameter by up to forty percent; compressing the selected prosthetic heart valve to a radially compressed configuration in which the selected prosthetic heart valve has a first diameter that is less than the nominal diameter; positioning the selected prosthetic heart valve within the native annulus; and expanding the selected prosthetic heart valve from the radially compressed configuration to a radially expanded configuration in which the prosthetic heart valve has a second diameter which is less than the nominal diameter by up to ten percent and which is greater than the first diameter.

[030] In some embodiments, the image is obtained using computed tomography.

[031] In yet another representative embodiment, one or more computer-readable storage media comprising instructions that can be executed by a computer is provided. The instructions are configured to: receive a measurement of a native annulus area of a native heart valve inputted by a user; calculate an area derived native annulus diameter based on the received measurement of the native annulus area; analyze hemodynamic characteristics of a plurality of prosthetic heart valves; determine a suggested prosthetic heart valve of the

plurality of prosthetic heart valves; determine a suggested expanded diameter of the suggested prosthetic heart valve; and determine an expected pressure gradient across the suggested prosthetic heart valve.

[032] The various innovations of this disclosure can be used in combination or separately. This summary is provided to introduce a selection of concepts in a simplified form that are further described below in the detailed description. This summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended to be used to limit the scope of the claimed subject matter. The foregoing and other objects, features, and advantages of the innovations will become more apparent in light of other portions of the disclosure, including the detailed description, drawings, and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[033] FIGS. 1A-1B are perspective views of a prosthetic heart, according to one embodiment.

[034] FIG. 1C is an enlarged, perspective view of the area beneath one of the commissures of the prosthetic heart valve of FIGS. 1A-1B.

[035] FIG. 2 is a side elevation of the sealing member of the prosthetic heart valve of FIG. 1.

[036] FIG. 3 is a perspective, sectional view of the sealing member of FIG. 1.

[037] FIG. 4 is a cross-sectional view of the prosthetic heart valve of FIG. 1, showing the flow of retrograde blood through the valve.

[038] FIG. 5 is an enlarged perspective view showing a portion of the inside of the prosthetic heart valve of FIG. 1.

[039] FIG. 6 shows a strip of fabric that can be used to form a sealing member, such as the sealing member of FIG. 3.

[040] FIGS. 7A-7B are perspective views of exemplary tubular bodies that can be used to form a sealing member for a prosthetic heart valve.

[041] FIG. 8 is a perspective view of a partially assembled prosthetic heart valve showing the attachment of leaflets using connecting skirts, according to one embodiment.

[042] FIG. 9 is a plan view of a leaflet and a connecting skirt used in the prosthetic heart valve of FIG. 8.

[043] FIGS. 10, 10A, 11A, and 11B are various views showing the attachment of the connecting skirt and the leaflet of FIG. 9.

[044] FIGS. 12, 12A, and 12B are various views showing the connection of the connecting skirt of FIG. 9 to the frame of the prosthetic valve of FIG. 8.

[045] FIG. 13A is a perspective view of a frame of a prosthetic heart valve and leaflets mounted inside the frame, according to one embodiment.

[046] FIG. 13B is an enlarged view of a portion of the frame and one of the leaflets of FIG. 13A.

[047] FIG. 14 is a plan view of a leaflet that can be used in a prosthetic heart valve, according to one embodiment.

[048] FIGS. 15A, 15B, 15C, 15D, 16, 17, 18, 19, 20, 21, 22, and 23 show various ways of connecting the cusp edge portion of a leaflet to a frame of a prosthetic heart valve using a connecting skirt.

[049] FIG. 24 is an enlarged, perspective view of the inside of a prosthetic heart valve, showing another way of connecting the cusp edge portion of a leaflet to the frame of the valve.

[050] FIGS. 25A, 25B, 26, 27, 28, 29, 30, 31, and 32 show alternative ways of connecting the cusp edge portion of a leaflet to a frame of a prosthetic heart valve, with and without a connecting skirt.

[051] FIG. 33 is a plan view of a leaflet that can be used in a prosthetic heart valve, according to one embodiment.

[052] FIGS. 34, 35, and 36 show the formation of one-half of a commissure using the leaflet of FIG. 33, according to one embodiment.

[053] FIG. 37 is a cross-sectional view of a commissure formed from two leaflets of the type shown in FIG. 33, according to one embodiment.

[054] FIG. 38 is a cross-sectional view of a commissure formed from two leaflets of the type shown in FIG. 33, according to another embodiment.

[055] FIG. 39 is a plan view of a leaflet that can be used in a prosthetic heart valve, according to another embodiment.

[056] FIG. 40 is a plan view of a leaflet that can be used in a prosthetic heart valve, according to another embodiment.

[057] FIGS. 41, 42, 43, 44, and 45 show the formation of a commissure from two of leaflets of the type shown in FIG. 40, according to one embodiment.

[058] FIG. 46 is a cross-sectional view of a commissure formed from two leaflets of the type shown in FIG. 40, according to one embodiment.

[059] FIG. 47 is a cross-sectional view of a commissure formed from two leaflets of the type shown in FIG. 33, according to another embodiment.

[060] FIG. 48 is a cross-sectional view of a commissure formed from two leaflets of the type shown in FIG. 40, according to another embodiment.

[061] FIG. 49 is a plan view of a leaflet that can be used in a prosthetic heart valve, according to another embodiment.

[062] FIGS. 50-51 are cross-sectional views of two embodiments of a commissure formed from two leaflets of the type shown in FIG. 49.

[063] FIGS. 52, 53, 54, and 55 are various views showing the attachment of the commissure of FIGS. 50 or 51 to the frame of a prosthetic heart valve using a commissure attachment member.

[064] FIG. 56 is a cross-sectional view of another embodiment of a commissure formed from two leaflets of the type shown in FIG. 33.

[065] FIGS. 57 and 58 are side elevation and perspective views, respectively, of a prosthetic heart valve, according to another embodiment.

[066] FIG. 59 is a plan view of the sealing member of the prosthetic heart valve of FIGS. 57-58, shown in a flattened configuration.

[067] FIGS. 60 and 61 are perspective and cross-sectional views, respectively, of a prosthetic heart valve, according to another embodiment.

[068] FIGS. 62, 63, and 64 show the sealing member of the prosthetic heart valve of FIGS. 60-61 being mounted on the frame of the valve.

[069] FIGS. 65 and 66 are perspective views of a prosthetic heart valve, according to another embodiment.

[070] FIG. 67 is a perspective view of a portion of the prosthetic heart valve of FIGS. 65-66.

[071] FIG. 68 is a perspective view of the sealing member of the prosthetic heart valve of FIGS. 65-66.

[072] FIG. 69 is a cross-sectional view showing the attachment of the cusp edge portion of a leaflet to a connecting skirt, according to another embodiment.

[073] FIG. 70 is a plan view of an embodiment of a connecting skirt for connecting the cusp edge portion of a leaflet to a frame, shown in the flattened configuration.

[074] FIG. 71 is a side elevation view of the frame of the prosthetic heart valve of FIGS. 65-66.

[075] FIG. 72 shows the mounting of a valve assembly inside of the frame of FIG. 71, according to one embodiment.

[076] FIG. 73 is an enlarged view of a portion of the frame and the valve assembly of FIG. 72.

[077] FIG. 74 is a perspective view of a leaflet of the prosthetic heart valve of FIGS. 65-66.

[078] FIG. 75A is a plan view of the leaflet of FIG. 74, shown in a flattened configuration.

[079] FIG. 75B is a plan view of the leaflet of FIG. 74 and the connecting skirt of FIG. 70 positioned along the cusp edge portion of the leaflet.

[080] FIG. 76 is a plan view of an embodiment of a commissure attachment member, shown in a flattened configuration.

[081] FIGS. 77 and 78 are perspective and cross-sectional views, respectively, of one of the commissures of the prosthetic heart valve of FIGS. 65-66.

[082] FIGS. 79 and 80 are perspective and top plan views, respectively, of a prosthetic heart valve, according to another embodiment.

[083] FIGS. 81 and 82 are perspective and top plan views, respectively, of a prosthetic heart valve, according to another embodiment.

[084] FIGS. 83 and 84 are perspective views of a prosthetic heart valve, according to another embodiment.

[085] FIGS. 85 and 86 are side and top plan views, respectively, of one of the commissures of the prosthetic valve of FIGS. 83-84.

[086] FIG. 87 depicts a flowchart of an exemplary method that can be employed when selecting a prosthetic heart valve size.

[087] FIG. 88 depicts a flowchart of another exemplary method that can be employed when selecting a prosthetic heart valve size.

[088] FIG. 89 depicts a schematic representation of a displayed graphical user interface of a software application utilizing the methods disclosed herein.

[089] FIG. 90 depicts a schematic representation of another displayed graphical user interface of a software application utilizing the methods disclosed herein.

[090] FIG. 91 depicts a schematic representation of another displayed graphical user interface of a software application utilizing the methods disclosed herein.

[091] FIG. 92 depicts a schematic representation of another displayed graphical user interface of a software application utilizing the methods disclosed herein.

[092] FIG. 93 depicts a schematic representation of an exemplary computing system for implementing the disclosed technology.

[093] FIG. 94 depicts a schematic representation of an exemplary mobile device for implementing the disclosed technology.

DETAILED DESCRIPTION

[094] General Considerations

[095] For purposes of this description, certain aspects, advantages, and novel features of the embodiments of this disclosure are described herein. The disclosed methods, apparatus, and systems should not be construed as being limiting in any way. Instead, the present disclosure is directed toward all novel and nonobvious features and aspects of the various disclosed embodiments, alone and in various combinations and sub-combinations with one another. The methods, apparatus, and systems are not limited to any specific aspect or feature or combination thereof, nor do the disclosed embodiments require that any one or more specific advantages be present or problems be solved.

[096] Although the operations of some of the disclosed embodiments are described in a particular, sequential order for convenient presentation, it should be understood that this

manner of description encompasses rearrangement, unless a particular ordering is required by specific language set forth below. For example, operations described sequentially may in some cases be rearranged or performed concurrently. Moreover, for the sake of simplicity, the attached figures may not show the various ways in which the disclosed methods can be used in conjunction with other methods. Additionally, the description sometimes uses terms like "provide" or "achieve" to describe the disclosed methods. These terms are high-level abstractions of the actual operations that are performed. The actual operations that correspond to these terms may vary depending on the particular implementation and are readily discernible by one of ordinary skill in the art.

[097] As used in this application and in the claims, the singular forms "a," "an," and "the" include the plural forms unless the context clearly dictates otherwise. Additionally, the term "includes" means "comprises." Further, the term "coupled" generally means physically, mechanically, chemically, magnetically, and/or electrically coupled or linked and does not exclude the presence of intermediate elements between the coupled or associated items absent specific contrary language.

[098] As used herein, the term "proximal" refers to a position, direction, or portion of a device that is closer to the user and further away from the implantation site. As used herein, the term "distal" refers to a position, direction, or portion of a device that is further away from the user and closer to the implantation site. Thus, for example, proximal motion of a device is motion of the device away from the implantation site and toward the user (e.g., out of the patient's body), while distal motion of the device is motion of the device away from the user and toward the implantation site (e.g., into the patient's body). The terms "longitudinal" and "axial" refer to an axis extending in the proximal and distal directions, unless otherwise expressly defined.

[099] <u>Exemplary Embodiments of Prosthetic Heart Valves</u>

[0100] The present disclosure concerns embodiments of implantable prosthetic devices and, in particular, implantable prosthetic valves, and methods for making such devices. In particular embodiments, the prosthetic device comprises a prosthetic heart valve, and can be configured to be implanted in any of the native heart valves (aortic, mitral, pulmonary, and tricuspid). In addition, the prosthetic heart valve can be, for example, a transcatheter heart valve, a surgical heart valve, or a minimally-invasive heart valve. The prosthetic valve also can comprise other types of valves implantable within other body lumens outside of the heart

or heart valves that are implantable within the heart at locations other than the native valves, such as trans-atrial or trans-ventricle septum valves.

[0101] The disclosed prosthetic heart valves are particularly suited for implantation in the native aortic valve. In the context of a prosthetic aortic valve, the terms “lower” and “upper” are used interchangeably with the terms “inflow” and “outflow”, respectively, for convenience. Thus, for example, the lower end of the prosthetic valve is its inflow end and the upper end of the prosthetic valve is its outflow end in the orientation shown in the drawings. However, it should be understood that the prosthetic valve can be implanted in the reverse orientation. For example, for implantation at the mitral valve position, the upper end of the prosthetic valve is the inflow end and the lower end of the valve is the outflow end.

[0102] FIG. 1A is a perspective view of a prosthetic heart valve 10, according to one embodiment. The illustrated valve is adapted to be implanted in the native aortic annulus, although in other embodiments it can be adapted to be implanted in the other native annuluses of the heart. The valve 10 can have three main components: a stent, or frame, 12, a valvular structure 14, and a sealing member 16. FIG. 1B is a perspective view of the prosthetic valve 10 with the components on the outside of the frame 12 (including the sealing member 16) shown in transparent lines for purposes of illustration.

[0103] The valvular structure 14 can comprise three leaflets 20, collectively forming a leaflet structure, which can be arranged to collapse in a tricuspid arrangement, although in other embodiments there can be greater or fewer number of leaflets (e.g., one or more leaflets 20). The lower edge of leaflet structure 14 desirably has an undulating, curved scalloped shape. By forming the leaflets with this scalloped geometry, stresses on the leaflets are reduced, which in turn improves durability of the valve. Moreover, by virtue of the scalloped shape, folds and ripples at the belly of each leaflet (the central region of each leaflet), which can cause early calcification in those areas, can be eliminated or at least minimized. The scalloped geometry also reduces the amount of tissue material used to form leaflet structure, thereby allowing a smaller, more even crimped profile at the inflow end of the valve. The leaflets 20 can be formed of pericardial tissue (e.g., bovine or porcine pericardial tissue), biocompatible synthetic materials, or various other suitable natural or synthetic materials as known in the art and described in U.S. Patent No. 6,730,118.

[0104] Each leaflet 20 can be coupled to the frame 12 along its inflow edge 30 (the lower edge in the figures; also referred to as “cusp edges”) and at commissures 32 of the valvular

structure 14 where adjacent portions of two leaflets are connected to each other, as further described below.

[0105] The frame 12 can be made of any of various suitable plastically-expandable materials (e.g., stainless steel, etc.) or self-expanding materials (e.g., Nitinol) as known in the art. When constructed of a plastically-expandable material, the frame 12 (and thus the prosthetic valve 10) can be crimped to a radially compressed state on a delivery catheter and then expanded inside a patient by an inflatable balloon or any suitable expansion mechanism. When constructed of a self-expandable material, the frame 12 (and thus the prosthetic valve 10) can be crimped to a radially compressed state and restrained in the compressed state by insertion into a sheath or equivalent mechanism of a delivery catheter. Once inside the body, the prosthetic valve can be advanced from the delivery sheath, which allows the valve to expand to its functional size.

