

defective, non-stenotic (non-calcified) native valve, although they also can be used to replace stenotic valves. One drawback associated with implanting a self-expanding prosthetic valve is that as the operator begins to advance the prosthetic valve from the open end of the delivery sheath, the prosthetic valve tends to “jump” out very quickly from the end of the sheath; in other words, the outward biasing force of the prosthetic valve’s frame tends to cause the prosthetic valve to be ejected very quickly from the distal end of the delivery sheath, making it difficult to deliver the prosthetic valve from the sheath in a precise and controlled manner and increasing the risk of trauma to the patient.

[005] Another problem associated with implanting a percutaneous prosthetic valve in a non-stenotic native valve is that the prosthetic valve may not be able to exert sufficient force against the surrounding tissue to resist migration of the prosthetic valve. Typically, the stent of the prosthetic valve must be provided with additional anchoring or attachment devices to assist in anchoring the prosthetic valve to the surrounding tissue. Moreover, such anchoring devices or portions of the stent that assist in anchoring the prosthetic valve typically extend into and become fixed to non-diseased areas of the vasculature, which can result in complications if future intervention is required, for example, if the prosthetic valve needs to be removed from the patient.

SUMMARY

[006] Certain embodiments of the present disclosure provide a prosthetic valve (*e.g.*, a prosthetic heart valve) and a valve delivery apparatus for delivery of the prosthetic valve to a native valve site via the human vasculature. The delivery apparatus can be particularly suited for advancing a prosthetic valve through the aorta (*i.e.*, in a retrograde approach) for replacing a diseased native aortic valve. The delivery apparatus in particular embodiments is configured to deploy a prosthetic valve from a delivery sheath in a precise and controlled manner at the target location within the body.

[007] In an aspect, a prosthetic valve delivery assembly comprises a prosthetic valve, an elongate first shaft located proximal to the prosthetic valve, a suture-retention member located distal to the first shaft, at least one slidable release member, a plurality of suture loops extending from the proximal portion of the suture-retention member, ~~and an outer sheath,~~ an elongate second shaft extending through the first shaft and the lumen of the suture-retention member and a nose cone mounted on a distal end portion of the second shaft distal to the suture-retention member. The prosthetic valve can comprise

a self-expandable stent having a plurality of apices spaced circumferentially around a first end portion of the stent, ~~wherein each apex has an aperture~~. The suture-retention member can comprise a proximal portion, ~~and a distal portion spaced from the proximal portion~~ and an intermediate shaft portion extending between and connected to the proximal portion and to the distal portion, the suture-retention member having a lumen extending through the proximal portion, the intermediate shaft portion, and the distal portion, the proximal portion being coupled to the first shaft. The at least one slidable release member can extend through the proximal portion and the distal portion of the suture-retention member. The plurality of suture loops can extend around the apices of the stent or through the apertures in the apices of the stent and around the release member at a location between the proximal and distal portions of suture-retention member, such that there is at least one of the suture loops that extends around every apex or through the an aperture of every apex. The outer sheath can be advanced over the prosthetic valve to retain the prosthetic valve in a radially compressed state, and can be retracted relative to the prosthetic valve to permit radial expansion of the prosthetic valve while the stent remains connected to the suture-retention member via the suture loops. After the entirety of the prosthetic valve is deployed from the sheath, the sheath can be advanced distally back over the prosthetic valve to cause the prosthetic valve to radially collapse as it is recaptured by the sheath.

[008] In some embodiments, the suture loops are formed from a single length of suture material.

[009] In some embodiments, ~~the shaft comprises a first shaft and the assembly further comprises a second-third shaft extending at least partially through the first shaft, wherein the outer sheath can be advanced or retracted relative to the prosthetic valve by rotating the second shaft relative to the first shaft.~~

[010] In some embodiments, the at least one release member is slidable relative to the suture-retention member, and when the release member is retracted proximally such that a distal end of the release member is proximal to the distal portion of the suture-retention member, the suture loops can slide off the distal end of the release member, thereby releasing the prosthetic valve from the suture-retention member.

[011] In some embodiments, at least a portion of the outer sheath comprises a slotted metal tube.

[012] In some embodiments, a distal end portion of the outer sheath comprises a delivery capsule connected to a distal end of the slotted metal tube, the delivery capsule configured to extend over and retain the prosthetic valve in the radially compressed state.

[013] In some embodiments, the delivery capsule comprises a polymer sleeve.

[014] In some embodiments, the sheath is at least about 3–10 cm in length and no greater than about 40 cm in length.

[015] In some embodiments, at least one of the suture loops has a greater thickness than others of the suture loops.

[016] In another aspect, a delivery apparatus for implanting a prosthetic valve comprises a first elongated shaft having a proximal end portion and a distal end portion, a second elongated shaft extending through the first shaft and having a proximal end portion and a distal end portion, and a delivery sheath having a distal end portion configured to receive and retain a prosthetic valve in a compressed delivery state and a proximal end portion connected to the distal end portion of the second elongated shaft. The second shaft can be rotatable relative to the first shaft but fixed against axial movement relative to the first shaft. The proximal end portion of the delivery sheath can be more flexible than the distal end portion of the sheath. The delivery sheath can be, without limitation, at least about 3–5 cm in length and no greater than about 40 cm in length. The second shaft can be configured to be rotatable relative to the first shaft such that rotation of the second shaft causes the delivery sheath to move axially relative to the first and second shafts.

