TOTAL HIP ARTHROPLASTY WITH AN UNCEMENTED FEMORAL COMPONENT

EXCELLENT RESULTS AT TEN-YEAR FOLLOW-UP

JEFFREY R. McLAUGHLIN, KYLA R. LEE

From the Kennedy Center for the Hip and Knee, Neenah, USA

We followed 138 patients (145 hips) who had had uncemented total hip arthroplasty using the Taperloc femoral component for a mean of ten years (8 to 12.5). No patient was lost to follow-up; 31 (31 hips) died before the minimum time of eight years for inclusion in the study, and 30 of these still had their femoral component in place. One well-fixed prosthesis had been exchanged at the time of acetabular revision. Of the remaining 114 hips, one femoral component required revision for aseptic loosening and one for sepsis. Three other well-fixed femoral components were removed during acetabular revision.

Complete clinical and radiological follow-up was obtained in the 109 hips which had not had revision. Clinically, 94 (87%) were rated good or excellent, eight (7%) fair and seven (6%) poor. The average Harris hip score increased from 48 before operation to 88 at the time of the last follow-up. Radiologically, 103 hips (94%) had fixation by bone ingrowth, three (3%) showed stable fibrous ingrowth and three (3%) were unstable. Osteolysis of the femoral cortex was seen in seven hips (6%), with major lysis in only one.

At a mean follow-up of ten years, the results of the Taperloc femoral component are comparable with those of modern techniques of cementing in primary total hip arthroplasty.

Substantial improvement in the duration of fixation of femoral components using modern cementing techniques has resulted in a resurgence of the use of cement on the femoral side in primary total hip arthroplasty (THA). The initial results using first-generation cementing techniques showed high failure rates. Stauffer1 found aseptic loosening of the femoral component in 30% of 231 THAs performed at the Mayo Clinic and reviewed after ten years. Sutherland et al2 described aseptic loosening of the femoral component in 28% of 78 THAs performed at the Cleveland Clinic at a ten-year follow-up with a revision rate of 12%. Similar findings have been reported by others.3-8 These poor results led to the development and widespread use of uncemented fixation and improvements in the design of the component and the technique when cement was used.

For a decade the proponents of biological fixation have compared their results with those of first-generation cementing techniques. With the dramatic improvements achieved using modern cementing techniques such comparisons are no longer valid. During this period the short-term and intermediate results of several uncemented femoral components have been presented. Many did not meet expectations and several designs such as the HGP (Harris Galante Prosthesis) have been discontinued. There have, however, now been similar advances in the design and use of uncemented prostheses. For example, the Taperloc femoral component (Biomet Inc, Warsaw, Indiana) is a circumferentially porous-coated titanium implant which achieves fixation medially and laterally in the proximal femur.

We report our results after ten years of the use of this prosthesis in regard to clinical outcome, the incidence of osteolysis and the efficacy of fixation.

PATIENTS AND METHODS

Between September 1983 and October 1985, 145 consecutive primary uncemented THAs were performed in 138 patients by a single surgeon, W. F. Kennedy. No patient was lost to follow-up and the outcome of every hip was determined. Of the 138 patients, 31 with unilateral procedures died before reaching a minimum follow-up of eight years, leaving 107 patients (114 hips) who were followed up for a...
mean of ten years (8 to 12.5). Of these, five had revision of the femoral component; three were removed during acetabular revision, one for sepsis and one for aseptic loosening. The remaining 102 (109 hips) therefore had a complete clinical and radiological follow-up. There were 51 women (57 hips) and 51 men (52 hips). Their mean weight was 80 kg (48 to 140) and their mean age 57 years (20 to 82).

For the 109 hips the preoperative diagnosis was osteoarthritis in 64 (58%), avascular necrosis in 14, developmental dysplasia in 12, rheumatoid arthritis in 11, hip fracture in five and post-traumatic osteoarthritis, slipped capital femoral epiphysis, and Legg-Perthes’ disease in one each.

The femoral implant was a collarless stem made of wrought titanium alloy Ti-6Al-4V (Taperloc; Biomet Inc, Warsaw, Indiana). The proximal 40% of the implant had a coating of identical titanium alloy 635 to 889 μm thick applied by a plasma-spray technique. The pore diameter varied through the coating from 92.3 μm at its inner surface to 480.3 μm at its outermost surface. The stem had a tapered rectangular shape designed to achieve fixation mediolaterally within the proximal femur. All the femoral components were of monobloc design with a titanium alloy (Ti-6Al-4V) head of 28 mm. A modular implant which is otherwise identical to the one described above is currently in clinical use (Fig. 1).

