PERCUTANEOUS AORTIC VALVE REPLACEMENT

Background of the Invention

This invention relates to aortic heart valves and, in particular, to a percutaneous aortic heart valve that is placed by a catheter or other means and held in place with a stent system without the need for surgery.

The aortic valve undergoes a series of changes based upon the initial structure at birth and the normal dynamic daily stresses. The trileaflet aortic valve normally will not become stenotic until the seventh decade of a person's life unless infectious processes are introduced earlier. The incidence of aortic stenosis can reach between two and nine percent of the people in this age range. The average mortality rate at all ages is nine percent a year which also increases as a population ages. Coupled with these facts is the likelihood that as a person ages and becomes symptomatic with aortic stenosis, he is less likely to be an operative candidate due to being physically unable to withstand the stresses of surgery. The mortality of octogenarians has been reported as high as 20% for aortic valve replacement which can preclude a reasonable attempt at the therapy of choice, e.g., surgical replacement of the aortic valve using the traditional method of open heart surgery.

It is therefore the primary object of the present invention to provide an aortic valve that can be placed nonsurgically.

Another object of the present invention as aforesaid is to provide an aortic valve which may be anchored in the ascending aorta by a stent system.

Yet another important object of the present invention is to provide an aortic valve as aforesaid which may be placed percutaneously.

Still another object of the present invention is to provide an aortic valve as aforesaid which functions without removal of the native aortic valve.

Another important object of the present invention is to provide an aortic valve as aforesaid which reduces regurgitation of a native aortic valve.

Yet another important object of the present invention is to provide an aortic valve as aforesaid which increases the effective aortic valve orifice area while minimizing the resultant aortic regurgitation.

Still another important object of the present invention is to provide an aortic valve as aforesaid which reduces left ventricle energy expenditure from aortic regurgitation.

(Docket 2895)

Yet another important object of the present invention is to provide an aortic valve as aforesaid which reduces long-term ventricular and aortic sequelae from pressure overload caused by aortic regurgitation.

Another important object of the present invention is to provide an aortic valve as aforesaid which can be placed nonsurgically so as to minimize the health risk to a patient during the procedure.

These and other objects and advantages of this invention are achieved by an artificial biomechanical aortic valve integrated with a stent system, which may be placed nonsurgically so as to minimize the risk to the patient during the procedure. The aortic valve is anchored in the ascending aorta with further support supplied in branch vessels or descending aorta as necessary due to the stress forces placed on the artificial valve by the normal hemodynamic pressures in the aorta. The valve is connected to the stent system by serially connected rods. Because of the relatively large surface area of the stent system, this design displaces the forces placed upon the artificial valve across this large surface area. Placing the device nonsurgically eliminates the need for a bypass pump or sternotomy and the associated postoperative risks.

These and other objects and advantages of this invention will become apparent from the following description taken in connection with the accompanying drawings, wherein is set forth by way of illustration and example, a now preferred embodiment of this invention.

Brief Description of the Drawings

Fig. 1 is a diagrammatic sectional view of a catheter containing aortic valve and stents of the present invention in the descending portion of an aorta.

Fig. 2 is a diagrammatic view of Fig. 1 with the catheter advanced to the ascending portion of the aorta.

Fig. 3 is a diagrammatic view of Fig. 2 with the aortic valve and stents being deployed into the aorta and the stents being expanded by inflation of a balloon.

Fig. 4 is a diagrammatic view of Fig. 3 with the stents expended and in place and the catheter removed.

Fig. 5 is a diagrammatic view of Fig. 4 showing the relationship between the placement of the stent system and valve to the aortic valve and left ventricle.

Fig. 6 is an umbrella aortic valve in a closed position.

Fig. 7 is a plan view of the umbrella aortic valve of Fig. 5.

Fig. 8 is the umbrella aortic valve of Fig. 5 in an open position.

Fig. 9 is a plan view of the umbrella aortic valve of Fig. 7.

Fig. 10 is a diagrammatic view of a cone-shaped aortic valve in a closed position.

Fig. 11 is a plan view of the cone-shaped valve of Fig. 9.

Fig. 12 is the cone-shaped valve of Fig. 9 in an open position.

Fig. 13 is a plan view of the cone-shaped valve of Fig. 11.

Fig. 14 is a diagrammatic view of another cone-shaped aortic valve in a closed position.

Fig. 15 is a plan view of the cone-shaped valve of Fig. 13.

