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Mid-term results and migration behaviour of a ti-alloy cemented stem

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Abstract Between 1991 and 1994, 147 patients (154 hips) underwent a primary cemented total hip replacement using the Ultima ti-alloy, collarless, double-tapered stem and a UHMWPE cup. The average age at operation was 66.4 years. Ninety-one patients (97 hips) were available for review with an average follow-up of 76 months. The Harris hip score had improved from pre-operative average of 43.1 (12.5–65.0) to the latest score of 88.9 (67.5–100). There were 11 revisions in total, eight of which were for aseptic stem loosening. The results of Kaplan-Meier survival analysis, based on stem revision for aseptic loosening as an end-point, was 92% at 8 years. Early stem migration analysis at 2 years was possible in 114 cases using digitised radiographs analysed by the EBRA method. Sixty-three stems had not migrated and 35 migrated less than 2 mm with only one of these ending in failure. Sixteen stems showed early migration of more than 2 mm and five of these failed. Early stem migration is predictive of stem failure. Osteolytic lesions occurred in 12 femurs and four of these stems failed.

Résumé Entre 1991 et 1994, 147 malades (154 hanches) ont subi une arthroplastie primaire cimentée qui utilise une tige à section décroissante Ultima sans collerette en alliage de Titane et une cupule de UHMWPE. L'âge moyen à l'opération était 66.4 ans. Quarante-vingt-onze malades (97 hanches) étaient disponibles pour la révision avec une moyenne de suivi de 76 mois. Le score de Harris s'est amélioré de la moyenne préopératoire de 43.1 (12.5 à 65.0) au score le plus tardif de 88.9 (67.5 à 100). Il y avait 11 révisions, huit pour descellement aseptique de la tige. La survie selon Kaplan-

Meyer, basée sur la révision de la tige pour descellement aseptique était 92% à huit années. L'analyse du descellement précoce de la tige à deux années était possible dans 114 cas utilisant des radiographies digitalisées analysées par la méthode EBRA. Soixante-trois tiges n'avaient pas migré et trente-cinq tiges avaient migré de moins de 2 mm avec seul cas évoluant vers un échec. Seize tiges ont montré une migration de plus de 2 mm avec finalement cinq échecs. La migration précoce de la tige est prédictif du descellement. Les lésions ostéolytiques se sont produites sur 12 fémurs conduisant à quatre échecs par descellement fémoral.

Introduction

We report the results from a prospective study of the Ultima stem (Johnson & Johnson, Leeds, UK) to assess its medium-term clinical results and migration behaviour using the EBRA measurement method. The Ultima straight stem is a collarless, modular implant made of ti-alloy and is designed for cement fixation.

Patients and methods

Between 1991 and 1994, 147 patients (154 hips) underwent a primary cemented total hip replacement (THR) as a consecutive series using the Ultima femoral stem and acetabular cup. Mean age of patients was 66.4 (26–87) years; 96 were women. The most common diagnosis was primary osteoarthritis, found in 129 hips. Patients also were classified into Charnley categories A, B or C, as related to the extent of arthrosis in the rest of their joints. On this basis, 81 hips were classified as category A, 56 as B and 17 as C.

A direct lateral approach without trochanteric osteotomy was used in all cases. Cementing technique routinely included the use of femoral occlusion, pulse lavage, retrograde filling with a cement gun and pressurisation. CMW cement (CMW Laboratories, Ltd) without antibiotic was used in all cases, with type 1 cement (normal viscosity) for the acetabulum and type 3 (low viscosity) for the femur. One intravenous dose of cefuroxime 1.5 g was administered with anaesthetic induction, and three 750 mg doses post-operatively. For DVT prophylaxis, all patients had anti-thrombotic stockings and low-molecular-weight heparin during hospitalisation, and were mobilised on the second post-operative

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day. They were followed up prospectively with a clinical and radiological review at 3, 6 12 and 24 months. Patients were recalled for assessment at a minimum of 5 years.

Clinical assessment was recorded on a standard proforma using the Harris hip score (HHS) [12]. Patients unable to attend for examination were contacted by telephone to provide information of their hip function. This was checked with their general practitioner, who was asked to obtain a recent X-ray of the hip where possible. Information regarding deceased patients was taken from relatives and their general practitioner.

Post-operative X-rays were analysed independently by the authors not personally involved in the surgery (RMDM and JM). They were assessed for cup inclination and stem alignment. Cement mantle thickness was measured in the three zones of the cup [6] and seven zones of the stem [11]. Stem cementing quality was also graded using Harris categories A–D [1]. Serial radiographs were analysed for any radiolucencies, osteolytic lesions and fractures of the cement mantle.

Migration analysis was performed using the EBRA method [2, 17, 18]. This is a computer-aided method based on the exclusion of digitised radiographs that do not meet set standards for comparability. For each patient, at least four suitable radiographs were required for measurement, and this is the reason for not reporting migration results on all the patients in the series. The 95% confidence limits are 1.0 mm for longitudinal and 0.8 mm for transverse migration.

