WEAR IN BEALL 104 PROSTHESIS/Silver, Wilson

The Pathology of Wear in the Beall Model 104 Heart Valve Prosthesis

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SUMMARY We examined 13 Beall model 104 prostheses recovered at surgery or autopsy 14 to 84½ months after insertion and observed the pattern of prosthetic wear. We defined wear as “mild” when the disc was notched but neither the metal of the struts was exposed nor the cloth seat torn. In “moderate” wear the disc was notched, the Teflon coating of the struts was worn away exposing the underlying metal but the cloth of the seat was not torn. The cloth seat was torn in “severe” wear, exposing the metal seat and causing a different pattern of disc erosion. In one case this allowed the disc to tilt into the valve lumen and, later, to escape from its cage. Most of the prostheses studied showed “moderate” or “severe” wear. We believe that some degree of wear is inevitable. Clinical signs and symptoms were not specific but a rough correlation existed between the severity of hemolysis, as indicated by serum LDH levels, and the degree of prosthetic wear. When wear was “severe,” the results of cardiac catheterization studies usually mirrored the change, but there were a few exceptions.

All patients with the Beall model 104 prosthesis may eventually develop “severe” wear, and we recommend regular reassessment with a view toward prosthetic replacement.

ALTHOUGH AN ARTIFICIAL HEART VALVE may be well designed, constructed of materials thought appropriate and be tested in the laboratory, it may behave in an unexpected fashion years after its insertion in man. When this occurs, the manufacturer either withdraws the prosthesis from use or modifies it to overcome the problem. Teflon, used both to form the disc and to coat the cage in the model 104 Beall disc valve prosthesis, wears with time and has now been replaced by pyrolytic carbon. Many patients had this model prosthesis inserted; approximately 3000 were sold between October 1969 and September 1975 (personal communication from Surgitool Division of Travenol Laboratories). Individuals with this older prosthesis thus form a special group that must be observed closely to avoid untoward events. In this paper, we present the pathology of wear in this prosthesis and discuss clinical parameters that may help a physician decide when to replace it.

Materials and Methods

At the Toronto General Hospital, between 1969 and 1973, Beall model 104 heart valve prostheses were inserted in the mitral area in 90 patients. Between 1973 and March 1977, 13 prostheses showing varying degrees of wear were studied in our laboratory. Each was examined in detail, its degree of wear established and it was photographed. Histological sections prepared from the organs of patients at autopsy were stained with hematoxylin and eosin and examined for Teflon

*Dupont tradename for a tetrafluorethylene resin

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and cloth emboli. Renal and heart sections were stained to demonstrate iron.

The clinical record from each patient was reviewed to establish the date of and indication for valve replacement; to look for evidence of mechanical dysfunction of the prosthesis revealed by symptoms, by auscultatory findings, or at cardiac catheterization; to determine the presence of excessive mechanical hemolysis indicated by serum lactic acid dehydrogenase (LDH) levels or anemia, and to find any other relevant clinical features unique to a case. In addition, we examined the left ventricular angiograms obtained at cardiac catheterization to search for unusual radiographic manifestations of prosthesis wear. Finally, in those cases coming to autopsy, we determined whether or not the worn prosthesis had caused a patient's death.

## Results

Clinical and pathological data on the 13 patients are shown in table 1. The sex and age of each at the time of prosthesis implantation are indicated. In addition to a Beall mitral valve, patients 1 and 2 had both tricuspid and aortic valves replaced while patients 6 and 11 had aortic prostheses inserted. Starr-Edwards ball valves were used for these other replacements. In patients 2, 6 and 11, all prostheses were inserted at one operation but, in patient 1, eight months elapsed between the mitral valve replacement and insertion of the Starr-Edwards prostheses. Both the Beall and Starr-Edwards prostheses were inserted to replace natural valves damaged by rheumatic valvular disease except in patient 7, who had ruptured mitral valve chordae tendineae, and patient 8, who had a prolapsed mitral valve due to myxomatous degeneration.

Table 1 shows the duration each Beall prosthesis was in situ, whether it was recovered at autopsy or surgery and the degree of wear each demonstrated. Five of the 13 patients had their prostheses removed surgically because of excessive wear. Of the remainder, two died as a direct result of prosthesis malfunction (patients 3 and 11), two died with prosthesis insufficiency as a significant contributory factor (patients 6 and 8) and, four died of causes not related to the prosthesis.

