Radiographic and Histologic Study of Porous Coated Tibial Component Fixation in Cementless Total Knee Arthroplasty

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ABSTRACT: Radiographic changes occurring beneath three types of non-cemented, porous coated, cobalt-chrome tibial components were retrospectively reviewed at a minimum of 1 year after arthroplasty. Radiolucent zones, radiodense lines, and loose sintered particles were commonly observed. These changes are consistent with non-rigid, fibrous tissue fixation. Histologic evaluation of two specimens retrieved at revision surgery revealed predominantly fibrous tissue within the porous surface under the tibial plateau. The long-term implication of fibrous tissue fixation of porous coated tibial implants is unknown.

Introduction

The bone-implant interface beneath non-cemented, porous coated total knee tibial components has come under recent scrutiny because of the propensity for fibrous tissue fixation and concern about inadequate fixation. The purpose of this study was to radiographically characterize this interface in 142 cases with a minimum 1-year follow up. Only the tibial component was analyzed as most knee arthroplasties fail due to tibial tray loosening.1 Radiographic features were correlated with the histologic appearance of the interface of two specimens retrieved at revision.

Materials and Methods

Implants

Three types of tibial components were reviewed: the PCA (Howmedica, Rutherford, NJ) prosthesis with a porous coated central keel, the PCA prosthesis with two porous coated pegs and a central screw, and the Synatomic (Depuy, Warsaw, IN) prosthesis with a central stem and two cancellous screws. All three components are cobalt-based alloy metal backed tibial tray components with polyethylene bearing surfaces. All possess a powder-made sintered porous surface on the metal backing and keel, peg, or stem.2 The average pore size is quoted in commercial literature as being 425 μ for the PCA devices and 200 μ for the Synatomic devices.

Patient Series

This study included 142 total knee replacements in 133 patients (9 bilateral cases). All of the surgery was performed in one hospital by one of three surgical teams. The study group consisted of 96 females and 46 males. The average patient age was 66.9 years (range, 26 to 86 years). The disease process included 101 (69%) osteoarthritis, 38 (26.8%) rheumatoid arthritis, two post-trauma, and one avascular necrosis. The average length of follow up was 22.4 months (range, 12 to 53 months).

Thirty PCA peg implants, 42 PCA keel implants, and 70 Synatomic implants were studied. Information on each of these groups is presented in Table 1. The difference in the length of follow up between prosthetic types reflects the order in which clinical trials with each were initiated.

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TABLE 1

PATIENT-RELATED INFORMATION AS A FUNCTION OF IMPLANT DESIGN

<table>
<thead>
<tr>
<th></th>
<th>Synatonic</th>
<th>PCA Peg</th>
<th>PCA Keel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Knees</td>
<td>70</td>
<td>30</td>
<td>42</td>
</tr>
<tr>
<td>Average age (years)</td>
<td>68.9</td>
<td>66.6</td>
<td>63.8</td>
</tr>
<tr>
<td>Range (years)</td>
<td>26-86</td>
<td>52-86</td>
<td>33-76</td>
</tr>
<tr>
<td>Average length of follow up (months)</td>
<td>14.1</td>
<td>26.8</td>
<td>34.9</td>
</tr>
<tr>
<td>Range (months)</td>
<td>12-22</td>
<td>13-39</td>
<td>12-53</td>
</tr>
<tr>
<td>Average HSS knee score</td>
<td>81.4</td>
<td>83.4</td>
<td>80.1</td>
</tr>
</tbody>
</table>

Fig. 1: Schematic representation of the six zones for evaluation of the bone-implant interface.

Radiographic Evaluation

Radiographs were taken immediately postoperatively and at 1-year intervals thereafter. At each time period, an erect 14 inch by 17 inch anteroposterior view and a lateral view of the knee prosthesis were obtained. Care was taken on the AP view to place the patella facing forward. Additional radiographs were taken to correct views that demonstrated differences in rotation or angulation which prevented proper comparison from one time period to the next.

The bone-implant interface underneath the metal-backed tibial tray was divided into six evaluation zones: three zones on the AP radiograph and three on the lateral view (Fig. 1). Each zone was examined for a decrease or increase in bone density adjacent to the implant. The radiographs were also checked for the presence of loose particles from the porous coating.

Histologic Evaluation

Two revised tibial components were processed for a histologic evaluation of the bone-implant interface. This involves dehydrating and defatting the specimen, embedding in polymethylmethacrylate, sectioning with a diamond-wheel cut-off machine, and polishing on petrographic grinding equipment so that the interface can be visualized by transmitting light microscopy.3,4

Clinical Evaluation

The Hospital for Special Surgery (HSS) knee clinical evaluation sheet was employed to rate knee pain, function, strength, stability, and range of motion.