[017] ~~In some embodiments,~~ The delivery apparatus further also comprises a screw connected to a distal end of the second shaft, and a nut mounted on the screw and connected to the delivery sheath such that rotation of the second shaft and the screw causes axial movement of the nut relative to the screw, thereby producing axial movement of the delivery sheath, wherein the delivery apparatus is sized such that when the delivery apparatus is advanced through the aorta and the prosthetic valve is positioned at the native aortic valve of a patient, the distal end portion of the delivery sheath is positioned in the ascending aorta, the screw is positioned in the descending aorta, and the proximal portion of the delivery sheath extends through the aortic arch from the distal end portion of the sheath to the nut.

[018] In some embodiments, the proximal end portion of the delivery sheath is between about 5 cm and about 30 cm in length.

We claim:

1. A prosthetic valve delivery assembly, comprising:

a prosthetic valve comprising a self-expandable stent having a plurality of apices spaced circumferentially around a first end portion of the stent, ~~wherein each apex has an aperture;~~

an elongate first shaft located proximal to the prosthetic valve;

a suture-retention member located distal to the first shaft, the suture-retention member comprising a proximal portion, ~~and a distal portion spaced from the proximal portion, and an intermediate shaft portion extending between and connected to the proximal portion and to the distal portion, the suture-retention member having a lumen extending through the proximal portion, the intermediate shaft portion, and the distal portion, the proximal portion being coupled to the first shaft;~~

at least one slidable release member extending through the proximal portion and the distal portion of the suture-retention member;

a plurality of suture loops extending from the proximal portion of the suture-retention member, around the apices of the stent or through the apertures in the apices of the stent, and around the release member at a location between the proximal and distal portions of suture-retention member, wherein there is at least one of the suture loops that extends around every apex or through the an aperture of every apex;

an elongate second shaft extending through the first shaft and the lumen of the suture-retention member;

a nose cone mounted on a distal end portion of the second shaft distal to the suture-retention member; and

an outer sheath which can be advanced over the prosthetic valve to retain the prosthetic valve in a radially compressed state and retracted relative to the prosthetic valve to permit radial expansion of the prosthetic valve, while the stent remains connected to the suture-retention member via the suture loops;

wherein after the entirety of the prosthetic valve is deployed from the sheath, the sheath can be advanced distally back over the prosthetic valve to cause the prosthetic valve to radially collapse as it is recaptured by the sheath.

2. The assembly of claim 1, wherein the suture loops are formed from a single length of suture material.

3. The assembly of claim 1, wherein ~~the shaft comprises a first shaft and the~~ assembly further comprises a ~~second~~ third shaft extending at least partially through the first

a second elongated shaft extending through the first shaft and having a proximal end portion and a distal end portion, the second shaft being rotatable relative to the first shaft but fixed against axial movement relative to the first shaft; ~~and~~

a delivery sheath having a distal end portion configured to receive and retain a prosthetic valve in a compressed delivery state, and a proximal end portion connected to the distal end portion of the second elongated shaft, wherein the proximal end portion is more flexible than the distal end portion, wherein the delivery sheath is at least about 5 cm in length and no greater than about 40 cm in length; and

a screw connected to a distal end of the second shaft, and a nut mounted on the screw and connected to the delivery sheath such that rotation of the second shaft and the screw causes axial movement of the nut relative to the screw, thereby producing axial movement of the delivery sheath;

wherein the second shaft is configured to be rotatable relative to the first shaft such that rotation of the second shaft causes the delivery sheath to move axially relative to the first and second shafts; and

wherein the delivery apparatus is sized such that when the delivery apparatus is advanced through the aorta and the prosthetic valve is positioned at the native aortic valve of a patient, the distal end portion of the delivery sheath is positioned in the ascending aorta, the screw is positioned in the descending aorta, and the proximal portion of the delivery sheath extends through the aortic arch from the distal end portion of the sheath to the nut.

~~11. The apparatus of claim 10, further comprising a screw connected to a distal end of the second shaft, and a nut mounted on the screw and connected to the delivery sheath such that rotation of the second shaft and the screw causes axial movement of the nut relative to the screw, thereby producing axial movement of the delivery sheath.~~

~~1211.~~ The apparatus of claim 10, wherein the proximal end portion of the delivery sheath is between about 2 cm and about 35 cm in length.

~~13~~12. The apparatus of claim 10, wherein the distal end portion of the first shaft extends through the delivery sheath and comprises a slotted metal tube.

~~14~~13. The apparatus of claim 10, further comprising:
a suture-retention member connected to the distal end portion of the first shaft;
a plurality of suture loops extending from the suture-retention member and
configured to extend through openings in a frame of the prosthetic valve; and

at least one slidable release member configured to extend through the suture-retention member and the suture loops to releasably secure the prosthetic valve to the suture-retention member.

~~15~~14. The apparatus of claim ~~14~~13, wherein:

the suture-retention member comprises a proximal portion and a distal portion spaced axially apart from the first portion;

the release member is slidable relative to the suture-retention member between a first position extending through the proximal and distal portions of the suture-retention member and a second position in which the release member is retracted to a location proximal of the distal portion of the suture-retention member;

wherein when the release member is in the first position and the suture loops extend through the openings of the frame and around the release member at a location between the proximal and distal portions, the prosthetic valve is secured to the suture-retention member;

wherein when the release member is in the second position, the suture loops can slide off a distal end of the release member to release the prosthetic valve from the suture-retention member.

~~16~~15. The apparatus of claim ~~14~~13, wherein the at least one release member comprises a plurality of release members extending through the suture-retention member.

~~17~~16. The apparatus of claim 10, wherein the proximal end portion of the outer sheath comprises a slotted metal tube.

~~18~~17. The apparatus of claim ~~17~~16, wherein the distal end portion of the outer sheath comprises a delivery capsule connected to a distal end of the slotted metal tube, the delivery capsule configured to extend over and retain the prosthetic valve in the compressed delivery state.

| ~~19~~18. The apparatus of claim ~~18~~17, wherein the delivery capsule comprises a polymer sleeve.