

[0019] In addition, it is desirable to provide devices and methods that can be utilized in a variety of implantation approaches. Depending on a particular patient's anatomy and clinical situation, a medical professional may wish to make a determination regarding the optimal method of implantation, such as inserting a replacement valve directly into the heart in an open procedure (open heart surgery or a minimally invasive surgery) or inserting a replacement valve from veins and via arteries in a closed procedure (such as a catheter-based implantation). It is preferable to allow a medical professional a plurality of implantation options to choose from. For example, a medical professional may wish to insert a replacement valve either from the ventricle or from the atrial side of the mitral valve.

[0020] Therefore, embodiments of the present invention seek to provides devices and methods that address these and other challenges in the art.

Summary

[0021] In one illustrative embodiment, the invention provides a system for replacing a native heart valve including an expansible helical anchor formed as multiple coils adapted to support a heart valve prosthesis. At least one of the coils is normally at a first diameter, and is expandable to a second, larger diameter upon application of radial outward force from within the helical anchor. A gap is defined between adjacent coils sufficient to prevent engagement by at least one of the adjacent coils with the native heart valve. An expansible heart valve prosthesis is provided and is configured to be delivered into the helical anchor and expanded inside the multiple coils into engagement with the at least one coil. This moves at least that coil from the first diameter to the second diameter while securing the helical anchor and the heart valve prosthesis together. The system further includes a seal on the expansible heart valve prosthesis configured to engage the helical anchor and prevent blood leakage past the heart valve prosthesis after implantation of the heart valve prosthesis in the helical anchor.

[0022] The system may include one or more additional aspects. For example, the helical anchor may include another coil that moves from a larger diameter to a smaller diameter as the heart valve prosthesis is expanded inside the multiple coils. The seal may take many alternative forms. For example, the seal can include portions extending between adjacent coils for preventing blood

support a heart valve prosthesis at the native heart valve. An expansible heart valve prosthesis is provided in this system and is capable of being delivered into the helical anchor and expanded inside the multiple coils into engagement with the at least one coil to secure the helical anchor and the heart valve prosthesis together. A guide structure on the expansible heart valve prosthesis is configured to guide the helical anchor into position as the helical anchor is extruded from a helical anchor delivery catheter.

[0026] The guide structure may further comprise an opening within a portion of the expansible heart valve prosthesis, such as an opening in a loop, a tube or simply an opening in the stent structure of the expansible heart valve prosthesis, for example. The opening may be configured to receive a helical anchor delivery catheter that carries the helical anchor during the implantation procedure. The opening may be located on an arm of the expansible heart valve prosthesis and the prosthesis may further comprise a plurality of arms configured to engage beneath the native heart valve. The guide structure may further comprise a tubular arm of the expansible heart valve prosthesis.

[0027] In another illustrative embodiment, a system for docking a mitral valve prosthesis and replacing a native mitral valve is provided and includes a coil guide catheter and a helical anchor adapted to be received in and delivered from the coil guide catheter. The helical anchor is formed as multiple coils having a coiled configuration after being delivered from the coil guide catheter and adapted to support the mitral valve prosthesis upon being fully delivered from the coil guide catheter and implanted at the native mitral valve. The system further includes a tissue gathering catheter including loop structure configured to be deployed to surround and gather the native chordae tendinae for allowing easier direction of the helical anchor in the left ventricle.

[0028] In another illustrative embodiment, an anchor for docking a heart valve prosthesis includes an upper helical coil portion, a lower helical coil portion, and a fastener securing the upper helical coil portion to the lower helical coil portion.

[0029] ~~In another illustrative embodiment~~ There is disclosed, a method of implanting a heart valve prosthesis in the heart of a patient includes holding a helical anchor in the form of multiple coils within an outer, flexible tube. The assembly of the outer, flexible tube and the helical anchor is secured to a helical delivery tool. The helical delivery tool is rotated adjacent to a native heart valve of the patient to

position the assembly on either or both sides of the native heart valve. The assembly is removed from the helical delivery tool, and the outer tube is removed from the helical anchor. The heart valve prosthesis is then implanted within the helical anchor.

[0030] Securing the assembly may further comprise positioning coils of the assembly generally along adjacent coils of the helical delivery tool. Removing the outer tube may further comprise holding the helical anchor with a pusher element, and pulling the outer tube off the helical anchor.

