

Publication No. 2012/0065729, filed June 23, 2011; the entire contents of each of which are hereby incorporated by reference in their entirety.

[0008] Sometimes the need for complete valve replacement may arise after a patient has already had an earlier valve replacement for the same valve. For example, a prosthetic heart that was successfully implanted to replace a native valve may itself suffer damage and/or wear and tear many years after initially being implanted. Implanting the prosthetic heart valve directly within a previously-implanted prosthetic heart valve may be impractical, in part because the new prosthetic heart valve (including the support structure and valve assembly) will have to reside within the annulus of the previously-implanted heart valve, and traditional prosthetic heart valves may not be configured to easily receive such a valve-within-a-valve implantation in a manner which provides secure seating for the new valve while also having a large enough annulus within the new valve to support proper blood flow therethrough.

[0009] Some attention has been paid to the problem of implanting a new valve within an old valve. In particular, the following disclose various solutions for valve-in-valve systems: U.S. Patent Publication No. 2010/0076548, filed September 19, 2008; and U.S. Patent Publication No. 2011/0264207, filed July 7, 2011.

[0010] Despite certain advances in the valve-in-valve area, there remains a need for a prosthetic heart valve which can properly replace a damaged heart valve, such as a prosthetic valve configured to replace a native valve via surgical implantation, but which also enable a replacement expandable prosthetic heart valve to be deployed therein at a later time without loss of flow capacity. The current invention meets this need.

SUMMARY OF THE INVENTION

[0010a] An aspect of the present invention provides a prosthetic heart valve having an inflow end and an outflow end, the prosthetic heart valve having a first unexpanded configuration and a second expanded configuration, the prosthetic heart valve comprising:
an inner support structure defined around a valve orifice, the support structure having a first inner diameter when the prosthetic heart valve is in the first unexpanded configuration and a second inner diameter when the prosthetic heart valve is in the second expanded configuration, the support structure configured when in the first unexpanded configuration to resist inward compression of the support structure and to permit radial expansion of the support structure to the second inner diameter when subjected to a dilation force, the support structure comprising a radially thin outer metallic support ring having an

undulating shape with three downward cusps alternating with three upward truncated commissures around its circumference and including a single expansion segment that will plastically expand when subjected to the dilation force, the support structure further including a radially thin stent ring disposed in concentric abutment with and radially inside the support ring and being continuous and integrally formed of a polymeric material, the stent ring defining commissure posts aligned with and extending above the truncated commissures of the support ring and cusp portions aligned with the support ring cusps, wherein the support ring and the stent ring are secured together with a suture passing radially through both at a point around their common circumference, the stent ring having weakened areas below each of the commissure posts configured to break before other portions of the stent ring when the support ring expands; and

a valve portion supported by the support structure that allows for one-way blood flow through the valve when the valve is in the first unexpanded configuration. [0010b] Another aspect of the present invention provides a prosthetic heart valve having a first unexpanded configuration and a second expanded configuration, the prosthetic heart valve comprising:

a support structure defining a circumference, the support structure having a first inner diameter when the prosthetic heart valve is in the first unexpanded configuration and a second inner diameter when the prosthetic heart valve is in the second expanded configuration, wherein the second inner diameter is larger than the first inner diameter, wherein the support structure resists inward compression when the prosthetic heart valve is in the first unexpanded configuration, the support structure comprising a support band with circumferentially overlapping free ends with at least one hole each that register and are circumferentially aligned and a weakened section comprising a suture passing radially through the registered hole(s) and is secured by tying that maintains the free ends aligned but is configured to structurally fail when the support structure is subjected to a dilation force greater than forces associated with normal cardiac cycling, the support structure further including a stent band connected to the support band and having upstanding commissure posts;

a valve portion having flexible leaflets supported by the support structure that allows for one-way blood flow through the valve when the valve is in the first unexpanded configuration; and

an undulating wireform covered with fabric to which the valve leaflets are partially connected around their peripheral edges, and the leaflets include outwardly-projecting tabs that pass outside of the wireform and attach to the commissure posts of the stent band.

[0011] There is also disclosed a number of prosthetic heart valves each having an inflow end and an outflow end. The prosthetic heart valves have a first unexpanded configuration and a second expanded configuration, and include a support structure that resists compression of the valve smaller than the unexpanded configuration, and enables expansion to the expanded configuration. Desirably, the heart valves prevent compression when subjected to a compressive force of between 1 and 5 atmospheres, and circumferentially expand from a first diameter to a second diameter when subjected to a dilation force of between 1 to 12 atmospheres, though between 1 and 8 atmospheres is more likely.

