The results of a proximally-coated cementless femoral component in total hip replacement

A FIVE- TO 12-YEAR FOLLOW-UP

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This study reviewed the results of a cementless anatomical femoral component to give immediate post-operative stability, and with a narrow distal section in order not to contact the femoral cortex in the diaphysis, ensuring exclusively metaphyseal loading.

A total of 471 patients (601 hips) who had a total hip replacement between March 1995 and February 2002 were included in the study. There were 297 men and 174 women. The mean age at the time of operation was 52.7 years (28 to 63). Clinical and radiological evaluation were performed at each follow-up. Bone densitometry was carried out on all patients two weeks after operation and at the final follow-up examination. The mean follow-up was 8.8 years (5 to 12).

The mean pre-operative Harris hip score was 41 points (16 to 54), which improved to a mean of 96 (68 to 100) at the final follow-up. No patient complained of thigh pain at any stage. No acetabular or femoral osteolysis was observed and no hip required revision for aseptic loosening of either component. Deep infection occurred in two hips (0.3%) which required revision. One hip (0.2%) required revision of the acetabular component for recurrent dislocation. Bone mineral densitometry revealed a minimal bone loss in the proximal femur.

This cementless anatomical femoral component with metaphyseal loading but without distal fixation produced satisfactory fixation and encourages proximal femoral loading.

The rationale for the design of a cementless anatomical femoral component with metaphyseal loading in total hip replacement (THR) is to transmit the forces from the hip to the proximal femur to maintain as much loading as possible at this site and reduce osteopenia. This approach will also preserve the endosteum of the diaphysis for any subsequent revision.1,2

Fetto, Bettinger and Austin3 proposed that in order to reproduce the compressive forces between the femoral head and the greater trochanter, a cementless anatomical femoral stem needed to engage this area by means of a lateral flare. Walker et al4 also suggested that the stem below the lesser trochanter would be unnecessary for a cementless anatomical stem with a lateral flare, and that a proximal implant would suffice.

This is a prospective, non-randomised study to evaluate the clinical and radiological results of a cementless anatomical femoral component with a lateral flare designed for metaphyseal loading and avoiding contact with the femoral cortex by its distal stem. The two primary radiological criteria evaluated were resorption of bone due to stress-shielding of the proximal femur, and the fixation of the stem.

Patients and Methods

Between March 1995 and February 2002, the author performed consecutive primary cementless THRs on 641 hips in 509 patients. Exclusion criteria for enrolment in this study were age over 70 years, patients who had rheumatoid arthritis, and a follow-up of less than five years after operation. This excluded 30 hips in 28 patients. A total of ten patients (ten hips) were lost to follow-up before two years after operation. No patient died in the interim. Therefore, 601 hips in 471 patients were available for clinical evaluation at a mean of 8.8 years (5 to 12). All patients were examined clinically and radiologically at each follow-up. The study was approved by the institutional review board, and all patients provided informed consent.

The mean age of the patients at the time of the THR was 52.7 years (20 to 63). There were 297 men and 174 women. The diagnosis was osteonecrosis of the femoral head in 247 patients (52.4%), osteoarthritis in 145 (30.8%), fracture of the femoral neck in 36 (7.7%), osteoarthrosis secondary to childhood pyogenic arthritis in 16 (3.4%), ankylosing...
spondylitis in 16 (3.4%), traumatic arthritis in ten (2.1%), and multiple epiphysseal dysplasia in one (0.2%). All hips with osteonecrosis had Ficat and Arlet stage III or IV changes. The presumed cause of osteonecrosis was ethanol abuse in 147 patients (59%), idiopathic in 74 (30%), and steroid use in 26 (11%).

The mean weight of the patients was 63.4 kg (47 to 111) and their mean height was 163.2 cm (140 to 183). The mean body mass index was 23.8 kg/m² (19.5 to 36.2).

A cementless Duraloc acetabular component (DuPuy, Leeds, United Kingdom) was used in all hips. These components are press-fitted after the acetabulum had been underreamed by 2 mm. One or two screws were used for additional fixation in 69 hips (11.4%); the remainder did not require any screws. A 28 mm internal diameter alumina ceramic liner was used in all hips regardless of the external diameter of the acetabular component, which ranged from 46 mm to 62 mm.

