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 exposed sooner. The incidence of aortic stenosis can reach between 2 to 5 % at these ages. 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 precludes a reasonable attempt at the therapy of choice.

In an attempt to formulate therapy for this class of patients I have designed a series of devices which can be placed noninvasively so as to minimize the risk to the patient during the procedure. This procedure involves Novell and 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 and calculate before the procedure. The valve would be connected to the stents by serially connected rods. This placement would displace the forces placed upon the artificial/biomechanical/bioprosthetic valve across a large surface area. FIGURE 1. There are several variations to the valve design that can be utilized using this technique. The first is the umbrella shaped valve, which would be placed in a position that was above the native valve, and when it collapsed, 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 upon enveloped within a rubber or plastic polymer that would withstand sheer stresses with opening and closing; 2. Rubber a
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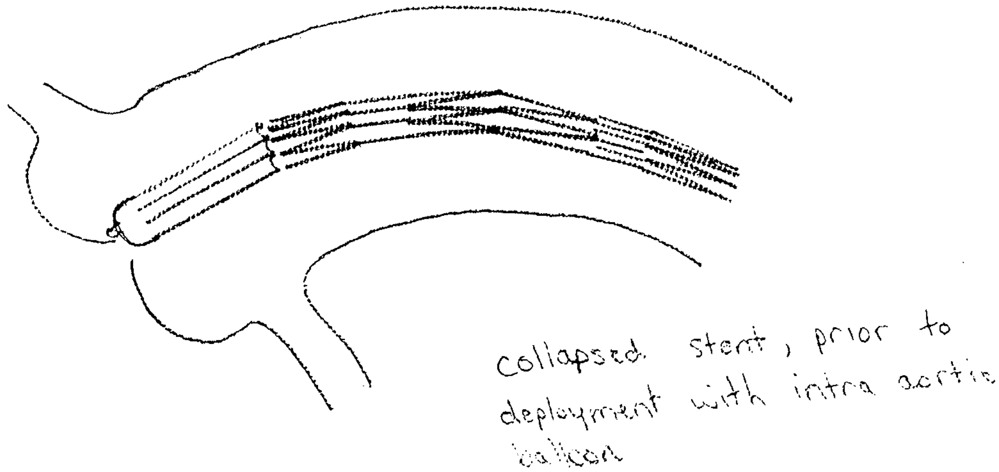
5/5/00 [signature] Tron Norrod

