Outcome of a hemispherical porous-coated acetabular component with a proximally hydroxyapatite-coated anatomical femoral component

A 12- TO 15-YEAR FOLLOW-UP STUDY

We reviewed 111 hemispherical Duraloc series-500 acetabular components with a minimum follow-up of 12 years. The mean clinical and radiological follow-up was 13.4 years (12 to 15). A Profile hydroxyapatite-coated anatomical femoral component was used in each case. Six patients had a late dislocation, for whom the polyethylene liner was exchanged. Each acetabular component was well fixed and all femoral components showed signs of bone ingrowth. The mean rate of femoral head penetration was 0.10 mm/year (0.021 to 0.481). The probability of not developing femoral cortical hypertrophy and proximal osteopenia by 12 years was 80.2% (95% confidence interval, 72.7 to 87.6) and 77.5% (95% confidence interval, 69.7 to 85.2), respectively. Despite these good clinical results, further follow-up is needed to determine whether these prostheses will loosen with time.

Despite changes in component design and polyethylene manufacture, polyethylene wear remains the most common cause of loosening of the acetabular component after total hip replacement.1,2 If the locking mechanism of a modular shell is inadequate, movement between a thin liner and the metal shell can generate debris and cause the polyethylene to fail.3

The Duraloc porous-coated titanium acetabular system (DePuy, Warsaw, Indiana) consists of a range of implants comprising a shell, which can be augmented by pegs or screws if a firm press-fit is not achieved, and a polyethylene liner which is secured within the shell by a ring-locking mechanism. Good clinical results have been reported with the earlier types of Duraloc component.4-6 In this study, we reviewed the 12- to 15-year results of the Duraloc series-500 acetabular component, paying particular attention to the rate of polyethylene wear, osteolysis and any adaptive bone changes.

Patients and Methods

The Duraloc series-500 (DePuy) is a metal-backed, porous-coated, hemispherical press-fit acetabular component composed of pure titanium beads sintered to a solid substrate with a pore size ranging from 200 μm to 300 μm. It has a central hole in the porous metallic shell and uses two anti-rotatory pegs to improve bone fixation. Its liner (Enduron, DePuy) has a 10° lip and is made of conventional 415 GUR polyethylene, which is ram-extruded and sterilised by gamma-irradiation in air. It is held within the shell by a metal ring (Sensor Ring; DePuy).

Between November 1992 and November 1995 we implanted 125 consecutive primary Duraloc series-500 components. A cementless Profile hydroxyapatite (HA)-coated anatomical femoral component (DePuy) with a 28 mm cobalt-chrome femoral head (Orthochrome; DePuy) was used in each case. We excluded patients over the age of 75, and those with a cylindrical femoral canal (younger patients with Dorr C cylindrical femora were included), incomplete radiographs or a follow-up of less than 12 years. This left 111 hips in 111 patients for analysis. There were 55 men and 56 women. Their mean age at operation was 57.3 years (21 to 72) and their mean body weight 71.0 kg (46 to 102). Their activity level using the grading system devised by Devane et al,7 was grade 1 and 2 in two hips, grade 4 in 41, and grade 5 in 23. Femoral bone quality was classified according to the system of Dorr et al:8 54 hips were type A, 38 type B, and 19 type C. The primary diagnosis was osteoarthritis in 66 hips, avascular necrosis in 19, developmental arthritis in nine, post-traumatic arthritis in nine, rheumatoid arthritis in three, and other diagnoses in five. Oral and written informed consent was obtained from each patient.
Each operation was performed through a posterolateral approach. The acetabulum was underreamed by 2 mm in accordance with the manufacturer’s instructions. No screws were used to secure the acetabular component in any case. The largest possible femoral component was used. The median acetabular component size was 54 mm (48 to 64), and the median femoral component size was 2 (0 to 5). Post-operatively, all patients received antibiotic prophylaxis (cephazolin 1 s every 8 hours for 48 hours) as well as subcutaneous heparin. Patients were non-weight-bearing for three weeks and then walked with the aid of crutches for the next six weeks.