All patients received an immediate post-operative stability cementless anatomic femoral component (IPS, DePuy) with a 28 mm alumina modular head. This is an anatomical metaphyseal filling titanium alloy component with a polished and tapered stem. It is designed to achieve immediate mechanical stability within the metaphysis, with close contact with the calcar. It has a pronounced lateral flare which rests on the inferolateral part of the greater trochanter, and an anteroposterior (AP) build-up to provide tight fixation within the femur in order to minimise axial and torsional micromovement. The transition zone between the load-bearing and non-load-bearing section of the stem is short, avoiding metal-to-bone contact below the metaphysis. The polished distal stem is short and narrow, and placed centrally in the femoral canal to avoid distal contact with the femur. The proximal 30% of the stem is porous-coated with sintered titanium beads, with a mean pore size of 250 mm to which a hydroxyapatite coating is applied to a thickness of 30 mm. There are nine available sizes for each side (Fig. 1).

All the operations were performed through a posterolateral approach. The femoral component was inserted with a press-fit technique. A transparent template with 15% magnification was used on pre-operative radiographs to identify the probable size of the component and the appropriate level for resection of the femoral neck. The proximal femur was prepared with broaches: reamers were never used. The size of the femoral component selected matched the size of the largest broach used. This would fill the femoral canal and leave little cancellous bone remaining. The dimension of the coated proximal region of the component is 0.5 mm larger than that of the prepared metaphysis.

The patients were allowed to stand on the second post-operative day, and progress to full weight-bearing with crutches as tolerated. They were advised to use a pair of crutches for six weeks and walk with a stick thereafter if required.

Clinical and radiological follow-up was undertaken at three months, six months and one year, and yearly thereafter. The Harris hip score was determined before surgery and at each follow-up examination. Patients scored thigh pain on a ten-point visual analogue scale (0 = no pain, 10 = severe pain).

The level of activity of the patients after the THR was assessed using the activity score of Tegner and Lysholm. This grading scale, with which work and sports activities are graded numerically, was used as a complement to the functional score. The patients were given a score according to the activities in which they engaged in daily life, ranging from zero points for a hip-related disability to ten points for participation in competitive sports at a national level.

The occurrence of any clicking sound emanating from the ceramic-on-ceramic bearing was recorded.

Radiographs were analysed by a research assistant who had no knowledge of the patient’s name. A supine AP radiograph of the pelvis with both hips in neutral rotation and no abduction was taken for every patient. Consistent positioning of the patient was ensured with the use of a frame which was placed at the end of a standard X-ray table. The patient’s feet were secured to polypropylene orthoses attached to the frame, which could be adjusted to accommodate patients of different height. Cross-table lateral radiographs of each hip were also taken.

The femoral morphology was determined in pre-operative radiographs using Dorr’s classification. The adequacy of the intramedullary filling by femoral component at the upper border of the lesser trochanter was recorded as satisfactory when it filled > 80% of the proximal part of the canal in the coronal plane and > 70% in the sagittal plane, according to a previously described method. The component was considered to be undersized if less of the canal was filled in either or both planes.

Loosening of the femoral component was defined when there was a progressive axial subsidence of > 3 mm, or varus or valgus shift of more than 3°. Stem subsidence was evaluated by measuring the distance between the tip of the greater trochanter and the upper margin of the lateral shoulder of the stem, as well as measuring the distance between the most proximomedial part of the porous-coated surface of the stem and the upper border of the lesser trochanter. These measured values in the AP radiographs taken two weeks after operation were compared with those in the AP radiographs taken at the final follow-up examination to define the amount of the subsidence. The intra-observer error for this measurement was determined by the intraclass correlation coefficient after repeated measurements three times at three day intervals. This was 0.97 (0.95 to 1.00), indicating excellent reproducibility. A femoral component was considered to be possibly loose when there was a complete radiolucent line surrounding the entire porous-coated surface on both the anteroposterior and the lateral radiographs.
ingrowth into the femoral components was considered to have occurred when there was a direct extension of the trabecular striation between the femur and the component.

Anteverision of the acetabular component was measured on the lateral radiograph of the hip as the angle between the horizontal line where the film cassette rested on the X-ray table and a second line marking the plane of opening of the acetabular component. To measure acetabular inclination, a line that joined the inferior margins of the teardrops was drawn on the AP pelvic radiograph. The intersection of that line with a line marking the plane of opening of the acetabular component determined the angle of inclination.

