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Survivorship of the Charnley Elite Plus cemented femoral stem

Received: 12 February 2005 / Accepted: 11 March 2005 / Published online: 14 June 2005
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Abstract We report the results of the Charnley Elite Plus femoral stem in multiple surgeons' hands at a minimum of 3 years after implantation. Over a 4-year period, 244 patients underwent 268 primary hip arthroplasty procedures using this particular stem. Patients underwent postal and radiographic review at a mean of 4.5 (3.0–6.8) years following their arthroplasty. There were five revision procedures for aseptic loosening (5/268; 1.9%). Radiological assessment revealed gross radiological failure in a further 12 femoral stems (12/208; 5.8%). In the best case scenario, using revision for aseptic loosening as the endpoint, the survivorship for this period was 98.1%. If radiographic failures are incorporated into this endpoint, survivorship is 93.1%. This failure rate at an early stage raises concerns as to the long-term survivorship of this prosthesis.

Résumé Nous rapportons les résultats de la tige fémorale Charnley Élite Plus dans les mains de multiples chirurgiens après un minimum d'implantation de trois années. Sur une période de quatre années, 244 malades ont subi 268 arthroplasties primaires de la hanche utilisant cette tige particulière. Les malades ont eu un examen postal et radiographique à une moyenne de 4,5 ans (3,0–6,8) après leur arthroplastie. Il y avait cinq révisions pour descellement aseptique (5/268 : 1,9%). L'estimation radiologique a révélé un échec certain pour 12 tiges fémorales supplémentaires (12/208 : 5,8%). Dans le meilleur scénario, en utilisant la révision pour descellement aseptique comme point final, la

survie pour cette période est de 98,1%. Si les échecs radiographiques sont incorporés comme événement final, la survie est de 93,1%. Ce taux d'échec à un stade précoce de l'évolution est une inquiétude pour la survie à long terme de cette prothèse.

Introduction

The long-term results of the Charnley femoral stem have been widely documented [7, 11, 16]. There have been numerous changes to the design and instrumentation of this original stem since its introduction in 1962, and the Charnley Elite Plus represents the fifth generation of this highly successful implant. The Elite Plus prosthesis differs from its predecessors in a variety of ways: In order to enhance proximal femoral loading, the neck and stem have a slimmer profile. The stem is slightly longer than the standard Charnley design, with seven sizes available. The instrumentation comprises incremental parallel-sided femoral canal reamers and proximal broaches, designed to give a complete cement mantle of at least 3 mm in thickness. There is an option of either a Zirconia ceramic or Ortron 90 metal modular head (Depuy, Leeds, UK), allowing for adjustment of both neck length and offset. Additionally, a PMMA distal centraliser may be used.

This study reviews our survivorship of the Charnley Elite Plus Femoral stem at a mean of 57 months post implantation across a single NHS hospital trust.

Materials and methods

Over a 4-year period, 268 Charnley Elite Plus femoral stems were implanted into 242 patients. These procedures were performed under the care of ten consultant orthopaedic surgeons in two different hospitals within the same city. Mean patient age at operation was 64 (31–97) years. There were 133 (55%) women and 109 (45%) men. Osteoarthritis was the most common pre-operative diagnosis (87%, 232 hips).

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A modified lateral approach without trochanteric osteotomy was used to provide access to the hip joint in 254 hips; the posterior approach was used in 12 hips. Third-generation cementing techniques [15] were used in 225 arthroplasties and second-generation in the remaining 43. Four different bone cements were used: Palacos R ($n=54$), Palacos LV ($n=90$), Simplex ($n=78$) or CMW 3 ($n=46$). Metal modular femoral heads were used in 120 hips and zirconia ceramic in 148. The operations were performed by orthopaedic surgeons of varying experience. Acetabular components were either cemented all-polyethylene cups from the Charnley/Elite range ($n=164$) or cementless Trilog cups ($n=104$) as part of a hybrid combination.

