PERCUTANEOUS AORTIC VALVE REPLACEMENT

The aortic valve undergoes a series of changes based upon the initial structure at birth and the dynamic stresses, which it has to undergo daily. The trileaflet aortic valve will not become stenotic usually until the 7th decade unless infectious processes are introduced sooner. The incidence of aortic stenosis can reach between 2 to 9 % in this age range. The average mortality rate at all ages is 9% /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. The mortality of octogenarians has been reported as high as 20% for aortic valve replacement that can preclude a reasonable attempt at the therapy of choice, which is surgical replacement.

In an attempt to formulate an effective therapy for this class of patients, I have designed a series of devices, which can be placed nonsurgically so as to minimize the risk to the patient during the procedure. This procedure involves novel as well as known equipment and techniques.

The first in a line of options involves the placement of an aortic valve incorporated within a stent. This device would be anchored in the ascending aorta with further support supplied in branch vessels or descending aorta as seen necessary by the stress forces placed upon the artificial valve and calculated before the procedure (please see appendix1). The valve would be connected to the stents by serially connected rods. This design would displace the forces placed upon the artificial/biomechanical/bioprosthetic valve across a large surface area. Placing the device nonsurgically eliminates the need for bypass pump or sternotomy for placement. FIGURE 1. There are several variations to the valve design that can be utilized using these techniques and concepts. The first is the umbrella shaped valve, which would be placed in a position above the native valve, and when it collapses, would seal the opening between the aorta and left ventricle. This would also make it ideal for those patients who primarily have aortic regurgitation. The hinges can be of several types: (in order to produce as much laminar flow characteristics as possible) 1. Stainless steel rods enveloped within a rubber or plastic polymer that would withstand

sheer stresses with opening and closing; 2. Rubber and plastic polymer with the thickest portion at the bases and the narrowest portions at the center so that it folds during systolic contraction of the left ventricle. The tip of the valve would be of a semicircular design to permit the much desired laminar flow characteristics of the aortic valve. This would decrease the shear stress placed upon the aortic root and ascending aorta. The design may also incorporate a semi circular configuration opposing the sinuses of valsalva so as to disperse the stress upon the aortic valve along a larger surface area and to maximize the flow characteristics to the coronary arteries. This valve would be placed within a catheter system. However a steering and placement mechanism, incorporating a connection of removable rods guided by a half ball configuration, may be necessary. The femoral artery would be accessed and cannulated. The femoral vein would be accessed and cannulated. Both an antegrade and retrograde approach would be used to place the stent/valve combination within the right anatomical position. The visualization would utilize continuous roentgenogram and ultrasound techniques, which are currently available. The most important visualization tool would be ICE (intracardiac echocardiography). In this valve model, direct connection of the valve to the aortic root would not be utilized unless the direction of the jet from the aortic valve made it necessary. The procedure would involve inflation of balloons within the aortic valve and ascending aorta to deploy the stent/valve combination. If traditional valvuloplasty does not produce significant enough opening of the aortic valve and relieve the gradient between the left ventricle and aorta then a series of further steps may be required.

Removal of the native aortic valve would not be necessary. The focus would instead be upon debulking of the native aortic valve. The central theme would hinge upon 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 valve post-procedure because an artificial valve designed to prevent aortic regurgitation would be in place. The valves are designed not to hinder the ejection of blood from the left ventricle, and to minimize the aortic regurgitant volume. These techniques may include the positioning of an Er-YSGG percutaneous laser to decalcify the valve and repeat balloon aortic valvuloplasty. If not effective then high frequency ultrasound percutaneously applied may be necessary. These techniques have been shown to be highly effective at producing debulking and preventing restenosis. However, they produce tremendous aortic regurgitation. This would not be a problem for the unattached valve which would work as stated previously for aortic regurgitation. If the desired

results were not seen then a host of options are still available; for example, two rings could be guided onto both the aortic and ventricular sides of the native aortic valve and pneumatically sealed together. Then expandable and retractable biotomes could be percutaneously placed for controlled dissection of the native aortic valve. Along this concept, the biotomes could be used for primary resection without stabilizing rings, but there would need to be a stabilization mechanism. 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. Excitingly, 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, without compromising the artificial valve. A tremendous advantage of this procedure would be its independence from a need for a percutaneous bypass pump.

The second valve design could be best described as a conical design. It would be composed of 16 to 32 individual rubber/plastic/metal plates, which would be interconnected by resistant fabric. **Figure 2** shows how this valve would be connected together. It would be placed in direct opposition of the native aortic valve. It would expand during systole and collapse during diastole. It would also be anchored along the aortic root wall with connecting rods to the ascending aortic stents. The rods would be placed between the right and left coronary ostia tangentially along the sinus of valsalva. In this design there would not be any intraluminal rods within the ascending aorta as with the umbrella design. The techniques described above to relieve the aortic stenosis would also be applicable to this valve. This valve however may not be the best valve for isolated aortic regurgitation given the direct placement of the valve over the native valve may impede opening and create an outflow obstruction. However, given the curved and redundant nature of this valve, and the fact that it centralizes the ejection jet from the left ventricle, it may produce the most laminar flow characteristics and the least hematologic sequelae. The edges may need to have a loose rim of pliable material, which act as a flap valve, to help reduce peri-valvular leaks (See appendix). To minimize components and to aid in miniaturizing the device for delivery, the connecting cones can be reduced to 2 - 4 interconnecting rods, which are draped in a sheet of fibrous polymer (See appendix).