Long-term survivorship of the Charnley Elite Plus femoral component in young patients

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We studied prospectively the long-term results of the Charnley Elite-Plus femoral stem in 184 consecutive young patients (194 hips). There were 130 men and 54 women with a mean age of 49.1 years (21 to 60). The predominant diagnosis was osteonecrosis of the femoral head (63.6%, 117 patients). Clinical and radiological evaluation was undertaken at each follow-up. The mean follow-up was 11.2 years (10 to 12).

The mean pre-operative Harris hip score was 43.4 (12 to 49) which improved to 91 (59 to 100) at the final follow-up. The survival of the femoral stem at 12 years was 99% with revision as the end-point. The mean annual linear wear of the polyethylene liner was 0.17 mm (0.13 to 0.22). The prevalence of acetabular osteolysis was 10.8% (21 hips) and osteolysis of the calcar femorale 12.9% (25 hips).

A third-generation cementing technique, accurate alignment of the stem and the use of a 22 mm zirconia head were important factors in the prevention of aseptic loosening of the Elite Plus femoral stem in these high-risk young patients.

The original Charnley low-friction arthroplasty (DePuy, Leeds, United Kingdom) has an unrivalled record of long-term success with a follow-up which exceeds 30 years.1-5 It has been shown that, even in younger patients it gives reasonable long-term results.6-9

The Elite Plus stem (DePuy) evolved in two stages from the original Charnley stem (DePuy). First, a modular head was introduced while maintaining the ortron 90 femoral stem (DePuy). Next, the geometry of the stem was changed. The flange was undercut, the diameter of the stem reduced, a centraliser was added and the neck-shaft angle was increased incrementally with the stem size from 135°.

Although the design features were claimed to be an improvement, the early clinical results were mixed. Some authors found an outcome similar to that of the conventional Charnley stem10 while others suggested that it was worse.11-15 Norton et al11 reported catastrophic early failure of this stem when used with a zirconia ceramic head and a Hylamer acetabular component. All failed because of aseptic loosening with progressive osteolysis or radiolucencies. Walton et al14 reported that 30.9% (52 of 168) had either been revised or had definite evidence of radiological loosening of one or other component at a mean of 6.4 years after surgery. Poor cementing technique and the use of low-viscosity cement contributed to the high rate of failure. Hauptfleisch et al15 had a survival rate of 59% at ten years when radiological loosening was taken as the end-point. They suggested that rotational instability was a further cause of failure.

In this prospective study we have evaluated the long-term results of the Elite-Plus femoral component in young patients, noting particularly the prevalence of aseptic loosening, wear of polyethylene and osteolysis.

Patients and Methods

We studied 184 consecutive patients (194 hips) under the age of 60 years who had undergone total hip replacement (THR) between June 1994 and June 1996 using a cementless Duraloc acetabular component (Depuy, Warsaw, Indiana) and a cemented Elite Plus femoral stem (DePuy). The study was approved by our internal review board, and each patient gave informed consent. All the operations were performed by the senior author (YHK). After a minimum of ten years no patient was lost to follow-up.

Our patient population was very different from that in the West. Most were under 50 years of age, were of light build and had osteonecrosis of the hips. There were 130 men and 54 women with a mean age at the time of operation of 49.1 years (21 to 60) and a mean weight of 62.1 kg (42 to 90). The diagnosis was osteonecrosis of the femoral head in 117 patients (63.6%), osteoarthritis in 41 (22.2%), ankylosing spondylitis in
12 (6.5%), osteoarthritis secondary to childhood septic arthritis in 6 (3.3%), multiple epiphyseal dysplasia in 4 (2.2%), and rheumatoid arthritis in 4 (2.2%). The mean follow-up was 11.2 years (10 to 12).

The leg length was measured before and after the operation both with a tape measure and with a scanogram. A Gibson posterolateral approach\textsuperscript{16} was used in all the hips. The patients were mobilised fully weight-bearing on crutches on the second day after the surgery. All acetabular components were press-fitted after under-reaming by 2 mm. Multiple screws were used in 80, and none in 114. A liner with an inner diameter of 22 mm made of conventional 1150 GUR polyethylene (DePuy, Leeds, United Kingdom), ram-extruded and sterilised with gas plasma, was used in each case.

In all patients the femoral stem was implanted with a 22 mm zirconia head. Cement was introduced using a so-called third-generation technique which comprised the use of Simplex P cement (Howmedica, Rutherford, New Jersey) in its dough stage, an intramedullary plug, pulsatile lavage, vacuum mixing of the cement, a cement gun, a proximal rubber seal and a centraliser on the stem.