Patients were contacted and asked to complete an Oxford hip score [5]. Patients were also asked to attend for a non-weight-bearing anteroposterior (AP) radiograph of the pelvis and a lateral radiograph of their hip arthroplasty.

All the radiographs were examined by the senior author (RAP) and compared with the original pre-operative films. Radiographs were examined for evidence of osteolysis around the femoral stem. Femoral osteolysis was defined as areas of endosteal or intra-cortical bone loss that were scalloped or had the appearance of destruction of bone. Also, a linear radiolucent zone of greater than 2 mm at the cement–bone interface was deemed to be osteolysis. Radiographs were also examined for evidence of osteolysis around the acetabular cup. When assessing radiolucent zones and osteolysis, Gruen's classification for the stem and DeLee and Charnley's classification for the cup were used [6, 8]. Osteolysis in four or more Gruen zones was

classified as a radiographic failure. A continuous radiographic line of two or more millimetres at the cement–bone interface of the acetabulum was also considered to be a radiographic failure.

The quality of femoral cementation was graded according to the method described by Barrack et al. [2]. The presence of contact between the tip of the femoral stem and the posterior femoral cortex was also noted.

Statistical analysis

Multivariate logistic regression with step-wise analysis was performed to identify risk factors associated with the presence of femoral osteolysis. The Mann–Whitney U test was used to determine whether there was any significant relationship between the Oxford hip scores and radiographic appearance. Life-table survivorship analysis was performed as described by Murray et al. [13] with confidence intervals calculated by the method described by Peto et al. [14] on a pre-formatted Excel spreadsheet program. The statistical packages used for analysis were SPSS 10.0 (SPSS, Chicago, IL, USA) and Excel (Microsoft).

Results

Of the 268 Elite Plus stems implanted, there had been 12 re-operations for all causes, and 16 patients (18 stems) had died. This left 238 stems available for review in 216 pa-

Fig. 1 Distribution of osteolysis.

Fig. 2 Barrack cementation grade.

tients. The mean follow-up was 54 (range 37–82) months. Two hundred twenty-one (91.6%) Oxford hip scores were returned, and 208 (87.4%) Elite Plus stems were reviewed radiographically. Of the 30 patients that failed to attend for a radiograph, there was no response from 15, nine were medically unfit, four had moved out of the region and one patient with bilateral hip arthroplasties refused to attend. All case notes were reviewed retrospectively. Of the 12 re-operations for all causes, five stems had been revised for aseptic loosening, four for recurrent dislocations, two for infection and one for a peri-prosthetic fracture following a road traffic accident. There were no stems known to be awaiting revision surgery.

On reviewing the radiographs, 161 out of 208 were classed as normal. Forty-seven had evidence of osteolysis around the stem or cup; 12 of these displayed extensive osteolysis and were considered to be radiographic failures. Distribution of osteolytic lesions is illustrated in Fig. 1. The radiographic appearance according to Barrack cementation grade is shown in Fig. 2.

Risk factors for the appearance of osteolysis around the femoral stem were analysed (grade of operating surgeon, age of patient, diagnosis, acetabular component, type of modular head, type of cement, Barrack cementation grade, cementation technique, presence of posterior femoral cortical contact). It was found that the only significant factor was the position of the femoral stem on the lateral radiograph ($p=0.001$; 95% CI 1.63–6.11). If the tip of the stem was in contact with the posterior femoral cortex, the likelihood of osteolysis being present was increased by a factor of 3.15. The percentage of correct prediction for this multivariate logistic regression model with step-wise analysis of the risk factors is 76.9%. This is considered to be a reliable model. There was no statistical significance between the presence of adverse radiographic features and the respective Oxford hip scores for these patients ($p=0.41$).

