appeared to be related to the age of the donor. We believe that the methods of preparation, storage and insertion can greatly influence the long term performance of the valves.

Aortic homografts continue to be our method of choice for all patients undergoing aortic valve replacement. However we feel that continued evaluation is required to define the performance of these valves for longer periods of time.

References

Hemodynamic Results of Aortic Valvular Replacement with the Porcine Xenograft Valve

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JOHN S. DOUGLAS, JR., M.D., CHARLES W. WICKLiffe, M.D.,
AND ELLIS L. JONES, M.D.

SUMMARY Twenty-three patients were evaluated by cardiac catheterization two to 12 months following aortic valve replacement with the porcine xenograft valve. These hemodynamic studies established a mean peak-to-peak systolic gradient across the prosthesis of 23 mm Hg with a range of 6-58 mm Hg. The mean effective orifice area was calculated to be 1.25 cm². The effective orifice area increased with increasing valve size from 0.99 cm² for the 19 mm prosthesis to 1.44 cm² for the 25 mm prosthesis. While in general the hemodynamics of the porcine xenograft valve are comparable to other available prostheses, the exceedingly small orifice areas (0.99 cm² and 1.03 cm²) calculated for the 19 mm and 21 mm prostheses render their use inadvisable.

SINCE THE ERA of prosthetic cardiac valves was opened in 1952 with the implantation of the caged ball prosthesis in the thoracic aorta by Hufnagel,, active investigation of new prosthetic models has continued because of dissatisfaction with the hemodynamic characteristics, the durability, or the thrombogenicity of previously available prostheses. Among the prosthetic valves presently under clinical investigation is the porcine xenograft aortic valve (fig. 1). This prosthesis is a composite tissue valve composed of porcine aortic leaflets mounted on a flexible stent and pretreated with a tanning agent (glutaraldehyde). The glutaraldehyde produces a cross-linkage between the collagen molecules and thus increases tissue strength. While the ease of implantation and the very low thrombogenicity of this particular prosthesis have been substantiated by previous investigations, its long-term durability remains unproven and its hemodynamic characteristics in the aortic position are untested. The present study defines the hemodynamic characteristics of this prosthesis in the aortic position.

Methods

Patient Population

The study population consisted of 23 patients who had aortic valve replacement with the porcine xenograft aortic valve at Emory University Hospital between July 1974 and July 1975. The patients were selected from the total group of patients receiving the porcine xenograft valve only on the basis of their willingness to participate in this study.

In 14 of these 23 patients valve replacement was performed for amelioration of calcific aortic stenosis; three patients had a mixed valve lesion with thickened, calcific, yet incompetent, leaflets; and only six patients had predominant aortic regurgitation. The valvular calcification extended into the anulus in five of the patients. Two of these patients, in addition, had a heavy bar of calcium extend from the anulus into the anterior leaflet of the mitral valve. Debridement of the calcium was successful in every case and in no instance did residual calcium hinder prosthesis implantation.

Nineteen patients were asymptomatic and in functional class I at the time of the postoperative hemodynamic evaluation. Three patients were in functional class II and one was in functional class III. The average age of the patients with aortic stenosis was 58 years, while the patients with aortic regurgitation and mixed valve lesions averaged 38 years and 42 years, respectively.

Hemodynamic Evaluation

These twenty-three patients were evaluated by left and right cardiac catheterization two to 12 months after valve replacement in order to establish the effective orifice area of the prosthesis and to determine the degree of regurgitant flow across the prosthesis during diastole.
Figure 1. Aortic outflow (A) and inflow (B) views of the Hancock porcine xenograft valve, Model 242.

All catheters were inserted via the Seldinger technique.9 A pigtail or multipurpose (Cordis A-2) catheter was positioned in the left ventricular chamber by crossing the prosthetic valve in 21 patients and by the transeptal approach in two patients. A second (multipurpose) catheter was positioned in the ascending aorta. The systolic gradient was established by measuring simultaneous equisensitive pressures from the ascending aorta and left ventricle both at rest and during exercise using a hand pedal ergometer. The exercise pressures were recorded during the third minute of sustained maximal exercise. Thermodilution cardiac outputs were calculated in conjunction with these pressure recordings. The mean pressure gradient was obtained by planimetric integration of the area between the simultaneously recorded left ventricular and aortic phasic pressure tracings during systole. These results were then incorporated into the formula of Gorlin and Gorlin10 to obtain the effective orifice area of the prosthesis.

After establishing the presence of a left ventricular outflow gradient, the catheter positioned in the left ventricular chamber was gradually withdrawn across the prosthesis until its tip lay adjacent to the tip of the catheter positioned in the ascending aorta. The recording of simultaneous equisensitive pressures from these two catheters during this pullback maneuver established that the gradient was valvular rather than subvalvular or supravalvular.