The hip was exposed through a posterolateral approach. The proximal femur was serially broached in increments of 2.5 mm until a press-fit was achieved. The rasp was introduced to the proximal femur in the same degree of version as the neck. A radiograph was taken during the operation to assess the position of the component.

Patients were assessed clinically by an office visit or by a questionnaire. The Harris hip score⁹ was used to determine the level of function before operation and at each subsequent follow-up. At the final follow-up 93 hips were examined during an office visit and 16 were evaluated by a questionnaire followed by a telephone interview.

All the radiographs were reviewed by an independent orthopaedic surgeon who had not carried out the operation. AP views of the hip and pelvis were taken together with a true lateral view of the hip. These were compared with the radiographs taken immediately after operation and at all subsequent reviews. The femur was divided into the seven Gruen zones,¹⁰ with corresponding areas on the lateral radiograph. The presence of radiolucencies or osteolysis was assessed¹¹ in each of the seven zones and recorded in increments of 0.5 mm. Progressive radiolucencies were identified and recorded. Radiolucencies with a scalloped or cystic appearance, or greater than 2 mm in width, were recorded as osteolysis.

Cortical hypertrophy was evaluated by measurement of the increase in cortical index. The presence of a halo, a partial or complete pedestal and spot welding were recorded.

The stability of the femoral component was assessed by the criteria of Engh et al.¹² A component was defined as having fixation by bone ingrowth when there was no subsidence and minimal or no formation of a radio-opaque line along the porous-coated portion of the implant (Fig. 2). Stable fibrous ingrowth occurred when an implant had no progressive migration irrespective of the presence of a radio-opaque line along the stem. An implant with definitive evidence of progressive migration was considered unstable.

Subsidence was determined by a comparison of two measurements between serial radiographs. First, we measured the vertical distance from the tip of the greater trochanter to the distal tip of the implant and then the vertical distance from the medial corner of the implant to the lesser trochanter. A difference of more than 4 mm between radiographs on both of these measurements was required to establish subsidence.

Stress shielding was determined by the classification of Engh et al.¹² First-degree stress shielding was defined as a slight rounding off of the proximal medial edge of the cut femoral neck and second-degree as rounding off of the proximal medial femoral neck combined with loss of medi-al cortical density at level one on the anteroposterior radiograph. Third-degree stress shielding was more extensive resorption of the cortical bone extending from level one into level two, and fourth-degree severe resorption of cortical bone extending below levels one and two into the diaphysis. Heterotopic ossification was evaluated by the classification of Brooker et al.¹³

We used Kaplan-Meier survival analysis to estimate cumulative survival for the femoral component. The
endpoint was defined as revision of the stem. Multivariate linear regression by ordinary least squares was used to determine the statistical significance of the relationships between the variables. The analysis of residuals in probability for linear regression by ordinary least squares failed to indicate non-normality in error distribution; this suggested that no multivariate autoregressive process was involved.

We examined the acetabular components although they were not the focus of this study. The prosthesis used in every case was a conically-shaped, threaded-ring titanium shell without porous coating (T-Tap; Biomet Inc, Warsaw, Indiana). Ultra-high-molecular-weight polyethylene powder HiFax 1900 MG (Himont USA, Wilmington, Delaware) was directly compression-moulded into the shell to form an articulating surface 28 mm in diameter.

RESULTS

Thirty-one patients with unilateral replacements died before the minimum eight-year follow-up, 30 with their femoral component in place. One well-fixed femoral prosthesis was revised during acetabular revision.

The remaining 114 hips in 107 patients were followed for a mean of ten years (8 to 12.5). Only one femoral stem required revision for aseptic loosening. Three other well-fixed stems were removed at the time of acetabular revision, two because of scratches on the non-modular titanium head and the other because the head obstructed the exposure. One femoral component was revised for sepsis. Three others appeared loose on the radiographs giving an overall rate of aseptic loosening of 4%. At an average of ten years, 96% of the stems remained in place (Fig. 3).

