Roentgenographic Identification of Starr-Edwards Prostheses

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SUMMARY
Since 1960, more than 100,000 Starr-Edwards prostheses have been inserted. In conjunction with a continuing program of bioengineering improvements which has alleviated many problems, certain complications have been associated with specific valve models. Thus, it is often useful to identify the valve model in the absence of a previous operative record. The various models of Starr-Edwards prostheses can be differentiated from plain chest roentgenograms. The identifying roentgenographic characteristics are described in this report.

Additional Indexing Words:
Starr-Edwards prosthesis  Chest roentgenogram  Cardiac surgery

Since the first successful clinical implantation of a prosthetic mitral valve by Starr in 1960, more than 100,000 Starr-Edwards prostheses have been inserted throughout the world. During this decade, a continuing program of bioengineering improvements has alleviated certain problems associated with early models, such as thromboembolism and ball variance. Concurrently, problems of cloth wear, hemolysis, and restricted poppet movement have occasionally been associated with specific valve models. Because of the large number of patients with Starr-Edwards prostheses, the mobility of patients, and the association of specific complications with certain prosthetic valve models, physicians may find it important to identify the Starr-Edwards prosthesis model in a patient whose operative history is unavailable.

This report reviews those characteristics of the various Starr-Edwards prostheses that permit their identification from standard chest roentgenograms. For each prosthesis, the roentgenographic appearance of three structures—the valve base, cage, and poppet—permits positive identification. Special studies are unnecessary unless poppet movement requires particular evaluation. (Barium-impregnated poppets are ordinarily radiolucent on the standard roentgenograms used in this report, but are detectable with high-resolution, image intensification fluoroscopy.) Engineering changes in different models are discussed briefly and are summarized in Table 1. These changes may not be synonymous with changes in radiographic appearance.

All Starr-Edwards heart valve prostheses have thus far been of the caged-ball design, with the two exceptions noted below. For the sake of brevity, reference is made henceforth to “mitral” and “aortic” prostheses, with the understanding that all mitral prosthesis models have been used for tricuspid replacement as well. The term “poppet” may refer to a ball or a disc.

Mitral Caged-Ball Prosthesis
Model 6000
This prosthesis (fig. 1), introduced in the summer of 1961, was the first generally available mitral caged-ball prosthesis; approximately 12,000 were inserted. Thromboembolic episodes are the major complications, but have not occurred after the seventh postoperative year in this clinic. Structural mechanical malfunction has not occurred, and there have been only two suspected instances of ball

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Dr. Bonchek is the recipient of Public Health Service Career Development Award HE 70035.
Supported in part by Public Health Service Training Grant HL 05693.
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### Table 1

#### Design Characteristics of Starr-Edwards Prostheses

<table>
<thead>
<tr>
<th>Model no.</th>
<th>Poppet</th>
<th>Sewing ring</th>
<th>Seat (orifice)</th>
<th>Cage (struts)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6000</td>
<td>Silicone rubber ball*</td>
<td>Flange design, Teflon knit</td>
<td>Heavy metal inflow face, concave shape</td>
<td>Four thick Stellite 21 metal struts, one-piece cage</td>
</tr>
<tr>
<td>6120</td>
<td>Silicone rubber ball*</td>
<td>Flange design, Teflon knit†</td>
<td>Less exposed metal, convex shape</td>
<td>Four thin Stellite 21 metal struts, one-piece cage</td>
</tr>
<tr>
<td>6300</td>
<td>Hollow Stellite 21 ball</td>
<td>Flange design, seamless Dacron knit‡</td>
<td>Dacron cloth-covered, convex shape</td>
<td>Four thin Stellite 21 metal struts, Dacron cloth-covered with two layers of tubular cloth; apex of cage open</td>
</tr>
<tr>
<td>6310</td>
<td>Hollow Stellite 21 ball</td>
<td>Flange design, seamless Teflon and polypropylene knit</td>
<td>Teflon cloth-covered, metal “studs” in orifice, convex shape</td>
<td>Four thin Stellite 21 metal struts, Teflon and polypropylene cloth-covered with two layers of tubular cloth; apex of cage open‡</td>
</tr>
<tr>
<td>6320</td>
<td>Hollow Stellite 21 ball</td>
<td>Flange design, seamless Teflon and polypropylene knit</td>
<td>Teflon cloth-covered; metal “studs” in orifice, convex shape</td>
<td>Four thin Stellite 21 metal struts, inner layer Teflon, outer layer polypropylene, tubular cloth covering; apex closed, one-piece cage</td>
</tr>
<tr>
<td>6500</td>
<td>Hollow Stellite 21 disc</td>
<td>Flange design, seamless Teflon knit</td>
<td>Teflon cloth-covered, convex shape</td>
<td>Four thin Stellite 21 metal struts, two-piece cage, low profile</td>
</tr>
<tr>
<td>6520</td>
<td>Ultrahigh molecular weight polyethylene disc, with titanium ring for radiopacity</td>
<td>Flange design, seamless Teflon and polypropylene knit</td>
<td>Teflon cloth-covered, convex shape</td>
<td>Low profile, four thin Stellite 21 metal struts, two-piece cage</td>
</tr>
</tbody>
</table>