Clinical evaluation included an assessment of pain, function, and range of movement according to the six-level scale described by Merle D’Aubigné and Postel. Patients were also asked about the location of any pain. Standard anteroposterior radiographs of the pelvis and lateral radiographs of the hip were taken immediately after the operation, and at six weeks, three, six and 12 months, and annually thereafter. The patient was positioned supine, with his/her feet together. The X-ray tube was positioned over the symphysis pubis 1 m from and perpendicular to the table. In order to avoid inter-observer error, measurements were made by a single observer, who had not been involved in the surgery. The component position was assessed according to the acetabular abduction angle, the height of the centre of the hip (measured from the centre of the femoral head perpendicular to the line drawn between the teardrops), and the horizontal distance of the component (measured from the centre of the femoral head to Köhler’s line). The acetabular abduction angle was classified as neutral (40° to 50°), horizontal (< 40°) or vertical (> 50°). Currently bone ingrowth into an acetabular component is inferred by the absence of the two classic signs of loosening, radiolucent lines and component migration. Because of the difficulty of detecting radiolucent lines around uncemented components, an acetabular component was considered to have migrated when there was a change of more than 5° in the acetabular abduction angle or a change of more than 3 mm in the height of the centre of the hip or the horizontal distance of the component. The distribution of any radiolucent gaps on the first post-operative radiograph and of radiolucent lines or osteolysis at the acetabular bone-prosthesis interface on the subsequent radiographs was recorded using the three zones described by DeLee and Charnley. Radiographs were scanned digitally, and linear polylethylene wear was estimated according to the method of Kim, Kim and Cho. Penetration of the prosthetic head into the polylethylene liner was measured with a computer-assisted edge-detection system and software specially designed to measure femoral head penetration into polyethylene (AutoCAD 2000 AutoDesk Inc, Sausalito, California). Radiographs were digitised using a scanner (Epson Expression 1680, Seiko Epson Corp., Nakano, Japan). Femoral head size was used as an internal reference. The measurements were repeated five times and the mean was recorded. The intra-class correlation coefficient was 0.9777 (95% confidence interval (CI) 0.9363 to 0.9897). The amount of penetration on the radiograph taken six weeks post-operatively was used as a reference for subsequent measurements, as in other series. Early wear occurring in the first post-operative year, and true wear, occurring later, were measured.

The position of the femoral component was defined as neutral, valgus (> 3 mm of lateral deviation) or varus (> 3 mm of medial deviation). Femoral canal fill, measured as the ratio of the width of the component to the width of the medullary canal, was determined at two levels: the middle of the femoral component (level A) and 1 cm proximal to the tip (level B). The distribution of any radiolucent lines or osteolysis on the anteroposterior radiographs was recorded using the zones described by Gruen, McNeice and Amstutz. Osteolysis was classified as extensive, intermediate or mild, according to the criteria of Goetz, Smith and Harris. Femoral osteopenia due to stress shielding and femoral component fixation were graded according to the criteria described by Engh, Bobyn and Glassman and Engh, Glassman and Suthers. Subsidence was defined as a distal change of at least 5 mm in the distance between the top of the femoral component and the greater trochanter when the initial post-operative radiographs were compared with those made at the follow-up evaluations. Kaplan-Meier survival analysis, with 95% confidence intervals, was used to estimate the cumulative probability of not having a late dislocation, femoral osteopenia, cortical hypertrophy, or osteolysis. Qualitative data were compared with the use of the chi-squared test or Fisher’s exact test, and quantitative data were compared with Student’s t-test, the Mann-Whitney U test or analysis of variance (ANOVA), depending on the distribution of the data. Cox multivariate regression analysis was used to assess the influence of various factors on survival time until an outcome event. The level of significance was set at p < 0.05.

Results

Two patients died from unrelated causes and 12 were lost to follow-up despite repeated attempts to contact them. This left 99 patients (111 hips).

There were two intra-operative calcar fractures (1.8%), both in patients with rheumatoid arthritis, which were treated with cerclage wires. The fractures healed without compromising bony ingrowth and the outcome was good. No hip became infected. No acetabular or femoral component was revised for loosening. Two patients sustained an undisplaced femoral fracture around the proximal mid-part of the femoral component after 16 and 20 months, respectively. Both fractures were treated conservatively and later healed uneventfully.