The one femoral prosthesis which required removal for aseptic loosening was revised ten months after the initial operation during which a fracture of the calcar occurred. After operation the stem subsided 2 cm and the patient had unremitting pain on weight-bearing. At revision the femoral component was grossly loose although the fracture of the calcar had united. It was revised and was still in place ten years later. The three well-fixed femoral components were replaced when revision of the acetabulum was required at 70, 74 and 81 months after the initial operation, respectively, and the stem which became infected was revised at 23 months.

At the final follow-up the average Harris hip score in those patients who had not required revision was 88 (33 to 100). The clinical outcome of 62 hips (57%) was graded excellent with a score of 90 or better, 32 (29%) were good, eight (7%) fair and seven (6%) poor. Sixty-nine hips (63%)...
had no pain, 32 (29%) only slight pain, six (6%) mild or occasional pain and two (2%) moderate pain. No hip had severe pain. There was mild pain in the thigh in four patients and moderate pain in two (Table I).

Of the eight hips with a fair hip rating, seven had a decrease in function from other unrelated medical causes and in the other pain was due to a loose acetabular component. Of the seven hips with a poor score, four had disability from unrelated medical causes and two had a loose acetabular component. Eighty-three patients (90 hips; 82%) could walk six blocks or more, four (four hips; 4%) could walk for two to three blocks, 12 (12 hips; 11%) could walk only in the house and three patients were not able to walk. For 79 patients (83 hips, 76%) no support was required when walking, 11 patients (13 hips, 12%) required a cane for long walks and seven (8 hips, 7%) always used a cane. Two required crutches or a frame and three patients were unable to walk.

Fixation by bone ingrowth was shown radiologically in 103 hips (94%), three showed fibrous ingrowth and three were loose. One in a patient with bilateral paralysis of the legs due to poliomyelitis, subsided by 15 mm over ten years; in the other two loose hips there was early subidence of 8 mm and 15 mm which did not progress. When last seen these patients had hip scores of 81 and 88.

Stress shielding was observed in 106 hips (97%). In 90 (85%) it was first or second degree, in 14 (13%) third degree and in two fourth degree.

Radiolucenties were seen in the region of the femoral component without porous coating in 75 hips (69%), most commonly in Gruen zone four. Radiolucenties in the porous-coated region were seen in 24 hips (22%). Using

<table>
<thead>
<tr>
<th>Table I. The Harris hip score in 102 patients (109 hips)</th>
<th>Number of hips</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Harris hip score classification</strong></td>
<td><strong>Number of hips</strong></td>
</tr>
<tr>
<td>Pain</td>
<td></td>
</tr>
<tr>
<td>None (44)</td>
<td>69</td>
</tr>
<tr>
<td>Slight (40)</td>
<td>32</td>
</tr>
<tr>
<td>Mild (30)</td>
<td>6</td>
</tr>
<tr>
<td>Moderate (20)</td>
<td>2</td>
</tr>
<tr>
<td>Severe (10)</td>
<td>0</td>
</tr>
<tr>
<td>Disabling (0)</td>
<td>0</td>
</tr>
<tr>
<td>Support</td>
<td></td>
</tr>
<tr>
<td>None (11)</td>
<td>83</td>
</tr>
<tr>
<td>Cane (long walks) (7)</td>
<td>13</td>
</tr>
<tr>
<td>Cane (full time) (5)</td>
<td>8</td>
</tr>
<tr>
<td>2 canes (2)</td>
<td>0</td>
</tr>
<tr>
<td>Crutches/frame (2)</td>
<td>2</td>
</tr>
<tr>
<td>Unable to walk (0)</td>
<td>3</td>
</tr>
<tr>
<td>Limp</td>
<td></td>
</tr>
<tr>
<td>None (11)</td>
<td>60</td>
</tr>
<tr>
<td>Slight (8)</td>
<td>38</td>
</tr>
<tr>
<td>Moderate (5)</td>
<td>6</td>
</tr>
<tr>
<td>Severe (0)</td>
<td>2</td>
</tr>
<tr>
<td>Unable to walk (0)</td>
<td>3</td>
</tr>
</tbody>
</table>

*rating points are values given in parentheses
multivariate regression analysis, no statistically significant relationship was found between aseptic loosening and radiolucencies in the porous (p = 0.14) and non-porous-coated (p = 0.12) regions of the femoral stem (Fig. 4).

Heterotopic ossification was seen in 81 hips (74%). Of these 27 (33%) were grade I, 25 (31%) grade II, 26 (32%) grade III, and three were grade IV.