Definite loosening of the acetabular component was diagnosed when there was a change in the position of the component (> 2 mm vertically and/or medially or laterally) or a continuous radiolucent line wider than 2 mm on both the anteroposterior and the lateral radiographs. Bone ingrowth into the acetabular component was considered to have occurred when there was direct contact of the trabecular striation between the acetabulum and the component.

A vertical change in the position of the acetabular component was measured between its inferior margin and the inferior margin of the ipsilateral teardrop, and a horizontal change was measured between the Köhler line and the centre of the outer shell of the acetabular component.

The sites of any osteolysis in the acetabulum were recorded according to the system of DeLee and Charnley, and those in the femur by the system of Gruen, McNeice and Amstutz. Osteolysis was defined as any discreet localised radiolucency, which had been absent on radiographs taken immediately after the THR.

Proximal femoral bone resorption was graded radiologically, with grade 1 indicating atrophy or rounding off of the calcar; grade 2, loss of density in the calcar region with preservation of the medial cortical wall to the level of the lesser trochanter; grade 3, loss of density in the calcar region with loss of the medial cortical wall to the level of the lesser trochanter; and grade 4, loss of density in the entire medial cortical wall distal to the level of the lesser trochanter. Measurement of linear wear of the alumina ceramic liner was attempted but was below the level of detection by the method used.

All patients underwent dual energy X-ray absorptiometry (DEXA) scanning of the pelvis and proximal femur using the same Hologic QDR 4500A densitometer (Hologic Inc., Waltham, Massachusetts) and the metal-removal hip-scanning mode. Acquisition of the pelvic scan commenced 2 cm below the lower border of the inferior pubic ramus, using a field width of 15 cm. The scans were orientated so that the acetabular component lay in the centre of the field. Acquisition was continued proximally to 2 cm above the lower limit of the ipsilateral sacroiliac joint. Acquisition of the femoral scan was started approximately 2.5 cm distal to the tip of the femoral component, with the longitudinal axis of the shaft of the prosthesis vertical and occupying the centre of the scan field. The scan was continued proximally to 2 cm above the tip of the greater trochanter. The first DEXA scan was taken two weeks after surgery and served as a baseline of bone mineral density (BMD) for the subsequent scans. Further scans were obtained at the final follow-up.

Heterotopic ossification, if present, was graded according to the classification of Brooker et al.
Statistical analysis. The changes in Harris hip score were evaluated with two-tailed Student's t-tests. The chi-squared test with Yates's correction was used to analyse complication rates and radiological data.\textsuperscript{16} Kaplan-Meier survival analysis\textsuperscript{17} was performed, with revision for any cause as the endpoint. Greenwood's formula\textsuperscript{18} was used to calculate confidence intervals. All statistical analyses were performed using the statistical package for social sciences, version 14.0 (SPSS Inc., Chicago, Illinois). Statistical significance was set at $p < 0.05$.

Results

The clinical and functional results improved significantly (Table I). The mean Harris hip score was 39 points (16 to 51) before surgery and 96 (68 to 100) at the final follow-up. In all, 367 patients (78%) had no detectable limp, 94 (20%) had a mild limp, and ten (2%) had a moderate limp. All but three patients reported a marked improvement in their ability to use stairs and public transport, put on footwear, and effect a pedicure after surgery. No patient had thigh pain at any follow-up examination.

Many patients were active despite post-operative advice to avoid activities involving high impact. Of the series, 437 patients had an activity score of 5 or 6 points at review, indicating participation in strenuous farm work (5 points) or playing recreational sports such as tennis (6 points). Only 25 patients, nine with ankylosing spondylitis, 13 with fracture of the femoral neck, and three with traumatic arthritis, had a score of one point.

A clicking sound was heard in two of the 601 hips (0.3%). This occurred in one patient who underwent bilateral simultaneous THRs. The noise was only heard while he was bearing weight, but he had no pain or other symptoms.