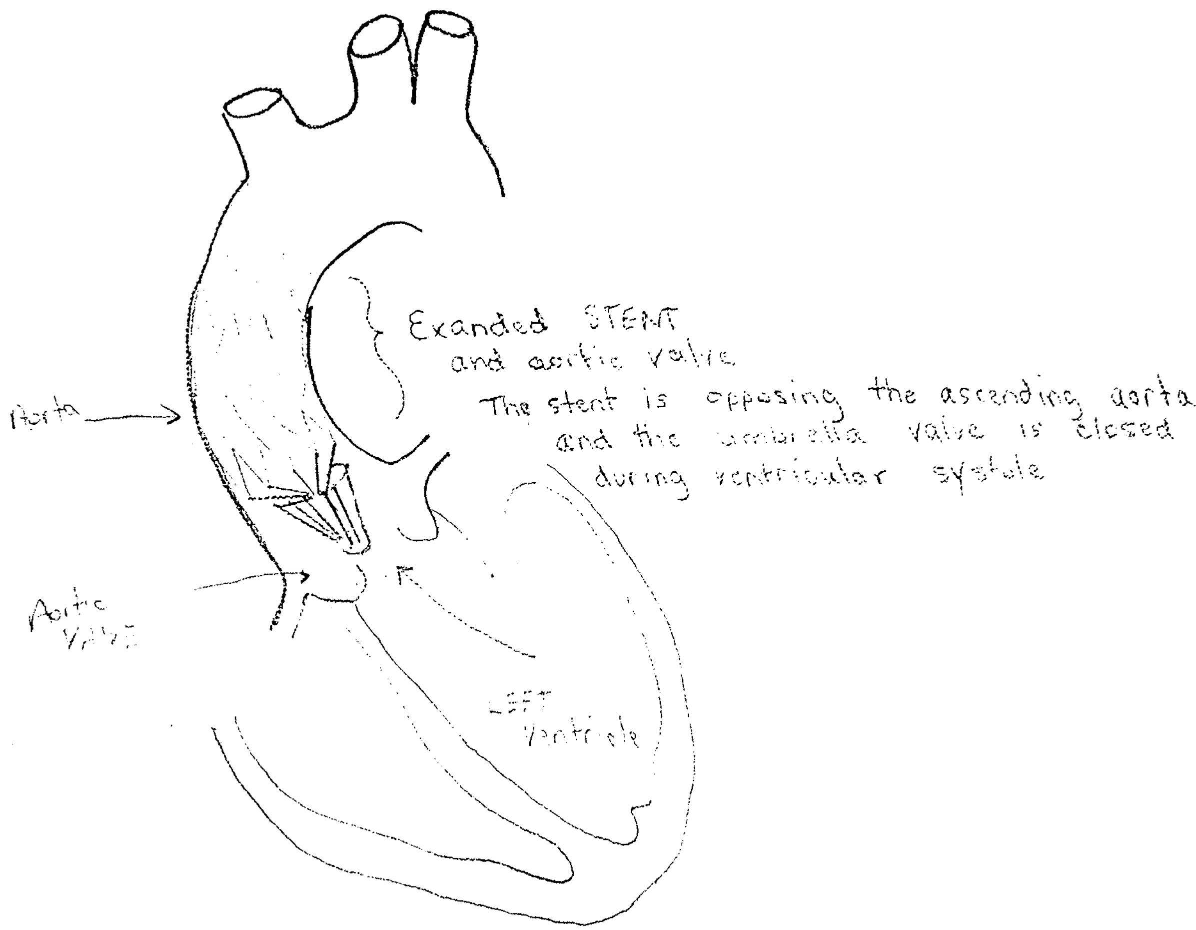
would be of a semicircular design to permit the much desired laminar flow characteristics of the aortic valve. This would decrease the shear stress placed upon the aortic root and ascending aorta. The design may also incorporate a semi circular configuration opposing the sinus's of valsalva so as to 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 place within a catheter system, which is standardly available. However a steering mechanism and placement mechanism incorporate a connection of removable rods which would be quided 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 and antegrade and retrograde approach would be used to place the stent/valve combination within the right anatomic position. The visualization would utilize continuous roentgram and ultrasound techniques, which are currently available. 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 stents/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. These would include the positioning of the 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. The technique are highly effective at producing debulking and stenosis; however, produce unwanted aortic regurgitation. This would not be a problem for the unattached valve which would work as stated previously for aortic regurgitation. If the desired result were not seen then two rings would be guided onto the aortic side of the aortic valve and the ventricular side of the aortic valve and pneumatically sealed together. Then expandable and retractable biotomes would be percutaneously placed for controlled dissection of the native aortic valve. There would not be a need for a percutaneous bypass pump during this procedure.

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. 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 least hematologic sequelae. The edges may need to have a loose rim of pliable material to help reduce peri-valvular leaks.

Other valvular designs which may prove valuable to this technique include the usage of cadaver/porcine incorporated valves placed within a percutaneously stented system and would have the benefits of favorable flow characteristics and hematological characteristics. Also tilted disk/duo disk design could be hinge and compacted within a percutaneous system to provide reasonable partition between the left ventricle and aorta. However these valves have shown to have less favorable hematological sequelae.

Figure 1


Collapsed stent, prior to
deployment with intra aortic
balloon


Exanded STENT
and aortic valve
The stent is opposing the ascending aorta
and the umbrella valve is closed
during ventricular systole
Aorta
Aortic
VALVE
LEFT
Ventricle

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