[0031] ~~In another illustrative embodiment~~ There is also disclosed, a method of implanting an expansible heart valve prosthesis in the heart of a patient includes delivering an expansible helical anchor in the form of multiple coils proximate the native heart valve. The expansible heart valve prosthesis is positioned within the multiple coils of the expansible helical anchor with the expansible heart valve prosthesis and the expansible helical anchor in unexpanded states. The expansible heart valve prosthesis is expanded against the expansible helical anchor thereby expanding the expansible heart valve prosthesis while securing the expansible heart valve prosthesis to the expansible helical anchor. A seal is carried on the helical anchor and/or on the heart valve prosthesis and extends between at least two adjacent coils for preventing blood leakage through the helical anchor and past the heart valve prosthesis.

[0032] There is also disclosed~~In another illustrative embodiment~~, a method of implanting an expansible heart valve prosthesis to replace a native heart valve of a patient includes delivering a helical anchor in the form of multiple coils proximate the native heart valve. The expansible heart valve prosthesis is delivered proximate the native heart valve. The helical anchor is guided generally around a periphery of the expansible heart valve prosthesis using guide structure carried on the expansible heart valve prosthesis. The expansible heart valve prosthesis is expanded against the helical anchor. As discussed above, the guide structure may take many different forms.

[0033] There is also disclosed~~In another illustrative embodiment~~, a method of implanting a helical anchor for docking a mitral heart valve prosthesis in a patient includes gathering the chordae tendinae using a tissue gathering catheter. A helical anchor is then delivered in the form of multiple coils proximate a native heart valve and around the gathered chordae tendinae.

[0034] There is also disclosed~~In another illustrative embodiment~~, a method of implanting a helical anchor for docking a heart valve prosthesis in a patient includes delivering an upper helical anchor portion comprised of upper coils to a position above a native heart valve, and delivering a lower helical anchor portion comprised of lower coils to a position below the native heart valve. The upper and lower helical anchor portions are secured together with a fastener either before or after delivery of each helical anchor portion.

[0035] In another illustrative embodiment, a system for replacing a native heart valve is provided and includes an expansible helical anchor formed as multiple coils adapted to support a heart valve prosthesis. At least one of the coils is normally at a first diameter, and is expandable to a second, larger diameter upon application of radial outward force from within the helical anchor. A gap is defined between adjacent coils sufficient to prevent engagement by at least one of the adjacent coils with the native heart valve. An expansible heart valve prosthesis is provided and is capable of being delivered into the helical anchor and expanded inside the multiple coils into engagement with the at least one coil. In this manner, the expansible coil moves from the first diameter to the second diameter while securing the helical anchor and the heart valve prosthesis together. The expansible heart valve prosthesis includes an inflow end and an outflow end. The inflow end is unflared and generally cylindrical, while the outflow end is flared in a radially outward direction.

[0036] Various additional advantages, methods, devices, systems and features will become more readily apparent to those of ordinary skill in the art upon review of the following detailed description of the illustrative embodiments taken in conjunction with the accompanying drawings.

Brief Description of the Drawings

[0037] FIG. 1 is a perspective view schematically illustrating the introduction of a helical anchor to the position of the native mitral valve.

[0038] FIG. 2A is an enlarged cross-sectional view illustrating an initial portion of the procedure shown in FIG. 1, but with use of a deflectable catheter.

[0039] FIG. 2B is a cross-sectional view of the heart similar to FIG. 2A, but illustrating deflection of the delivery catheter and introduction of the helical anchor underneath the native mitral valve.

29. The system of claim 25, wherein the expansible heart valve prosthesis further comprises a plurality of arms configured to engage beneath the native heart valve.

30. The system of claim 25, wherein the guide structure further comprises a tubular arm of the expansible heart valve prosthesis, the tubular arm carrying the helical anchor therein for extrusion and deliver to the native heart valve.

31. A system for docking a mitral valve prosthesis and replacing a native mitral valve, comprising:

a coil guide catheter;

a helical anchor adapted to be received in and delivered from the coil guide catheter, the helical anchor formed as multiple coils having a coiled configuration after being delivered from the coil guide catheter and adapted to support the mitral valve prosthesis upon being fully delivered from the coil guide catheter and implanted at the native mitral valve; and

a tissue gathering catheter including loop structure configured to be deployed to surround and gather the native chordae tendinae for allowing easier direction of the helical anchor in the left ventricle.

32. An anchor for docking a heart valve prosthesis, comprising:

an upper helical coil portion;

a lower helical coil portion; and

a fastener securing the upper helical coil portion to the lower helical coil portion.