#### Mitral prostheses

- **1000** Silicone rubber ball* | Teflon knit, cone shape | Heavy metal inflow face, “feet” in orifice, concave shape | Three heavy Stellite 21 metal struts, one-piece cage |
- **1200** Silicone rubber ball* | Teflon knit,† cone shape | Little exposed metal in inflow face, convex shape | Three thin Stellite 21 metal struts, one-piece cage |
- **1260** Barium-impregnated silicone rubber ball | Seamless Teflon knit, cone shape | Very little exposed metal in inflow face, convex shape | Three thin Stellite 21 metal struts, one-piece cage |
- **2300** Hollow Stellite 21 ball | Seamless Dacron‡ knit, cone shape | Dacron cloth-covered, convex shape | Three thin Stellite 21 metal struts, Dacron cloth-covered with two layers of tubular cloth; apex of cage open |
- **2310** Hollow Stellite 21 ball | Seamless Teflon and polypropylene knit, cone shape | Teflon cloth-covered, convex shape, “studs” in orifice | Three thin Stellite 21 metal struts, Teflon inner layer and polypropylene outer layer tubular cloth covering; apex of cage open‡ |
- **2320** Hollow Stellite 21 ball | Seamless Teflon and polypropylene knit, cone shape | Teflon cloth-covered, convex shape, “studs” in orifice | Three thin Stellite 21 metal struts, Teflon inner layer and polypropylene outer layer tubular cloth covering; apex of cage closed |

*Barium-impregnated poppets were occasionally supplied.
†Seamless sewing ring, 1967.
‡Changed to Teflon after May, 1968.
§Apex closed after December, 1969.
variance due to lipid infiltration of the silicone rubber ball. The identifying roentgenographic traits are: (1) A heavy valve base of "double doughnut" configuration. (2) Four struts that are thicker than those of subsequent models and are joined at the apex of the cage. (3) A radiolucent poppet. (A small number of barium-impregnated radiopaque poppets were supplied upon request.)

Model 6120
This prosthesis (fig. 2) was introduced in early 1966 with an extended cloth covering of the inflow orifice that greatly diminished the incidence of thromboembolism. Approximately 10,000 have been inserted, and this model is still being manufactured. Structural mechanical malfunction or ball variance have not been reported. The roentgenographic traits are: (1) A delicate valve base without the scalloping of the model 6120, but with a concave, perforated configuration. (2) Four thin struts which are not joined at the apex of the cage. (3) A radiopaque poppet which (in systole) seats relatively far from its equator. This latter feature is the most characteristic trait in contrast with subsequent models.

Model 6310
This prosthesis (fig. 4), introduced in the fall of 1968, was also totally cloth covered and had a Stellite poppet; approximately 4,500 were inserted. Hydraulic function was substantially improved by a "composite seat" of metal studs that projected through the cloth lining of the valve seat. This prevented excessive tissue ingrowth and allowed a larger orifice. Thromboembolic episodes have occurred in only 5% of patients, and rarely more than
1 year postoperatively. The roentgenographic traits are: (1) A delicate, concave valve base without scalloping. Perforations may or may not be apparent and the composite seat studs may be difficult to delineate. (2) Thin struts not joined at the apex. In valves manufactured after December, 1969, however, the struts were joined at the apex. (3) A radiopaque poppet which seats closer to its equator in systole. If the studs of the composite seat cannot be delineated on the X-ray, this latter feature reliably differentiates this model from the model 6300.

Model 6320

This prosthesis was introduced in the fall of 1970 and is currently in use. Only minor engineering details differentiate this valve from the model 6310, and the struts diverge slightly toward the apex. This feature is not apparent roentgenographically, and the two models are virtually indistinguishable. Since neither valve has been associated with mechanical malfunction or ball change, differentiation does not affect the management of an individual patient.

Mitral Low-Profile Prosthesis

There have been two “low-profile” Starr-Edwards valves that utilized a caged-disc instead of a caged-ball design.

Model 6500

This prosthesis (fig. 5) was first introduced in the fall of 1968 and approximately 2,500 were inserted. The cage and disc were made of Stellite 21 and were not cloth covered. Thromboembolic episodes are common, but “cocking” of the disc unrelated to thrombosis has not been reported. The roentgenographic traits are: (1) A low-profile cage with crossing struts. (2) A radiopaque poppet.

