Aortic Replacement
Clinical Experience with a Semirigid Ball-Valve Prosthesis

By ALBERT STARR, M.D., M. LOWELL EDWARDS, B.S., COLIN W. MCCORD, M.D., and HERBERT E. GRISWOLD, M.D.

COMPLETE valvular replacement is the only feasible method for treatment of many cases of aortic valvular disease. While the long-term results will not be known for some time, the prognosis without operation, in carefully selected patients, is so poor as to justify this approach. Our total experience, consisting of a group of 16 such patients undergoing aortic replacement with the ball-valve prosthesis in various stages of development, forms the basis of this preliminary report.

Flexible leaflets of porous or nonporous materials, as single units or in tricuspid assembly, have been used for aortic replacement during the past few years, with satisfactory results. Harken has reported on the use of an aortic ball-valve prosthesis which has not yet gained widespread use.1 Engineering experience gained from the development of the mitral ball valve in this laboratory and the excellent long-term results following its clinical use prompted a re-evaluation of this type of prosthesis in the aortic root.2,3

The Prosthesis

The prosthesis currently used is shown in figure 1. Construction materials are identical to those used in the mitral ball valve. It consists of a silicone rubber ball enclosed in a highly polished cage of Stellite 21, a Vitalium-like alloy. Fixation in the first five clinical implantations was afforded by a tightly knitted short Teflon cloth sleeve which projects upward from the prosthesis. It was recognized, however, that a more compressible sewing margin would greatly facilitate insertion by allowing easy passage of the prosthesis into the decompressed aorta, and that following release of the aortic clamp, this margin should be sufficiently expansile to allow a good fit in the distended aorta. Accordingly, in all subsequent operations, the important features of the current sewing ring were employed. These consist of a more loosely knit, and hence more elastic, cloth pressed into an accentuated, slightly lengthened, conical sleeve.

The external diameter of each size may vary by as much as 0.2 to 0.3 inches, depending upon the size and the forces acting upon it. The semirigid nature of the prosthesis, in addition to facilitating insertion, has allowed a reduction in the number of different sizes necessary for dog implantation. Three or four sizes will suffice to cover the entire range for most patients. Intermediate sizes may offer some advantages in permitting the maximum orifice for flow in a given aortic root, but are not essential for patient survival. The design of the cloth margin as an upward projecting sleeve rather than as a simple ring also affords an immediate seal between sutures.

While the change in the fixation ring was a critical factor in reducing operative difficulties, other modifications were subsequently made involving the body of the prosthesis. These consisted of the streamlining of the inlet and outlet faces, shortening of the cage, reduction in the thickness of the struts, and adoption of a three-strut design. The reduction in the number of struts from four to three facilitates insertion by allowing more room for the tying of knots. The positioning of the prosthesis with a strut at each commissure ensures that there will be no impingement of this structure upon the coronary ostia.

The most radical departure from the mitral
Figure 1

The current aortic ball-valve prosthesis. A. Inlet face showing the three projections for preventing prolapse of the ball. B. Outlet face showing streamlined design. C. Group of the smaller-sized valves and holder. Three larger sizes complete the set.

prosthesis in body design has been the development of a double-seating mechanism for the current aortic ball valve (fig. 1) used in patients 10, 11, 14, 15, and 16. The purpose of this design change is to allow the use of the smallest possible ball with the largest possible valvular orifice. A bloodtight seal is produced by a circular seat similar to the mitral prosthesis, except that the orifice-size to ball-diameter ratio is increased from 0.8 to 0.91, and the angle of the seat is more acute to the center line. Prolapse of the ball through the seat during valvular closure is prevented by a secondary seat produced by three projections into the orifice. The projections are designed to prevent prolapse with pressures more than 10 times the normal diastolic blood pressure, and do not take up sufficient flow area to diminish hydraulic function significantly.

