

[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. Pat. 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 proper positioning of the heart valve, for example on the balloon prior to inflation as well as at implantation location, so as to prevent final positioning of a reversed valve. A further important design parameter is minimization of paravalvular leak (PVL). PVL may include complications such as blood flowing through a channel between the structure of the implanted valve and cardiac tissue, for example as a result of a lack of appropriate sealing.

SUMMARY

[007] An exemplary embodiment of a prosthetic heart valve may include an annular frame, a leaflet structure positioned within the frame, and two or more axially spaced annular outer skirts positioned around an outer surface of the frame. The two or more outer skirts may each have a cylindrical shape when mounted on the frame so as to extend completely around the outer surface of the frame. The two or more outer skirts may each comprise an inflow edge secured to the frame and an outflow edge, wherein the outflow edges of the two or more outer skirts may define one or more upper openings allowing retrograde blood flow between the outer surface of the frame and the two or more skirts to create a plurality of regions of turbulent blood flow along the prosthetic valve. The two or more outer skirts may be positioned in series along the length of the frame between an inflow edge of the frame and an outflow edge of the frame.

[008] Some embodiments of an implantable prosthetic valve may be radially collapsible to a collapsed configuration and radially expandable to an expanded configuration. Some embodiments of the prosthetic valve may comprise an annular frame, a leaflet structure positioned within the frame, and a plurality of outer skirts positioned around an outer surface of the frame. Each outer skirt may comprise an inflow edge secured to the frame and an outflow edge secured at intervals to the frame. The plurality of outer skirts may include a first outer skirt and a second outer skirt, wherein in

the expanded configuration the first and the second outer skirts may include openings unsecured to the frame between the intervals.

[009] In some embodiments, the inflow edge of the first outer skirt may be secured to the frame with sutures including radiopaque material. In some embodiments, the first outer skirt may comprise markings formed from radiopaque dye.

[010] In some embodiments, the openings of the first outer skirt and the second outer skirt may be circumferentially aligned. Additionally and/or alternatively, in some embodiments, the openings may not lie flat against the outer surface of the frame and are spaced radially outward from the frame in the expanded configuration. Additionally and/or alternatively, the inflow edge of the second outer skirt may contact the outflow edge of the first outer skirt without any axial spacing between. The outflow edge of at least one of the plurality of outer skirts may be unsecured to the frame. The axial height of a least two of the plurality of skirts may be the same.

[011] Some embodiments of a prosthetic heart valve may include an annular frame having an inflow end and an outflow end, a leaflet structure positioned within the frame and an annular skirt mounted on the frame. The skirt may comprise radiopaque markings, which can comprise one or both of radiopaque sutures and radiopaque dye, to facilitate positioning of the prosthetic valve under fluoroscopy.

[012] The foregoing and other objects, features, and advantages of the disclosure will become more apparent from the following detailed description, which proceeds with reference to the accompanying figures.

BRIEF DESCRIPTION OF THE DRAWINGS

[013] FIG. 1 shows a perspective view an exemplary embodiment of a prosthetic heart valve.

[014] FIG. 2 shows a top view of the prosthetic heart valve of FIG. 1

[015] FIG. 3 shows a perspective view of an exemplary frame of the prosthetic heart valve of FIG. 1.

We claim:

1. An implantable prosthetic valve comprising:
an annular frame;
a leaflet structure positioned within the frame; and
two or more axially spaced annular outer skirts positioned around an outer surface of the frame, the two or more outer skirts each having a cylindrical shape when mounted on the frame so as to extend completely around the outer surface of the frame and comprising an inflow edge secured to the frame and an outflow edge, wherein the outflow edges of the two or more outer skirts define one or more upper openings allowing retrograde blood to flow between the outer surface of the frame and the two or more skirts to create a plurality of regions of turbulent blood flow along the prosthetic valve, wherein the two or more outer skirts are positioned in series along the length of the frame between an inflow edge of the frame and an outflow edge of the frame.
2. The valve of claim 1, wherein the inflow edge of at least one of the two or more outer skirts is secured to the frame with sutures including radiopaque material.
3. The valve of any of claims 1-2, wherein at least one of the two or more outer skirts comprises markings formed from radiopaque dye.
4. The valve of any of claims 1-3, wherein the outflow edges of at least two of the two or more outer skirts are secured at intervals to the frame and includes openings between the intervals that are unsecured to the frame.
5. The valve of any of claims 1-4, wherein the one or more openings do not lie flat against the outer surface of the frame in an expanded configuration.
6. The valve of any of claims 1-5, wherein outflow edge of at least one of the two or more outer skirts is unsecured to the frame.
7. The valve of any of claims 1-6, wherein the axial spacing between the two or more outer skirts is less than the axial height of a least one of the two or more outer skirts.

8. The valve of any of claims 1-7, wherein the inflow edge of at least one of the two or more outer skirt contacts the outflow edge of another one of the two or more outer skirts without any axial spacing between.

9. The valve of any of claims 1-8, wherein each of the inflow edges of the two or more outer skirts is straight and each of the outflow edges of the two or more outer skirts defines a plurality of alternating projections and notches.

10. An implantable prosthetic valve that is radially collapsible to a collapsed configuration and radially expandable to an expanded configuration, the prosthetic valve comprising:

an annular frame;

a leaflet structure positioned within the frame; and

a plurality of axially spaced outer skirts positioned around an outer surface of the frame, each outer skirt having a cylindrical shape when mounted on the frame so as to extend completely around the outer surface of the frame and comprising an inflow edge secured to the frame and an outflow edge secured at intervals to the frame, the plurality of outer skirts including a first outer skirt and a second outer skirt, wherein in the expanded configuration the first and second outer skirts include openings unsecured to the frame between the intervals, wherein the plurality of outer skirts are positioned in series along the length of the frame between an inflow edge of the frame and an outflow edge of the frame.

11. The valve of claim 10, wherein the first outer skirt comprises markings formed from radiopaque dye.

12. The valve of any of claims 10-11, wherein the plurality of outer skirts further includes a third outer skirt, wherein in the expanded configuration the third outer skirt includes openings unsecured to the frame between the intervals.

13. The valve of any of claims 10-12, wherein the openings of the first outer skirt and the second outer skirt are circumferentially aligned.

14. The valve of any of claims 10-13, wherein the openings do not lie flat against the outer surface of the frame in the expanded configuration.

15. The valve of any of claims 10-14, wherein the inflow edge of the second outer skirt contacts the outflow edge of the first outer skirt without any axial spacing between.

16. The valve of any of claims 10-15, wherein outflow edge of at least one of the plurality of outer skirts is unsecured to the frame.

17. The valve of any of claims 10-16, wherein the axial height of at least two of the plurality of skirts is the same.

18. The valve of any of claims 10-17, wherein each of the inflow edges of the plurality of outer skirts is straight and each of the outflow edges of the plurality of outer skirts defines a plurality of alternating projections and notches.