The survivorship using revision for aseptic loosening as the endpoint was 98.1% at 6–7 years (95% CI 99.7–96.2) (Table 1; Fig. 3). If the radiographic failures are combined to this endpoint, the survivorship falls to 93.7%. With

Table 1 Life-table analysis of Elite Plus total hip replacements (THRs) using revision for aseptic loosening as the endpoint

Years since operation	Number at start	Failure	Withdrawn (died)	Lost to follow-up	Number at risk	Annual failure rate (%)	Annual success rate (%)	Survival rate (%)	Standard error (%)	95% confidence interval	95% (Peto) confidence limit (upper)	95% (Peto) confidence limit (lower)
0–1	268	0	1	0	268.0	0.00	100.00	100.00	0.00	0.00	100.00	100.00
1–2	267	0	3	0	267.0	0.00	100.00	100.00	0.00	0.00	100.00	100.00
2–3	264	1	4	0	264.0	0.38	99.62	99.62	0.38	0.74	100.36	98.88
3–4	259	0	5	13	252.5	0.00	100.00	99.62	0.39	0.76	100.38	98.86
4–5	254	3	4	6	251.0	1.20	98.80	98.43	0.78	1.53	99.95	96.90
5–6	247	0	1	10	242.0	0.00	100.00	98.43	0.79	1.56	99.98	96.87
6–7	246	1	0	1	245.5	0.41	99.59	98.02	0.88	1.73	99.74	96.29

Fig. 3 Survival curve for the Charnley Elite Plus total hip replacement with revision for aseptic loosening as the endpoint.

revision for all causes as the endpoint, survivorship is 95.5%.

Discussion

The Swedish National Hip Arthroplasty Register reports a survivorship of 94.9% at 5 years for the Elite Plus femoral stem [1]. Results from single-surgeon cohorts have reported varying success [10, 12]. Our analysis establishes the survivorship of this particular stem in multiple surgeons' hands and therefore reflects its outcome within a general orthopaedic environment. In this situation, a 'best case scenario' survivorship of 98.1% at 7 years is acceptable. Of potential concern however, is the radiographic presence of osteolysis, with only 77.4% being categorised as normal.

On reviewing these radiographs with osteolysis, there appeared to be a typical mechanism of stem failure: a char-

acteristic lytic lesion developed when the distal tip of the prosthesis was close to or in contact with the distal femoral cortex (Fig. 4). This was then followed by progressive osteolysis, cement fragmentation and prosthetic subsidence with further diffuse osteolysis.

The Elite Plus stem and associated instrumentation are designed to incorporate the concepts of third-generation cementing techniques [15] and the creation of a complete cement mantle. We believe that this, and indirectly the modular head, may be contributing to the early radiographic failures: modularity of the prosthetic head allows the surgeon to make adjustments to neck length and offset after implantation of the definitive stem. In performing a trial reduction at this stage, a significant torsional load may be imparted to the stem at a time when the cement mantle may not be completely hardened, thus resulting in distortion of the internal dimensions of the cement mantle. The Elite Plus stem design is shape-closed, as opposed to ta-

Fig. 4 Development of a typical osteolytic lesion

pered stems, which are force-closed designs [9]. If the cement mantle is distorted, the proximal part of the stem becomes partially unloaded. Load is then imparted to the slim, parallel-sided distal stem. If the stem tip is abutting or close to the femoral cortex, it will punch through. Axial micro-motion is then possible, with resultant surface abrasion of the non-polished stem surface. An effective third joint space exists at the tip, and the cycle of osteolysis progresses as described by Beaulé et al. [3].

Whilst every effort is made to ensure that the cement mantle has hardened prior to performing a trial reduction, the hardening behaviour of cement under operating conditions can significantly differ from the statements in the manufacturer's instructions. This hypothesis may account for the significantly increased likelihood of radiographic osteolysis if the distal tip of the femoral stem is in contact with the posterior femoral cortex. The majority of these femoral stems were implanted through a modified lateral approach whereby the natural tendency is for the stem to lie in an antero-posterior position [4].

Modern cementing techniques may have several advantages. However, when using a non-polished, shape-closed design as opposed to a polished tapered design, it is essential to achieve accurate stem alignment with avoidance of any torsional load during the terminal curing phase of the cement, thereby avoiding any distortion of the cement mantle. The high incidence of radiographic abnormalities warrants the need for regular review of patients with this prosthesis.

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