Cementless total hip replacement using second-generation components

A 12- TO 16-YEAR FOLLOW-UP

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We reviewed 123 second-generation uncemented total hip replacements performed on 115 patients by a single surgeon between 1993 and 1994. The acetabular component used in all cases was a fully porous-coated threaded hemispheric titanium shell (T-Tap ST) with a calcium ion stearate-free, isostatically compression-moulded polyethylene liner. The titanium femoral component used was a Taperloc with a reduced distal stem. No patient was lost to follow-up. Complete clinical and radiological follow-up was obtained for all 123 hips at a mean of 14 years (12 to 16). One femoral component was revised after a fracture, and three acetabular components for aseptic loosening. No additional femoral or acetabular components were judged loose by radiological criteria. Mild proximal femoral osteolysis was identified in two hips and minor acetabular osteolysis was present in four. The mean rate of penetration of the femoral head was 0.036 mm/year (0.000 to 0.227).

These findings suggest that refinements in component design may be associated with excellent long-term fixation in cementless primary total hip replacement.

Cementless implants for primary total hip replacement (THR) have been used for over 25 years. Although the delineation between first- and second-generation cementing techniques is clear,1-4 the difference between first- and second-generation cementless implants is not as clear. Several early cementless hip replacements performed poorly, as they were complicated by thigh pain, subsidence, severe polyethylene wear, osteolysis and premature failure.5-8 However, during the same period excellent long-term results have been published with regard to some early cementless implants.9-13

In 1983, United States Food and Drug Administration approval was granted to use a first-generation titanium cementless THR. This consisted of a non-modular tapered femoral component (Taperloc, Biomet, Warsaw, Indiana) and a non-porous-coated, conically shaped threaded ring acetabular shell (T-Tap, Biomet). At a mean follow-up of 20 years, 9% of the femoral components and 57% of the acetabular components had required revision.9

Incremental improvements in the design of both components were made over a period of ten years. In 1993 we began using a second-generation uncemented THR in which substantial changes had been made. On the femoral side, the tapered stem now had a modular femoral head-neck junction and a 28 mm chrome-cobalt femoral head. The diameter of the distal non-porous-coated portion of the stem was substantially reduced to allow easier insertion in patients with a tight femoral isthmus. The acetabular component was changed considerably from a conically shaped threaded component without porous coating to a fully porous-coated hemisphere with threads (T-Tap ST). The polyethylene liner was isostatically compression moulded from Himont 1900 resin (Montell Polyolefins, Wilmington, Delaware), which is calcium (Ca²⁺) stearate-free.

We now describe our results at 12 to 16 years using this second-generation hip replacement and compare the incidence of loosening and revision to our previous experience using a first-generation device.

Patients and Methods

Between September 1993 and November 1994, 172 consecutive primary uncemented THRs were performed on 162 patients using second-generation femoral, acetabular and polyethylene components by a single surgeon (JRM) at one centre. The outcome regarding fixation, retention or revision of the components was determined in all 172 hips. Before obtaining a minimal 12-year follow-up, 47 patients (49 hips) had died with the original THR in place, leaving 115 patients (123 hips)
available for review. The mean age of the patients at the
time of surgery was 64 years (27 to 82). There were 59
women (62 hips) and 56 men (61 hips) who were followed
for a mean of 14 years (12 to 16). The pre-operative diag-
nosis was osteoarthritis in 104 hips (84%), rheumatoid
arthritis in 12 (10%), avascular necrosis in three (2%),
developmental dysplasia in two (2%) and previous slipped
capital femoral epiphysis in two (2%).

The second-generation Taperloc femoral component
(Biomet) was used in all patients. The first-generation
Taperloc femoral component had a non-modular collarless
stem made of wrought titanium alloy (Ti-6Al-4V). It had a
tapered rectangular shape, designed to achieve fixation
medially within the proximal femur. The proximal
40% of the implant had a coating of identical titanium
alloy 635 µm to 889 µm thick, applied by a plasma spray
technique, and it had a 28 mm titanium head. The second-
generation Taperloc stem has a modular head-neck articu-
lation and a reduced distal stem for patients with a narrow
femoral isthmus (Fig. 1). A 28 mm diameter cobalt-
chromium femoral head was used in all cases.