[0106] Suitable plastically-expandable materials that can be used to form the frame 12 include, without limitation, stainless steel, a nickel based alloy (e.g., a cobalt-chromium or a nickel-cobalt-chromium alloy), polymers, or combinations thereof. In particular embodiments, frame 12 is made of a nickel-cobalt-chromium-molybdenum alloy, such as MP35N™ (tradename of SPS Technologies), which is equivalent to UNS R30035 (covered by ASTM F562-02). MP35N™/UNS R30035 comprises 35% nickel, 35% cobalt, 20% chromium, and 10% molybdenum, by weight. It has been found that the use of MP35N to form frame 12 provides superior structural results over stainless steel. In particular, when MP35N is used as the frame material, less material is needed to achieve the same or better performance in radial and crush force resistance, fatigue resistances, and corrosion resistance. Moreover, since less material is required, the crimped profile of the frame can be reduced, thereby providing a lower profile valve assembly for percutaneous delivery to the treatment location in the body.

[0107] The frame 12 in the illustrated embodiment comprises a plurality of circumferentially extending rows of angled struts 22 defining rows of cells, or openings, 24 of the frame. The frame 12 can have a cylindrical or substantially cylindrical shape having a constant diameter from an inflow end 26 to an outflow end 28 of the frame as shown, or the frame can vary in diameter along the height of the frame, as disclosed in U.S. Publication No. 2012/0239142.

[0108] The sealing member 16 in the illustrated embodiment is mounted on the outside of the frame 12 and functions to create a seal against the surrounding tissue (e.g., the native leaflets

and/or native annulus) to prevent or at least minimize paravalvular leakage. The sealing member 16 can comprise an inner layer 34 (which can be in contact with the outer surface of the frame 12) and an outer layer 36. The sealing member 16 can be connected to the frame 12 using suitable techniques or mechanisms. For example, the sealing member 16 can be sutured to the frame 12 via sutures 38 that can extend around the struts 22 and through the inner layer 34. In alternative embodiments, the inner layer 34 can be mounted on the inner surface of the frame 12, while the outer layer 36 is on the outside of the frame.

[0109] The outer layer 36 can be configured or shaped to extend radially outward from the inner layer 34 and the frame 12 when the prosthetic valve 10 is deployed. As best shown in FIG. 3, when the prosthetic valve is fully expanded outside of a patient's body, the outer layer 36 can expand away from the inner layer 34 to create a space 40 between the two layers. Thus, when implanted in the body, this allows the outer layer 36 to expand into contact with the surrounding tissue.

[0110] In the illustrated embodiment, the outer layer 36 comprises a lower tapered wall section 36a that extends outwardly from the frame in a direction from the inlet end to the outlet end, an upper tapered wall section 36b that extends outwardly from the frame in a direction from the outlet end to the inlet end, and a central wall section 36c that extends between the lower and upper tapered wall sections. The central wall section 36c can extend parallel to the longitudinal axis of the prosthetic valve as shown. In alternative embodiments, the upper and lower wall sections can extend perpendicularly relative to the longitudinal axis of the prosthetic valve. In alternative embodiments, the outer layer 36 can be formed by connecting together (such as by stitching) separate fabric components (for example, separate pieces of material for each wall section 36a, 36b, 36c) to form a three-dimensional structure without shape setting.

[0111] The inner layer 34 desirably is formed with at least one aperture or opening, and more desirably a plurality of apertures, or openings, 42 (FIG. 5). As best shown in FIG. 4, retrograde blood (indicated by arrows 44) can flow along the outside of the leaflets 20, through the cells 24 of the frame, through the openings 42 in the inner layer 34 and into the space 40 between the inner and outer layers 34, 36, to facilitate expansion of the sealing member 16 and creating a seal against the surrounding tissue. In some embodiments, the outer layer 36 can be formed with a plurality of apertures, or openings, which can allow blood to flow into the sealing member at least during valve deployment.

[0112] In the illustrated embodiment, the inner layer 34 is formed with one or more openings 42 along the portions of the inner layer that face the outflow surface 70 of the leaflets (the areas of the frame between the commissures) to allow retrograde blood to flow through the frame at those locations. The portions of the inner layer 34 covering the frame in the areas between the cusp edge portions of the leaflets completely cover the openings in the frame at those locations to prevent antegrade blood from flowing through the frame at those locations. In alternative embodiments, the inner layer can have portions that cover the areas of the frame between the cusp edge portions of the frame and cut-out sections along the portions of the frame facing the outflow surface of the leaflets (see the sealing members 702, 802, described below).

[0113] As shown in FIG. 5, the openings 42 can be centered at junctions 50 where the frame struts 22 intersect, which inhibits material of the inner layer 34 surrounding the openings from protruding inwardly through the frame and contacting the leaflets.

[0114] The sealing member 16 can be formed from fabric or non-fabric materials such as PET, PTFE, ePTFE, polyurethane, silicone, polyester, wire mesh, natural tissue (e.g., pericardium) and/or other suitable materials configured to restrict and/or prevent blood-flow therethrough. In some embodiments, the sealing member can be formed from a generally flat strip, folded lengthwise to form the inner and outer layers, and then formed into a tube, such as by welding or stitching the ends together. In other embodiments, the sealing member 16 can be formed by weaving, knitting, or braiding the sealing member into a tubular shape. The bulge in the outer layer 36 can be formed, for example, by shape-setting the material to a desired configuration (e.g., as shown in FIGS. 1 and 2). The shape-setting of the outer layer can allow the outer layer to be self-expandable or induce radial expansion of the outer layer. Additionally or alternatively, the outer layer 36 can be self-expandable by including Nitinol threads in the outer layer.

[0115] In alternative embodiments, the inner layer 34 does not have any openings 42, but can be formed from a porous material that allows blood to flow through the inner layer. For example, in some embodiments, the inner layer 34 can be formed from a relatively more porous material than the outer layer 36. In further alternative embodiments, the outer layer 36 need not be configured to extend away from the outer surface of the frame and instead can have a shape that conforms to the outer surface of the frame. For example, the outer layer 36 can be generally tubular to correspond to the shape of the frame 12. In some embodiments, the outer layer can be formed from a fabric having a pile layer (e.g., a velour fabric) having

fibers or yarns forming looped or cut piles that help seal against the surrounding tissue. Sealing members formed from such fabrics are further described in U.S. Application No. 62/513,348, filed May 31, 2017.

[0116] FIG. 6 shows a strip of fabric that can be used to form the sealing member 16, according to one embodiment. As shown, a fabric strip can comprise a center section 52 and first and second longitudinal edge portions 54, 56 extending along opposing sides of the center section 52. The center section 52 can include three sets of one or more openings 42 (e.g., three openings in each set in the illustrated embodiment). The openings 42 are positioned to correspond with the position of junctions 50 below the commissures of the prosthetic valve. The first and second longitudinal edge portions 54, 56 can be folded over the center portion 52 and secured to each other, such as with stitching, to form the sealing member. The longitudinal edge portions 54, 56 collectively form the outer layer 36, while the center portion 52 forms the inner layer 34.

[0117] FIGS. 7A and 7B are perspective views of exemplary tubular bodies that can be used to form a sealing member 16. Referring to FIG. 7A, a tubular body 80 can comprise an upper portion 82 and a lower portion 84. The upper portion 82 can include a radial bulge 86. The tubular body 80 can be formed, for example, by three-dimensional weaving, knitting, or braiding. The lower portion 84 can be folded or inverted into the upper portion 82 to form a sealing member having an outer layer formed by the upper portion 82 and an inner layer formed from the lower portion 84.

[0118] Referring to FIG. 7B, a tubular body 90 can comprise a cylindrical central portion 92, a flared upper portion 94, and a flared lower portion 96. The tubular body 90 can be formed, for example, by three-dimensional weaving, knitting, or braiding. The upper portion 94 can folded or inverted over the lower portion 94 to form two layers of a sealing member.

[0119] FIGS. 8-13 illustrate a technique for mounting the inflow edges 30 of the leaflets 20 to the frame 12, according to one embodiment. In the illustrated embodiment, a connecting skirt 100 is secured to a lower edge portion 102 (also referred to as a cusp edge portion) of each leaflet. As best shown in FIG. 9, each connecting skirt 100 can comprise an elongated, generally rectangular body 104 formed with a plurality of flaps 106a, 106b formed along opposing longitudinal edges of the body 104. The skirt 100 can comprise any suitable synthetic material (e.g., PET) or natural tissue.

[0120] Referring to FIGS. 10 and 10A, to secure a connecting skirt 100 to a leaflet 20, the body 104 is folded along a central longitudinal fold bisecting the body to form folded portions 110a, 110b, which are then placed on opposite sides of the lower edge portion 102 of the leaflet 20 such that the flaps 106a are adjacent the outer surface of the leaflet and the flaps 106b are adjacent the inner surface of the leaflet. A suture can then be used to form stitches 108 that extend through the opposing portions 110a, 110b of the body 104 and the lower edge portion 102 of the leaflet and longitudinally along the length of the lower edge portion 102. FIG. 11A shows a flattened view of the leaflet 20 with the skirt 100 folded around the lower edge portion 102 of the leaflet. FIG. 11B shows a flattened view of the leaflet 20 and the skirt 100 after being secured to the leaflet with stitches 108.

[0121] Referring to FIGS. 12, 12A, and 12B, each pair of flaps 106a, 106b are folded away from the leaflet 20 over a respective strut 22 of the frame and secured in place with stitches 112 that extend through the flaps 106a, 106b along a stitching line outside of the frame 12. As best shown in FIG. 12B, the connecting skirt 100 mounts the leaflet to the frame 12 such that the lower edge portion 102 extends radially inwardly at about a 90-degree angle relative to the frame 12. This effectively moves the bending axis of the lower edge portion 102 inwardly away from the inner surface of the frame and toward the center of the frame.

[0122] As best shown in FIG. 8, each of the skirts 100 is secured to the frame along a diagonal line 116 extending along the curved surface of the frame defined by a diagonally extending row of struts 22 extending from the inflow end of the frame toward the outflow end. As such, the lower edge portion 102 of each leaflet is also positioned along a respective diagonal line 116 defined by a respective diagonally extending row of struts 22. This advantageously reduces tension and the formation of wrinkles in the leaflets 20.

[0123] The attachment along diagonal lines 116 also helps reduce the crimping profile of the prosthetic valve when the prosthetic valve is radially compressed to its delivery configuration. In particular, struts in a circumferentially extending row of struts of the frame are moved or bent toward each other during the crimping process while struts lying along diagonally extending lines 116 substantially retain their alignment relative to each other along lines 116 during the crimping process. As such, the connecting skirts 100 (which typically are formed from non-stretchable materials) do not inhibit movement or deformation of the struts relative to each other. Also, since the cusp edge portions of the leaflets move with the connecting skirts during crimping, stretching of the leaflets along the cusp edge portions is prevented or at least minimized.

[0124] FIG. 13A is a perspective view of the frame 12 and the leaflets 20 supported in the frame shown in their mounted configuration with the connecting skirts 100 removed for purposes of illustration. FIG. 13B is an enlarged, partial cross-sectional view of the frame and a leaflet. As can be seen, the lower edge portion 102 of the leaflet extends perpendicularly or inversely parallel relative to the frame, creating a gap G between the inner surface of the frame and the bending axis 114 of the leaflet 20. Advantageously, this helps prevent or at least minimize contact of the outer surfaces of the leaflets with the frame and other relatively abrasive components, such as sutures, when the leaflets open during valve operation, thereby inhibiting undesirable abrasion of the leaflets that occurs through contact with the frame. The enlarged spaced between the leaflet and the frame also can promote blood washing over the leaflets at the bending axes of the leaflets.

[0125] Moreover, with known prosthetic valves, care must be taken to prevent the leaflets from extending through the open cells of the frame during crimping so as to prevent damage to the leaflets. For example, known crimping devices for prosthetic valves can include features or accessories that press the leaflets away from the frame or shield the leaflets from extending through the frame cells during crimping. In contrast, the skirts 100 assist in maintaining at least the inflow portions of the leaflets spaced from inner surface of the frame during crimping of the prosthetic valve to reduce the need for such specially designed crimping accessories.

[0126] Further, the connecting skirts 100 (and the other connecting skirts described herein) can facilitate assembly of the prosthetic valve compared to known assembly techniques. For example, the leaflets and the skirts can be assembled while the leaflets are in a flattened configuration, prior to forming the tubular (annular) configuration the valvular structure 14. Automated or semi-automated techniques can be used to suture the skirts to the leaflets. Also, once the valvular structure is placed inside of the frame, the lower edge portions 102 of the leaflets can be secured to the frame with stitching that is completely outside of the frame 12. This can substantially reduce assembly time as the assembler does not have to thread the needle for forming stitches 112 in and out of the cells 24 of the frame.

[0127] As further shown in FIGS. 13A-13B, each leaflet 20 comprises opposing tabs 60. Each tab 60 can be secured to an adjacent tab 60 of an adjacent leaflet 20 to form a commissure that is secured to the frame 12. Each tab 60 can be folded to form a radially extending layer 60a and a circumferentially extending layer 60b facing the frame. Methods

for mounting commissures to the frame are described in detail below and can be incorporated into the prosthetic valve shown in FIGS. 13A-13B.

[0128] The tab layer 60a can have an inclined edge 62 that extends radially inwardly from a location on the frame to a coaptation edge 64 of the leaflet. The inclined edge 62 also extends in an axial direction from the location on the frame to the coaptation edge 64. This places the center of the coaptation edge 64 (halfway between adjacent commissures) lower than the commissures and the attachment areas of the tabs 60 to the frame. In other words, the commissures are located at different locations along the height of the frame than the centers of the coaptation edges 64. This configuration is advantageous in that more evenly distributes stress along the tabs 60 during valve cycling. In some embodiments, the entire coaptation edge 64 of a leaflet is below the location where the commissures are attached to the frame, at least when the leaflets are in the closed positions.

[0129] During valve cycling, the leaflets can articulate at the inner most edges 66 of the tab layers 60a, which helps space the leaflets away from the frame during normal operation of the prosthetic valve. This is particular advantageous in cases where the prosthetic valve is not fully expanded to its nominal size when implanted in a patient. As such, the prosthetic valve can be implanted in a wider range of patient annulus sizes. Under relatively higher forces, such as when the prosthetic valve is radially compressed for delivery, the leaflets can splay apart from each other at the frame to relieve stress on the leaflets.