Prior to its clinical use, the aortic ball-valve prosthesis was extensively tested in the dog, and long-term-survival animals are still alive more than eight months after implantation. These studies establish the feasibility of a subcoronary ball valve without the need for aortic root enlargement.4

Clinical Material

Information concerning all patients who underwent aortic replacement with the ball-valve prosthesis at this clinic is shown in table 1. Only those patients whose operations could not be postponed were selected for operation during this period of evaluation of the ball-valve prosthesis. The ages ranged from 18 to 60 years, and only three of the patients were under the age of 40. All except one were men. Four patients had pure aortic regurgitation without extensive calcification. Five had pure calcific stenosis. Seven had mixed stenotic lesions with severe calcification and with varying degrees of regurgitation. Three patients had severe congestive failure at the time of operation, despite prolonged preoperative treatment.
### Table 1

**Clinical Experience with Aortic Ball Valve**

<table>
<thead>
<tr>
<th>Patient no.</th>
<th>Age</th>
<th>Sex</th>
<th>Type</th>
<th>Date</th>
<th>Prosthesis</th>
<th>Pump time</th>
<th>Result</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>52</td>
<td>M</td>
<td>Calcific combined A.S. &amp; A.I.</td>
<td>9/20/61</td>
<td>Rigid</td>
<td>2 hrs., 12 min.</td>
<td>D</td>
<td>Died of dislocation at two weeks</td>
</tr>
<tr>
<td>2</td>
<td>40</td>
<td>M</td>
<td>Calcific combined A.S. &amp; A.I.</td>
<td>10/25/61</td>
<td>Rigid</td>
<td>3 hrs., 43 min.</td>
<td>D</td>
<td>Died of renal shutdown at two weeks</td>
</tr>
<tr>
<td>3</td>
<td>45</td>
<td>M</td>
<td>Calcific combined</td>
<td>10/26/61</td>
<td>Rigid</td>
<td>1 hr., 58 min.</td>
<td>D</td>
<td>Died of coronary embolus at eight months</td>
</tr>
<tr>
<td>4</td>
<td>55</td>
<td>F</td>
<td>Calcific pure A.S.</td>
<td>11/16/61</td>
<td>Rigid</td>
<td>3 hrs., 8 min.</td>
<td>D</td>
<td>Died of CVA at five days</td>
</tr>
<tr>
<td>5</td>
<td>59</td>
<td>M</td>
<td>Calcific pure A.S.</td>
<td>12/21/61</td>
<td>Rigid</td>
<td>4 hrs., 25 min.</td>
<td>D</td>
<td>Heart not resuscitated due to coronary disease</td>
</tr>
</tbody>
</table>

**Group II**

<table>
<thead>
<tr>
<th>Patient no.</th>
<th>Age</th>
<th>Sex</th>
<th>Type</th>
<th>Date</th>
<th>Prosthesis</th>
<th>Pump time</th>
<th>Result</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>55</td>
<td>M</td>
<td>Calcific pure A.S.</td>
<td>3/7/62</td>
<td>Semirigid</td>
<td>3 hrs., 20 min.</td>
<td>D</td>
<td>Died of erosion of aorta at six months</td>
</tr>
<tr>
<td>7</td>
<td>41</td>
<td>M</td>
<td>Calcific combined</td>
<td>3/22/62</td>
<td>Semirigid</td>
<td>2 hrs., 5 min.</td>
<td>A</td>
<td>Doing well, full activity</td>
</tr>
<tr>
<td>8</td>
<td>18</td>
<td>M</td>
<td>Pure A.I.</td>
<td>5/9/62</td>
<td>Semirigid</td>
<td>2 hrs., 15 min.</td>
<td>A</td>
<td>Doing well, full activity</td>
</tr>
<tr>
<td>9</td>
<td>52</td>
<td>M</td>
<td>Pure A.I.</td>
<td>6/7/62</td>
<td>Semirigid</td>
<td>2 hrs., 29 min.</td>
<td>A</td>
<td>Doing well, full activity</td>
</tr>
<tr>
<td>10</td>
<td>49</td>
<td>M</td>
<td>Calcific combined</td>
<td>8/2/62</td>
<td>Current</td>
<td>2 hrs., 31 min.</td>
<td>A</td>
<td>Doing well, convalescing</td>
</tr>
<tr>
<td>11</td>
<td>38</td>
<td>M</td>
<td>Calcific combined</td>
<td>8/15/62</td>
<td>Current</td>
<td>3 hrs., 12 min.</td>
<td>A</td>
<td>Doing well, convalescing</td>
</tr>
<tr>
<td>12</td>
<td>60</td>
<td>M</td>
<td>Calcific A.S.</td>
<td>8/21/62</td>
<td>None</td>
<td>3 hrs., 57 min.</td>
<td>D</td>
<td>Both coronaries torn by cannulas duct; atherosclerosis</td>
</tr>
<tr>
<td>13</td>
<td>31</td>
<td>M</td>
<td>Pure A.I.</td>
<td>8/22/62</td>
<td>Semirigid</td>
<td>2 hrs., 14 min.</td>
<td>A</td>
<td>Doing well, convalescing</td>
</tr>
<tr>
<td>14</td>
<td>46</td>
<td>M</td>
<td>Pure A.I.</td>
<td>8/29/62</td>
<td>Current</td>
<td>2 hrs., 38 min.</td>
<td>A</td>
<td>Postoperative, no complications</td>
</tr>
<tr>
<td>15</td>
<td>44</td>
<td>M</td>
<td>Calcific combined</td>
<td>9/6/62</td>
<td>Current</td>
<td>3 hrs., 15 min.</td>
<td>A</td>
<td>Postoperative, no complications</td>
</tr>
<tr>
<td>16</td>
<td>45</td>
<td>M</td>
<td>Calcific bicuspid</td>
<td>9/13/62</td>
<td>Current</td>
<td>2 hrs., 25 min.</td>
<td>A</td>
<td>Postoperative, doing well</td>
</tr>
</tbody>
</table>