~~33. A method of implanting a heart valve prosthesis in the heart of a patient, comprising:~~

~~— holding a helical anchor in the form of multiple coils within an outer, flexible tube;~~

~~securing the assembly of the outer, flexible tube and the helical anchor to a helical delivery tool;~~

~~rotating the helical delivery tool adjacent to a native heart valve of the patient to position the assembly on either or both sides of the native heart valve;~~

~~removing the assembly from the helical delivery tool;~~

~~removing the outer tube from the helical anchor; and~~
~~implanting the heart valve prosthesis in the helical anchor.~~

34. ~~The method of claim 33, wherein securing the assembly further comprises positioning coils of the assembly generally along adjacent coils of the helical delivery tool.~~

35. ~~The method of claim 33, wherein removing the outer tube further comprises holding the helical anchor with a pusher element, and pulling the outer tube off the helical anchor.~~

36. ~~A method of implanting an expansible heart valve prosthesis in the heart of a patient, comprising:~~

~~—— delivering an expansible helical anchor in the form of multiple coils proximate the native heart valve,~~

~~—— positioning the expansible heart valve prosthesis within the multiple coils of the expansible helical anchor with the expansible heart valve prosthesis and the expansible helical anchor in unexpanded states,~~

~~—— expanding the expansible heart valve prosthesis against the expansible helical anchor thereby expanding the expansible heart valve prosthesis while securing the expansible heart valve prosthesis to the expansible helical anchor; and~~

~~carrying a seal on the helical anchor and extending between at least two adjacent coils for preventing blood leakage through the helical anchor and past the heart valve prosthesis.~~

37. ~~A method of implanting an expansible heart valve prosthesis in the heart of a patient, comprising:~~

~~—— delivering an expansible helical anchor in the form of multiple coils proximate the native heart valve,~~

~~—— positioning the expansible heart valve prosthesis within the multiple coils of the expansible helical anchor with the expansible heart valve prosthesis and the expansible helical anchor in unexpanded states,~~

~~—— expanding the expansible heart valve prosthesis against the expansible helical anchor thereby expanding the expansible heart valve prosthesis while~~

~~securing the expansible heart valve prosthesis to the expansible helical anchor;
and~~

~~carrying a seal on the expansible heart valve prosthesis and extending
between at least two adjacent coils for preventing blood leakage through the
helical anchor and past the heart valve prosthesis.~~

~~38. — A method of implanting an expansible heart valve prosthesis to replace
a native heart valve of a patient, comprising:~~

~~—— delivering a helical anchor in the form of multiple coils proximate the
native heart valve,~~

~~—— delivering the expansible heart valve prosthesis proximate the native
heart valve;~~

~~guiding the helical anchor generally around a periphery of the expansible
heart valve prosthesis using guide structure carried on the expansible heart
valve prosthesis; and~~

~~expanding the expansible heart valve prosthesis against the helical
anchor.~~

~~39. — The method of claim 38, wherein guiding the helical anchor further
comprises:~~

~~—— directing the helical anchor through a guide structure of an arm
extending underneath the native heart valve.~~

~~40. — The method of claim 38, wherein guiding the helical anchor further
comprises:~~

~~—— directing the helical anchor through an opening of the expansible heart
valve prosthesis.~~

~~41. — The method of claim 40, wherein the opening is in a loop of an arm
extending underneath the native heart valve.~~

~~42. — The method of claim 40, wherein the opening is in a tubular arm
extending underneath the native heart valve.~~

43. — A method of implanting a helical anchor for docking a mitral heart valve prosthesis in a patient, comprising:

— gathering the chordae tendinae using a tissue gathering catheter; and
— delivering a helical anchor in the form of multiple coils proximate a native heart valve and around the gathered chordae tendinae.

44. — A method of implanting a helical anchor for docking a heart valve prosthesis in a patient, comprising:

— delivering an upper helical anchor portion comprised of upper coils to a position above a native heart valve;

— delivering a lower helical anchor portion comprised of lower coils to a position below the native heart valve; and

— securing the upper and lower helical anchor portions together with a fastener.

4533. A system for replacing a native heart valve, the system comprising:

an expansible helical anchor formed as multiple coils adapted to support a heart valve prosthesis, at least one of the coils being normally being at a first diameter, and being expandable to a second, larger diameter upon application of radial outward force from within the helical anchor, wherein a gap is defined between adjacent coils sufficient to prevent engagement by at least one of the adjacent coils with the native heart valve; and

an expansible heart valve prosthesis capable of being delivered into the helical anchor and expanded inside the multiple coils into engagement with the at least one coil to move the at least one coil from the first diameter to the second diameter while securing the helical anchor and the heart valve prosthesis together, wherein the expansible heart valve prosthesis includes an inflow end and an outflow end, the inflow end being unflared and generally cylindrical, the outflow end being flared in a radially outward direction.