The degree of regurgitant flow was determined by supravalvular aortography and graded 1 to 4+ on the basis of the criteria set forth by Cohn et al.8

Results

The hemodynamic data accumulated on the 23 patients are presented in table 1. The mean peak to peak systolic gradient of 23 mm Hg with a range of 6–58 mm Hg indicates that postoperatively all patients would be defined as having mild to moderate aortic stenosis. A comparison of the mean preoperative and postoperative gradients in those patients receiving a porcine valve for amelioration of aortic stenosis, however, reveals a 65 mm Hg reduction in resting transvalvular gradient following valve replacement. The reduction in the peak to peak systolic gradient with valve replacement ranged between 18 and 94 mm Hg. The smallest reduction in gradient (18 mm Hg after implantation of a 19 mm prosthesis) was recorded in the only patient who remained in functional class III following valve replacement.

A more precise method of determining the degree of obstruction of left ventricular outflow offered by the prosthesis is to calculate the effective orifice area (table 1). Comparison of the mean calculated orifice areas for the various size prostheses suggests that the effective orifice area becomes progressively larger with increasing valve size. This trend toward lessening the degree of obstruction of left ventricular outflow with increasing valve size is confirmed by matching the calculated valve area for individual patients against the designated valve size for that particular patient (fig. 2). This plot reveals a variation in the effective orifice areas for any designated valve size resulting in overlap of the effective orifice areas among different sizes.

The other hemodynamic parameter evaluated in these patients was the degree of regurgitation flow across the prosthesis. Eight of the 23 patients had evidence of regurgitation, but only one had a regurgitant flow as great as

<table>
<thead>
<tr>
<th>Valve size (manufacturer's designation)</th>
<th>Average gradient (mm Hg)</th>
<th>Valve area (cm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rest Peak</td>
<td>Rest Mean</td>
</tr>
<tr>
<td>19 mm (N = 3)</td>
<td>28</td>
<td>(21)</td>
</tr>
<tr>
<td>21 mm (N = 6)</td>
<td>22</td>
<td>(18)</td>
</tr>
<tr>
<td>23 mm (N = 7)</td>
<td>19</td>
<td>(16)</td>
</tr>
<tr>
<td>25 mm (N = 6)</td>
<td>19</td>
<td>(17)</td>
</tr>
<tr>
<td>27 mm (N = 1)</td>
<td>20</td>
<td>(13)</td>
</tr>
<tr>
<td><strong>Total Group</strong></td>
<td><strong>23</strong></td>
<td><strong>(18)</strong></td>
</tr>
<tr>
<td><strong>Mean</strong></td>
<td><strong>6–58</strong></td>
<td><strong>(4–38)</strong></td>
</tr>
<tr>
<td><strong>Range</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
end-diastolic pressure (LVEDP) following operation and an improvement in functional class in all but one patient.

**Discussion**

While this study establishes that the porcine xenograft valve affords significant hemodynamic improvement for patients with severe aortic valvular disease, it also indicates that a degree of left ventricular outflow obstruction exists postoperatively. A postoperative gradient of some degree would be expected from the prosthesis structure. As is the case with all aortic prostheses, implantation of the xenograft aortic valve narrows the left ventricular outflow tract so that its measured diameter is reduced by the width of the prosthesis base and sewing ring. Moreover, the effective orifice area of the prosthesis itself, as determined in this study, is significantly less than the theoretical valve area which is calculated from the measured orifice diameter of the prosthesis (table 2). This reduction probably reflects, in part, the conical shape of the valve. The porcine valve assumes the shape of a truncated cone with the stents slanting inward as they extend upward from the valve anulus. An additional obstructive feature of this prosthesis might be the muscular shelf included at the base of the right coronary leaflet. The width of the muscular shelf is variable and the pliability of this leaflet seems related to the proportion of muscle to cusp tissue. Upon recognition of the small effective orifice areas for the smaller size valves, as recorded in this study, Hancock Laboratories has begun to discard those valves with a larger proportion of muscle tissue in hopes of improving their hemodynamic performance (personal correspondence from Hancock Laboratories).