*All group II patients received the semirigid prosthesis. Those prostheses with the latest, streamlined, body changes are described as "current." A.S., aortic stenosis; A.I., aortic insufficiency; D, died; A, alive; CVA, cerebral vascular accident.
(patients 3, 7, 14). Seven had congestive cardiac failure that responded to medical measures prior to operation (patients 1, 2, 8, 9, 10, 11, 15). All patients were severely incapacitated by dyspnea on exertion or angina and all except patient number 16 were unable to work.

All patients had right- and left-heart catheterizations prior to operation, except for patient number 5, who was considered too ill for such studies. At operation, this patient had severe narrowing of the left coronary ostium and only mild aortic stenosis. All patients in the stenotic or mixed group had significant gradients across the aortic valve, and most patients had elevated wedge, left atrial, or left ventricular end-diastolic pressures at rest or with mild exercise, indicating left ventricular failure.

Operative Technique

The aortic valve was exposed by means of high-flow cardiopulmonary bypass, generalized hypothermia to 30°C, and left ventricular apical vent. The operation is best done in the beating heart with continuous coronary perfusion. If this is not possible, the intermittent coronary perfusion of ice-cold blood with periods of anoxia no longer than 15 minutes is preferable to prolonged cold anoxic arrest. Resection poses no problem if the attached margin of the leaflet is thin and delicate. If massive calcification is present, care must be taken to prepare a clean bed, free of projecting material, for the prosthesis. This is best done by incising the intima at the leaflet-aortic junction and by bold, sharp, and blunt dissection, removing the leaflet in one piece.

The selection of a prosthesis that will pass easily into the aortic root is of prime importance. If the prosthesis is too large, there may be leak or coronary occlusion due to malposition, difficulty in closing the aortotomy, or late pressure necrosis. The proper position of the prosthesis is such that the Teflon cloth margin lies below the level of the aortic annulus in the commissure area.

Double-armed 0 silk sutures are passed through the rim or residual leaflet, including annulus, to within 5 or 6 mm. of the commissures. Six to nine sutures are required for each leaflet, and when they are all in place, each arm is passed through the prosthesis from outer to inner surface. The valve is then slid down into place and the sutures tied and cut. The need for additional sutures is carefully assessed before closure of the aortotomy. Following the establishment of a satisfactory seal, the apex is elevated to flush out air, and the apical vent is removed.

Results

The first five patients (group I) who were operated upon with the early, completely rigid prosthesis died. Patient number 1 expired of dislocation when all of the 3-0 silk sutures used to anchor the prosthesis tore, leaving the knots on the prosthesis and the loops in the aortic root. Patient number 2 died of renal shutdown related to hemolysis. Patient number 3 died suddenly, while at work, eight months after operation. At autopsy, the prosthesis was seen to have been placed too high, and the clot which formed on the cloth margin extended directly into the left coronary orifice. Patient number 4, after a stormy few days, became comatose and died of bilateral carotid thrombosis. Patient number 5 had narrowing of the left coronary orifice to pinpoint size by atherosclerosis and could not be resuscitated.