[0130] The commissures and the coaptation edges of the leaflets typically are relatively bulky portions of leaflets and can inhibit full radial compression of the prosthetic valve if they are at the same height along frame. Another advantage of the commissure tabs 60 shown in FIGS. 13A-13B is that the commissures and the coaptation edges are separated from each other in the axial direction when prosthetic valve is radially compressed for delivery into a patient's body. Separating these portions of the leaflets reduces the overall crimp profile of the prosthetic valve.

[0131] FIGS. 14 and 15A-15D show an alternative technique for mounting the lower edge portion 102 of a leaflet to the frame 12 using a connecting skirt 100. As shown in FIG. 14, slits 120 can be formed along the lowermost section of the edge portion 102 to facilitate folding of the edge portion during the assembly process. FIGS. 15A-15D show a step-by-step process for attaching the skirt 100 to the leaflet 20 and then mounting the skirt to the frame.

[0132] Referring first to FIG. 15A, the skirt 100 is folded to form a first layer 124 and a second layer 126 and the folded skirt is placed along the upper surface of the leaflet 20. The edge portion 102 of the leaflet is then wrapped around the folded edge of the skirt 100 to form a first leaflet layer 128 and a second leaflet layer 130 sandwiching the layers 124, 126 of the skirt. The layers 124, 126, 128, 130 can then be secured to each other with stitches 132 that extend through all four layers and longitudinally along the length of the edge portion 102 of the leaflet. An advantage of folding the edge portion 102 of the leaflet is that the leaflet can better resist pull through of the stitches 132.

[0133] Referring to FIG. 15B, the second layer 126 of the skirt can then be folded around the two leaflet layers 128, 130 to form a third skirt layer 134 adjacent the second leaflet layer 130 and a fourth skirt layer 136 adjacent the first leaflet layer 128. Referring to FIG. 15C, the first skirt layer 124 can then be folded back over the third skirt layer 134 to form a fifth skirt layer 138. The fourth skirt layer 136 can folded back over itself to form a sixth skirt layer 140. All six skirt layers and the two leaflet layers can be secured together with stitches 142 extending through all eight layers and longitudinally along the length of the edge portion 102 of the leaflet. In addition, the fifth and sixth layers 138, 140, respectively, can be secured together at a location spaced radially outward from the leaflet 20 with stitches 144 that extend through both layers and longitudinally along the length of the skirt 100.

[0134] The leaflet and skirt assembly can then be secured to the frame 12. As shown in FIG. 15D, for example, layers 138, 140 of the skirt can be placed below struts 22 of the frame and secured to the frame using, for example, stitches 146 that extend around the struts and through the layers 138, 140. Alternatively, the stitches 144 also can be wrapped around the struts of the frame to mount the leaflet and skirt assembly, in lieu of or in addition to stitches 146. Thus, the lower edge portion of each leaflet extends along a diagonal line just below the line 116 (FIG. 8) defined by the diagonal row of struts. Mounting the skirt below the diagonal row of struts 22 reduces motion of the skirt relative to the frame and resulting abrasion of the skirt so as to protect against tearing of the skirt during operation of the prosthetic valve.

[0135] In alternative embodiments, the skirt can be secured to the frame by placing the fifth layer 138 over the struts and the sixth layer 140 below the struts and securing those layers directly to each other outside of the frame (e.g., with sutures), similar to the way the skirt is secured to the frame in FIG. 12.

[0136] FIGS. 16-18 show alternative configurations for assembling a skirt 100 and a leaflet 20 utilizing a folded leaflet edge portion. In FIG. 16, the skirt 100 is folded around the leaflet layers 128, 130 to form a first skirt layer 150 below the leaflet layer 130, a second skirt layer 152 between the leaflet layers 128, 130, and a third skirt layer 154 above the leaflet layer 128. The leaflet and the skirt can be secured to each other using stitches 156 that extend through the skirt layers 150, 152, 154 and the leaflet layers 128, 130 and longitudinally along the length of the leaflet edge portion 102. The configuration of FIG. 16 utilizes less skirt layers than FIGS. 15A-15D and can permit a lower overall crimp profile for the prosthetic valve 10. FIG. 17 is similar to FIG. 16 except that the first skirt layer 150 is folded inwardly to form an additional fourth skirt layer 158 between the first skirt layer 150 and the lower surface of the leaflet 20. The fourth skirt layer 158 can help inhibit abrasion of the leaflet by positioning the edge of the skirt away from the articulating portion of the leaflet. FIG. 18 utilizes the same configuration as the embodiment of FIGS. 15A-15D except that in the embodiment of FIG. 18, stitches 160 extend through skirt layers 124, 126, 134, 136 and leaflet layers 128, 130 but not skirt layers 138, 140. The leaflet and skirt assemblies shown in FIGS. 16-18 can be secured to a frame 12 as previously described.

[0137] FIGS. 19-21 show another configuration for assembling a leaflet 20 and a skirt 100. As shown in FIG. 19, the skirt 100 is folded around a lower edge portion 102 of the leaflet 20 to form first and second skirt layers 170, 172 on the lower surface of the leaflet and third and fourth skirt layers 174, 176 on the upper surface of the leaflet. The inner edges of the folded layers can be secured with stitches 178 extending through all four layers 170, 172, 174, 176 and longitudinally along the length of the skirt and the leaflet. As shown in FIGS. 20 and 21, the skirt 100 can then be mounted to the frame 12 by positioning the outer edges of skirt layers 170, 176 below the diagonal row of struts 22 and securing those layers to each other and the struts with stitches 180. The stitches 180 extend through layers 170, 176 and around struts 22' that intersect with the struts 22 that form the diagonal row 116 of struts 22 above the row.

[0138] FIG. 22 shows a similar configuration to that shown in FIGS. 19-21 except that sections of the lower edge portion 102 of the leaflet extend through the cells of the frame. A first row of stitches 182 can be used to secure the lower edge portion 102 of the leaflet and the inner edges of the folded layers 170, 172, 174, 176. A second row of stitches 184 can be used to secure the lower edge portion 102 of the leaflet and the outer edges of the folded layers 170, 172, 174, 176 at a location outside of the frame. The lower edge portion 102 of

the leaflet can be formed with a series of slits 186 spaced along the length of the leaflet corresponding to location of struts 22 to allow the sections of the lower edge portion 102 to be extended through the cells of the frame.

[0139] FIG. 23 is a schematic representation of mounting the leaflets 20 to the frame utilizing connecting skirts 100. In the illustrated embodiment, the outer edges of the connecting skirts 100 can be secured to an annular inner skirt 190 (e.g., with sutures, an adhesive, or welding), which in turn can be secured to the struts of the frame (e.g., with sutures, an adhesive, or welding). Alternatively, the outer edges of the connecting skirts 100 can be mounted directly to the struts of the frame without an inner skirt 190, as previously described with respect to the embodiments in FIGS. 8-22. The inner edges of the connecting skirts 100 can be connected to respective lower edge portions 102 of the leaflets (e.g., by sutures), which can be spaced from the inner surface of the inner skirt 190 and/or the frame 12 by the connecting skirts. In particular embodiments, for example, the width of a skirt 100 between the lower edge of the respective leaflet 20 and the inner surface of the inner skirt 190 and/or the frame 12 can be about 1 mm to about 5 mm.

[0140] Forming the connecting skirts 100 from a fabric (e.g., PET) can promote tissue ingrowth and the formation or deposition of biological components, such as fibrin and other blood components along the upper surface of the connecting skirts during valve operation. Due to the material deposition of the skirts 100, they effectively become thicker and stiffer, thereby resisting flexing of the skirts during valve cycling. As a result, the normally closed position of the leaflets is dictated by diastolic pressure on the leaflets. During the systolic phase, the skirts 100 can remain substantially stationary, creating a gap between the leaflets and the inner surface of the inner skirt 190 and/or the frame 12 to protect against abrasion of the leaflets through contact with those components of the prosthetic valve.

[0141] FIGS. 24-25 show another configuration for mounting the lower, scalloped-shaped edge portions 102 of the leaflets to the frame 12. As shown in FIG. 24, the lower edge portion 102 of a leaflet 20 can be folded upwardly toward the outflow end of the frame and against the inner surface of the frame to create a bending axis between the lower edge portion and the remaining portion of the leaflet that can articulate toward and away from the frame during valve cycling. The bending axis of the leaflets is therefore spaced inwardly from the frame, which can provide several advantages, including protection against leaflet abrasion during valve cycling, reduction of stress along the lower edge of the leaflets during valve closure, improved blood-washing of the leaflets (thus eliminating or at least minimizing early

calcification in those areas), and improved closing action of the leaflets. A reinforcing member 200, such as a wire, chord, sleeve, fabric or suture, can be placed along the upper surface of the leaflet at the bending axis where the lower edge portion 102 intersects with the articulating portion of the leaflet. In other embodiments, the reinforcing member 200 can be placed along the lower surface of the leaflet. The reinforcing member 200 can comprise, for example, a multi-filament suture (e.g., an Ethibond suture).

[0142] The leaflet 20 can be coupled to the frame 12 using various techniques or mechanisms. As shown in FIGS. 25A-25B, for example, the leaflet 20 can be coupled to the frame 12 with a connecting skirt 202 having an inner longitudinal edge portion 204 and an outer longitudinal edge portion 206. The inner edge portion 204 can be folded upwardly against the lower edge portion 102 of the leaflet. The outer edge portion 206 can be folded downwardly against an outer skirt 210 (which can comprise, for example, the sealing member 16) mounted on the outside of the frame. The outer edge portion 206 can contact the outer skirt 210 through the cells of the frame at a location below a diagonal row of struts 22. The connecting skirt 202 can comprise two layers 202a, 202b of material formed, for example, by folding the skirt lengthwise prior to assembling the skirt to the leaflet. Alternatively, the connecting skirt 202 can comprise a single layer of material.

[0143] The inner edge portion 204 can be secured to the leaflet 20 with stitches 208 extending through the skirt 202, the leaflet 20, and the reinforcing member 200 and longitudinally along the leaflet and the skirt. The outer edge portion 206 can be secured to the outer skirt 210 via stitches 212 that extend through the connecting skirt 202 and the outer skirt 210 and longitudinally along the connecting skirt. As shown in FIG. 25B, the connecting skirt 202 also can be secured directly to the frame via the stitches 212 or separate stitches that extend through the outer edge portion 206 of the skirt 202 and around junctions 50 of the frame where two struts intersect. The connecting skirt can be left unattached to apices 216 formed by the intersection of respective pairs of struts 22 at the inflow end of the frame.

[0144] The row of stitches 212 desirably extends above the apices 216 as shown to prevent the leaflets from protruding below the inflow end of the frame so as to protect against the leaflets contacting adjacent native tissue, such as calcium nodes, prior to or during deployment of the prosthetic valve 10. Having the lower edge portions 102 of the leaflets folded upwardly away from the connecting skirt 202 and toward the outflow end of the frame

can minimize the amount of overlapping layers of material of the skirt 202, the leaflet 20 and the frame 12 so as to reduce the overall crimp profile of the prosthetic valve.

[0145] FIG. 26 shows an alternative configuration for mounting the leaflets 20 to the frame using the connecting skirts 202. The embodiment of FIG. 26 can be the same as the embodiment of FIGS. 24 and 25 except that the outer edge portion 206 of the connecting skirt 202 extends between a lower edge portion of an upper outer skirt 218 and an upper edge portion of a lower outer skirt 220. The connecting skirt 202, the upper outer skirt 218, and the lower outer skirt 220 can be secured to each other with stitches 222 extending through all three layers of material.

[0146] FIG. 27 shows another alternative configuration for mounting the leaflets 20 to the frame using the connecting skirts 202. The embodiment of FIG. 27 can be the same as the embodiment of FIGS. 24 and 25 except that the outer edge portion 206 of the connecting skirt 202 can be folded upwardly toward the outflow end of the frame. The outer edge portion 206 can be secured to the outer skirt 210 with stitches 212.

[0147] FIGS. 28 and 29 illustrate in greater detail different ways of stitching the inner edge portion 204 of the connecting skirt 202 to the lower edge portion 102 of a leaflet 20. In FIG. 28, the stitches 208 extend through the inner skirt layer 202b but not the outer skirt layer 202a. In FIG. 29, the stitches 208 extend through both skirt layers 202a, 202b.

[0148] FIG. 30 shows another configuration for mounting the lower edge portions 102 of the leaflets to the frame 12. As shown in FIG. 30, the lower edge portion 102 of a leaflet can be coupled to the frame 12 with a connecting skirt 230 having an upper edge portion 232 and a lower edge portion 234. The upper edge portion 232 can be secured to an outer skirt 210 at a location above a diagonal row of struts 22 via stitches 236 that extend through the outer skirt and the connecting skirt. The lower edge portion 234 of the connecting skirt can be secured to the outer skirt at a location below the diagonal row of struts 22 via stitches 238 that extend through the outer skirt and the connecting skirt. An intermediate portion of the connecting skirt (between the upper and lower edge portions 232, 234) can extend over the diagonal row of struts.

[0149] As shown in FIG. 30, the spacing between the row of struts and the stitching 236 desirably is greater than the spacing between the row of struts and the stitching 238, which can increase the contact angle of the skirt and the struts 22. The encircled area 240 in FIG. 30 represents the contact area where contact between the connecting skirt 230 and the frame

12 occurs, or where a majority of the contact between the connecting skirt and the frame occurs. Under systole, the angle of the skirt 230 relative to a transverse axis of the frame (the transverse axis being perpendicular to a longitudinal axis of the frame) at the contact area 240 is about 60 to 90 degrees, or more preferably about 70 to 90 degrees, or even more preferably about 80 to 90 degrees. Increasing the contact angle of the skirt can reduce bending stresses in the skirt during valve cycling to improve durability of the skirt. Further, the connecting skirt 230 can be sized or configured such that during diastole, the connecting skirt can move slightly radially inwardly under blood pressure and separate from the skirt 230 from the struts 22 so as to remove or minimize contact between the skirt and struts.

[0150] FIG. 31 shows another configuration for mounting the lower edge portions 102 of the leaflets to the frame 12 with connecting skirts 230 similar to the embodiment of FIG. 30 except that the upper edge portion 232 of the connecting skirt is secured to an upper diagonally extending row of struts 22a and the lower edge portion 234 of the connecting skirt is secured to a lower diagonally extending row of struts 22b. In this manner, the lower edge portion 102 of the leaflet can be secured to the connecting skirt 230 between the upper and lower rows of struts. The upper edge portion 232 of the connecting skirt can be at least partially wrapped around the struts 22a of the upper row and secured in place by loop stitches 250 extending through the skirt and around the struts 22a. The lower edge portion 234 of the connecting skirt can be at least partially wrapped around the struts 22b of the lower row and secured in place by loop stitches 252 extending through the skirt and around the struts 22b. Attaching the connecting skirt 230 to two adjacent diagonally extending rows of struts in the manner shown in FIG. 31 can prevent or at least minimize relative motion between the connecting skirt and the frame to improve durability of the skirt.