The normal Beall model 104 prosthesis has a low profile, disc-type design. The sewing ring, disc seat and the lining of the prosthesis lumen are fully covered with Dacron® velour (fig. 1A & B). The Teflon disc occluder has biconvex surfaces and, around its perimeter, a flat edge between these surfaces (fig. 1C). The struts and bars of the cage that enclose the disc are also coated with Teflon (figs. 1A & B).

By our definition, the disc edge is notched (primary notch) in "mild" wear, either at four locations, corresponding to the struts of the cage, or at multiple sites around its perimeter (fig. 2). The Teflon on the struts also wears, more on the two dependent struts situated posteriorly in the heart, and as a result, the dark underlying metal is revealed through the thinned and now translucent white Teflon coating. However, naked metal is not exposed nor is the cloth seat worn. Primary disc notching is usually more marked in "moderate" wear, producing either a cloverleaf (fig. 3A) or scalloped outline (fig. 4D). Nevertheless, the disc edge is still flat. The definitive difference between "mild" and "moderate" wear is that, in the latter, the plastic coating some or all of the struts is worn through so that the underlying metal is exposed on the luminal aspect (fig. 3B). Usually, wearing of the Teflon exposed the metal at the base of a strut but metal sometimes first appeared at its apex. When several prostheses were examined, a progression of wear exposing metal from the strut base toward its apex was observed. All prostheses showing "moderate" wear had metal exposed on the two dependent struts. The nondependent struts showed changes described above as "mild" wear, or exposed metal. Whatever the findings, wear was always more obvious on the two dependent struts. This observation, made originally on prostheses at autopsy, subsequently permitted the accurate orientation of those that had been excised surgically. The cloth seat may be frayed in "moderate" wear but is not torn.

### Table 1. Patient Data and Relationship between Prosthesis Wear and Clinical Parameters

<table>
<thead>
<tr>
<th>Pt/Age</th>
<th>Sex</th>
<th>Prosthesis recovered at</th>
<th>Duration in situ (mo)</th>
<th>Degree of wear</th>
<th>Mitral insufficiency note</th>
<th>Cardiac cath findings</th>
<th>LDH levels (normal range 50-190 ml.U./ml)</th>
<th>Hemolytic anemia</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/F /43</td>
<td>N</td>
<td>14</td>
<td>Mild</td>
<td>—</td>
<td>No MI</td>
<td>275</td>
<td>—</td>
<td></td>
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<tr>
<td>2/F /45</td>
<td>N</td>
<td>29½</td>
<td>Moderate</td>
<td>—</td>
<td>ND</td>
<td>435</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>3/F /59</td>
<td>N</td>
<td>31½</td>
<td>Moderate</td>
<td>+ (2/6)</td>
<td>ND</td>
<td>1320</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>4/F /32</td>
<td>N</td>
<td>49</td>
<td>Moderate</td>
<td>+ (2/6)</td>
<td>ND</td>
<td>790</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>5/F /57</td>
<td>S</td>
<td>60½</td>
<td>Moderate</td>
<td>+ (3/6)</td>
<td>Severe MI</td>
<td>1050</td>
<td>+ (periprosthetic)</td>
<td></td>
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<tr>
<td>6/F /61</td>
<td>N</td>
<td>66½</td>
<td>Severe</td>
<td>+ (4/6)</td>
<td>ND</td>
<td>1150</td>
<td>+†</td>
<td></td>
</tr>
<tr>
<td>7/M /69</td>
<td>N</td>
<td>67</td>
<td>Severe</td>
<td>+ (2/6)</td>
<td>ND</td>
<td>1120</td>
<td>+†</td>
<td></td>
</tr>
<tr>
<td>8/F /65</td>
<td>N</td>
<td>67½</td>
<td>Severe</td>
<td>+ (3/6)</td>
<td>Moderate MI</td>
<td>2700</td>
<td>+†</td>
<td></td>
</tr>
<tr>
<td>9/F /57</td>
<td>S</td>
<td>73</td>
<td>Severe</td>
<td>—</td>
<td>Mild MI</td>
<td>2350</td>
<td>+†</td>
<td></td>
</tr>
<tr>
<td>10/M /43</td>
<td>S</td>
<td>74</td>
<td>Severe</td>
<td>+ (3/6)</td>
<td>Moderate MI</td>
<td>900</td>
<td>+</td>
<td></td>
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<tr>
<td>11/M /56</td>
<td>N</td>
<td>78</td>
<td>Severe*</td>
<td>+ (1/6)</td>
<td>Mild MI</td>
<td>2300</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>12/F /56</td>
<td>S</td>
<td>83</td>
<td>Severe</td>
<td>+ (1/6)</td>
<td>Severe MI</td>
<td>2250</td>
<td>+</td>
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<tr>
<td>13/F /37</td>
<td>S</td>
<td>84½</td>
<td>Severe</td>
<td>+ (2/6)</td>
<td>Moderate MI</td>
<td>900</td>
<td>—</td>
<td></td>
</tr>
</tbody>
</table>