While recognition of the obstructive nature of this particular prosthetic model is important, this characteristic must be evaluated by comparison with other currently available prostheses. Table 3 presents the published data on the mechanical prostheses most often implanted in the aortic position. A comparison of these results with our data reveals that the effective orifice area for the porcine valve is com-

---

**TABLE 2. Current Porcine Aortic Valve Prosthesis**

<table>
<thead>
<tr>
<th>Manufacturer's size designation</th>
<th>Tissue anulus diameter range (mm)</th>
<th>Orifice area range (cm²)</th>
<th>Effective orifice area (cm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>19 mm</td>
<td>19.0-19.9</td>
<td>1.5 -1.74</td>
<td>0.99</td>
</tr>
<tr>
<td>21 mm</td>
<td>21.0-21.9</td>
<td>2.0 -2.24</td>
<td>1.03</td>
</tr>
<tr>
<td>23 mm</td>
<td>23.0-23.9</td>
<td>2.5 -2.74</td>
<td>1.29</td>
</tr>
<tr>
<td>25 mm</td>
<td>25.0-25.9</td>
<td>3.75-3.99</td>
<td>1.44</td>
</tr>
</tbody>
</table>

**TABLE 3. Prosthetic Aortic Valves—Postoperative Hemodynamics**

<table>
<thead>
<tr>
<th>Valve type</th>
<th>No.</th>
<th>Average gradient (mm Hg)</th>
<th>Average valve area (cm²)</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starr-Edwards 1000</td>
<td>10</td>
<td>21</td>
<td>1.5</td>
<td>Britsow et al.⁹</td>
</tr>
<tr>
<td>Starr-Edwards 2300</td>
<td>8</td>
<td>41</td>
<td>0.92</td>
<td>Kloster et al.¹⁰</td>
</tr>
<tr>
<td>Starr-Edwards 2310</td>
<td>46</td>
<td>17.5</td>
<td>1.43</td>
<td>Rodriguez et al.¹¹</td>
</tr>
<tr>
<td>Starr-Edwards 2310</td>
<td>15</td>
<td>15</td>
<td>1.5</td>
<td>Kloster et al.¹²</td>
</tr>
<tr>
<td>Smeloff-Cutter</td>
<td>7</td>
<td>19</td>
<td>1.36</td>
<td>McHenry et al.¹³</td>
</tr>
<tr>
<td>Kay-Shiley</td>
<td>28</td>
<td>25</td>
<td>1.36</td>
<td>Bjork et al.¹⁴</td>
</tr>
<tr>
<td>Bjork-Shiley</td>
<td>57</td>
<td>18.7</td>
<td>1.37</td>
<td>Starek et al.¹⁵</td>
</tr>
<tr>
<td>Lillehei-Kaster</td>
<td>26</td>
<td>37</td>
<td>1.25</td>
<td>Morris et al.</td>
</tr>
</tbody>
</table>
TABLE 4. Effective Orifice Area

<table>
<thead>
<tr>
<th>Aortic diameter of prosthesis</th>
<th>Bjork12</th>
<th>Lillehei14</th>
<th>Kaster</th>
<th>Hancock</th>
</tr>
</thead>
<tbody>
<tr>
<td>21 mm</td>
<td>1.30 ± .25</td>
<td>1.30 ± .23</td>
<td>1.03 ± .19</td>
<td></td>
</tr>
<tr>
<td>23 mm</td>
<td>1.70 ± .49</td>
<td>1.40 ± .24</td>
<td>1.29 ± .26</td>
<td></td>
</tr>
<tr>
<td>25 mm</td>
<td>2.2 ± .5</td>
<td>1.90 ± .31</td>
<td>1.42 ± .23</td>
<td></td>
</tr>
</tbody>
</table>

Another feature common to the ball valve prosthesis is a mean systolic gradient greater than the peak systolic gradient. This unusual relationship reflects the fact that the pressure gradient is present primarily in early systole presumably secondary to poppet inertia. A similar pressure relationship was noted in 6 of our 23 patients.

These gradients across the Hancock porcine valve were also examined from a time perspective (fig. 3). The comparatively small effective orifice area demonstrated in the four valves evaluated more than six months after implantation could be a coincidental finding or reflect either improved surgical technique or progressive stenosis of the prosthesis. Although the only change in our surgical technique was the adoption of Teflon felt pledges for buttressing, the fact that three of these four patients, versus only two of the remaining eight patients on the graph, received their valves early in our surgical experience suggests improved surgical technique as a possible contributory factor.

While clinical investigation of the porcine valve must be continued to resolve the issue of its long term durability with regard to both tissue degeneration and alteration of leaflet pliability, the comparatively good hemodynamic results with the larger sized valves coupled with the low incidence of thromboembolic complications makes it a highly acceptable prosthesis for aortic valve replacement. The small effective orifice areas for the 19 mm and 21 mm porcine valves, however, argue against the continued use of these small sizes.

References
7. Goring R, Goring SG: Hydraulic formula for the calculation of the area of the stenotic mitral valve, other cardiac valves and central circulatory shunts. I. Am Heart J 41: 1, 1951

FIGURE 3. Plot of the effective prosthetic orifice areas arranged according to the months elapsing between surgery and hemodynamic evaluation.
Hemodynamic results of aortic valvular replacement with the porcine xenograft valve.
D C Morris, S B King, J S Douglas, Jr, C W Wickliffe and E L Jones

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