Clinical and radiological follow-up was carried out after six weeks, three and six months, at one year and annually thereafter. The Harris hip score\textsuperscript{17} was established pre-operatively and at each follow-up examination. Thigh pain was recorded by the patient using a 10-point visual analogue scale,\textsuperscript{18} with 0 indicating no pain and 10 severe pain.

Table I. The clinical findings of the use of the Elite Plus femoral stem in 184 patients (194 hips)

<table>
<thead>
<tr>
<th>Mean (range) Harris hip score (points)</th>
<th>Pre-operatively</th>
<th>Post-operatively</th>
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<tbody>
<tr>
<td></td>
<td>43.4 (12 to 49)</td>
<td>91 (59 to 100)</td>
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<tr>
<th>Grading (number, % of hips)</th>
<th>Excellent (≥ 90 points)</th>
<th>Good (80 to 89 points)</th>
<th>Fair (70 to 79 points)</th>
<th>Poor (≤ 70 points)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>82 (42.2)</td>
<td>101 (52.1)</td>
<td>8 (4.1)</td>
<td>3 (1.6)</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Prevalence of thigh pain (number, %)</th>
<th>1 (0.5)</th>
</tr>
</thead>
</table>

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<tr>
<th>Use of walking aids pre-operatively (number, % of patients)</th>
<th>None</th>
<th>One stick</th>
<th>One crutch</th>
<th>Two crutches</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>38</td>
<td>52 (28.2)</td>
<td>37 (20.1)</td>
<td>57 (31.0)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Use of walking aids post-operatively (number, % of patients)</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>184</td>
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</table>

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<thead>
<tr>
<th>Mean (cm, range) limb length</th>
<th>Pre-operative</th>
<th>Post-operative</th>
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<tr>
<td></td>
<td>1.8 (1.2 to 3.8) shorter on the operative side</td>
<td>0.7 equal in 144 patients (0.4 to 2.0) longer in 40 patients by a measurement with a scanogram</td>
</tr>
</tbody>
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The femoral bone type was determined pre-operatively using the isthmus ratio of Dorr.\textsuperscript{19} Radiographs taken at six weeks were analysed for alignment of the stem (valgus, varus or neutral) and the cement mantle was graded using the method described by Barrack, Mulroy and Harris.\textsuperscript{20} Heterotopic ossification, if present, was graded according to the classification of Brooker et al.\textsuperscript{21}

The final follow-up radiographs were analysed for radiolucent lines around acetabular zones I, II and III of DeLee and Charnley\textsuperscript{22} and the femoral zones 1 to 14 of Gruen, McNeice and Amstutz.\textsuperscript{23} Vertical migration of the acetabular component was measured between its inferior margin and the inferior margin of the ipsilateral teardrop, and horizontal migration between Köhler’s line and the centre of the outer shell of the component.\textsuperscript{24} Loosening of the acetabular component was diagnosed when there was a change in its position or a continuous radiolucent line wider than 2 mm on both the anteroposterior and the lateral radiographs. The criteria used to define loosening of the cemented femoral stem have been described previously.\textsuperscript{20}

The location and extent of osteolysis were determined by measuring the length and width of the osteolytic lesion in each zone. Linear wear of the liner was measured by a software program (Microsoft Corp., Redmond, Washington).\textsuperscript{25} The mean interobserver difference was 0.04 mm (0.03 to 0.06) and the interclass correlation coefficient 0.97.
Volumetric wear was calculated using the equation
\[ v = \pi r^2 w \]
where \( v \) = volumetric wear, \( r \) = the radius of the femoral head and \( w \) = measured linear wear.

The angles of anteversion and abduction of the acetabular component were measured, and an attempt was made to correlate wear of the liner with them.

**Statistical analysis.** This was performed using the chi-squared test with Yates’s correction,26 Student’s two-tailed t-test and analysis of variance. The Kaplan-Meier curve method27 was used for survival analysis and Greenwood’s formula28 to calculate the confidence interval (CI) of survival at a particular point in time.

**Results**

**Clinical findings.** The clinical results improved substantially after the operation (Table I). The mean pre-operative Harris hip score was 43.4 points (12 to 49) which improved to 91 points (59 to 100) post-operatively. A total of 82 hips (42.2%) were rated excellent, 101 (52.1%) good, 8 (4.1%) fair and 3 (1.6%) poor. One patient had thigh pain at follow-up because of aseptic loosening of the femoral stem.