Results

Radiographic Evaluation

Several types of appearances of the tibial implant-bone interface were classified. In 19 cases, no radiographic changes were apparent at the most recent review. However, in the majority of cases, some type of change was noticeable. Radiographic changes included: 1) sclerotic lines surrounding the implant, particularly at the stabilization points (the keel, pegs, or central stem), either in apparent contact with the porous coating or not; 2) lucencies at the bone-implant interface associated with or without adjacent sclerotic lines; and 3) loose particles from the porous coating. Table 2 lists the frequency of each of these changes for each implant type.

Sclerotic lines. Sclerotic lines were present in 116 of the 142 cases (82%) reviewed. Of these, 92 knees (79%) had three or fewer zones involved. Twenty-five (22%) had sclerotic lines in all three zones on the lateral view. Thirty (26%) had lines apparent in all three zones on the AP view. Nine (8%) had extensive sclerotic lines which were located in all six tibial zones. These sclerotic lines appeared to be either closely apposed to the implant interface (Fig. 2) or more obviously separated from the implant by a distinct lucency (Fig. 3). The lucency varied from 0.5 mm to 2 mm in width. The sclerotic line usually paralleled the implant surface but occasionally showed slight divergence (Fig. 4).
TABLE 2
SUMMARY OF RADIOGRAPHIC FINDINGS

<table>
<thead>
<tr>
<th></th>
<th>Synatomic Post/2 Screw</th>
<th>PCA Pegs/Screw</th>
<th>PCA Central Keel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lucencies</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>17 (24%)</td>
<td>18 (60%)</td>
<td>27 (64%)</td>
</tr>
<tr>
<td>1-3 zones</td>
<td>46 (66%)</td>
<td>12 (40%)</td>
<td>14 (33%)</td>
</tr>
<tr>
<td>&gt; 3 zones</td>
<td>7 (10%)</td>
<td>0</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Sclerotic lines</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>5 (7%)</td>
<td>12 (40%)</td>
<td>9 (21%)</td>
</tr>
<tr>
<td>1-3 zones</td>
<td>30 (43%)</td>
<td>14 (47%)</td>
<td>22 (52%)</td>
</tr>
<tr>
<td>&gt; 3 zones</td>
<td>35 (50%)</td>
<td>4 (13%)</td>
<td>11 (26%)</td>
</tr>
<tr>
<td>Loose particles</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>69 (99%)</td>
<td>8 (27%)</td>
<td>3 (7%)</td>
</tr>
<tr>
<td>1-3 zones</td>
<td>1 (1%)</td>
<td>13 (43%)</td>
<td>13 (31%)</td>
</tr>
<tr>
<td>&gt;3 zones</td>
<td>0</td>
<td>9 (30%)</td>
<td>26 (62%)</td>
</tr>
</tbody>
</table>

**Lucencies.** Lucencies were seen both with (Fig. 2, 3, 4) and without (Fig. 5) adjacent sclerotic lines. There was a total of 143 zones with an apparent lucency. Of these, 113 (79%) were associated with an adjacent sclerotic line. In 80 of 142 implants (70%), lucencies were absent in all six zones.

**Loose particles.** Small radiopaque particles which appeared to be loosened porous coating material were observed in 62 of the 142 (44%) cases (Fig. 6). In all but one case, this occurred with PCA components.

Apart from these specific changes, a slight loss of bone density was occasionally seen about the periphery of the tibial plateau. The bone appeared as if a rounding off of the bone had occurred at the edges, especially if the tibial plateau extended wider than the implant tray. This rounding off appears similar to the rounding off that occurs in the hip, where the unstrained calcar resorbs in response to stress relief.4 No extensive bony resorption was seen in these 142 cases.

**Histologic Evaluation**

A Synatomic tibial implant was removed due to instability during revision surgery 1 year after initial surgery. Lateral radiographs revealed a lucency and sclerotic line posteriorly, but none anteriorly (Fig. 7). Histology revealed a small amount of bone ingrowth anterior to the fixation post but a fibrous tissue membrane posteriorly (Fig. 7). There was an increase in the thickness of the fibrous membrane with increasing posterior location. A small amount of bone growth within the fixation post was apparent.

A PCA pegged tibial implant was removed due to pain 2 years after surgery. A thin lucency and sclerotic line were visible radiographically, similar to Figures 2 and 4. A plaque of cancellous bone adhered to the central posterior portion of the implant upon removal (Fig. 8). Histology showed bone growth into the fixation peg but none under the plate (Fig. 8). The porosity under the plate was filled with dense connective tissue.

**Clinical Evaluation**

The average preoperative knee rating was 60.3 and the average postoperative score was 81.7. No differences in the postoperative scores in the three types of prostheses evaluated could be detected.

**Discussion**

Loosening of the tibial component has been the most frequent mode of latent failure of cemented...
total knee arthroplasties. As a possible solution to this problem, a number of porous coated implant systems, designed for biologic fixation by bone ingrowth, have been designed and evaluated. Clinical scores with these implants are reported to be equivalent to those with cement at the 2-year follow up. These studies suggest, however, that it takes longer for patients with cementless implants to achieve these equivalent scores, particularly in terms of pain relief.