Following this experience, aortic operation was deferred until the previously outlined changes in the prosthesis were made. In 11 subsequent patients (group II), there was one operative death and one late death. The operative death occurred in a 60-year-old patient (number 12) with severe coronary arterial disease. During resection of the valve, both coronary arteries were torn off the aorta by the coronary cannulas. Since aortic replacement was planned for this patient, he is included as an operative death. The late death (number 6) occurred at another hospital six months after operation. Autopsy revealed erosion of the prosthesis through the noncoronary sinus into the right atrium. This patient had a small aortic root with congenital aortic calcific stenosis. The smallest-sized prosthesis then available was too large and was impacted into place with great difficulty. Smaller sizes were subsequently designed and used in similar patients.

With the exception of patient number 12, in whom resuscitation was not possible, all patients in group II were removed from cardiopulmonary bypass with ease, and during their subsequent course had evidence of an excellent cardiac output. Pressure measurements across the prosthesis, obtained by needle puncture at the time of operation, revealed no significant gradient even with the smaller
sizes. Tracheotomy and artificial ventilation were performed prophylactically in one patient (number 7). Transient atrial fibrillation or flutter with 2:1 block occurred in a few patients, but responded to appropriate treatment. All patients are free of cardiac symptoms, despite the severity of their preoperative disease.

The patient is not aware of the open and closure sounds of the prosthesis, nor is the prosthesis audible without a stethoscope. While no murmurs are present in the immediate postoperative period, a short systolic ejection murmur becomes evident with increased activity after a few days. This murmur is absent, or less intense, with the current, more streamlined, prosthesis.

The major factor in the improvement of results following development of the semirigid prosthesis is the ease with which it can be inserted deep into the aortic root. However, during the course of this experience, there were other modifications in operative techniques. The management of coronary perfusion during the aortotomy was improved. The prophylactic use of mannitol in the group II patients allowed prolonged perfusion without fear of renal shutdown. Hence, if continuous coronary perfusion was not possible, time was available for intermittent perfusion while other manipulations in the aortic root could be safely postponed.

Anticoagulant treatment was routinely used following the coronary embolus described in patient number 3. Although this occurred following improper implantation of the earlier-type, rigid prosthesis, it would appear prudent to use anticoagulant treatment until more information is obtained concerning the incidence of thrombotic complications. Since July, 1962, all patients have received such treatment with heparin in the immediate postoperative period (started on the sixth day) and oral medication subsequently.

Summary
A ball-valve prosthesis for aortic replacement has been described which, while it is similar to the mitral ball valve in terms of materials and construction, is quite different in sewing margin and internal geometry. Implantation is greatly facilitated by the flexibility of the prosthesis in terms of external diameter, and by the availability of a full set of varying sizes for obtaining a proper fit. Widening of the aortic root by patch grafting has not been necessary. Long-term survival has been achieved in the dog, and early clinical results are most promising.

While the selection of the ideal aortic valvular replacement must await further experience with all types of prostheses, continued evaluation of the ball valve in the aortic position, in carefully chosen patients, is indicated.

Acknowledgment
The authors wish to thank Mr. R. E. Astle, Mr. Donald P. Shiley, and the staff of the Edwards Laboratories, Santa Ana, California, from whom the prostheses used in the study were obtained.

References
Aortic Replacement: Clinical Experience with a Semirigid Ball-Valve Prosthesis
ALBERT STARR, M. LOWELL EDWARDS, COLIN W. MCCORD and HERBERT E. GRISWOLD

Circulation. 1963;27:779-783
doi: 10.1161/01.CIR.27.4.779
Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 1963 American Heart Association, Inc. All rights reserved.
Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circ.ahajournals.org/content/27/4/779

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published in Circulation can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial Office. Once the online version of the published article for which permission is being requested is located, click Request Permissions in the middle column of the Web page under Services. Further information about this process is available in the Permissions and Rights Question and Answer document.

Reprints: Information about reprints can be found online at:
http://www.lww.com/reprints

Subscriptions: Information about subscribing to Circulation is online at:
http://circ.ahajournals.org/subscriptions/