The acetabular component used in all the patients was
the T-Tap ST (Biomet). The first generation T-Tap compo-
ponent was a conically shaped threaded titanium shell with-
out porous coating (Fig. 2). The T-Tap ST is a threaded
hemispherical titanium shell, fully porous-coated with
plasma spray. The inner metallic surface is smooth and
designed to achieve maximum conformity of the shell and
liner in order to reduce backside wear. ArCom (Biomet)
polyethylene was used as the bearing surface in all aceta-
bular components in this series. This is an isostatic compres-
sion-moulded polyethylene, packaged in argon gas and
manufactured from Himont 1900 resin (Montell Poly-
olefins), which is Ca²⁺ stearate-free.

Operative technique. A posterolateral approach to the hip
was used. The tapered femoral component is designed to
achieve fixation medially within the proximal aspect
of the femur. Raspig of the femoral canal was performed
in increments of 2.5 mm until a press fit was achieved. The
prosthetic stem used was the same size as the last rasp.
The acetabulum was reamed progressively in 2 mm increments
until circumferential contact with bleeding cancellous bone
was obtained. The acetabulum was under-reamed by 1 mm.
The optimum alignment chosen for the acetabular
component was 45° of abduction and 15° of anteversion. An intra-operative radiograph was obtained for every hip to assess the position of the components and the leg lengths. Intravenous antibiotics were administered pre-operatively and were continued for 48 hours after operation. Patients were allowed to fully weight-bear with crutches or a walker for four weeks, and thereafter advanced as tolerated. Warfarin was administered orally on the day of surgery and continued for one month.

**Evaluation.** The procedures for this study were approved by the Institutional Review Board and written informed consent was obtained from all the patients. Complete clinical and radiological follow-up at a minimum of 12 years after the index operation was obtained for all 115 living patients (123 hips). Radiological evaluation at a mean of 14 years (12 to 16) consisted of anteroposterior (AP) views of the hip and pelvis and a true lateral view of the hip. These were compared with the immediate post-operative radiographs and with those obtained at subsequent follow-up. They were evaluated by an independent investigator (KRL). The femur was divided into the seven zones described by Gruen, McNeice and Amstutz.14 The presence of radiolucencies and osteolysis was assessed in each of the zones and recorded. Radiolucencies with a scalloped or cystic appearance, or > 2 mm in width, were recorded as osteolysis. All measurements were corrected for magnification based on the true size of the femoral head. Loosening of the femoral component was evaluated by the criteria of Engh, Bohyn and Glassman.15 Subsidence was determined by a comparison of two measurements between serial radiographs, as described by Pellegrini, Hughes and Evarts.16 A difference > 3 mm was required to define subsidence. The acetabular components were evaluated for radiolucencies and osteolysis in the zones described by DeLee and Charney.17 Fixation of the acetabular component was assessed by the criteria of Massin, Schmidt and Engh.18 It was considered loose if there was migration from the inter-teardrop or vertical line, a continuous radiolucency, or a change > 4° in the angle of abduction. A quantitative measurement of linear wear was evaluated using the technique described by Livermore, Illstrup and Morrey.19 A computer-assisted method of edge detection was used to measure penetration of the femoral head into the acetabular component (Roman VI.70).20

The Roman VI.70 software (Institute of Orthopaedics, Oswestry, United Kingdom) is a radiological measurement program that uses a digital equivalent of the Livermore method to measure linear wear of polyethylene. The annual rate of penetration of the femoral head was calculated with single-image analysis using the latest AP post-operative radiograph. The known diameter of the femoral head was used to correct for magnification. Each radiograph was measured three separate times without knowledge of the previous reading, and the mean was recorded. The intraclass variance was 0.028.

All 115 living patients (123 hips) were assessed clinically at a minimum of 12 years post-operatively. The Harris hip score was used to determine the functional level and to evaluate pain.21 In addition, the presence or absence of thigh pain was recorded. The level of activity was evaluated by the classification of Johnston et al.22

**Statistical analysis.** Kaplan-Meier survival analysis23 was used to estimate a cumulative survival function for the femoral and acetabular components, with revision for any reason and revision for aseptic loosening as the endpoints. Student's t-test was used to determine the statistical significance of polyethylene wear and the incidence of osteolysis. Pearson's correlation coefficients were calculated to determine the statistical significance of correlations between polyethylene wear and the potential influence of the patient's age, gender and body mass index. The Fisher's exact test was used to compare the rates of revision of the femoral and acetabular components in this series with those of our previous report.24 A p-value < 0.05 was considered significant.