*Disc had embolized to celiac axis in this case.

†Highest serum lactic acid dehydrogenase (LDH) level nearest death or surgical removal of prosthesis recorded.

*Hemolytic anemia treated with blood transfusions.

Abbreviations: N = neutrop; S = surgery; † = present; — = absent; ND = test not done; MI = mitral insufficiency.

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*Dacron is the Du Pont tradename for a polyester fiber.*
When wear is "severe" the cloth seat is worn through and tears around part or all of the perimeter of the valve lumen on its ventricular aspect (fig. 4B & C). This exposes underlying metal, which now becomes the seat, and a right angle of metal between the seat and wall of the lumen (fig. 4B & C). If the tear is extensive, one cloth margin is freed and herniates into the prosthesis lumen and toward the atrium, effectively stenosing the lumen (figs. 4A & B). The other margin remains tethered on the seat and thrombus can accumulate between it and the adjacent metal.

Continued contact of the disc with the metal seat, and particularly with the metal angle, changes the pattern of disc wear. Its flat edge becomes worn and bevelled up to an angle of 45° (figs. 4D, 5B, and 6B). Initially, the bevelling causes a reduction of the disc diameter on the atrial surface but with time a reduction in total disc diameter occurs. The diameter is always reduced more on the atrial than the ventricular aspect of the disc (fig. 4D). Slight bevelling may be caused by a disc hitting worn Dacron velour but most is caused by it hitting the exposed metal, especially the angle. Bevelling, with a reduction in disc diameter, allows a disc to tilt into the valve lumen (fig. 5A). If this occurs, the disc develops secondary notches in its perimeter at the pivot point (figs. 5A and B, 6A and B). Tilting may permit the disc to stick in an open position. Alternatively, if the reduction in disc diameter is marked, it may escape from the cage, as occurred in patient 11, causing his death. The disc outline may be a cloverleaf (fig. 3A), scalloped (fig. 4D), or irregular shape (fig. 6A & B). Strut changes are like those described in "moderate" wear. In addition, the Teflon coating the bars of the cage may be flattened slightly but naked metal is not exposed.

Distal Teflon emboli were found as doubly refractile material incorporated in giant cells and within the lumen of small vessels (fig. 5C), in the hearts of seven of eight patients studied at autopsy and also in other organs. Presumably, cloth emboli may also occur, although none were found.

Exertional dyspnea, gradually worsening over a period of months, was the most common clinical presentation associated with prosthesis wear. This affected patients 3 through 13. Patients 1 and 2 did not have this symptom. Wear in their prostheses had not progressed sufficiently to cause regurgitation. In all patients with dyspnea a murmur of mitral insufficiency was heard. In most, it was constant from beat to beat but in one (patient 13) it varied from beat to beat. The intensity of the murmur did not always coincide with the severity of prosthesis insufficiency at cardiac catheterization (when that procedure was done) nor with the degree of prosthesis wear (table 1). For example, patient 12 had only a grade I/VI murmur yet severe regurgitation was found at catheterization and the prosthesis showed "severe" wear. In two other cases (patients 9 and 11), a Grade I murmur was associated with mild insufficiency at catheterization but both prostheses showed "severe" wear when recovered. Retrospective examination of the left ventricular angiogram (before dye injection) from patient 11 showed the disc tilting into the prosthesis lumen in a manner that could be produced by placing the eroded disc into the valve lumen at postmortem examination (fig. 5A). A careful frame-by-frame analysis of disc movement had to be done to appreciate the tilt.