The functional results were also improved markedly after the operation. Before the operation, 38 patients (20.7%) used no walking aids, 52 (28.2%) used a stick, 37 (20.1%) a crutch and 57 (31.0%) two crutches. At final follow-up no patient needed a walking aid. Their ability to use stairs and public transport and to put on footwear and cut their toenails was markedly improved post-operatively.

**Radiological findings.** The radiological results were excellent (Table II). The cement mantle was graded A in 173 hips (89.2%) and B in 21 (10.8%) (Fig. 1). The stems were in the neutral position in 182 hips (93.8%) and in slight varus in the remaining 12 (6.2%). Two hips (1%) were loose and one had a radiolucent line of more than 1 mm in several zones (Fig. 2). One acetabular component was unstable and one showed signs of fibrous ingrowth. The Dorr bone type was A in 177 of 194 hips (91%) and type B in 17 hips (9%).
The mean thickness of the polyethylene liner was 11.2 mm (8.8 to 12.2). The mean linear wear was 1.89 mm (1.4 to 2.5), and the mean volumetric wear 718.09 mm (531.9 to 930.9). The mean annual linear wear was 0.17 mm (0.13 to 0.22), and the mean annual volumetric wear 64.5 mm (49.4 to 83.6). Greater wear occurred in patients under 40 years of age (Student’s t-test, p = 0.0139), men (chi-squared test, p = 0.028), and in those with a higher abduction angle of the acetabular component (Student’s t-test, p = 0.031). No significant relationship was found between wear and diagnosis (chi-squared test, p = 0.23), weight (Student’s t-test, p = 0.022), hip score (Student’s t-test, p = 0.17), range of movement (Student’s t-test, p = 0.25), or degree of anteversion (Student’s t-test, p = 0.38).

One hip had extensive osteolysis on both sides of the joint (Fig. 3) and is awaiting revision. Acetabular osteolysis was clearly identified in 21 hips (10.8%), and 25 (12.9%) had a radiolucency in the calcar which was presumed to be due to osteolysis. All of these lesions measured less than 1 cm² and none were seen to have progressed on serial radiographs. No distal osteolysis was seen.

One hip was revised early for infection and another at two years for fracture around a loose stem. Two acetabular com-

![Fig. 1a](image1a.png) ![Fig. 1b](image1b.png)

*Fig. 1a* A) Anteroposterior and b) lateral radiographs of the hips of a 41-year-old woman with multiple epiphyseal dysplasia 11 years after operation. The femoral stems are well aligned with a grade-A cement mantle and there is no osteolysis or radiolucent lines.

![Fig. 2a](image2a.png) ![Fig. 2b](image2b.png)

*Fig. 2a* A) Anteroposterior and b) lateral radiographs of the right hip of a 44-year-old man with spontaneous ankylosis eight years after operation showing cement fractures in zones 1 and 7 of the femur and a radiolucent line of > 2 mm at the cement-bone interface elsewhere.

![Fig. 3a](image3a.png) ![Fig. 3b](image3b.png)

*Fig. 3a* A) Anteroposterior and b) lateral radiographs of the left hip of a 28-year-old man with developmental dysplasia of the hip seven years after operation showing extensive osteolysis.
ponents were revised for recurrent dislocation. Two hips had aseptic loosening, one of the femoral stem and one of the acetabular component. Both patients were advised to have a revision operation but refused. When revision was used as the end-point for failure, Kaplan-Meier survival analysis showed a rate of survival of 98% (95% confidence interval (CI), 0.93 to 1.00) at 12 years for the acetabular component and of 99% (95% CI 0.95 to 1.00) for the femoral stem. When loosening was used as the end-point for failure, the survival rate of both the acetabular and femoral components was 99.5% (95% CI 0.98 to 1.00).

Complications. A linear fracture of the calcar occurred at operation in two hips, both of which were treated by a Dall-Miles cable (Howmedica, Rutherford, New Jersey). The fractures healed completely around a stable prosthesis.

There was one displaced spiral fracture of the femur around the tip of the stem, type 2 according to the system of Johansson et al,29 which was treated by open reduction and internal fixation using multiple Dall-Miles cables. The fracture healed completely and the prosthesis remained stable.

Five hips (2.6%) dislocated on one or more occasions. Three were treated successfully by closed reduction and abduction bracing for three months and the other two had to be revised.

One hip had an asymptomatic avulsion fracture of the greater trochanter and one had a perforation of the lateral femoral cortex but a grade-A cement mantle. Two hips developed grade-III heterotopic ossification.