Transient level 4 pain in the thigh was present in three hips for the first two years: of these, two had a Dorr type B femoral canal and the other had a Dorr type C canal. At final follow-up there was level 5 pain in 14 hips, and level
OUTCOME OF HEMISPHERICAL POROUS-COATED ACETABULAR COMPONENT WITH AN ANATOMICAL FEMORAL COMPONENT

The mean post-operative pain rating was 5.7 (2 to 6), having improved from a mean of 2.5 (2 to 3) pre-operatively. Hip function was difficult to evaluate in cases of bilateral disease. The mean walking function rating increased from 2.4 (2 to 3) to 5.6 (2 to 6), and the mean sum for the arc of motion from 2.4 to (2 to 3) to 5.1 (1 to 6).

Six patients had a late dislocation (five years or more after surgery). All late dislocations were associated with repeated subluxations and were initially treated by closed reduction. The polyethylene liner was eventually changed to a lipped liner in all except one case, in whom a dual mobility component (Serf, Decines, France) was used and the complication has not recurred. The soft tissues were reconstructed as securely as possible. Each of the six dislocating hips exhibited cold flow at the rim of the polyethylene liner and less containment. Data on the patients who dislocated are listed in Table I. The mean time to dislocation was 78.8 months (62 to 102). The cumulative probability of not having a late dislocation was 94.4% (95% CI, 90.1 to 98.7) at 12 years (Fig. 1). Only the six-week post-operative femoral penetration was associated with late dislocation (Student’s t-test p = 0.043).

Radiological analysis. There were 67 neutral (60%), 36 vertical (33%), and eight horizontal components (7%). The mean abduction acetabular angle was 45.4° (30° to 60°), the mean height of the femoral head centre of the hip was 23.3 mm (0 to 40), and the mean horizontal distance of the component was 32.1 mm (10 to 45). There were 24 hips with a lucency around the component on the first post-operative radiograph. Of these, 12 had a lucency in one zone, ten in two zones, and two in three zones. No hip had a lucency around the component at five years, and no new lucency appeared after ten years. No component migrated (Fig. 2). Acetabular osteolysis in zones 2 and 3 was only seen in one hip; the patient is asymptomatic after 14 years. His radiograph shows femoral head penetration of 2 mm, femoral osteolysis in Gruen zone 7 and stable fixation of the acetabular component.

The mean six-week post-operative femoral head penetration into the polyethylene liner was 0.18 mm (0.10 to 0.82). The subsequent mean penetration was 0.10 mm/year (0.021 to 0.481). The mean penetration at one year was 0.30 (0.09 to 1.13). The mean femoral head penetration was 1.23 mm (0.6 to 3.56) after 11 years (Fig. 3). A quarter of the hips showed excessive penetration of ≥0.13 mm/year. Only a younger age (mean 52.0 (SD 11.6) versus mean 58.9 years (SD 10.0) (Mann-Whitney U test, p = 0.033) was significantly associated with excessive penetration (≥0.13

Table I. Late dislocations

<table>
<thead>
<tr>
<th>Case</th>
<th>Age at surgery (yrs)</th>
<th>Gender</th>
<th>Diagnosis</th>
<th>Component size (mm)</th>
<th>Interval since surgery (mths)</th>
<th>Post-operative radiological wear (mm)</th>
<th>Mean wear (mm/yr)</th>
<th>Wear at dislocation (mm)</th>
<th>Subluxation</th>
<th>Recurrent dislocations</th>
<th>Definite closed reduction</th>
<th>Exchange liner</th>
<th>Major trauma</th>
<th>Neurologic impairment</th>
<th>Excessive alcohol intake</th>
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<td>1</td>
<td>64</td>
<td>Female</td>
<td>Necrosis</td>
<td>50</td>
<td>102</td>
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<td>Female</td>
<td>Osteoarthritis</td>
<td>54</td>
<td>90</td>
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<td>0.07</td>
<td>0.66</td>
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<td>No</td>
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<tr>
<td>3</td>
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<td>Male</td>
<td>Necrosis</td>
<td>54</td>
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<td>0.60</td>
<td>0.37</td>
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<td>0.12</td>
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<tr>
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<tr>
<td>6</td>
<td>72</td>
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<td>56</td>
<td>72</td>
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<td>0.02</td>
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</tr>
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</table>

Graph showing the Kaplan-Meier cumulative probability of not having a late dislocation. The upper and lower curves represent the 95% confidence intervals.