Fig. 16 is the cone-shaped aortic valve of Fig. 13 in an open position.

Fig. 17 is a plan view of the cone-shaped valve of Fig. 15.

Fig. 18 is a diagrammatic view of a cadaver/porcine incorporated valve and stent system.

Fig. 19 is a plan view of the cadaver/porcine valve of Fig. 18.

Description of the Preferred Embodiment

Turning more particularly to the drawings, Fig. 1 illustrates a sectional diagrammatic view of a cannular catheter 20 in the descending portion 22 of aorta 24. Cannular catheter 20 contains a balloon catheter 26 which is surrounded by a wire mesh tube or stent system 28 connected to artificial valve 30.

The stent system 28 is made up of a small slotted stainless steel tube or series of interconnected rods which form an expandable cylindrical lattice or scaffolding. The stent system 28 is initially collapsed to a small diameter around an angioplasty balloon 29 so that it and valve 30 may be guided into place using an antegrade approach through the fermoral artery (not shown) to the ascending aorta 32 (Fig. 2).

Once cannular catheter 20 is located in ascending aorta 32 above native aortic valve 34, the balloon catheter 26 is deployed (Fig. 3) to place the valve/stent combination 36 in the correct anatomical position so that valve 30 is above aortic valve 34 (Fig. 4) and below coronary arteries 38 so that the openings to coronary arteries 38 are unobstructed. When the valve/stent combination 36 is correctly placed, the balloon 29 is inflated to expand the stent scaffolding 28 and force the stent system 28 against the inner walls of ascending aorta 32 to anchor valve 30 in place. After balloon 29 is deflated and balloon catheter 26 is removed, the stent 28 remains locked in place. The stent lattice 28 may extend into descending aorta 32 or branch vessels (not shown) to further support and secure valve 30 in place.

Once the valve and stent combination 36 is in place, the balloon 29 is deflated and balloon catheter 26 is retracted into cannular catheter 20. Both catheters 26 and 20 are removed from aorta 24 through the fermoral artery (not shown).

Simultaneously with placement of the valve/stent combination 36, the fermoral vein would be accessed and cannulated to guide a balloon catheter into the left ventricle using a retrograde approach to perform a valvoplasty by inflating the balloon within the aortic valve. The purpose of the valvoplasty is to force the aortic valve open to relieve the pressure gradient between the left ventricle 40 (Fig. 5) and aorta 24. Visualization to place the catheters within the aorta 24 and left ventricle 40 would be accomplished using

continuous roentgenogram and ultrasound techniques, such as intracardiac echocardiography (ICE) or fluoroscopy, which are known in the art.

Use of this valve/stent combination 36 precludes removal of the native aortic valve 34. The focus would instead be upon debulking of the native aortic valve 34. The main purpose is abolition of the resting gradient. The techniques employed would attempt to achieve a large effective aortic valve area regardless of the functioning of the native aortic valve 34 post-procedure because an artificial aortic valve 30 designed to prevent aortic regurgitation would be in place. Aortic valve 30 is designed not to hinder the ejection of blood from the left ventricle, and to minimize the aortic regurgitant volume. The techniques used to debulk the native aortic valve may include positioning of an Er-YSGG percutaneous laser to decalcify the valve and repeat balloon aortic valvuloplasty. If this is not effective then high frequency ultrasound percutaneously applied to the aortic valve may be necessary.

These techniques have been shown to be highly effective at producing debulking and preventing restenosis and increasing the effective aortic valve orifice area. However, they produce tremendous aortic regurgitation. This would not be a problem for the unattached valve 30 which would work as disclosed below for aortic regurgitation.

If these techniques do not produce the desired result of increasing the effective aortic valve orifice area then a host of options are still available. For example, two rings may be guided onto both the aortic and ventricular sides of the native aortic valve and pneumatically sealed together. Then expandable and retractable biotomes may be percutaneously placed for controlled dissection of the native aortic valve. The biotomes may be used for primary resection without stabilizing rings, but there would need to be a stabilization mechanism for the native aortic valve. Another such mechanism could employ the use of a micro screw into the native valve, which would act as an anchor to guide a biotome onto the native valve. Then the biotomes would take small snips in a controlled fashion off of the native valve. This would gradually increase the effective orifice area. Because the artificial valve is not anchored or dependent upon the native valve for its function, this technique could be easily reapplied, if the native valve were to restenose,

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.