Another sign of prosthesis wear was jaundice, the result of severe mechanical hemolysis. This affected two individuals (patients 6 and 7). All patients had some degree of hemolysis as indicated by elevated serum LDH levels and all that were autopsied had renal hemosiderosis. Patients 1 and 2 had...
"mild" or "moderate" prosthesis wear, no valvular regurgitation and serum LDH levels less than 500 mIU/ml. In contrast, nine other patients had hemolytic anemia. All had mitral regurgitation and serum LDH levels that ranged from 900–2700 mIU/ml. In seven the prosthesis wear was "severe" and in the remaining two it was "moderate." The severity of anemia varied widely. In three cases (patients 6, 7 and 8) repeated blood transfusions were required and all showed cardiac hemosiderosis at autopsy. Transfusion requirements in patient 7 rose from two units of packed cells quarterly to two units per fortnight. Neither of the last two cases (patients 4 and 11) had hemolysis severe enough to cause hemolytic anemia. Their serum LDH levels were 790 and 900 mIU/ml, respectively. Patient 4 showed "moderate" prosthesis wear and the other "severe" wear.

Discussion

Almost ten years ago, Beall introduced a low profile disc valve (model 103) as a mitral valve prosthesis. Its base was covered with Dacron velour, both to eliminate the interface between the metal seat and cloth sewing ring, from which thromboemboli were believed to arise, and to allow tissue encapsulation of the valve seat. Thus, in theory, only the cage and disc occluder would eventually be in contact with the blood. Teflon was chosen to cover the cage and make the disc because it was both thromboresistant and did not develop variance, a then recently recognized problem with silicone rubber occluders. Approximately 14,000 model 103 prostheses were sold between March 1967 and September 1975 (personal communication from Surgitool Division of Travenol Laboratories). When compared to other prostheses, the model 103 substantially reduced the incidence of thromboembolic complications but poor abrasive wear properties of Teflon led to disc wear and prosthesis insufficiency.

Therefore, in October 1969 the model 104 prosthesis was marketed. It had a compression molded Teflon disc that was significantly denser than the extruded disc in the model 103 and was twice as thick at its perimeter. In addition, the thickness of the Teflon coating of the struts was doubled. Initially, no significant wear was reported with the model 104, except for two unusual cases described by Beall et al. where the myocardium inhibited normal disc movement. With longer experience functionally significant wear has been noted.

Our study of 13 model 104 prostheses recovered from 14 to 84½ months after insertion reveals a spectrum of wear,
The severity of which increases in rough proportion to the duration a prosthesis has been in situ (fig. 7). Wear likely increases linearly with time because it is caused by the disc repeatedly impacting on both the cage and valve seat. However, the rate of wear may change significantly when different materials come into contact with each other. For example, disc wear may be accelerated when either the metal of the struts or the seat is exposed. Our results suggest that the period of "mild" wear may develop within 2½ years after insertion, that "moderate" wear may develop in the next three years and that "severe" wear tends to occur 5½ or more years after insertion. However, as indicated in figure 7, and because we could be dealing with a biased population, these intervals must be considered only a rough guide to the sequence of wear. It is possible that in individual cases only "mild" wear might be present after several years.

Is wear inevitable with this type of prosthesis? If the base were encased in tissue, as might be expected, the seat would be covered as part of the process and "severe" wear might be delayed or prevented. However, tissue ingrowth cannot protect the struts or disc, so "mild" and "moderate" wear are inevitable. Our observations indicate that the cloth of the seat, which in the unused prosthesis slopes gently from its perimeter toward the valve lumen, compacts with time and after innumerable blows from the disc. This both thins and spreads the cloth so that it may extend into the lumen. Eventually, the thinned cloth wears through and tears less than 1 mm from the lumen margin. A thin layer of greyish tissue extends between the fibers of the cloth and across the seat for a variable distance. It may thicken but never covers either the point of contact between disc and seat or the edge between seat and lumen. As these are the sites of cloth wear, "severe" wear with the risk of disc embolization also appears to be inevitable. As the pattern of wear progresses thrombus can develop at cloth/metal interfaces increasing the risk of thromboemboli in a patient. The use of pyrolytic carbon to coat the cage and disc in the model 105 and 106 Beall prostheses may completely prevent or, at least, significantly delay "mild" and "moderate" wear. Even so, in these prostheses, the disc still strikes a cloth seat.