[0151] FIG. 32 shows another configuration for mounting the lower edge portions 102 of the leaflets to the frame 12 without any connecting skirts. In the embodiment of FIG. 32, the lower edge portion 102 of a leaflet 20 can be folded upwardly against a diagonal row of struts 22 and secured in place with loop stitches 254 extending around the struts 22 and through the leaflet edge portion 102 at a first location, through the reinforcing member 200, and through the leaflet edge portion 102 at a second location. Placing the folded edge portion 102 of the leaflet parallel to the inner surfaces of the struts can minimize wear of the leaflets due to motion of the leaflets relative to the frame. The elimination of the skirts in this embodiment can reduce the overall crimp profile of the prosthetic valve and can achieve a tighter

connection between the leaflets and the frame to reduce relative motion between these two components.

[0152] FIGS. 33-37 show a technique for mounting the commissures of a valvular structure to a frame, such as the commissures 32 to the frame 12, according to one embodiment. FIG. 33 shows a leaflet 300 having a lower edge portion 302 that can be mounted to the frame 12 using any of the previously described embodiments. The lower edge portion 302 terminates at its upper ends at two laterally projecting integral lower tabs 304. Projecting from the upper corners of the leaflet 300 are integral upper tabs 306 (also referred to as commissure tabs). The upper tabs 306 can be spaced from the lower tabs 304 by side edges 338 defining laterally extending gaps or recesses in the leaflet.

[0153] To assemble the commissure, each upper tab 306 is folded along a horizontal fold line 308 to form first and second tab layers 306a, 306b, as shown in FIG. 33 (see also FIG. 37). A first vertically extending reinforcing member 310 can be placed against the first tab layer 306a adjacent its inner edge. A second vertically extending reinforcing member 312 can be placed against the second tab layer 306b opposite the first reinforcing member 310. The first and second tab layers 306a, 306b can be secured to each other with stitching 314 that extends through the first and second tab layers 306a, 306b and the first and second reinforcing members 310, 312.

[0154] The first and second tab layers 306a, 306b can then be folded lengthwise along a vertical fold line as shown in FIG. 35 to form an outer folded portion 316 and an inner folded portion 318 that extends radially inwardly from the outer folded portion 316. A third vertically extending reinforcing member 320 can be placed against the first folded layer 306a of the outer folded portion 316 and a commissure attachment member 322 can be placed against the second folded layer 306b of the outer folded portion 316. The outer folded portion 316 can be secured to the commissure attachment member 322 with stitches 324 that extend through the third reinforcing member 320, the first and second tab layers 306a, 306b, and the commissure attachment member 322. The outer edges of the first and second tab layers 306a, 306b can be further secured to the commissure attachment member 322 with stitches 326. The upper tab 306 of a second leaflet 300 can be assembled in the same manner with respective reinforcing members and attached to the commissure attachment member 322 adjacent the first leaflet to form a commissure 328 as shown in FIG. 37. The commissure attachment member 322 can then be secured to the struts of the frame (see, e.g., FIG. 65), as further described below.

[0155] The folded tab layers 306a, 306b, reinforced by the first and second reinforcing members 310, 312, can be more resistant to bending, or articulating, than the portions 330 of the leaflets that are radially inward of the tab layers. This causes the leaflets 300 to articulate primarily at inner edges 332 of the folded layers 306a in response to blood flowing through the prosthetic valve during operation of the prosthetic valve in the body, as opposed to articulating about respective axes on or adjacent the metal struts of the frame. Because the leaflets articulate at a location spaced radially inwardly from the frame 12, the leaflets can avoid contact with and damage from the frame. This is particularly advantageous in cases where the prosthetic valve is not fully expanded to its nominal size when implanted in a patient's body. As such, the prosthetic valve can be implanted in a wider range of patient annulus sizes.

[0156] Under high forces, the folded tab layers 306a, 306b of adjacent leaflets can splay apart from each other about respective axes 334 (FIG. 37) adjacent to the frame 12, with each inner folded portion 318 folding out against the respective outer folded portion 316. For example, this can occur when the prosthetic valve 10 is compressed and mounted onto a shaft of a delivery apparatus, allowing for a smaller crimped diameter. The folded tab layers can also splay apart about their axes 334 when the balloon of the balloon catheter is inflated during expansion of the prosthetic valve, which can relieve some of the pressure on the commissures caused by the balloon and so the commissures are not damaged during expansion.

[0157] When the leaflets 300 are mounted to the frame, the lower tabs 304 of each leaflet can be folded downwardly against the cusp edge portion 302 and held in place, such as with sutures. The folded lower tabs 304 help reinforce the connection between the cusp edge portions 302 of the leaflets and the frame along the upper sections of the cusp edge portions adjacent the commissures. The folded lower tabs 304 also move the bending axes of the upper sections of the cusp edge portions inwardly and away from the inner surface of the frame to prevent or minimize contact between the leaflets and the frame in the areas below the commissures.

[0158] The side edges 338 between the lower and upper tabs 304, 306 can be left unattached to the frame of the prosthetic valve (see FIG. 1C). The unattached side edges 338 provide several advantages, including reducing stress in the leaflets, by allowing greater elongation or stretching of the leaflets in the axial direction when the prosthetic valve is compressed from the radial expanded state to the radial compressed state during the crimping process and by allowing greater elongation or stretching of the leaflets in the radial direction when the

prosthetic valve is expanded to its radial expanded state. The unattached side edges 338 also allow blood to flow in the space between a pair of side edges 338 of adjacent leaflets and the inner surface of the frame to reduce stagnant blood flow and thrombosis. During diastole, the adjacent side edges 338 can coapt with each other and prevent retrograde blood from flowing between the side edges 338. During systole, the adjacent side edges 338 can separate from each other and allow antegrade blood to flow between side edges 338 and help wash away blood from the areas underneath the commissures.

[0159] The reinforcing members 310, 312, 320 desirably comprise relatively soft and flexible, non-metallic materials. For example, the reinforcing members can comprise multi-filament sutures (e.g., Ethibond sutures) or strips of synthetic material, such as fabric (e.g., PET) or non-fabric material (e.g., silicone or polyurethane), or natural tissue (e.g., pericardium). The commissure attachment member 322 similarly can comprise a soft and flexible, non-metallic material, such as strips of synthetic material, such as fabric (e.g., PET) or non-fabric material (e.g., silicone or polyurethane), or natural tissue (e.g., pericardium). Hence, in the illustrated embodiment, the commissure 328 does not include metallic components or other materials having similar rigidity. The absence of such materials can reduce abrasion and wear of the leaflet material and reduce the overall crimp profile of the prosthetic valve.

[0160] FIG. 38 shows a modification of the embodiment shown in FIG. 37. The embodiment of FIG. 38 can be same as that shown in FIG. 37 except that the pair of folded layers 306a, 306b of adjacent leaflets 300 can be secured to each other with a suture 336 that extends through the reinforcing members 310, 312 and the tab layers 306a, 306b of each leaflet 300. Securing the leaflets together can reinforce the bending axes of the articulating portions 330 of the leaflets during normal valve operation.

[0161] FIG. 39 shows an alternative embodiment of a leaflet 340, which is similar to the leaflet 300, except that the leaflet 340 includes upper tabs 341 that project laterally a greater distance than the upper tabs 306. Each upper tab 341 can be folded widthwise along a respective vertical fold line 342 to form two folded tab layers that are paired with folded tab layers of an adjacent leaflet to form a commissure as previously described.

[0162] FIGS. 40-46 show another embodiment of a leaflet and a method for forming a commissure from two leaflets. As shown in FIG. 40, a leaflet 400 comprises a lower edge portion 402 terminating at lower tabs 404, upper tabs 406 (also referred to as commissure

tabs) spaced from the lower tabs 404 by gaps 408. The lower tabs 404 can be folded downwardly against the lower edge portion 402 to reinforce those areas of the leaflet and to move the bending axes of the upper sections of the edge portions 402 (the portions just below the commissures) inwardly away from the inner surface of the frame, as previously described.

[0163] Each upper tab 406 includes a lower tab portion 410, an upper tab portion 412 extending from the lower tab portion, and a side tab portion 414 extending laterally inwardly from the upper tab portion. To form a commissure, a reinforcement member 418 (e.g., a multi-filament suture or a strip of fabric) can be placed vertically along the upper tab portion 412 in the manner shown in FIG. 41. The side tab portion 414 can then be folded along a fold line 416 against the upper tab portion 412 as shown in FIGS. 41-42. The dual layer of the side tab portion 414 and the upper tab portion 412 can then be folded along horizontal fold line 420 against the lower tab portion 410, as depicted in FIGS. 42-43.

[0164] As shown in FIG. 44, a commissure attachment member 422 can then be placed against the rear (outer) surface of the lower tab portion 410 and secured to the upper tab 406 with stitching 424 that extends through the upper tab portion 412, reinforcement member 418, the side tab portion 414, the lower tab portion 410, and the commissure attachment member 422. The three layers formed by the lower tab portion 410, the upper tab portion 414, and the side tab portion 414 can then be folded into an L-shape to form an outer folded portion 426 adjacent the commissure attachment member 422 and an inner folded portion 428 extending radially inwardly from the outer folded portion as shown in FIG. 46. As shown in FIG. 46, the tab layers of the outer folded portion 426 can be further secured to the commissure attachment member 422 with stitches 432. The upper tab 406 of another leaflet can be assembled in the same manner and secured to the same commissure attachment member 422 to form a commissure 430 as shown in FIGS. 45-46.

[0165] As described above, the stitches 424 can extend through each layer formed by the lower tab portion 410, the upper tab portion 414, and the side tab portion 414. As shown in FIG. 46, the stitches 424 from each commissure tab 406 can extend diagonally toward each other to compress the folded commissure tabs 406 against each other and the commissure attachment member 422. In alternative embodiments, the stitches 424 can be placed through the reinforcement member 418, the side tab portion 414 and the lower tab portion 410 prior to folding the upper tab portion and the side tab portion along fold line 420. In this manner, the stitches 424 need not extend through the upper tab portion 412, as depicted in FIG. 46. In some embodiments, another reinforcement member 438 can be placed against the outer

surface of the commissure reinforcement member 422 (FIG. 46). The stitches 424 from each commissure tab 406 can extend through the reinforcement member 438 at the same location as shown or at spaced apart locations.

[0166] The commissure 430 can function similar to the commissure 328 described above. Thus, during normal valve cycling, the leaflets 400 can articulate about respective axes at the inner ends 434 of the tab layers 412. The compression of the folded commissure tabs 406 by stitches 424 helps maintain the normal bending axes of the leaflets 400 away from the frame. During valve deployment, the leaflets can splay apart from each other at an axis 436 adjacent the commissure attachment member 422.

[0167] FIG. 47 shows an alternative configuration for forming a commissure. The embodiment of FIG. 47 is similar to the embodiment of FIGS. 33-37 except that a vertical reinforcement member 344 can be placed between two layers of the commissure tab of the leaflet. The commissure can be formed by placing the reinforcement member 344 on tab portion 306a prior to folding tab portion 306a along fold line 308. After folding the commissure tab 306, the folded layers 306a, 306b can be secured to the commissure attachment member 322 with stitches 346 that extend through the reinforcement member 344, both tab layers 306a, 306b, and the commissure attachment member 322.

[0168] FIG. 48 shows an alternative configuration for forming a commissure similar to FIG. 46, except that each folded commissure tab 406 is secured to a separate reinforcing member 438 (one of which is shown in FIG. 48). Also, stitches 440 can secure the side tab portion 412 to the reinforcing member 418.

[0169] FIGS. 49-54 show another embodiment of a leaflet and a method for forming a commissure 32 from two leaflets. As shown in FIG. 49, a leaflet 500 comprises a lower edge portion 502 terminating at lower tabs 504, upper tabs 506 (also referred to as commissure tabs) spaced from the lower tabs 504 by gaps 508. The lower tabs 504 can be folded downwardly against the lower edge portion 502 to reinforce those areas of the leaflet and to move the bending axes of the upper sections of the edge portions 502 (the portions just below the commissures) inwardly away from the inner surface of the frame, as previously described.

[0170] Each commissure tab 506 includes a lower tab portion 510 and an upper tab portion 512. To form a commissure, the upper tab portion 512 is folded along fold line 514 against the lower tab portion 510. The dual layer comprising tab portions 510, 512 can then be folded along a vertical fold line 516 to form a first layer 518, a second layer 520, a third layer

522, and a fourth layer 524 from each commissure tab 506, as depicted in FIGS. 50-52. A reinforcement member 526, such as strip of fabric (e.g., PET), can be positioned between the second layer 520 and the third layer 522.

[0171] The commissure tab 506 of another leaflet 500 is folded in the same manner and placed against the folded commissure tab of the first leaflet within a commissure attachment member 528. The commissure attachment member 528 can be folded as shown in FIG. 50 to form a central outer portion 530, outer end portions 532, and side portions 534, each comprising first and second layers 534a, 534b of material extending from respective ends of an end portion 532 and the central outer portion 530. The side portions 534 can be placed against respective fourth layers 524 of the commissure tabs.

[0172] As shown in FIG. 50, the layers 534a, 534b of each side portion 534 can be secured to each other with stitching 536. Each side portion 534 can be secured to a commissure tab 506 with stitching 538 extending through a respective reinforcing member 526, respective third and fourth layers 522, 524, and both layers of a respective side portion 534. The commissure attachment member 528 can be secured to the struts 22 of a frame 12 with sutures or other techniques or mechanisms.

[0173] FIG. 51 shows another way of securing the folded commissure tabs 506 to the commissure attachment member 528. As shown in FIG. 51, for each commissure tab, a row of laterally extending stitches 540 can be used to secure the inner end portions of the layers 534a, 534b of the side portion, the third and fourth layers 522, 524, and the reinforcing member 526. A diagonally extending row of stitches 542can be used to secure the reinforcing member 526, the third and fourth layers 522, 524, and the rear end portions of layers 534a, 534b of the side portion.

[0174] As shown in FIG. 52-53, each commissure 32 can include an inner sleeve 544 and an outer support member 546. The inner sleeve 544 can comprise first and second portions 544a, 544b, each of which extends around the outer side as well as the upper and lower portions of a respective folded commissure tab 506. The adjacent upper ends 548 of the first and second portions 544a, 544b can be secured to each other (e.g., with sutures) at the center of the commissure 32. The adjacent lower ends of the first and second portions 544a, 544b can be secured to each other (e.g., with sutures) in a similar manner at the center of the commissure 32. Each of the side portions 534 of the commissure attachment member 528 can be secured to one of the first and second portions 544a, 544b of the inner sleeve (e.g.,

with sutures). The outer support member 546 can be secured to the central outer portion 530 and/or the end portions 532 of the commissure attachment member 528 (e.g., with sutures).