Discussion

Norton et al11 described early catastrophic failure of the Elite Plus femoral stem. They were unable to identify technical errors such as malpositioning or deficiency of the cement mantle which would have accounted for this. They found that the wear rate of the Hylamer polyethylene liner (0.32 mm/year; DePuy, Warsaw, Indiana) was approximately double that of conventional polyethylene, causing progressive osteolysis and aseptic loosening. They concluded that there was a substantial problem associated with the Hylamer-zirconia articulation. While they suspected Hylamer to be the weak link in the articulation, it was possible that the zirconia femoral head contributed to the problem.

One possible problem with the use of zirconia is in vivo phase transformation.30 Such transformation from the tetragonal phase into the monoclinic phase is accompanied by an increase in the volume of the ceramic head of 3% and increased surface roughness resulting in faster wear of the polyethylene liner. Kim, Kim and Cho31 observed greater wear with the Hylamer-zirconia articulation than with a conventional polyethylene-cobalt-chromium joint. In another study, however, Kim32 found that the rate of wear of the conventional polyethylene liner was significantly lower in hips with a zirconia head than in those with a cobalt-chromium head, presumably because the zirconia heads had a smoother articulating surface without phase transformation. In our series, the mean rate of wear of the zirconia-conventional polyethylene articulation was 0.17 mm/year. The lower wear rate of conventional polyethylene in our series compared with that of Hylamer in the series of Norton et al11 appeared to be associated with a lower prevalence of osteolysis and aseptic loosening.

Walton et al14 observed that 30.9% (52 of 168) of Elite Plus hips had either been revised or had definite evidence of loosening within six years. They found that a defective femoral cement mantle and the use of low-viscosity cement contributed to the high rate of aseptic loosening.

We believe that several factors were responsible for our good results including the use of a third-generation cementing technique, no defects in the mantle, a neutral position of the stem, the presence of strong trabecular bone in young patients, the use of a 22 mm femoral head resulting in low volumetric wear of the polyethylene liner and a population of small, light patients.

Hauptfleisch et al15 reported a rate of survival of 83% at ten years of the Elite Plus femoral stem when revision was taken as the point of failure and of 59% when radiological loosening of the stem was used. Their studies suggested that the Elite Plus femoral stem was intrinsically rotationally unstable. They claimed that this resulted from the many small changes made at its introduction. In their series, however, they used low-viscosity cement, which was not vacuum-mixed and did not have a proximal seal. We believe that their high failure rate was attributable to a poor cementing technique and the use of low-viscosity cement.

Perhaps the radiological feature which best predicts early prosthetic failure is the grading of the cement mantle according to Barrack et al.20 Other important predictors are a deficient cement mantle (< 1 mm),34 stem-cortex contact and marked (> 4˚) valgus or varus positioning of the stem.34 In our series, the use of a modern cementing technique and components meant that there were no grade-C or grade-D cement mantles or marked malalignment of the stem. This, we believe, led to the excellent results.

Hartley et al15 reported that 34.2% (13 of 38 hips) which had undergone THR for osteonecrosis using a 28 mm femoral head, had more than 2 mm of wear of the polyethylene liner after five years. Kim et al31 observed that zirconia femoral heads tended to be associated with a higher rate of wear (0.22 mm/year) than cobalt-chromium heads (0.14 mm/year). In a further study of young patients with osteonecrosis, Kim et al18 found that after a mean of 7.2 years the mean amount of linear wear of the polyethylene liner by a 22 mm head was 5.6 mm and the mean annual wear rate was 0.81 mm/year. The young patients in our present study had much less linear wear, although much more than that noted in older patients.36 We attribute the high rate of linear wear in our study to the youth and high activity of our patients and the high dislocation rate to the use of a 22 mm head and the habit of squatting on the floor.

The rate of osteolysis in zone 7 (the calcar femorale) was 12.9% (25 hips) in our study which was higher than that (7%, 7 of 103 hips) reported by Mulroy and Harris37 in patients
Our finding of osteolysis exclusively in zones 1 and 7 of the so-called effective joint space. The low prevalence of osteolysis reported by Kim et al. in a previous study.

Advances in the technique of cementing and the proper positioning of the Elite Plus femoral stem have greatly improved the long-term survival of the implant in young patients. Although the prevalence of aseptic loosening of the components was very low, the high rate of linear wear of the polyethylene liner in these active young patients should stimulate the search for new bearing surfaces.

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


