and create better long-term outcomes compared to existing devices, delivery systems, and open-chest surgical procedures.

SUMMARY OF THE INVENTION

[0022a] According to an aspect of the present invention, there is provided a bioprosthetic atrioventricular valve comprising: a valved stent assembly comprising a structural frame support expandable from a collapsed to an expanded shape and having an atrial inflow orifice and a ventricular outflow orifice and a tapered dimension along the height of the structural frame support wherein the atrial inflow orifice has a smaller diameter than the ventricular or outflow orifice; a precut mesh layer covering the interior surface of the structural frame support from the atrial inflow orifice to the ventricular outflow orifice; a tissue valve having at least two leaflets and affixed about the inner surface of the structural frame support and having a height and a diameter approximately the same as the height and diameter of the structural frame support; and a first tissue engaging structure extending from a portion of the structural support frame proximate to the atrial inflow orifice and a second tissue engaging structure extending from a portion of the structural frame support proximate to the ventricular outflow orifice for grasping tissue at both the atrial and ventricular aspect of the native valve annulus.

[0023] The current invention pertains to restoring function to cardiovascular valves, including repair and replacement of any of the four heart valves, but particularly the placement of prosthetic replacements for the atrioventricular valves. The invention also includes devices and methods using an integrated system comprising replacement valves and a delivery system specially designed for use with the replacement valves of the invention. The system is comprised of both the valved stent specific for a target valve, e.g. the tricuspid or mitral valve, and a delivery system also specific to the target valve. Thus, the invention is comprised of each of the two devices individually and in the complementary combination of

the separate devices.

[0024] The methods of the invention include techniques for controlled deployment of the prosthetic valve that are enabled by the unique design of the delivery system and the valve. In particular, these mechanisms enable controlled deployment and release of the prosthetic valve such that the surgeon can carefully control placement of the valve at the target site and dictate the rate of expansion of the replacement prosthesis during delivery and assure landing of the valved stent in the proper zone during implantation.

[0025] Specifically, the invention provides a valved stent for implantation at a native valvular annulus, preferably an atrioventricular valve, comprising: a support structure, wherein the support structure is expandable from a collapsed shape to an expanded shape; a tissue valve with at least one leaflet, the tissue valve being connected to the support structure; and both superior and inferior (upper and lower) means for fixing and stabilizing the stented valve onto the valvular annulus, wherein the means for fixing and stabilizing the valved stent are located at an exterior circumference of the support structure. The fixation and stabilization of the valved stent at the native annulus can also be described having fixing and stabilizing structures

We claim:

1. A bioprosthetic atrioventricular valve comprising:

a valved stent assembly comprising a structural frame support expandable from a collapsed to an expanded shape and having an atrial inflow orifice and a ventricular outflow orifice and a tapered dimension along the height of the structural frame support wherein the atrial inflow orifice has a smaller diameter than the ventricular or outflow orifice;

a precut mesh layer covering the interior surface of the structural frame support from the atrial inflow orifice to the ventricular outflow orifice;

a tissue valve having at least two leaflets and affixed about the inner surface of the structural frame support and having a height and a diameter approximately the same as the height and diameter of the structural frame support; and

a first tissue engaging structure extending from a portion of the structural support frame proximate to the atrial inflow orifice and a second tissue engaging structure extending from a portion of the structural frame support proximate to the ventricular outflow orifice for grasping tissue at both the atrial and ventricular aspect of the native valve annulus.

2. The bioprosthetic atrioventricular valve of claim 1, wherein the first tissue engaging structure is in annular atrial skirt extending radially from the structural frame support at an angle between 85 and 95°.

3. The bioprosthetic atrioventricular valve of claim 1, wherein the second tissue engaging structure is a plurality of ventricular tines extending radially away from a plurality of hubs located circumferentially around the ventricular or outflow orifice.

4. The bioprosthetic atrioventricular valve of claim 1, wherein the distance between the first tissue engaging structure and the second tissue engaging structure is between 5.5 and 9.0 mm.

5. The bioprosthetic atrioventricular valve of claim 4, wherein the distance between the first tissue engaging structure and the second tissue engaging structure is between 7.0 and

8.0 mm.

6. The bioprosthetic atrioventricular valve of claim 1, wherein the total height of the structural frame support is less than 25 mm.

7. The bioprosthetic atrioventricular valve of claim 6, wherein the ratio of the diameter of the atrial inflow orifice relative to the ventricular outflow orifice is between approximately 0.60 and approximately 0.90.

8. The bioprosthetic atrioventricular valve of claim 7, wherein the ratio of the diameter of the atrial inflow orifice relative to the ventricular outflow orifice is between approximately 0.70 and approximately 0.85.

9. The bioprosthetic atrioventricular valve of claim 1, where in the diameter of the ventricular or outflow orifice is greater than 30 mm.

10. The bioprosthetic atrioventricular valve of claim 1, wherein the first tissue engaging portion is covered with a mesh layer covering a portion of the annular structure thereof comprising an upper surface, a lower surface, or combinations thereof

11. A bioprosthetic valve delivery system comprising:

a capsule located at the distal end of a steerable catheter and containing the bioprosthetic atrioventricular valve of claim 1,

a nose cone distal to the capsule and affixed to a wire traversing the tissue valve and the length of the steerable catheter,

a plurality of release wires traversing the length of the steerable catheter and traversing a crown of the bioprosthetic atrioventricular valve of claim 1 to maintain the bioprosthetic atrioventricular valve of claim 1 in a collapsed configuration,

a proximal handle containing control mechanisms for each of steering the distal end of the steerable catheter, sliding the capsule axially to deploy the bioprosthetic valve of claim 1, and controlling tension in the plurality of release wires.

12. The bioprosthetic valve delivery system of claim 11, wherein the release wires

traverse a tab holder located proximate to the distal end of the steerable catheter and form a loop to engage a tab fixture on the tab holder.

13. The bioprosthetic delivery system of claim 11, further comprising alignment pins that traverse the steerable catheter and are affixed to the capsule such that the selective orientation of the alignment pins steers the distal end of the delivery system.

14. The bioprosthetic delivery system of claim 11, wherein the bioprosthetic valve has a total height of the structural frame support is less than 25 mm, a ratio of the diameter of the atrial inflow orifice relative to the ventricular outflow orifice is between approximately 0.60 and approximately 0.90, and a diameter of the ventricular or outflow orifice is greater than 30 mm.

15. The bioprosthetic delivery system of claim 11, wherein the proximal handle, the steerable catheter, the tissue valve, the capsule, are traversed by a catheter guidewire attached to the distal nose cone.