At the final follow-up, cortical hypertrophy was seen in 59 hips (54%), spot welding in 96 (88%), a halo in 53 (49%), a complete pedestal in 20 (18%) and a partial pedestal in 28 (26%). Multivariate regression analysis showed no statistically significant relationship between clinical outcome and cortical hypertrophy (p = 0.29), spot welding (p = 0.07), a halo (p = 0.25) or a pedestal (p = 0.33). Osteolysis was found to have no statistically significant relationship with cortical hypertrophy.
(p = 0.92), spot welding (p = 0.36), a halo (p = 0.45) or a pedestal (p = 0.65).

The immediate postoperative radiographs showed that the stem lay in neutral in 61 hips (56%), in valgus in 42 (38%) and in varus in six. At the final follow-up the radiographs showed that seven had moved by an average of 3.2 mm, two into varus, two into valgus and three in a neutral direction. Chi-squared analysis showed a trend but no statistically significant relationship between the initial alignment of the femoral component and osteolysis (p = 0.06) and no relationship with aseptic loosening (p = 0.47).

Of the 109 hips which had not undergone revision of the femoral component, cortical osteolysis was present in seven (6%) (Fig. 5). It was seen in five of the 106 hips in which the femoral component was well fixed and in two of the three with loosening. This difference was statistically significant as determined by a two-tailed Fisher’s exact test (p = 0.02). Major osteolysis occurred in only one hip. Osteolysis involved one Gruen zone in four patients, two Gruen zones in two patients and 12 Gruen zones in the patient with major lysis (Fig. 6). Of the seven hips four were in valgus, two lay in neutral and one was in varus.

Kaplan-Meier survivorship analysis with revision as the endpoint gave a 96% chance of survival for the femoral component (95% confidence interval 0.92 to 1.00) at 11 years (Fig. 7).

There were intraoperative and postoperative complications in 11 patients (11 hips). Three had postoperative dislocations, all treated closed, without subsequent dislocation. Deep-vein thrombosis was seen and treated in two patients. Two superficial wound infections required intravenous antibiotics. There was one case of partial sciatic nerve palsy which resolved. One patient developed jaundice and a chemical hepatitis from halothane anaesthesia and one acute cholecystitis requiring cholecystectomy. Fracture of the calcar occurred while implanting the femoral component in one, as previously noted.

Of the acetabular components, 63 (58%) required revision and 36 (42%) remained in place. No statistically significant
relationship between acetabular revision and loosening of the femoral component was found ($p = 0.13$).

**DISCUSSION**

In our series, five femoral components required revision, one for aseptic loosening and four for other reasons; 96% of the implants were still in place, with an average Harris hip score of 88. Three additional femoral prostheses (3%) were considered loose by radiological criteria. These results at an average of ten years using this uncemented femoral component are comparable with those achieved with second-generation cementing techniques.

With the early techniques of cementing the femoral component in primary THA, inadequate fixation led to failure rates from aseptic loosening ranging from 19.8% to 57%. Modern techniques have reduced the incidence of aseptic loosening of the femoral component at a mean follow-up of 12 years to 6%. Similar results have been reported by Goetz et al.,

Weidenhielm et al.,

and Oishi, Walker and Colwell. The intermediate results using several cementless THAs have been discouraging. Engh et al.

reported a 6% incidence of aseptic loosening of the femoral component at five to seven years. The incidence using the AML stem at five to seven years was reported as 22% by Beauchene et al. and as 56% by Kim and Kim at seven years. Reported incidences of osteolysis using a PCA prosthesis vary between 10% and 33%. These devices incorporate circumferential porous coating to impede particle migration and osteolysis, proximal femoral fixation to prevent stress shielding, and a tapered distal tip to reduce thigh pain. Pellegrini et al. have used the Tri-lock femoral component which includes these features and achieved a 2% incidence of revision for aseptic loosening at 6.5 years. Hozack et al., using the Taperloc femoral component, reported 100% fixation of the femoral prosthesis at a follow-up of between two and six years; 98% of patients had no pain or only slight pain. In our series the results using the Taperloc femoral component are excellent, with revision for aseptic loosening at ten years in only 1%, similar to those achieved using contemporary cementing techniques. No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

**REFERENCES**


THE JOURNAL OF BONE AND JOINT SURGERY