Teflon wear in the Beall valve prosthesis illustrates the

![Figure 5](image-url) "Severe" wear in prosthesis, recovered after 78 months, from patient 11. The bevelled disc edge has permitted it to tilt into the valve orifice (A) forming secondary notches at the pivot point (one defined by the arrow, the other hidden by the strut). A close view of the disc from this prosthesis (B) shows the bevelling (between arrows) and secondary notching. The scale indicates 1 cm. A Teflon embolus, found in a myocardial vessel, in this case, is surrounded by mononuclear and multinucleated giant cells in (C). (H & E X 40).

![Figure 6](image-url) Ventricular and atrial surfaces of a disc from a prosthesis showing "severe" wear (patient 8; prosthesis had been in situ 67½ months). Note the bevelled edge on atrial surface (B) and the irregular disc outline. The scale indicates 1 cm.

![Figure 7](image-url) The severity of prosthesis wear related to the duration each prosthesis had been in situ.
problem of applying the results of tests done on a prosthesis in vitro to the situation in vivo. The model 103 prosthesis was tested beyond 10^6 cycles, equivalent to 25 years service, in an accelerated “bench-test” without noticeable wear yet readily visible disc notching was observed clinically as early as 16 days after implantation. We noticed that strut wear associated with disc wear was always more marked on the two struts related to the posterior aspect of the heart and in the dependent position when the body is erect or supine. This suggests that gravity, acting on the disc, has an important role in causing the wear which occurs in vivo. Support for this concept comes from in vitro tests of the model 104 prosthesis done using a lateral load applied to the disc. These produced significant disc notching in less than 10^6 cycles. We believe that manufacturers should angle a prosthesis to conform both to its anatomic orientation and with respect to gravity when testing the durability of a prototype.

The geometry of a low profile disc valve prosthesis imposes stringent requirements on the abrasive wear properties of the disc material. A disc moves up and down much more frequently than it rotates and, as it does so, it tends to strike the struts of the valve cage at the same points around its perimeter. Furthermore, when opening and closing, a disc frequently does not stay perpendicular to the central axis, thereby increasing the stress on both its edge and the struts. Indeed, loss of disc substance has been reported where discs are made of materials such as silicone rubber or polypropylene which, like Teflon, have poor resistance to abrasive wear. In several of the Beall prostheses we examined, four evenly placed primary notches were found corresponding to the points of strut impact. When marked, they produce a clefted or clefted disc outline (fig. 3A), indicating that negligible disc rotation occurs over what must be a long period. No obvious constraint to disc rotation exists either before or after notchting develops and a few of the prostheses had many notches at their perimeter suggesting free rotation (fig. 4D). We cannot explain this variation.

We believe that wear in the Beall model 104 prosthesis is inevitable. As a result, all patients who have had their prosthesis in situ for more than five years should be assessed regularly, as “severe” wear may develop rapidly. The history and physical examination, the laboratory investigation of hemolysis and noninvasive investigations such as phonocardiography, combined echocardiography and cinetocardiography, and finally, cardiac catheterization, alone or in combination may provide evidence of prosthesis wear. In some cases, changes in the patients’ symptoms and the presence of severe hemolysis (e.g., LDH greater than 1000 mU/ml) are better indicators of prosthesis wear than the severity of regurgitation through the prosthesis at cardiac catheterization. However, radiographic analysis of disc movement at cardiac catheterization may show it tilting into the valve lumen on closure. We noted this, retrospectively, in one patient whose severely worn disc embolized three months after cardiac catheterization.

We stress the danger of placing too much reliance on any one investigation, even cardiac catheterization, when considering the diagnosis of prosthesis wear. Some patients who have had this prosthesis inserted may fare better than our results suggest. However, the possibility of sudden death due to disc embolization and the difficulty in predicting the severe wear that may cause the event remain as concerns. All patients at risk should be monitored vigilantly.

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