Model 6520

This prosthesis (fig. 6) was introduced in the summer of 1970 and is currently in use. The cage is made of Stellite 21 and is not cloth covered, and the poppet is ultrahigh-density polyethylene with a metal ring embedded in the periphery for radiopacity. Thus far thromboembolic complications have been rare, and mechanical malfunction has not occurred. The roentgenographic traits are: (1) A low-profile cage with crossing struts. (2) A radiolucent poppet with a faintly radiopaque ring within the poppet.
Aortic Caged-Ball Prosthesis

Model 1000

This prosthesis (fig. 7) was introduced in 1961 and approximately 10,000 were inserted. The major complications are thromboembolic episodes and ball variance which occur at any postoperative interval. The roentgenographic traits are: (1) A heavy, conical valve base with three “feet” projecting into the orifice. (2) Three thin struts which are fused at the apex of the cage. (3) A radiolucent poppet.

Model 1200

This prosthesis (fig. 8) was introduced in early 1966 and approximately 7,500 were implanted. The three “feet” were eliminated from the valve base, and the amount of metal exposed at the inflow orifice was reduced. Thromboembolic episodes continued to occur only up to 4 years postoperatively in this clinic. Documented ball variance due to lipid infiltration of the silicone rubber ball has been reported in only two patients. The roentgenographic traits are: (1) A more delicate valve base with no projecting “feet” and a tapered support at each strut junction. (2) Three thin struts that are fused at the
apex. (3) A radiolucent poppet with exceptions as discussed earlier due to the addition of barium sulfate in some models.

**Model 1260**

This prosthesis was introduced in September, 1968, and is still being manufactured; approximately 7,500 have been inserted thus far. It is similar to the model 1200, but the amount of metal exposed at the inflow orifice is reduced. Roentgenographically the valve is not readily differentiated from the model 1200 but this does not affect patient management. A barium impregnated poppet is supplied in this model.

**Model 2300**

This prosthesis (fig. 9) was introduced in the fall of 1967 and approximately 7,500 were implanted. The valve base and cage were completely cloth covered, and the hollow poppet was made of Stellite 21. Thromboembolic complications were significantly reduced in incidence and did not occur more than 1 year postoperatively in this clinic. As in the model 6300 mitral prosthesis, pressure gradients across the valve indicated compromised hydraulic...
function in some patients. Cloth tears have been reported with some frequency, but ball changes have not occurred. The roentgenographic features are: (1) A convex valve seat which may or may not appear perforated. (2) Three thin struts which are not joined at the apex of the cage. (3) A radiopaque poppet which seats far from its equator in diastole. This latter trait is the most characteristic roentgenographic feature in contrast to subsequent models.

Model 2310

This prosthesis (fig. 10) was introduced in the fall of 1968 and approximately 7,500 were implanted. Hydraulic function was improved by a “composite seat” of metal studs which projected through the cloth lining of the valve seat.

In certain model 2310 prostheses designated as “close-clearance” models and distributed for a short period in 1970, clearance between the cage and poppet was reduced. In some of these prostheses the poppet impacted in the open position after a variable interval postoperatively, and acute aortic insufficiency resulted. These “close-clearance” prostheses are not distinguishable radiographically from other model 2310 prostheses.

The roentgenographic traits of the model 2310 are: (1) A delicate, concave valve base which may or may not appear perforated. (The metal studs of the composite seat may be difficult to delineate in poor-quality films.) (2) Three thin struts which are open at the apex of the cage. After December, 1969, the struts were joined at the apex. (3) A radiopaque poppet which seats close to its equator in diastole. If the composite seat studs are not visible, this latter feature reliably differentiates this model from the 2300.

Model 2320

This prosthesis was introduced in the fall of 1970 and is currently in use. The struts diverge slightly toward the apex to increase the cage to poppet clearance, but this is not readily apparent, and this model may be indistinguishable from the model 2310 roentgenographically.

An interesting phenomenon has been observed in five patients in this clinic with model 2310 or 2320 prostheses. In standard chest X-rays of other patients, the poppet is at the valve base or apex, because the poppet is best delineated only when stationary (fig. 11A). In these five patients diastolic

Figure 11

(A) Normal poppet movement in a model 2310 aortic prosthesis. The poppet is at the apex of the cage. (B) Poppet position in systole, as seen in five patients with normal hydraulic function. The poppet strikes the apex of the cage in early systole, and then rests below the apex throughout mid-systole, due to eddy currents.
films are unremarkable, but systolic films often show the poppet in the midportion of the cage, suggesting restricted poppet movement (fig. 11B).

Cineradiography in these patients shows that the poppet does strike the apex of the cage in early systole, and then comes to rest below the apex throughout midsystole. This is attributed to eddy currents in the stream of blood that cause a "negative lift" behind the poppet due to the Bernoulli effect. No hemodynamic abnormalities were found at catheterization in two patients. A poppet which does not appear at the apex of the cage on plain roentgenograms should be assessed by simple fluoroscopy, or cineradiography for permanent documentation. Unrestricted poppet movement will ordinarily be seen.
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Circulation. 1973;47:154-161
doi: 10.1161/01.CIR.47.1.154

Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 1973 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/47/1/154

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