**Results**

There were 123 THRs in 115 patients available for review. A revision for aseptic loosening had been required in three acetabular components (2%) at seven, seven and 11 years post-operatively. No femoral component had required revision for aseptic loosening, but one had needed a further operation following a peri-prosthetic fracture of the femur one year after the initial procedure.

Radiographs of all 123 hips in 115 living patients were obtained at a minimum of 12 years after operation with a mean follow-up of 14 years (12 to 16). Of the 122 hips that had not undergone revision of the femoral component, all had achieved fixation by ingrowth of bone. Radiolucencies were seen around the porous-coated region of the femoral component in eight hips (7%), most commonly in Gruen zone 1. All measured 1.5 mm or less. Mild focal osteolysis confined to Gruen zone 7 was identified around two stems (2%).

Radiological analysis of the 120 acetabular components that had not been revised showed a mean angle of abduction of 41° (24° to 52°). Radioluencies were present in 14 hips (12%); in zone A in 12 (10%) and zone C in two (2%). All measured 1.0 mm or less. All the 120 acetabular components were considered to be stable. None of the patients with radiolucencies about the acetabular components had pain. Osteolysis was identified in four hips (3%); two in zone A, one in zone B and one in zone C. The radiographs obtained for the three patients who had undergone acetabular revision demonstrated a continuous radiolucency measuring 2 mm in two hips and migration of the component in one.

The incidence of aseptic loosening observed on radiography and of revision for aseptic loosening of the femoral and acetabular components is presented in Table I.

The mean rate of penetration of the femoral head into the polyethylene liner was 0.036 mm/year (0.000 to 0.227). No statistically significant correlation was found between the rate of polyethylene wear and the age of the patient (p = 0.069), gender (p = 0.12) or the body mass index.
Table I. Prevalence of aseptic loosening and revision of the femoral and acetabular components

<table>
<thead>
<tr>
<th></th>
<th>All hips (n = 172)</th>
<th>Hips in living patients (n = 123)</th>
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<tbody>
<tr>
<td><strong>Femoral components (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Revision loosening</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Revision all reasons</td>
<td>1 (1)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Radiological loosening</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Total</td>
<td>1 (1)</td>
<td>1 (1)</td>
</tr>
<tr>
<td><strong>Acetabular components (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Revision loosening</td>
<td>3 (2)</td>
<td>3 (2)</td>
</tr>
<tr>
<td>Revision all reasons</td>
<td>3 (2)</td>
<td>3 (2)</td>
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<tr>
<td>Radiological loosening</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Total</td>
<td>3 (2)</td>
<td>3 (2)</td>
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(p = 0.94) (Pearson's correlation test). According to Fisher's exact test, no statistically significant difference was found between the mean rate of linear polyethylene wear and osteolysis (p = 0.0625).

In the 115 patients (123 hips) the mean Harris hip score had increased from 44 (31 to 68) pre-operatively to 89 (63 to 100) at the final follow-up. Thigh pain was present in four hips (3%). The clinical outcome according to the Harris hip score was rated excellent in 66 hips (54%), good in 42 (34%), fair in 14 (11%) and poor in one (1%). Of the patients with a fair or poor hip score, one had unremitting pain due to spinal stenosis. The remainder had disability from medical causes unrelated to their hip arthroplasty. A total of 15 patients (15 hips) performed strenuous manual labour, ten (11 hips) moderate manual labour, 56 (61 hips) light manual labour, 26 (28 hips) were semi-sedentary and eight (eight hips) were sedentary.

**Survival analysis.** With revision for any reason as the endpoint, Kaplan-Meier analysis demonstrated a 99% chance of survival for the femoral component at 16 years (95% confidence interval (CI) 94 to 99) and a 98% chance of survival for the acetabular component (95% CI 93 to 99). With revision for aseptic loosening as the endpoint, Kaplan-Meier analysis estimated a 100% chance of survival for the femoral component at 16 years and a 98% chance of survival for the acetabular component (95% CI 93 to 99).