Radiographs taken two weeks after surgery showed satisfactory filling in all hips, 570 (95%) femoral components were in a neutral position and 31 (5%) were in varus. In the 31 hips with varus alignment of the component, there was contact between the distal stem and the femoral cortex but no thigh pain was reported in these cases of inadvertent endosteal contact. There was no change in the position of these varus components on the radiographs between two weeks after the operation and final follow-up. The morphology of the proximal femur was Dorr type A in 517 hips (86%) and type B in 84 (14%). At the latest evaluation, 523 hips (87%) had grade 2 stress-shielding bone loss and 78 (13%) had grade 3 loss at the calcar. No hip had grade 4 bone loss. No acetabular or femoral osteolysis was identified.

No hip had migration of the femoral component in excess of 2 mm. No hip had a radiolucent line around the porous-coated surface of the femoral component on either AP or lateral radiographs. Radiodense lines without intervening radiolucent lines were present in 367 hips (61%) around the polished distal stem, and 234 hips (39%) had radiodense lines with less than 1 mm intervene radiolucent lines around the polished distal stem. A distalpedestal was observed in 12 hips (1.9%). No hip had distal cortical hypertrophy. All femoral components had obtained bone ingrowth at the latest follow-up (Fig. 2). The mean inclination of the acetabular component was 38.9° (35° to 49°) and its mean angle of anteversion was 22.5° (15° to 40°). No hip had a radiolucent line around the acetabular component on either AP or lateral radiographs. In 18 hips (3%) an initial gap seen between the acetabulum and the acetabular component was filled in completely by apparent bone ingrowth at the final review. All acetabular components were deemed to have bone ingrowth at the latest follow-up examination (Fig. 2).

Around the acetabular component the mean BMD significantly increased in zone I but was significantly reduced in zone II by the final review. There was a slight increase in zone III by the final review. Around the femoral component the BMD was significantly reduced in zones 6 and 7 and was slightly reduced in zone 1. The mean BMD in zones 2, 3, 4 and 5 increased slightly by final review (Table II).

No hip required revision of any component for aseptic loosening. Both components were revised in two hips (0.3%) because of deep infection at six months and one year respectively. One acetabular component (0.2%) was revised following recurrent dislocation. Kaplan-Meier survival analysis, with revision as the endpoint for failure, revealed a ten-year rate of survival for the acetabular component of 99.5% (95% confidence interval (CI) 0.96 to 1.00) and 99.7% (95% CI 0.98 to 1.00) for the femoral component. When aseptic loosening was used as the end-point for failure, the survival rate of the both components was 100% (95% CI 0.98 to 1.00).

Complications. Intra-operative linear fractures at the calcar occurred in five hips (0.8%). These were treated with Dall-Miles cabling (Howmedica, Rutherford, New Jersey): all

\begin{table}[h]
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\caption{Harris hip scores of 471 patients (601 hips) showing the distribution of the score, by number and percentage of hips and the mean (range) pre-operatively and at a mean follow-up of 8.8 years.}
\begin{tabular}{|c|c|c|c|c|c|c|}
\hline
 & \textbf{Harris hip score distribution} & & & & & \\
 & \textbf{Number of hips} & \textbf{Excellent (90 to 100)} & \textbf{Good (80 to 89)} & \textbf{Fair (70 to 79)} & \textbf{Poor (< 70)} & \textbf{Mean Harris hip score (range)} & \textbf{p-value (Student's two-tailed $t$-test)} \\
\hline
\textbf{Pre-operative} & 601 & 0 & 0 & 71 (12) & 530 (88) & 39 (16 to 51) & < 0.001 \\
\textbf{Follow-up} & 601 & 565 (94) & 22 (3.7) & 11 (1.8) & 3 (0.5) & 96 (68 to 100) & < 0.001 \\
\hline
\end{tabular}
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healed completely and osseointegration of the prosthesis was achieved.

One hip (0.2%) had an avulsion fracture at the greater trochanter. There was no instability and no other problems.

Dislocation occurred in three hips (0.5%), two of which were treated successfully with closed reduction and an abduction brace for three months. The remaining hip required revision of the acetabular component.

Grade 1 heterotopic ossification occurred in 29 hips (5%), and grade 2 heterotopic ossification in five (0.8%). No hip had a grade 3 or 4 heterotopic ossification.