[0175] As shown in FIG. 54, at least a portion of the outer support member 546 can be positioned outside of the frame 12. The outer support member 546 can be secured (e.g., with sutures) to each strut 22 of a set of struts forming a cell of the frame. In the illustrated embodiment, for example, the outer support member 546 can be sutured to each strut of a diamond-shaped cell comprised of four struts 22. The inner sleeve 544 and the outer support member 546 can comprise any suitable relatively flexible and soft material as previously described for the reinforcement members and the commissure attachment members of the embodiments described above. In particular embodiments, the inner sleeve 544 and the outer support member 546 comprise PET fabric.

[0176] FIG. 55 shows a modification of the commissure 32 shown in FIGS. 52-54. The embodiment of FIG. 55 can be the same as the embodiment of FIGS. 52-54, except that the former includes reinforcing members 554 in the form of multi-filament sutures positioned between the second and third layers 520, 522 of each commissure tab 506.

[0177] FIG. 56 shows an alternative embodiment for forming a commissure from two leaflets 300. The commissure tabs 306 can be folded in a manner similar to that described above for the embodiment of FIGS. 33-37. As shown, a reinforcement member 350 (e.g., strips of PET fabric or other material) can be placed at the fold of each layer 306a. A commissure attachment member 352 can be placed against the outer folded portions 316 of each layer 306b and folded in the manner shown in FIG. 56 to create three layers of material 352a, 352b, 352c at each layer 306b. For each commissure tab 306, stitches 354 can be used to secure the reinforcement member 350, layers 306a, 306b and the three folded layers of the commissure attachment member 352.

[0178] FIGS. 57-58 show a prosthetic valve 600, according to another embodiment. The prosthetic valve 600 can be similar to the prosthetic valve 10 described above except for the configuration of the sealing member. The prosthetic valve 600 in the illustrated embodiment comprises a sealing member 602 comprising an inner portion or layer 604 and an outer portion or layer 606. The inner layer 604 is mounted inside of the frame 12 and comprises three triangular shaped portions 608. FIG. 59 shows the sealing member 602 in a flattened configuration prior to attachment to the frame. The half triangular portions at each end of the

sealing member form a triangular portion 608 when the sealing member is formed into a tubular or annular shape with the ends connected to each other.

[0179] The upper edge portion 610 of the inner layer is shaped to correspond to the shape of the lower edge portions 102 of the leaflets 20. The lower edge portions 102 of the leaflets 20 can be connected directly to the upper edge portion 610 of the inner layer 604 (e.g., with sutures), using connecting skirts (e.g., any of the connecting skirts described herein, such as skirts 100) or other mounting techniques described herein. The upper edge portion 610 of the inner layer 604 can be secured to the struts 22 of the frame 12, such as with the sutures used to connect the inner layer to the leaflets or with separate sutures that extend around the struts 22 and through the inner layer. The inner layer 604 functions to prevent antegrade blood from flowing outwardly through the cells of the frame below the inflow edges of the leaflets.

[0180] The outer layer 606 can be wrapped around the inflow end 26 of the frame and secured (e.g., with sutures) along its upper edge portion 612 to the struts 22 on the outside of the frame 12. Individual sutures can be used to secure the outer layer 606 at circumferentially spaced apart locations to the apices at the inflow end 26 of the frame.

[0181] The outer layer 606 can be shaped or configured to extend radially outwardly from the frame when the prosthetic valve is radially expanded to its functional size to create a space 614 between the frame and the outer layer 606. Upon deployment in a patient's body, retrograde blood can flow over the outer surface of the leaflets 20, through the cells of the frame, and into the space 614 inside of the outer layer 606 to facilitate creation of a seal against the surrounding tissue. The absence of material inside of the frame facing the movable portions of the leaflets 20 can reduce the overall crimp profile of the prosthetic valve and can inhibit abrasion of the leaflets 20, especially in cases where the prosthetic valve is not fully expanded to its nominal size. Consequently, this can allow the prosthetic valve to be implanted in a wider range of patient annulus sizes.

[0182] The sealing member 602 can be formed from the same materials and using the same techniques as described above for the sealing member 16.

[0183] FIGS. 60-61 show a prosthetic valve 700, according to another embodiment. The prosthetic valve 700 can similar to the prosthetic valve 10 described above except for the configuration of the sealing member. The prosthetic valve 700 in the illustrated embodiment comprises a sealing member 702 comprising an inner portion or layer 704 and an outer portion or layer 706. The inner layer 704 is mounted outside of the frame 12 and comprises

three triangular shaped portions 708. In particular embodiments, the triangular shaped portions 708 are connected only by a thin strip 705.

[0184] FIG. 62 shows the sealing member 702 prior to assembling it on the frame 12 and folded into its final shape. When mounting the sealing member 702 on the frame 12, the sealing member can first be placed on the frame as shown in FIG. 63 such that the inflow end portion of the inner layer 704 is adjacent the inflow end 26 of the frame. The triangular portions 708 are shaped to correspond to the shape of the lower edge portions 102 of the leaflets 20 and cover the openings in the frame between adjacent edge portions 102 underneath each commissure. By virtue of the shape of the triangular portions 708, the inner layer 704 does not cover the portions of the frame facing the outflow surfaces of the leaflets.

[0185] The lower edge portions 102 of the leaflets 20 can be connected directly to the upper edge portion 710 of the inner layer 704 (e.g., with sutures), using connecting skirts (e.g., any of the connecting skirts described herein, such as skirts 100) or other mounting techniques described herein. The inner layer 704 functions to prevent antegrade blood from flowing outwardly through the cells of the frame below the inflow edges of the leaflets.

[0186] The outer layer 706 can then be folded over the inner layer 704 toward the inflow end 26 of the frame such that the upper end of the pre-folded outer layer becomes the lower (inflow) end of the outer layer and lies adjacent the inflow end 26 of the frame, as shown in FIG. 60. Folding the outer layer over the inner layer inverts the outer layer such that the inner surface of the pre-folded outer layer becomes the outer surface of the outer layer and the outer surface of the pre-folded outer layer becomes the inner surface of the outer layer in its folded, assembled state. FIG. 64 shows the sealing member 702 in its final, folded state apart from the rest of the prosthetic valve for purposes of illustration. After folding the outer layer 706, the inflow and/or outflow ends of the outer layer can be secured to the struts 22 of the frame (e.g., with sutures).

[0187] The sealing member 702 can be formed from the same materials and using the same techniques as described above for the sealing member 16. In alternative embodiments, the inner layer 704 and the outer layer 706 can be separate pieces of material, which can be secured to each other (e.g., with sutures) at their inflow ends and/or outflow ends.

[0188] Similar to the embodiment of FIGS. 57-59, the outer layer 706 can be shaped or configured to extend radially outwardly from the frame when the prosthetic valve is radially expanded to its functional size to create a space 714 between the frame and the outer layer

706. Upon deployment in a patient's body, retrograde blood can flow over the outflow surface 70 of the leaflets 20, through the cells of the frame, and into the space 714 inside of the outer layer 706 in the direction of arrows 716 to facilitate creation of a seal against the surrounding tissue. The triangular shaped portions 708 prevent antegrade blood from flowing through the frame at locations between the cusp edge portions 102 of the leaflets. The absence of material inside of the frame can reduce the overall crimp profile of the prosthetic valve and can inhibit abrasion of the leaflets 20, especially in cases where the prosthetic valve is not fully expanded to its nominal size. Consequently, this can allow the prosthetic valve to be implanted in a wider range of patient annulus sizes.

[0189] FIG. 65 shows a prosthetic valve 800, according to another embodiment. The prosthetic valve 800 can include a sealing member 802 mounted to the frame 12 as described above in connection with the embodiment of FIGS. 60-63. The prosthetic valve 800 can include leaflets 814 connected to each other at their outflow ends to form commissures 810 that are mounted to the cells at the outflow end of the frame. The commissures 810 can be formed by folding commissure tabs of the leaflets and securing them to a commissure attachment member 812. Each commissure attachment member 812 can be sutured to four struts 22 that define a closed cell 24 of the frame. A method for forming the commissures 810 and mounting them to a cell 24 via the commissure attachment members 812 is described in detail below.

[0190] FIG. 68 show the sealing member 802 apart from the other components of the prosthetic valve. The sealing member 802 comprises an inner layer 804 and an outer layer 806. The inner layer 804 can comprise a plurality of triangular-shaped portions 808. The sealing member 802 can have the same or similar construction as the sealing member 702, except that the triangular-shaped portions 808 are not connected to each other at their lower (inflow) ends. The sealing member 802 can be mounted to frame 12 as described above in connection with sealing member 702.

[0191] Referring to FIGS. 74-78, a method for forming the commissures 810 and mounting them to the frame 12 will be described. As best shown in FIG. 75, each leaflet 814 has a lower or cusp edge portion 816 that can be mounted to the frame 12 using any of the previously described embodiments. The lower edge portion 816 terminates at its upper ends at two laterally projecting integral lower tabs 818. Projecting from the upper corners of the leaflet 814 are integral upper tabs 820 (also referred to as commissure tabs). The upper tabs

820 can be spaced from the lower tabs 818 by side edges 819 forming laterally extending gaps or recesses 822 in the leaflet.

[0192] As shown in FIG. 75B, each upper tab 820 is folded along a fold line 824 to form first and second tab layers 820a, 820b, similar to the technique described above for leaflet 300 shown in FIGS. 33-37. The upper tab 820 is secured to a commissure attachment member 812, along with the upper tab 820 of an adjacent leaflet to form a commissure 810, as further described below. FIG. 76 shows a commissure attachment member 812 in a flattened configuration prior to folding and attachment to the leaflets. Each commissure attachment member 812 in the illustrated configuration comprises first and second side portion 828a, 828b projecting laterally from a central portion 830. As shown, the outer peripheral edges 832 of the side portions 828a, 828b can be shaped to correspond to one half of a diamond-shaped cell 24 of the frame 12 to facilitate mounting of the commissure attachment member 812 to the struts 22 of the frame 12, as further described below.

[0193] Referring to FIGS. 77-78, after the upper tab 820 of a leaflet 814 is folded, a vertical reinforcement 826 can be secured to the inner surface of tab layer 820a, such as with stitching. The folded tab layers 820a, 820b can be secured to a side portion 828a or 828b of the commissure attachment member 812. The folded tab layers also can be folded along a vertical fold line at the reinforcement 826 in an L-shape such that the tab layer 820b forms a first circumferentially extending layer 834a and a first radially extending layer 834b that is generally perpendicular to the layer 834a and the tab layer 820a forms a second inner circumferentially extending layer 836a and a radially extending layer 836b that is generally perpendicular to the layer 836a. Another upper tab 820 of an adjacent leaflet 814 can be similarly folded and secured to the other side portion 828a or 828b of the commissure attachment member 812.

[0194] The commissure attachment member 812 can be folded as shown in FIG. 78 to form an inner layer 838 and two intermediate layers 840 and two outer layers 842. Each folded upper tab 820 can be secured to the inner layer 383 and an intermediate layer 840 with stitching 844. In the illustrated embodiment, stitching 844 is shown extending through the reinforcement member 826, a layer 836a, a layer 834a, layer 838, and a layer 840. However, during the assembly process, multiple stitches can be employed to secure each layer to an adjacent layer as each folded is created. For example, layers 834a, 836a can be secured to each other and a reinforcement member 826 with separate stitching, and additional stitching can then be used to secure the leaflet layers to the inner layer 838 of the commissure

attachment member 812, and further stitching can be used to secure an intermediate layer 840 to the inner layer 838. As best shown in FIG. 78, the commissure attachment member 812 can be folded to leave a small gap 846 between the outer layers 842.

[0195] The outer layers 842 can be secured to the frame 12, such as by suturing the outer peripheral edges 832 to struts 22 with stitching 848. As mentioned above, the outer peripheral edges 832 of the commissure attachment member 812 can generally correspond to the shape of a closed cell of the frame 12. For example, as shown in FIG. 71, the frame 12 in the illustrated embodiment comprises a plurality of generally diamond-shaped cells 24, each of which is formed by struts 22a, 22b, 22c, and 22d. Stitching 848 can be used to suture the outer peripheral edges 832 of the commissure attachment member 812 to struts 22a, 22b, 22c, 22d forming a closed cell 24. The commissure attachment member 812 can further include an upper tab 850 and a lower tab 852 projecting from the upper and lower edges of the central portion (FIG. 76). Stitching 848 can also be used suture the upper tab 850 an apex 854 formed by the intersection of struts 22a, 22c and to suture the lower tab 852 to a junction 856 formed by the intersection of struts 22b, 22d.

[0196] The inflow or cusp edge portions 816 of the leaflets 814 can be secured to the frame 12 using a plurality of connecting skirts 860 (FIG. 70), which can be formed of the same materials as described above for the connecting skirt 100 (e.g., PET fabric). In the illustrated embodiment, a single connecting skirt 860 is provided for the cusp edge portion 816 of each leaflet 814 and is sized to extend along the entire length of a cusp edge portion 816 to locations just below the lower tabs 818 of the leaflet 814. FIG. 75B shows a connecting skirt 860 placed along the cusp edge portion 816 of a leaflet 814 prior to being attached to the leaflet with sutures. The connecting skirt 860 can include a central portion 860a sized to extend over the central lower edge portion and two side portions 860b sized to extend over the angled side edge portions extending from the lower central portion to the lower tabs 818. The connecting skirt 860 can be formed with slits 862 partially separating the side portions 860b from the central portion 860a to facilitate alignment of the skirt along the cusp edge portion as shown in FIG. 75B.

[0197] In alternative embodiments, plural connecting skirts can be provided for the cusp edge portion of each leaflet (e.g., the central portion 860a and the side portions 860b can be separate pieces of fabric). In another embodiment, a single connecting skirt can be used to secure all of the leaflets to the frame; i.e., a single connecting skirt can be sized to extend along the cusp edge portions of all of the leaflets.

[0198] Prior to attaching the leaflets to the frame, a connecting skirt 860 can be attached to the cusp edge portion of each leaflet. As shown in FIG. 69, a connecting skirt 860 can be folded lengthwise to form two fold layers 864a, 864b and placed against the inflow surface of the cusp edge portion 816. A reinforcing member or chord 866 (e.g., an Ethibond suture) can be placed against the outflow surface of the cusp edge portion opposite the connecting skirt 860. The reinforcing member 866 and the fold layers 864a, 864b can be sutured to each other and to the cusp edge portion 816 with stitching 868, which can be a single suture or multiple sutures extending through one or more layers of material.