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mm/year). However, the patients with greater penetration tended to be more active (activity level ≥ 4 according to Devane et al,7 Mann-Whitney U test, p = 0.058), heavier, (weight > 80 kg, Mann-Whitney U-test, p = 0.296), and to have a greater mean abduction angle (> 50° vertical) than patients with less penetration (chi-squared test, p = 0.445).

There were 83 femoral components (75%) in neutral, 22 (20%) in valgus, and six (5%) in varus. The mean femoral canal fill was 89.5% (67% to 100%) at the middle third of the femoral component (level A) and 89.6% (63% to 100%) at the distal end of the femoral component (level B). The canal fit was better in funnel-shaped femora than in Dorr C cylindrical femora (ANOVA, p < 0.01) (Table II). All femoral components showed bony ingrowth, even the Dorr C femoral canals. There were three hips with 5 mm of non-progressive painless femoral component subsidence, two in Dorr C femoral canals (with a mean canal fill < 70%) and one in a Dorr type B femoral canal (with 86% canal filling). Radiolucent and radiodense lines were uncommon and were only found around the proximal corner of the femoral component. Four hips showed signs of femoral osteolysis at a mean 61.9 months (16 to 96) from surgery. This was only associated with femoral cortical thickening (Cox multivariate regression analysis p = 0.05). The cumulative probability of not having femoral osteolysis at 12 years was 93.4% (95% CI, 92.9 to 99.8). All osteolytic lesions were proximal and focal. Osteolysis was mild in three hips and intermediate in one. According to the Cox multivariate regression analysis, the risk of femoral osteolysis increased with the appearance of cortical thickening (hazard ratio = 12.5, 95% CI, 1.3 to 120.8, p = 0.028). The mean time from surgery to the appearance of femoral cortical thickening in 22 hips was 43.6 months (13 to 60). Cortical thickening was related to the presence of femoral osteolysis (Cox multivariate regression analysis p < 0.001) and proximal femoral osteopenia (Cox multivariate regression analysis p = 0.012). The cumulative probability of not having cortical thickening at 12 years in the follow-up study was 80.2% (95% CI, 72.7 to 87.6). According to the Cox multivariate regression analysis, the risk of appearance of cortical thickening increased with the presence of femoral osteolysis (hazard ratio = 6.7, 95% CI 1.88 to 23.8, p = 0.003) and proximal femoral osteopenia (hazard ratio = 2.62, 95% CI 1.11 to 6.19, p = 0.028). Proximal femoral osteopenia due to stress shielding was common in this study. Engh et al21 grade 1 osteopenia was present in most hips. Grade 2 was seen in 24 hips and grade 3 in one. The mean time from operation to the appearance of grade 2 osteopenia was 25.3 months (13 to 60). Femoral osteopenia was related to female gender (Cox multivariate regression analysis p = 0.004), weight > 80 kg (p = 0.021), Dorr femoral type grade B (p = 0.036), and cortical thickening (p = 0.001). The cumulative probability of not having
grade 2 osteopenia at 12 years was 77.5% (95% CI, 69.7 to
85.2). According to the Cox multivariate regression anal-
ysis, the risk of appearance of proximal femoral osteopenia
(grades 2 and 3) increased with female gender (hazard ratio = 3.121, 95% CI, 1.39 to 6.79, p = 0.013), and cortical
thickening (hazard ratio = 3.07, 95% CI, 1.39 to 6.79, p = 0.006).

Discussion
This study shows that the porous, modular, cementless,
two-pegged acetabular component Duraloc 500 inserted
with a press-fit technique provides good clinical results. No
components were revised for loosening, and no radiological
loosening was seen in the current series.