**Discussion**

The proximal geometry of the immediate post-operative stability stem is designed to achieve immediate mechanical stability within the metaphysis, with the narrow distal stem functioning as an alignment guide at the time of implantation. The distal section does not contribute to the fixation. In this series of active young patients, the immediate post-operative stability femoral stem achieved excellent clinical results.

The predominant diagnosis in this series was osteonecrosis of the femoral head. In a histomorphometric evaluation of iliac bone biopsies, Arlot et al. found that all of their 77 patients with osteonecrosis of the femoral head had evidence of osteoporosis or osteomalacia. They suggested that this underlying metabolic bone disease could produce a defect in healing of microfractures and could impair bone ingrowth into the cementless total hip prosthesis. In a histological study, Calder, Pearse and Revell found that patients with osteonecrosis of the femoral head which also involved proximal Gruen zones 1, 2, 6, and 7 had evidence of extensive osteocyte death. In their series of 16 patients, ten had a diagnosis of sickle-cell disease or steroid-
induced osteonecrosis. They proposed that osteonecrosis in these regions may reduce the remodelling capacity of bone at the implant-bone or implant-cement interface and thus impair osseointegration and adequate fixation of the prosthesis. In contrast, Kim and Kim 21 found that the majority of patients who had idiopathic or osteonecrosis secondary to ethanol abuse had normal or nearly normal bone in the acetabulum and in the areas of the proximal part of the femur which are crucial for fixation of the implant. Osteonecrosis was predominantly confined to the femoral heads. In our series, the excellent results in patients with osteonecrosis of the femoral head support the findings of Kim and Kim. 21

Mallory et al 22 reported the survival of 120 Mallory-Head tapered cementless femoral stems (Biomet, Warsaw, Indiana) at 12.2 years follow-up was 97.5%. However, they observed bone resorption of the proximal femur related to stress shielding in 22 hips (18%) and femoral osteolysis in 35 hips (29%). Laupacis et al 23 reported a 95% survival rate of 126 Mallory-Head tapered cementless THRs at 6.3 years follow-up.

In two series reporting the Zweymüller Alloclassic cementless femoral component (Alloclassic-SL, Allopro AG, Baar, Switzerland) the survival was 99% and 100% at ten and 11.3 years follow-up, respectively. 24,25 However, cases of proximal osteolysis and osteopenia were observed.

The survival of the Trilock femoral component (DePuy, Warsaw, Indiana) has been reported as 95.5% at 15 years follow-up 26 but with associated proximal femoral resorption due to stress shielding in just under half the patients.

In the current study there was an absence of osteolysis, and only mild stress shielding was observed. I believe that the absence of contact between the distal stem and the femoral cortex minimises stress shielding related proximal femoral bone resorption. Although biological fixation only occurs proximally with the metaphyseal loading cementless stem, the segment with the attached bone would act as a single unit, which explains the mild proximal stress shielding, which is less marked at the junction of the coated and uncoated stem surfaces where the forces are concentrated (Table II).

The absence of detectable acetabular or femoral osteolysis appeared to be attributable to the use of an alumina-on-alumina ceramic bearing with negligible wear particles and solid fixation of the component in the acetabulum and in the proximal femur, limiting the so-called effective joint space. 27 The absence of osteolysis in our series echoes the similar findings for other ceramic-on-ceramic THRs 28,29 and for metal-on-metal articulations. 30

Compared with baseline values, the BMD changed in all zones of the acetabulum. There was an increase in the BMD in zone 1 adjacent to the prosthetic rim, and a reduction in the central pelvic zone, suggesting that when loaded the fully-fixed acetabular component transfers most of the load peripherally near the rim, and stress shielding of the medial cancellous bone occurs.

A high prevalence of thigh pain has been reported after cementless THRs 9,31–34 which has been attributed to micro-movement of the stem in the presence of a tightly-fitted distally rigid stem. The absence of thigh pain in our study may be attributed to the axial and torsional stability of the stems and an absence of contact between the distal stem and the femoral cortex.

It is recognised that as this study relates to a single implant design the results should be extrapolated to other designs and bearing materials with caution. Another weakness is that the migration analysis did not use the more precise methods of radiostereophotogrammetric analysis 35 or Ein Bild Roentgen Analyse. 36

In conclusion, a metaphyseal loading cementless anatomical immediate post-operative stability femoral component without distal stem fixation has demonstrated satisfactory fixation.

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References