[0199] When suturing the reinforcing chord 866 to the leaflet 814, the lower tabs 818 can be folded downwardly against the cusp edge portion 816 (see FIG. 75B) and the reinforcing chord 866 can be placed over the folded lower tab 818. The upper ends of the connecting skirt 860 can be sized to extend over the folded lower tabs 818. Stitching 868 can be used to secure the reinforcing chord 866 in place against the folded lower tab 818. In particular embodiments, as best shown in FIG. 67, the reinforcing chord 866 can extend along the folded lower tab 818 of one leaflet 814, through the space between a pair of adjacent lower tabs 818 and a pair of upper tabs 820 under a commissure 810, and then along the lower tab 818 and the cusp edge portion of the adjacent leaflet 814. In some embodiments, a single reinforcing chord 866 extends continuously along the cusp edge portions 816 of all of the leaflets and through the spaces beneath each commissure 810. In other embodiments, plural reinforcing chords 866 can be used, with one reinforcing chord secured to the cusp edge portion of each leaflet. Where multiple reinforcing chords 866 are used, the ends of each chord can be connected (e.g., by tying or knotting) to adjacent ends of the other chords. For example, adjacent ends of two chords can be connected to each in the space underneath a commissure.

[0200] FIGS. 69, 72 and 73 illustrate the connection of the connecting skirts 860 to the frame 12, according to one embodiment. As shown, the connecting skirt can be sutured to struts 22 of the frame forming a diagonal line extending from a commissure 810 to the inflow end of the frame. In particular embodiments, one or both layers 864a, 864b of the connecting skirt can be secured to junctions 856 (FIG. 71) by individual stitches 872, and further with whip stiches 874 that are formed along the length of a struts 22 between two junctions 856. Each whip stitch 874 can extend through an edge portion 870 and around a strut 22 multiple times along the length of the strut. The whip stitches 874 optionally can extend through the cusp edge portion 816, as depicted in FIG. 69.

[0201] In alternative embodiments, the cusp edge portions 816 of the leaflets 814 can be mounted to the frame and/or the inner layer 804 of the sealing member using any of the techniques described herein. For example, any of the techniques or configurations described above with respect to FIGS. 10-12B or 14-32 can be used to mount the leaflets 814 to the frame 12, without or without a reinforcing chord 866.

[0202] As discussed above in connection with the embodiment shown in FIGS. 33-37, the folded lower tabs 818 help reinforce the connection between the cusp edge portions 816 of the leaflets and the frame along the upper sections of the cusp edge portions adjacent the commissures 810. The folded lower tabs 304 also move the bending axes of the upper sections of the cusp edge portions inwardly and away from the inner surface of the frame to prevent or minimize contact between the leaflets and the frame in the areas below the commissures. In the illustrated embodiment, each lower tab 818 forms one additional layer of leaflet material on the upper (outflow) surface of the leaflet. In alternative embodiments, each lower tab 818 can be configured to form multiple additional layers of leaflet material, such as two, three, or four layers, on the upper surface of the leaflet to move the bending axes of the leaflet below the commissures even further away from the inner surface of the frame.

[0203] The side edges 819 between the lower and upper tabs 818, 820 can be left unattached to the frame of the prosthetic valve, as best shown in FIG. 67 and as previously described with respect to the configuration shown in FIG. 1C. As previously described, the unattached side edges 819 allow greater elongation or stretching of the leaflets in the axial direction when the prosthetic valve is compressed and allowing greater elongation or stretching of the leaflets in the radial direction when the prosthetic valve is expanded. During diastole, the adjacent side edges 819 can coapt with each other and prevent retrograde blood from flowing between the side edges 819. During systole, the adjacent side edges 819 can separate from each other and allow antegrade blood to flow between side edges 819 and help wash away blood from the areas underneath the commissures 810.

[0204] After the leaflet assembly (the leaflets 814 and the connecting skirts 860) is mounted to the frame, the sealing member 802 can be placed over and mounted to the frame as described above in connection with FIGS. 60-64. The triangular-shaped portions 808 of the inner layer 804 of the sealing member can be sutured to struts 22 of the frame and/or to one or both layers 864a, 864b of connecting skirts 860 with sutures 872 (see FIG. 69).

[0205] FIGS. 79-80 shows a prosthetic valve 900, according to another embodiment. The prosthetic valve 900 can similar to the prosthetic valve 10 described above except for the configuration of the sealing member. The prosthetic valve 900 in the illustrated embodiment comprises a sealing member 901 comprising a first layer 902 and a second layer 904, both of which are mounted on the outside of a frame 12. The first layer 902 comprises a plurality of diamond-shaped portions 908 connected to each other at their upper (outflow) ends. The second layer 904 comprises a plurality of triangular-shaped portions 910 connected to each other at their lower (inflow) ends. The triangular-shaped portions 910, which are circumferentially aligned with commissures 906 of the prosthetic valve, are interspersed between the diamond-shaped portions 908, which are circumferentially aligned with the leaflets 20. As shown, the diamond-shaped portions 908 and the triangular-shaped portions 910 can overlap each to some extent in the vicinity of the commissures 906.

[0206] The triangular-shaped portions 910 generally correspond to the shape of the space between adjacent leaflets 20. The lower (inflow) end of the second layer 904 can be secured to the inflow end of the frame (e.g., with sutures). The lower edge portions 102 of the leaflets 20 can be coupled to the frame 12, such as with connecting skirts 100 as previously described, and the connecting skirts 100 can be secured to the sides of the triangular-shaped portions 910 (e.g., with sutures) through the cells of the frame. In this manner, the triangular-shaped portions 910 block antegrade blood from flowing outwardly through the cells the frame. The triangular-shaped portions 910 can also engage surrounding tissue to help seal the prosthetic valve and inhibit paravalvular leakage in conjunction with the diamond-shaped portions 908.

[0207] The first layer 902 can be secured to the frame 12 (e.g., with sutures) at the inflow end of each diamond-shaped portion 908 and at junctions 912 where the diamond-shaped portion 908 are connected to each other along the outflow edge of the first layer. The diamond-shaped portions 908 are configured to extend radially away from the frame to engage and seal with surrounding tissue when the prosthetic valve is deployed. The outflow edge of the first layer 902 between junctions 912 can remain unattached to the frame to receive retrograde blood between the first layer 902 and the frame. In some embodiments, the diamond-shaped portions 908 are configured to form an annular wave shape around the outside of the frame, as depicted in FIG. 67. In some embodiments, the outflow edge of the first layer 902 also can be secured to the frame (e.g., with sutures) at locations 914 between the junctions 912 to induce the first layer 902 to assume the wave shape when the prosthetic valve is expanded.

[0208] Although in the illustrated embodiment the first layer has diamond-shaped portions and the second layer has triangular shaped portions, other shapes are possible. For example, the portions 908, 910 of the first and second layers, can be square, oval, rectangular, circular, or combinations of one or more of these shapes.

[0209] In alternative embodiments, the portions 908 of the first layer 902 can be separate pieces of material that are not connected to each other. Similarly, the portions 910 of the second layer 904 can be separate pieces of material that are not connected to each other. For example, FIGS. 81-82 show a prosthetic valve 1000 comprising a sealing member in the form of alternating diamond-shaped portions 1002 and triangular-shaped portions 1004 positioned around the outside of the frame. The diamond-shaped portions 1002 can be circumferentially aligned with the leaflets 20 and the triangular-shaped portions 1004 can be circumferentially aligned with the commissures 1006 of the leaflets. Each portion 1002, 1004 can be a separate piece of material that is sutured or otherwise secured to a frame 12 at its inflow and outflow ends. The diamond-shaped portions 1002 and the triangular-shaped portions 1004 can extend away from the frame 12 and engage surrounding tissue when the prosthetic valve is expanded.

[0210] FIGS. 83-84 shows a prosthetic valve 1100, according to another embodiment. The prosthetic valve 1100 can include a sealing member 1102 mounted to the frame 12 as described above in connection with the embodiment of FIGS. 60-63. The prosthetic valve 1100 can include leaflets 1114 connected to each other at their outflow ends to form commissures 1110 that are mounted to the cells at the outflow end of the frame. The commissures 1110 can be formed by folding commissure tabs of the leaflets and securing them to a commissure attachment member 1112, which is then mounted to the frame. Each leaflet 1114 can have a lower or cusp edge portion 1116 that is folded upwardly toward the outflow end of the frame 12 as previously described and secured to the frame with a respective connecting skirt 1118, such as described above in connection with FIGS. 69-73. Any of the other techniques for mounting the cusp edge portions of the leaflets to the frame disclosed herein also can be used.

[0211] FIGS. 85-86 show a commissure 1110 formed from two leaflets 1114. As shown, each leaflet can have a commissure tab folded to form a first layer 1120, a second layer 1122, and a third layer 1124. Reinforcement members 1126 can be positioned between the second and third layers 1122, 1124. The commissure attachment member 1112 can be folded to form a center portion 1128, two side flaps 1130, and two pairs of fold layers 1132, 1134 that

extend radially alongside third layers 1124 of the leaflets. The leaflets layers 1120, 1122, 1124 and the layers 1132, 1134 of the commissure attachment member 1112 can be secured to each other with one or more sutures 1136 and 1138. Each suture 1136, 1138 can form multiple in and out stitches that extend through all of these layers. As shown in FIG. 86, suture 1136 can form a stitch that extends over the upper edges of leaflet layers 1120, 1122, 1124. The side flaps 1130 can be sutured to the struts 22 of the frame, as shown in FIGS. 72 and 77.

[0212] As shown in FIG. 85, each leaflet can have opposing recessed side edges 1140 underneath each commissure that can remain unattached to the frame to promote blood flow in the areas underneath the commissures, as previously described. Each leaflet can also have opposing lower tabs 1142 (FIG. 84) similar to lower tabs 818 of prosthetic valve 800. A reinforcing chord, such as reinforcing chord 866 can be secured to the cusp edge portions 1116 of the leaflets as described above in connection with prosthetic valve 800.

[0213] Any of various delivery techniques can be used to deliver any of the prosthetic heart valves disclosed herein. In a retrograde approach, a prosthetic valve can be mounted in a radially compressed state along the distal end portion of the delivery catheter, and the delivery catheter and the prosthetic valve can be advanced through the aorta to the native aortic valve. Once the prosthetic valve is positioned within the native aortic valve, the prosthetic valve can be expanded, such as by inflating a balloon or another expansion device.

[0214] As noted above, any of the prosthetic valves disclosed herein can be configured to be self-expandable or can be expandable by applying an expansion force with a balloon or another type of expansion mechanism. An example of a delivery catheter that has an inflatable balloon for implanting a plastically-expandable prosthetic heart valve (which can be used for implanting any of the prosthetic valves disclosed herein) is disclosed in U.S. Publication No. 2017/0065415. An example of a delivery catheter that can be used to deliver a self-expandable prosthetic heart valve (which can be used for implanting any of the prosthetic valves disclosed herein) is disclosed in U.S. Publication No. 2014/0343670.

[0215] <u>Exemplary Systems and Methods for Sizing and Implanting Prosthetic Heart Valves</u>

[0216] The prosthetic heart valves disclosed herein can be manufactured in various sizes to accommodate variation in patients' native anatomy. The "size" of a prosthetic heart valve can correspond to its nominal expanded diameter. For example, in some embodiments, a prosthetic heart valve configured for native aortic valve implantation can be manufactured in

20 mm, 23 mm, 26 mm, and 29 mm sizes. In other embodiments, a prosthetic heart valve can be manufactured in various other sizes.

[0217] Some prosthetic heart valves are configured such that each valve size can be expanded to a range of diameters (e.g., using a balloon). For example, a prosthetic heart valve with a nominal diameter of 23 mm (also referred to as a "23 mm valve") can be expanded to diameters within the range of 20-26 mm in some embodiments or to diameters within a range of 22-24 mm in other embodiments. A prosthetic heart valve having an expanded diameter less than its nominal diameter is referred to herein as "under expanded" or "under deployed." For example, a 23 mm valve expanded to a 22 mm diameter is under expanded. A prosthetic heart valve expanded to its nominal diameter is referred to herein as "nominally expanded" or "nominally deployed." For example, a 23 mm valve expanded to a 23 mm diameter is nominally deployed. A prosthetic heart valve having an expanded diameter greater than its nominal diameter is referred to herein as "over expanded" or "over deployed." For example, a 23 mm valve expanded to a 24 mm diameter is over expanded.

[0218] Prior to or as a part of the delivery procedure, a prosthetic heart valve size must be selected. Prosthetic heart valve size can impact several factors, including the prosthetic heart valve's ability to resist migration relative to the native annulus and/or the impact the prosthetic heart valve has on the native tissue. For example, a prosthetic heart valve that is too small may migrate from the annulus and embolize. A prosthetic heart valve that is too large may damage native tissue if it is fully expanded or may not properly function if it is grossly under expanded (e.g., the leaflets may not fully open and/or will contact the frame when the leaflets open).

[0219] The size of the prosthetic heart valve can also impact blood flow characteristics (also referred to as "hemodynamics"), such as the pressure gradient across the prosthetic heart valve. Pressure gradient across the prosthetic heart valve is directly proportionate to the amount of force necessary to move blood from one side of the valve (e.g., the left ventricle) to the other (e.g., into the aorta). As such, a lower pressure gradient across the prosthetic heart valve is desirable because it can reduce the amount of work the heart must perform for adequate circulation.

[0220] Selecting a prosthetic heart valve size can include multiple factors including the size of the patient's native annulus, the severity of calcification, other anatomical factors, etc. FIG. 87 depicts a flowchart of an exemplary method 1200 that can be employed when

selecting a prosthetic heart valve size. An initial process is to determine the patient's native annulus area and/or diameter (see process block 1210). This can be accomplished, for example, by scanning the patient's native annulus using various imaging techniques, including computed tomography ("CT"), and by measuring the images to obtain the area of the native annulus. The area can be used to determine the diameter. The native annulus area and/or diameter can also be determined using other measurement techniques including inserting measuring device (sometime referred to a "valve sizer") into the native annulus and measuring the native annulus area and/or diameter. The native annulus area and/or diameter can be measured, for example, at the basal ring of the aortic valve during ventricular systole.