There are several limitations to our study, of which the
principal is the relatively small cohort available for study.
Additionally we did not randomise these components with
other designs for comparison and no analysis of inter-
observer variability was undertaken for the radiological
measurements. The investigating surgeon examined the
radiographs and entered the data on forms on the day of the
clinic visit but as it was not feasible to measure polyeth-
ylene wear, alignment, fit or fill in the clinic, these measure-
ments were performed by another author on a separate
occasion. There may therefore be some bias in the radi-
ological assessment. We accept that our assessment of loosen-
ing, polyethylene wear and subsidence may not be entirely
exact, but clinically and radiologically we could find no evi-
dence of loosening. Although the absence of signs of loosen-
ing may suggest that a component is stable, it has been
previously observed that this does not necessarily indicate
that there has been osseointegration of the component.11

Metal backing in acetabular component design provides
structural support by absorbing the forces radiating
through the polyethylene,24 but gaps between the shell and
the liner can cause device failure. The Sensor-ring locking
design (DePuy), can conform to dimensional variations
that can occur to the polyethylene in vivo.25 Although digitised
measurement methods are more accurate than manual,
good-quality radiographs are needed to view the margins
of the component and femoral head clearly. Digital imaging
methods similar to ours have been validated in studies using
phantom models and retrieved components,15,26,27 but they
have not been replicated with radiographs obtained in vivo.28 The precision achieved with phantom studies is bet-
ter than that in clinical studies, as scatter, absorption of
radiation by soft tissues, and in vivo penetration patterns
cannot be recreated in the laboratory.28

We found only one example of acetabular osteolysis in our
series. This occurred in the 14th post-operative year and was
associated with 2 mm of liner penetration. Pittro et al29
reported retroacetabular stress shielding with uncemented
press-fit components using quantitative CT-assisted
osteodensitometry. These radiological changes are expected
when the bone density is reduced by 70%30 and are thought
to be due to cortical transfer in uncemented components. This
occurs more frequently with uncemented components.31

The risk of dislocation after total hip replacement is the
result of many factors. Late dislocation has been associated
with female gender, osteonecrosis of the femoral head or
fracture of the proximal femur, increased soft-tissue compli-
ance, trauma, excessive alcohol intake, neurological decline,
component malposition and polyethylene wear.32,35

Coventry33 reported that patients with late dislocation had a
greater range of hip movement, especially in flexion. He pos-
tulated that, over time, stretching of the pseudocapsule led to
soft-tissue incompetence and dislocation. It is possible that
if the static soft-tissue restraints and muscle strength around
the hip deteriorate with time, a problem with a malposi-
tioned implant may be unmasked and present as a late dislo-
cation.32 Repeated subluxation was associated with late
dislocation. Subluxation can lead to polyethylene cold flow
at the rim of the liner, containment loss and late disloca-
tion.36 We observed cold flow of the polyethylene at the rim
of the liner and reduced containment at the time of revision.
This reduced the survival rate of the component to 94.4% at
12 years. Only post-operative femoral penetration measured
from the reference radiograph was associated with late dislo-
cation in the current series.

We have had good clinical results with the HA-coated Pro-
file femoral component in the present series. Like Kelly et
al,37 we have also achieved good clinical and radiological
results in patients with Dorr type C femoral bone. The low
prevalence of thigh pain in our study is probably attributable
to the axial and torsional stability of the anatomic femoral
component.38 Other series in which the femoral component
had an HA-coating have noted an absence of thigh pain.39,40

Femoral osteopenia and cortical thickening were common in
this series, and are probably due to the concentration of
stress in the transient zone between the stiff area around the
femoral component and the elastic area below the implant.41
The Profile femoral component is rigid and promotes tight
distal canal filling, which may result in stress concentrations
at the tip.32 Bone remodelling changes occur less frequently
with tapered femoral component designs, whether HA-
coated or not.41-45 However, Karachalios et al46 believe that
the relevance of stress shielding in total hip replacement has
been overestimated in the literature.

Only one of the Duraloc 500 acetabular components,
showed any sign of osteolysis. Polyethylene wear was still
the most frequent cause of failure, resulting in recurrent
dislocation in six patients. The polyethylene liner was
exchanged after repeated dislocations, to good effect. The Profile HA-coated anatomical femoral component also gives good clinical results and excellent bone fixation after ten years, although cortical hypertrophy and proximal osteopenia were frequent. Despite these good clinical results for the Duraloc 500 Profile association components, we currently recommend the use of Duraloc acetabular components associated with a tapered femoral component which is less rigid than the Profile femoral component, in order to reduce the frequency of bone remodelling changes as far as possible. Further follow-up is needed to establish whether long-term fixation is maintained, and whether the Duraloc 500 acetabular component will eventually loosen with osteolysis. The rate of polyethylene wear will need to be carefully monitored.

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