It is apparent from this study that the radiographic appearance of the interface between porous coated metal tibial trays and the tibial plateau is often suggestive of fixation by fibrous, not osseous, tissue.

The incidence of lucencies was high (30% to 60%), particularly with the Synatomic implants, however the incidence of sclerotic lines was higher (60% to 90%). These incidences must be considered minimum values as it can be difficult to visualize a sclerotic line or lucency with standard radiographs. If the implant surface is angled as little as 3° to the x-ray beam, the fixation interface can be hidden from view. Additionally, a slight lucency can easily be hidden by bone on either side of the lucency.

Histologic analysis of the retrieved specimens showed little or no bone ingrowth under the tibial plateau, a finding that has been corroborated by other studies. It is noteworthy that the one common region of bone ingrowth with tibial components is in the peg(s) or stem(s). It is also interesting that the retrieved Synatomic component did show some bone ingrowth anteriorly, but not posteriorly. This histologic picture is suggestive of fixation in the anterior region, rocking about this fixation fulcrum during loading, and the creation of a divergent fibrous tissue interlayer posteriorly.

Radiographic changes reported in this study are very similar to the changes noted beneath the tibial component of cemented total knee arthroplasties and femoral components of porous coated, non-cemented total hip arthroplasties that have not become ingrown to bone. Similar radiographic changes also have been reported adjacent to the tibial component of smooth metal implants and beneath polyethylene, as seen with the tibial component of early Freeman-Samuelson knee arthroplasties.
Histologic correlation with these radiographic changes in all instances has been the same. The lucency represents a layer of fibrous tissue and the sclerotic line represents a supporting area of densification of bone. The width of the lucency correlates with the thickness of the layer of fibrous tissue. A divergent or widely separated white line is suggestive of a greater degree of implant movement. Such findings could account for the less satisfactory results in terms of early pain relief with cementless total knee replacements.\textsuperscript{5,6}

The lucencies and sclerotic lines are believed to result from inadequate mechanical fixation of the tibial implant. Excessive motion at the bone-implant interface leads to increased wear of the implant, which can result in accelerated loosening and failure. Therefore, achieving proper fixation is crucial for long-term implant survival.
Fig. 7C: Histological section prepared through the implant. There is some bone contact with the porous surface anteriorly (left field), but a widening interfacial space posteriorly (right field).

Fig. 7D: Higher magnification of the anterior interface illustrating slight bone ingrowth.

Fig. 7E: Higher magnification of the posterior interface illustrating extensive fibrous tissue ingrowth and the space between underlying bone.

interface has been shown to inhibit bone ingrowth and cause fibrous tissue fixation. Improvement in initial tibial implant stability would appear to be necessary if bone ingrowth fixation is to be achieved more consistently. Overall, the Synatomic implants were associated with higher incidences of lucencies and sclerotic lines than the PCA implants. This is possibly explained by biomechanical differences in the implant designs. The PCA implant has a flat polyethylene bearing surface with only a slight posterior lip. This low constraint design minimizes forces that are transferred to the bone-implant interfaces. The Synatomic implant possesses matching radii of curvature between the femoral condyles and the polyethylene tibial plateaus. This more constrained articulation reduces stress on the polyethylene but is more resistive to rotational and translational forces, and thus causes higher stress transfer to the bone-implant interfaces.

A very high percentage of cases with PCA implants showed loosened particles from the porous coating. This finding corroborates that of Rosenqvist et al in their study of PCA knee prostheses. The presence of a few loose particles on the immediate postoperative radiograph is probably insignificant since even with a well-sintered porous surface, the occasional particle can be dislodged during impaction. Large or increasing numbers of particles suggest inadequate manufacturing technique and possible fatigue failure of the coating-substrate interface—a potentially serious problem. The presence of many loose particles, usually in a concentrated area, is commonly associated with significant implant instability and either micromotion or implant shift.

In view of the findings from this study and others, the efficacy and longevity of fibrous tissue fixation of porous coated tibial components used in total knee arthroplasty is questioned. Fibrous ingrowth can create a strong interface, sometimes stronger than the cancellous bone of the proximal tibia, judging by the plaques of cancellous bone that avulse from the plateau when implants are removed in revision surgery. It also is known, however, that cementless knees are generally less pain free in the first postoperative year than cemented knees, a fact likely
attributable to the lack of rigid fixation at the bone-implant interface. In the hip, there is strong evidence in favor of bone ingrowth fixation for superior clinical scores. Concerning longevity, fibrous tissue fixation of porous coated femoral hip prostheses has appeared stable beyond 5 years postoperatively. The long-term fate of fibrous tissue fixation of porous coated tibial knee components is unknown.

References


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