[0221] A prosthetic heart valve expanded to a particular size (e.g., 23 mm) can be used for a range of native annulus areas/diameters without migrating or causing tissue damage. In some embodiments, the disclosed prosthetic heart valves can be "oversized" relative to a native annulus up to 40% and can be "undersized" relative to the native annulus up to 10%. In particular embodiments, the disclosed prosthetic heart valves can be oversized relative to the native annulus up to 20% and can be undersized relative to the native annulus up to 5%. "Oversized" means that the expanded diameter of the prosthetic heart valve is greater than the determined native annulus diameter. "Undersized" means that the expanded diameter of the prosthetic heart valve is less than the determined native annulus diameter. Undersizing can also be referred to with negative numbers, and oversizing can be referred to with positive numbers. For example, a prosthetic heart valve undersized by 10% can be referred to as "-10%", and a prosthetic heart valve oversized by 10% can be referred to as "10%."

[0222] The prosthetic heart valves disclosed herein can be implanted in a relative wide range of annulus sizes for each valve size and/or each expanded diameter range for a particular valve size. For example, a 20 mm valve can be deployed (e.g., under deployed, nominally deployed, and/or over deployed) within a native annulus having a diameter within the range of 16 mm to 24 mm or, in some embodiments, within a native annulus having a diameter in the range of 18.3-20.5 mm. In another example, a 23 mm valve can be deployed (e.g., under deployed, nominally deployed, and/or over deployed) within a native annulus having a diameter within the range of 19 mm to 27 mm or, in some embodiments, within a native annulus having a diameter in the range of 20.5-22.4 mm. In another example, a 26 mm valve can be deployed (e.g., under deployed, nominally deployed, and/or over deployed) within a native annulus having a diameter within the range of 23 mm to 29 mm or, in some embodiments, within a native annulus having a diameter in the range of 23.5-27.2 mm. In

another example, a 29 mm valve can be deployed (e.g., under deployed, nominally deployed, and/or over deployed) within a native annulus having a diameter within the range of 25 mm to 33 mm or, in some embodiments, within a native annulus having a diameter in the range of 25.1-30.8 mm.

[0223] This versatility can result in one than one prosthetic heart valve covering the determined native annulus area/diameter (see decision block 1230). For example, two valve sizes (e.g., a 23 mm valve and a 26 mm valve) can cover a native valve having an area of 408 mm^2 and a diameter of 22.8 mm. Also, the 23 mm valve size can be nominally expanded (i.e., to a 23 mm diameter) or over expanded (i.e., to a 24 mm diameter) to cover this native valve size. When multiple valve sizes and/or deployed diameters are available, the hemodynamic characteristics (e.g., pressure gradient) can be analyzed for each valve (see process block 1240). The desired valve size and/or diameter can be selected based on the analysis (see process block 1250). If only one prosthetic heart valve size and diameter cover the determined native annulus area/diameter, then the prosthetic heart valve can be selected (see decision block 1260).

[0224] FIG. 88 depicts a flowchart of another exemplary method 1300 that can be employed when selecting a prosthetic heart valve size and/or deployed diameter. The method 1300 can include determining the native annulus area and/or diameter (see process block 1310), determining which prosthetic heart valve size and/or deployed diameter covers the determined native annulus area and/or diameter (see process block 1320), and determining whether more than one prosthetic heart valve size and/or deployed diameter covers the determined native annulus area and/or diameter. The processes 1310, 1320, and 1330 of the method 1300 can be performed similar to the manner in which the processes 1210, 1220, and 1230 of the method 1200 are performed, respectively.

[0225] If a plurality of prosthetic heart valve sizes and/or diameters cover the determined native annulus area and/or diameter, the method can include determining which prosthetic heart valve has the largest size and/or deployed diameter (see process block 1340). The prosthetic heart valve with the largest size and/or deployed diameter can then be selected (see process block 1350). In many instances, the prosthetic heart valve with the largest size and/or deployed diameter will have the lowest pressure gradient, thus making it the desired prosthetic heart valve. Therefore, the disclosed prosthetic heart valves and disclosed methods can produce exceptionally good hemodynamics when the prosthetic heart valve is oversized

relative to the native annulus and under expanded relative to the nominal diameter of the prosthetic heart valve.

[0226] In some embodiments, the selected prosthetic heart valve has a nominal diameter that is greater than a native annulus diameter of a native annulus (in other words it is oversized) by up to 40%; in others, by up to 30%; in others by up to 20%; and in others, by up to 10%. In some embodiments, the selected prosthetic heart valve has a nominal diameter that is within the range of 5-40% greater than a native annulus diameter of a native annulus; in others, within the range of 5-35%; in others, within the range of 5-30%; in others, within the range of 5-25%; in others, within the range of 5-20%; in others, within the range of 5-15%; in others, within the range of 5-10%. In some embodiments, the selected prosthetic heart valve has a nominal diameter that is within the range of 10-40% greater than a native annulus diameter of a native annulus; in others, within the range of 10-35%; in others, within the range of 10-30%; in others, within the range of 10-25%; in others, within the range of 10-20%; in others, within the range of 10-15%. In some embodiments, the selected prosthetic heart valve has a nominal diameter that is within the range of 15-40% greater than a native annulus diameter of a native annulus; in others, within the range of 15-35%; in others, within the range of 15-30%; in others, within the range of 15-25%; in others, within the range of 15-20%. In some embodiments, the selected prosthetic heart valve has a nominal diameter that is within the range of 20-40% greater than a native annulus diameter of a native annulus; in others, within the range of 20-35%; in others, within the range of 20-30%; in others, within the range of 20-25%. In some embodiments, the selected prosthetic heart valve has a nominal diameter that is within the range of 25-40% greater than a native annulus diameter of a native annulus; in others, within the range of 25-35%; in others, within the range of 25-30%. In some embodiments, the selected prosthetic heart valve has a nominal diameter that is within the range of 30-40% greater than a native annulus diameter of a native annulus; in other, by 30-35%. In some embodiments, the selected prosthetic heart valve has a nominal diameter that is within the range of 35-40% greater than a native annulus diameter of a native annulus. As used herein, the term “within the range of x-y%” means the values x and y and all values in between. For example, within the range of 5-10% includes 5%, 6%, 7%, 8%, 9%, and 10%, as well as non-whole integers such as 5.25%, 6.1%, 7.67%, 8.8%, 9.15%, etc. and subranges such as 5-7% and 6.5-9.75%.

[0227] In some embodiments, the selected prosthetic heart valve can be under expanded (or under deployed) compared to the nominal diameter by up to 10%; in others, by up to 9%; in

others by up to 8%; in others, by up to 7%; in others, by up to 6%; in others, by up to 5%; in others, by up to 4%; in others, by up to 3%; in others, by up to 2%; in others, by up to 1%. In particular embodiments, the selected prosthetic heart valve can be under expanded within a range of 1-10% compared to the nominal diameter; in others, by 1-9%; in others, by 1-8%; in others, by 1-7%; in others, by 1-6%; in others, by 1-5%; in others, by 1-4%; in others, by 1-3%; in others, by 1-2%; as well as non-whole integers within the ranges and subranges (e.g., 0.1-4%, 2-8%, 3-5%, etc.).

[0228] If only one prosthetic heart valve and/or deployed diameter covers the determined native annulus area and/or diameter, the prosthetic heart valve covering the range can be selected (see process block 1360).

[0229] In some embodiments, the method 1200 and/or the method 1300 can further include determining which valve models cover the determined native annulus area and/or diameter. For example, a manufacturer may have multiple models, such as “Valve A” and “Valve B.” Each valve model may come in a number of sizes (e.g., 20 mm, 23 mm, 26 mm, 29 mm), which can be expanded to a deployed diameter (e.g., 23 mm for a 23 mm valve) or a range of diameters (e.g., 21-24 mm for a 23 mm valve). The method 1200 can include analyzing the hemodynamic characteristics of each model, comparing the characteristics of each model to the other models, and/or selecting the model, size, and/or expansion diameter based on the analysis and comparison.

[0230] As one example, for a native valve having an area of 408 mm^2 and a diameter of 22.8 mm, two valve models can be used: Valve A or Valve B. For Valve A, two valve sizes can be used: a 23 mm valve or a 26 mm valve. Also, the 23 mm size of Valve A can be nominally expanded to a 23 mm diameter or over expanded to a 24 mm diameter. The 26 mm size of Valve A can be under expanded to 25 mm. For Valve B, one valve size and expansion diameter, i.e., 23 mm, can be used for the native anatomical dimensions. The hemodynamic characteristics of each possible configuration can be analyzed and compared.

[0231] In certain instances, the methods described above (including methods 1200, 1300) can be integrated into a software application (“app”) for a computing device (e.g., a desktop computer, laptop computer, tablet, smartphone, etc.).

[0232] In one particular embodiment, the app can be configured to display a graphical user interface (“GUI”) 1400 on a display of a computing device, as shown in FIG. 89. The GUI 1400 can include a data entry window 1402 configured to receive a determined native

annulus area, which can be entered by a user or received from another computing device or database. Referring to FIG. 90, upon receiving the native annulus area, the software can be configured to perform the method 1200 and display the entered native annulus area (see display window 1404), the determined native annulus diameter (see display window 1406), the available prosthetic heart valve options (see display window 1408), and hemodynamic data for the available prosthetic heart valves (see display windows 1410, 1412, 1414).

[0233] In another embodiment, the app can be configured to display a GUI 1500 on a display of a computing device, as shown in FIG. 91. The GUI 1500 can include a data entry window 1502 configured to receive a determined native annulus area, which can be entered by a user or received from another computing device or database. Referring to FIG. 92, upon receiving the native annulus area, the software can be configured to perform the method 1300 and display the entered native annulus area (e.g., 531 mm^2) (see display window 1504), the determined native annulus diameter (e.g., 26.0 mm) (see display window 1506), the suggested prosthetic heart valve model and size (e.g., Valve A – 29 mm) (see display window 1508), the suggested valve expanded diameter (e.g., 27.8 mm) (see display window 1510), hemodynamic data for the suggest valve (e.g., 3.8 mmHg) (see display window 1512), as well as delivery apparatus information including the inflated balloon diameter (e.g., 28.3 mm) (see display window 1514) and/or the balloon inflation volume (e.g., 26 mL) (see display window 1516).

[0234] Additional Examples of Systems and Methods of Sizing and Implanting Prosthetic Heart Valves

[0235] Provided below is an enumerated list of additional examples of the disclosed technology.

[0236] 1. A method of selecting a prosthetic heart valve, comprising:

determining a native annulus area of a native annulus of a native heart valve by taking an image of the native annulus and measuring the image;

determining which prosthetic heart valves of a plurality of prosthetic heart valves covers the determined native annulus area;

analyzing hemodynamic data of each prosthetic heart valve of the plurality of prosthetic heart valves; and

selecting a desired prosthetic heart valve of the plurality of prosthetic heart valves based on the analyzed hemodynamic data.

[0237] 2. The method of example 1, wherein the hemodynamic data includes a pressure gradient across the prosthetic heart valve, wherein the pressure gradient is blood pressure at an outflow end of the prosthetic heart valve divided by blood pressure at an inflow end of the prosthetic heart valve.

[0238] 3. The method of either example 1 or example 2, wherein the selected prosthetic heart valve has the lowest pressure gradient of the prosthetic heart valves covering the determined native annulus area.

[0239] 4. The method of any one of examples 1-3, wherein the selected prosthetic heart valve has the largest nominal diameter of the prosthetic heart valves covering the determined native annulus area.

[0240] 5. The method of any one of examples 1-4, wherein the selected prosthetic heart valve has the largest expanded diameter of the prosthetic heart valves covering the determined native annulus area.

[0241] 6. The method of any one of examples 1-5, further comprising determining a diameter of the native annulus, wherein the selected prosthetic heart valve has an expanded diameter that is less than the determined diameter of the native annulus.

[0242] 7. The method of example 6, wherein the expanded diameter is within a range of 0-10% less than the determined diameter of the native annulus.

[0243] 8. The method of example 6, wherein the expanded diameter is within a range of 0-5% less than the determined diameter of the native annulus.

[0244] 9. The method of any one of examples 1-8, further comprising determining a diameter of the native annulus, wherein the selected prosthetic heart valve has an expanded diameter that is greater than the determined diameter of the native annulus.

[0245] 10. The method of example 9, wherein the expanded diameter is within a range of 0-40% greater than the determined diameter of the native annulus.

[0246] 11. The method of example 9, wherein the expanded diameter is within a range of 0-20% greater than the determined diameter of the native annulus.

[0247] 12. The method of any one of examples 1-11, wherein the prosthetic heart valve is balloon expandable.

[0248] 13. The method of any one of example 1-11, wherein the method is executed as an application on a computing device.

[0249] 14. The method of any one of examples 1-13, wherein the method further comprises implanting the selected prosthetic heart valve in the native annulus.

[0250] 15. A method of implanting a prosthetic heart valve, comprising:

determining a diameter of a native heart valve annulus;

advancing a prosthetic heart valve through a patient's vasculature to the native heart valve annulus, wherein the prosthetic heart valve is in a radially collapsed configuration, and wherein the prosthetic heart valve comprises:

a frame comprising an inflow end and an outflow end and being radially collapsible and expandable between the radially collapsed configuration and a radially expanded configuration; and

a valvular structure mounted within the frame and comprising a plurality of leaflets that regulate flow of blood through the frame, wherein each leaflet comprises opposing upper tabs on opposite sides of the leaflet, opposing lower tabs on opposite sides of the leaflets below the upper tabs, a cusp edge portion extending between the lower tabs, the cusp edge portion being fixed relative to the frame, wherein each upper tab is paired with an adjacent upper tab of an adjacent leaflet to form a plurality of commissures that are fixed relative to the frame, and wherein each lower tab is folded to form at least one fold layer along the cusp edge portion of the respective leaflet; and

expanding the prosthetic heart valve from the radially collapsed configuration to the radially expanded configuration, wherein in the radially expanded configuration, the prosthetic heart valve has an outer diameter that is larger than the determined diameter of the native heart valve annulus.

[0251] 16. The method of example 15, wherein the outer diameter of the prosthetic heart valve in the radially expanded configuration is within a range of 5-40% larger than the determined diameter of the native heart valve annulus.

[0252] 17. The method of example 15, wherein the outer diameter of the prosthetic heart valve in the radially expanded configuration is within a range of 10-20% larger than the determined diameter of the native heart valve annulus.

[0253] 18. The method of example 15, wherein the outer diameter of the prosthetic heart valve in the radially expanded configuration is less than a nominal diameter of the prosthetic heart valve.