WHAT IS CLAIMED IS:

1. A prosthetic heart valve having an inflow end and an outflow end, the prosthetic heart valve having a first unexpanded configuration and a second expanded configuration, the prosthetic heart valve comprising:

an inner support structure defined around a valve orifice, the support structure having a first inner diameter when the prosthetic heart valve is in the first unexpanded configuration and a second inner diameter when the prosthetic heart valve is in the second expanded configuration, the support structure configured when in the first unexpanded configuration to resist inward compression of the support structure and to permit radial expansion of the support structure to the second inner diameter when subjected to a dilation force, the support structure comprising a radially thin outer metallic support ring having an undulating shape with three downward cusps alternating with three upward truncated commissures around its circumference and including a single expansion segment that will plastically expand when subjected to the dilation force, the support structure further including a radially thin stent ring disposed in concentric abutment with and radially inside the support ring and being continuous and integrally formed of a polymeric material, the stent ring defining commissure posts aligned with and extending above the truncated commissures of the support ring and cusp portions aligned with the support ring cusps, wherein the support ring and the stent ring are secured together with a suture passing radially through both at a point around their common circumference, the stent ring having weakened areas below each of the commissure posts configured to break before other portions of the stent ring when the support ring expands; and

a valve portion supported by the support structure that allows for one-way blood flow through the valve when the valve is in the first unexpanded configuration.

2. The prosthetic heart valve of claim 1, wherein the expansion segment comprises a series of interconnected struts connected end-to-end by hinge-like connections which forms an accordion-like structure having substantially diamond-shaped cells.

3. The prosthetic heart valve of claim 1, wherein the valve portion has flexible leaflets and further including a cloth covering surrounding the support structure and

facilitating attachment of peripheral edges of the flexible leaflets along an outflow edge of the support structure.

4. The prosthetic heart valve of claim 1, wherein the expansion segment comprises a serpentine structure formed by metallic struts.

5. The prosthetic heart valve of claim 4, wherein the struts are compressed closely together, with minimal distances between adjacent struts in the unexpanded configuration to prevent inward compression of the structure to a smaller diameter.

6. A prosthetic heart valve having a first unexpanded configuration and a second expanded configuration, the prosthetic heart valve comprising:

a support structure defining a circumference, the support structure having a first inner diameter when the prosthetic heart valve is in the first unexpanded configuration and a second inner diameter when the prosthetic heart valve is in the second expanded configuration, wherein the second inner diameter is larger than the first inner diameter, wherein the support structure resists inward compression when the prosthetic heart valve is in the first unexpanded configuration, the support structure comprising a support band with circumferentially overlapping free ends with at least one hole each that register and are circumferentially aligned and a weakened section comprising a suture passing radially through the registered hole(s) and is secured by tying that maintains the free ends aligned but is configured to structurally fail when the support structure is subjected to a dilation force greater than forces associated with normal cardiac cycling, the support structure further including a stent band connected to the support band and having upstanding commissure posts;

a valve portion having flexible leaflets supported by the support structure that allows for one-way blood flow through the valve when the valve is in the first unexpanded configuration; and

an undulating wireform covered with fabric to which the valve leaflets are partially connected around their peripheral edges, and the leaflets include outwardly-projecting tabs that pass outside of the wireform and attach to the commissure posts of the stent band.

7. The prosthetic heart valve of claim 6, wherein the support band has an undulating shape with alternating cusp and commissure portions, and the free ends overlap at one of the cusp portions.
8. The prosthetic heart valve of claim 6, wherein the support band has an undulating shape with alternating cusp and commissure portions, and the free ends overlap at one of the commissure portions.
9. The prosthetic heart valve of claim 6, wherein the stent band is arranged concentrically within the support band.
10. The prosthetic heart valve of claim 9, wherein the support band and the stent band are secured together at at least one point around the circumference of the support structure.
11. The prosthetic heart valve of claim 9, wherein the stent band comprises a polymeric material and the support band comprises a metal.
12. The prosthetic heart valve of claim 9, wherein the stent band comprises a weakened section configured to stretch or structurally fail when the support structure is subjected to the dilation force.
13. The prosthetic heart valve of claim 6, wherein the stent band commissure posts are aligned with and extend above the commissure portions of the support band and the stent band has cusps aligned with the support band cusp portions, and there are a plurality of weakened sections in the stent band located at each of the commissure posts.
14. The prosthetic heart valve of claim 6, wherein the support band comprises a metal and each overlapping free end has a series of holes that circumferentially align with the same number of holes in the other overlapping free end.
15. The prosthetic heart valve of claim 14, wherein the support band has an undulating shape with alternating cusp and commissure portions, and the free ends overlap at one of the cusp portions.

16. The prosthetic heart valve of claim 6, further including a cloth covering surrounding the support structure and facilitating attachment of peripheral edges of the flexible leaflets along an outflow edge of the support structure.

17. The prosthetic heart valve of claim 12, wherein the stent band includes a plurality of structurally weakened areas at an inflow edge below each of the commissure posts.

18. The prosthetic heart valve of claim 17, wherein the structurally weakened areas comprise notches at the inflow edge of the stent band.

19. The prosthetic heart valve of claim 6, further including a unique identifier on the support structure visible from outside the body after implant that identifies the support structure as being expandable.

20. The prosthetic heart valve of claim 1, further including a unique identifier on the support structure visible from outside the body after implant that identifies the support structure as being expandable.