**Discussion**

We have previously reported a study of a first-generation non-modular Taperloc femoral component and a non-porous coated threaded conical acetabular shell (T-Tap) at a mean follow-up of 20 years. In that series of 145 THRs only one femoral component (0.7%) required revision for aseptic loosening. However, 12 additional femoral components (8%) had been revised. In each case the femoral component was not loose. In eight cases it was revised because the non-modular head blocked exposure during acetabular revision, or because of instability that could not be addressed with an exchange of the femoral head or a longer femoral neck in a monobloc component. Four well-fixed femoral components were revised for late sepsis. In the current series no femoral component required revision for aseptic loosening, and no femoral component required revision because of a loose acetabular component. The higher incidence of revision of the femoral component in the first-comparison with the second-generation Taperloc stems in these two studies was statistically significant (p = 0.003) (Fisher's exact test). In our earlier series 57% of the first-generation non-porous-coated acetabular components had been revised for aseptic loosening, and an additional 17% were loose by radiological criteria. In the current series, three acetabular components (2%) required revision for aseptic loosening and none were loose by radiological criteria. The difference in the incidence of acetabular revision between these two studies was statistically significant (p = 0.001) (Fisher's exact test).

Several series using early or first-generation cementless THR have been published. Many of these record a high incidence of thigh pain, revision and osteolysis. Kim reported a mean follow-up of 19.4 years of 110 THRs using the PCA prosthesis (Stryker, Rutherford, New Jersey). Acetabular revision for aseptic loosening was required in 21%, with osteolysis noted in 54%. Revision of the femoral component for aseptic loosening was required in 7%, with osteolysis recorded in 40%. Thigh pain was experienced in 12% of patients. High rates of failure due to aseptic loosening of the femoral component have been observed by Clohisy and Harris at ten years using the HGP femoral component (Zimmer, Warsaw, Indiana). In their series of 77 hips, 19% of the femoral components that were not porous-coated circumferentially were revised and a further 11% were loose by radiological criteria. Osteolysis was identified in 60%.

Intermediate-term results using second-generation cementless femoral and acetabular components have now been published. Archibeck et al. used the Multi-block femoral component (Zimmer), and at a mean follow-up of nine years, 99% remained in place, with osteolysis occurring in 7%. Cavinini, D'Arienzo and Innocenti described 106 THRs using the second-generation Reflective acetabular component (Smith & Nephew, Memphis, Tennessee) with a GUR 1050 calcium stearate-free polyethylene liner. After 12.1 years, five components (4.6%) had been revised, only one (0.9%) for aseptic loosening. Osteolytic lesions were seen around six components (5.8%). Similar excellent results were observed by García-Rey, García-Cimbrelo and Cordero-Ampuero with the Duraloc series-500 component (DePuy, Warsaw, Indiana) at 13.4 years.

The rate of wear of polyethylene and the incidence of osteolysis in this series were low. Proximal femoral osteolysis was identified around two femoral components (2%), distal osteolysis in none (0%). Acetabular osteolysis was seen around four shells (3%). We believe that the low incidence of osteolysis was due to the low incidence of loosening, which has been observed to increase the rate of osteolysis, and to the use of a high-quality polyethylene.
The polyethylene used in all hips in this series was manufactured with Himont 1900 resin (Montell Polyolefins), which is Ca²⁺ stearate-free. The resin was isostatically compression moulded and packaged in an inert environment. We have noted that the acetal component was designed to reduce backside wear. Further improvements include a better locking mechanism, a smooth inner metallic surface, enhanced conformity of the shell and liner, and no screws. James et al. observed 54% less wear at ten years in direct compression-moulded polyethylene acetabular liners manufactured from Himont 1900 resin (Montell Polyolefins) compared to liners manufactured with ram-extruded bar stock polyethylene.

The mean rate of wear of polyethylene in hips associated with Ca²⁺ stearate-containing ram-extruded polyethylene has ranged from 0.10 mm/yr to 0.024 mm/yr in several published series. The incidence of femoral osteolysis has ranged from 10% to 60%, with acetal osteolysis ranging from 7% to 54%. Alzheimer's disease is a cross-linked, the Ca²⁺ stearate-free compression-moulded polyethylene has demonstrated a significantly lower rate of wear and of peri-prosthetic osteolysis than ram-extruded polyethylenes. In several published reports the mean rate of polyethylene wear has ranged from 0.041 mm/yr to 0.079 mm/yr. In this study the mean rate of polyethylene wear was 0.036 mm/yr. The incidence of femoral and acetabular osteolysis was 2% and 3%, respectively. These results compare favourably with hips associated with ram-extruded polyethylene.

The most significant finding of this report was the substantial reduction in the rate of revision of the femoral and acetabular components using a second-generation cementless THR compared with our earlier findings using first-generation devices. Refinements in the design of components can have a substantial impact on the longevity of a THR.

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