[0254] 19. A method of implanting a prosthetic heart valve, comprising:

determining a native annulus area and a native annulus diameter of a native annulus of a native heart valve by taking an image of the native annulus, obtaining measurements of the native annulus from the image, and calculating the area and the diameter of the native annulus based on the measurements;

determining which prosthetic heart valves of a plurality of prosthetic heart valves covers the determined native annulus area;

analyzing hemodynamic data of each prosthetic heart valve of the plurality of prosthetic heart valves;

selecting a prosthetic heart valve of the plurality of prosthetic heart valves based on the analyzed hemodynamic data, wherein the selected prosthetic heart valve has a nominal diameter that is greater than the determined native annulus diameter by up to forty percent;

compressing the selected prosthetic heart valve to a radially compressed configuration in which the selected prosthetic heart valve has a first diameter that is less than the nominal diameter;

positioning the selected prosthetic heart valve within the native annulus; and

expanding the selected prosthetic heart valve from the radially compressed configuration to a radially expanded configuration in which the prosthetic heart valve has a second diameter which is less than the nominal diameter by up to ten percent and which is greater than the first diameter.

[0255] 20. The method of example 19, wherein the image is obtained using computed tomography.

[0256] 21. One or more computer-readable storage media comprising instructions that can be executed by a computer, wherein the instructions are configured to:

receive a measurement of a native annulus area of a native heart valve inputted by a user;

calculate an area derived native annulus diameter based on the received measurement of the native annulus area;

analyze hemodynamic characteristics of a plurality of prosthetic heart valves;

determine a suggested prosthetic heart valve of the plurality of prosthetic heart valves;

determine a suggested expanded diameter of the suggested prosthetic heart valve; and determine an expected pressure gradient across the suggested prosthetic heart valve.

[0257] Example Computing Device

[0258] FIG. 93 depicts a generalized example of a suitable computing system 1600 in which the described innovations may be implemented. The computing system 1600 is not intended to suggest any limitation as to scope of use or functionality, as the innovations may be implemented in diverse general-purpose or special-purpose computing systems. For example, the computing system 1600 can be used to implement hardware and software.

[0259] With reference to FIG. 93, the computing system 1600 includes one or more processing units 1610, 1615, non-volatile memory 1620, and memory 1625. In FIG. 93, this basic configuration 1630 is included within a dashed line. The processing units 1610, 1615 execute computer-executable instructions, including instructions for generating shape models, locating fiducials in images, and/or aligning an output device with an article as disclosed herein. A processing unit can be a general-purpose central processing unit ("CPU"), processor in an application-specific integrated circuit ("ASIC"), or any other type of processor. In a multi-processing system, multiple processing units execute computer-executable instructions to increase processing power. For example, FIG. 93 shows a central processing unit 1610 as well as a graphics processing unit ("GPU") or co-processing unit 1615. The tangible memory 1625 may be volatile memory (e.g., registers, cache, RAM), non-volatile memory (e.g., ROM, EEPROM, flash memory, etc.), or some combination of the two, accessible by the processing unit(s). The memory 1625 stores software 1680 implementing one or more innovations described herein, in the form of computer-executable instructions suitable for execution by the processing unit(s).

[0260] A computing system may have additional features. For example, the computing system 1600 includes storage 1640, one or more input devices 1650, one or more output devices 1660, and one or more communication connections 1670. An interconnection mechanism (not shown) such as a bus, controller, or network interconnects the components of the computing system 1600. Typically, operating system software (not shown) provides an operating environment for other software executing in the computing system 1600, and coordinates activities of the components of the computing system 1600.

[0261] The tangible storage 1640 may be removable or non-removable, and includes magnetic disks, magnetic tapes or cassettes, CD-ROMs, DVDs, or any other medium which

can be used to store information and which can be accessed within the computing system 1600. The storage 1640 stores instructions for the software 1680 implementing one or more innovations described herein.

[0262] The input device(s) 1650 may be a touch input device such as a keyboard, mouse, pen, or trackball, a voice input device, a scanning device, microphone, button, pedal, or another device that provides input to the computing system 1600. For video encoding, the input device(s) 1650 may be a camera with an image sensor, video card, TV tuner card, or similar device that accepts video input in analog or digital form, or a CD-ROM, CD-RW, DVD, or Blu-Ray that reads video samples into the computing system 1600. The output device(s) 1660 may be a display, printer, speaker, CD-writer, or another device that provides output from the computing system 1600.

[0263] The communication connection(s) 1670 enable communication over a communication medium (e.g., a connecting network) to another computing entity. The communication medium conveys information such as computer-executable instructions, compressed graphics information, video, or other data in a modulated data signal. The communication connection(s) 1170 are not limited to wired connections (e.g., megabit or gigabit Ethernet, Infiniband, Fibre Channel over electrical or fiber optic connections) but also include wireless technologies (e.g., RF connections via Bluetooth, WiFi (IEEE 802.11a/b/n), WiMax, cellular, satellite, laser, infrared) and other suitable communication connections for providing a network connection for the disclosed agents, bridges, and agent data consumers. In a virtual host environment, the communication(s) connections can be a virtualized network connection provided by the virtual host.

[0264] Some embodiments of the disclosed methods can be performed using computer-executable instructions implementing all or a portion of the disclosed technology in a computing cloud 1690. For example, disclosed computer-readable instructions can be executed by processors located in the computing environment 1630, or the disclosed computer-readable instructions can be executed on servers located in the computing cloud 1690.

[0265] Computer-readable media are any available media that can be accessed within a computing environment 1600. By way of example, and not limitation, with the computing environment 1600, computer-readable media include memory 1620 and/or storage 1640. As should be readily understood, the term computer-readable storage media includes the media

for data storage such as memory 1620 and storage 1640, but does not include transmission media such as modulated data signals or other transitory signals.

[0266] The innovations can be described in the general context of computer-executable instructions, such as those included in program modules, being executed in a computing system on a target real or virtual processor. Generally, program modules include routines, programs, libraries, objects, classes, components, data structures, etc. that perform particular tasks or implement particular data types. The functionality of the program modules may be combined or split between program modules as desired in various embodiments. Computer-executable instructions for program modules may be executed within a local or distributed computing system.

[0267] Example Mobile Computing Device

[0268] FIG. 94 is a block diagram of a mobile computing device 1700 capable of implementing the techniques and solutions described herein. The mobile device 1700 includes a variety of optional hardware and software components, shown generally at 1702. In general, a component 1702 in the mobile device 1700 can communicate with any other component of the device, although not all connections are shown, for ease of illustration. The mobile device 1700 can be any of a variety of computing devices (e.g., cell phone, smartphone, handheld computer, laptop computer, notebook computer, tablet device, slate device, media player, Personal Digital Assistant (PDA), camera, video camera, etc.) and can allow wireless two-way communications with one or more mobile communications networks 1704, such as a Wi-Fi, cellular, or satellite network.

[0269] The illustrated mobile device 1700 includes a controller or processor 1710 (e.g., signal processor, microprocessor, ASIC, or other control and processing logic circuitry) for performing such tasks as signal coding, data processing, input/output processing, power control, and/or other functions. An operating system 1712 controls the allocation and usage of the components 1702 and support for one or more application programs 1714 such as a valve sizing tool that implements one or more of the innovative features described herein. In addition to valve sizing software, the application programs can include common mobile computing applications (e.g., telephony applications, email applications, calendars, contact managers, web browsers, messaging applications), and/or any other computing application.

[0270] The illustrated mobile device 1700 includes memory 1720. Memory 1720 can include non-removable memory 1722 and/or removable memory 1724. The non-removable

memory 1722 can include RAM, ROM, flash memory, a hard disk, or other well-known memory storage technologies. The removable memory 1724 can include flash memory or a Subscriber Identity Module (SIM) card, which is well known in Global System for Mobile Communications (GSM) communication systems, or other well-known memory storage technologies, such as "smart cards." The memory 1720 can be used for storing data and/or code for running the operating system 1712 and the application programs 1714. Example data can include web pages, text, images, sound files, video data, or other data sets to be sent to and/or received from one or more network servers or other devices via one or more wired or wireless networks. The memory 1720 can be used to store a subscriber identifier, such as an International Mobile Subscriber Identity (IMSI), and an equipment identifier, such as an International Mobile Equipment Identifier (IMEI). Such identifiers can be sent to a network server to identify users and equipment.

[0271] The mobile device 1700 can support one or more input devices 1730, such as a touch screen 1732 (e.g., capable of capturing finger tap inputs, finger gesture inputs, or keystroke inputs for a virtual keyboard or keypad), microphone 1734 (e.g., capable of capturing voice input), camera 1736 (e.g., capable of capturing still pictures and/or video images), physical keyboard 1738, buttons and/or trackball 1740 and one or more output devices 1750, such as a speaker 1752 and a display 1754. Other possible output devices (not shown) can include piezoelectric or other haptic output devices. Some devices can serve more than one input/output function. For example, touch screen 1732 and display 1754 can be combined in a single input/output device.

[0272] The mobile device 1700 can provide one or more natural user interfaces. For example, the operating system 1712 or applications 1714 can comprise speech-recognition software as part of a voice user interface that allows a user to operate the device 1700 via voice commands. For example, a user's voice commands can be used to provide input to a valve sizing tool.

[0273] A wireless modem 1760 can be coupled to one or more antennas (not shown) and can support two-way communications between the processor 1710 and external devices, as is well understood in the art. The modem 1760 is shown generically and can include, for example, a cellular modem for communicating at long range with the mobile communication network 1704, a Bluetooth-compatible modem 1764, or a Wi-Fi-compatible modem 1762 for communicating at short range with an external Bluetooth-equipped device or a local wireless data network or router. The wireless modem 1760 is typically configured for communication

with one or more cellular networks, such as a GSM network for data and voice communications within a single cellular network, between cellular networks, or between the mobile device and a public switched telephone network (PSTN).

[0274] The mobile device 1700 can further include at least one input/output port 1780, a power supply 1782, a satellite navigation system receiver 1784, such as a Global Positioning System (GPS) receiver, sensors 1786 such as an accelerometer, a gyroscope, a compass, or an infrared proximity sensor for detecting the orientation and motion of device 1700, and for receiving gesture commands as input, a transceiver 1788 (for wirelessly transmitting analog or digital signals) and/or a physical connector 1790, which can be a USB port, IEEE 17394 (FireWire) port, and/or RS-232 port. The illustrated components 1702 are not required or all-inclusive, as any of the components shown can be deleted and other components can be added.

[0275] The mobile device 1700 can be part of an implementation environment in which various types of services (e.g., computing services) are provided by a computing "cloud." For example, the cloud can comprise a collection of computing devices, which may be located centrally or distributed, that provide cloud-based services to various types of users and devices connected via a network such as the Internet. Some tasks (e.g., processing user input and presenting a user interface) can be performed on local computing devices (e.g., connected devices) while other tasks (e.g., storage of data to be used in subsequent processing) can be performed in the cloud.

[0276] Although FIG. 94 illustrates a mobile device 1700, more generally, the techniques and solutions described herein can be implemented with devices having other screen capabilities and device form factors, such as a desktop computer, a television screen, or device connected to a television (e.g., a set-top box or gaming console). Services can be provided by the cloud through service providers or through other providers of online services. Thus, the valve sizing techniques and solutions described herein can be implemented with any of the connected devices as a client computing device. Similarly, any of various computing devices in the cloud or a service provider can perform the role of a server computing device and deliver map data or other data to the connected devices.

[0277] In view of the many possible embodiments to which the principles of the disclosure may be applied, it should be recognized that the illustrated embodiments are only examples

and should not be taken as limiting the scope of the claims. Rather, the scope of the claimed subject matter is defined by the following claims and their equivalents.

CLAIMS:

1. A method of selecting a prosthetic heart valve comprising:

taking an image of the native heart valve annulus;

obtaining measurements of the native heart valve annulus from the image, and calculating the native annulus area and the native annulus diameter based on the obtained measurements;

determining from a set of expandable prosthetic heart valves a first prosthetic heart valve configured to cover the native annulus diameter and the native annulus area, the first prosthetic heart valve having a first deployed diameter range, wherein the native annulus diameter is within the first deployed diameter range;

determining from a set of expandable prosthetic heart valves a second prosthetic heart valve configured to cover the native annulus diameter and the native annulus area, the second prosthetic heart valve having a second deployed diameter range that is different from the first deployed diameter range, wherein the native annulus diameter is within the second deployed diameter range;

determining one or more first suggested expanded diameters for the first prosthetic heart valve based on the native annulus diameter;

determining a pressure gradient across the first prosthetic heart valve at each of the one or more first suggested expanded diameters based at least in part on pressure values from hermodynamic data of the first prosthetic heart valve;

determining one or more second suggested expanded diameters for the second prosthetic heart valve based on the native annulus diameter;

determining a pressure gradient across the second prosthetic heart valve at each of the one or more second suggested expanded diameters based at least in part on pressure values from hermodynamic data of the second prosthetic heart valve; and

selecting the prosthetic heart valve with the suggested expanded diameter resulting in the lowest pressure gradient from the first and second prosthetic heart valves.

2. The method of claim 1, wherein taking the image of the native heart valve annulus is performed by obtaining the image using computed tomography.

3. The method of claim 1, wherein the suggested expanded diameter of the selected prosthetic heart valve is within a range of 0 to 40% greater than the native annulus diameter.

4. The method of claim 1, wherein the suggested expanded diameter of the selected prosthetic heart valve is within a range of 0 to 20% greater than the native annulus diameter.

5. A computing device comprising a processing unit and a memory storing software implementing a method of one of the claims 1 to 4, the software being in the form of computer-executable instructions suitable for execution by the processing unit.

6. The computing device of claim 5, which is a mobile computing device.

7. A computer-readable storage medium comprising instructions that can be executed by a computer and instruct the computer to:

calculating native annulus area and native annulus diameter of a native heart valve annulus based on measurements obtained from an image of the native heart valve annulus;

determine from a set of expandable prosthetic heart valves a first prosthetic heart valve configured to cover the native annulus diameter and the native annulus area, the first prosthetic heart valve having a first deployed diameter range, wherein the native annulus diameter is within the first deployed diameter range;

determine from a set of expandable prosthetic heart valves a second prosthetic heart valve configured to cover the native annulus diameter and the native annulus area, the second prosthetic heart valve having a second deployed diameter range that is different from the first deployed diameter range, wherein the native annulus diameter is within the second deployed diameter range;

determine one or more first suggested expanded diameters for the first prosthetic heart valve based on the native annulus diameter;

determine a pressure gradient across the first prosthetic heart valve at each of the one or more first suggested expanded diameters based at least in part on pressure values from hermodynamic data of the first prosthetic heart valve;

determine one or more second suggested expanded diameters for the second prosthetic heart valve based on the native annulus diameter;

determine a pressure gradient across the second prosthetic heart valve at each of the one or more second suggested expanded diameters based at least in part on pressure values from hermodynamic data of the second prosthetic heart valve; and

select the prosthetic heart valve with the suggested expanded diameter resulting in the lowest pressure gradient from the first and second prosthetic heart valves.