Migration of the femoral component during the first 2 years was defined as “early migration”. Migration, recorded at the most recent radiograph, was defined as “total migration”. Acetabular cup migration was measured for proximal and medial migration. Total cup migration was defined as the sum of proximal and medial migration.

Statistical analysis

Standard Kaplan-Meier survival analysis was performed, and the 95% confidence intervals were calculated for the prosthesis as a unit and for the stem and cup individually. Patients with no record of implant loosening-related failure were censored at the last point in time where the implant was known to be functioning. This time point was either the most recent date of examination or the most recent X-ray update. Adequate information was available to calculate survival estimates at 8 years post-operatively.

The two-tailed Fisher's exact test was used to determine whether early subsidence greater than 2 mm or cement mantle grade were related to late aseptic loosening. Logistic regression was used to relate stem size with aseptic failure, and a one-way ANOVA was used to determine if mantle grade was related to subsidence.

Results

There were two early dislocations, both treated successfully with closed reduction. Two patients died in the early post-operative period of hospitalisation due to cardiovascular incidents. Thirty-two patients (33 hips) died subsequently due to unrelated causes. The average time from operation to death in this group was 36.7 (3–84) months. None of the deceased had their hips revised or had developed pain in the hip area prior to death.

Five patients were lost to follow-up and, for another six, clinical information was available only by telephone. Eleven hips had been revised at the time of review; one for sepsis and ten for aseptic loosening (five stems, two cups and three of both components). The time to aseptic stem failure was 62.3 (18–100) months.

Fig. 1 Absolute numbers of areas of osteolysis and the cement mantle thickness (average and range), as related to DeLee Charley zones of the acetabulum

Ninety-one patients corresponding to 97 hips were still available for review, with an average follow-up of 76 (60–109) months. Their average pre-operative HHS had been 43.1 (12.5–65.0), and the most recent score at the latest follow up was 88.9 (67.5–100). Based on aseptic revision as the end point, the estimated 8-year survival for the stem only was 92.2%, for cup alone 93.7% (CI 87–99) and for both components 90.4% (CI 83–97).

From visual assessment of the pre-discharge X-rays, 83 stems were classified as neutral, 58 in valgus and 13 in varus. Cementing quality was classified in 59 hips as grade A, 60 as B, 26 as C and nine as D.

The angle of cup inclination ranged from 39° to 60° (average 46°0). The acetabular cement mantle thickness is seen in Fig. 1. Ninety-three cups showed no radiolucent line at the bone-cement interface at the early post-operative radiograph. Radiolucent lines were present in zone 1 in 19 hips, zone 2 in two, and zone 3 in four. In eight hips, radiolucent lines were present in more than one zone of the acetabular interface.

Serial radiographs of 125 hips with a minimum follow-up of 24 months were available for visual assessment. In 21 hips, the stem had developed non-progressive radiolucent lines in one or two Gruen zones. Focal osteolysis restricted to one zone was present in 12 hips (Fig. 2).

EBRA measurement of femoral stem migration was possible only on 114 of the radiographs. Sixty-three stems showed no early migration at 2 years and only one of these failed later. Another 35 stems showed early migration less than 2 mm, of which one was revised for aseptic loosening. Early migration of more than 2 mm was seen in 16 stems, of which five were revised for aseptic loosening (Tables 1 and 2). Early stem migration of more than 2 mm was significantly related with aseptic failure ($P=0.0012$, two-tailed Fisher's exact test).

At final review, the total stem migration was measured. Sixty-one stems never underwent migration.

CEMENT MANTLE THICKNESS AND OSTEOLYTIC LESIONS

Fig. 2 Absolute numbers of areas of osteolysis and the cement mantle thickness (average and range), as related to the Gruen zones of the femoral stem

Twenty-eight stems showed total migration of less than 2 mm. In 17 stems, the migration was between 2 mm and 3 mm, and in eight more than 3 mm.

The relation between the cement mantle quality category, early stem migration and aseptic failure is shown in Table 2. Both early migration and total migration were significantly related to poor cement quality categories C and D ($P=0.003$ and $P=0.0001$ respectively, one-way ANOVA). If the mantle was not category A, there was a significant chance of aseptic failure occurring ($P=0.04$, two-tailed Fisher's exact test). Stem size was analysed relative to the number of aseptic failures, but there was no statistical correlation demonstrated. Four cases with focal osteolysis demonstrated early migration of 2.5–3 mm, and two of these went on to require revision.

New, non-progressive radiolucent lines developed around 32 cups over time. In addition, focal osteolysis

Table 2 Aseptic failures and early subsidence

Early subsidence	Number stems	Failures
≥ 2 mm	16	5
< 2 mm	35	1
0 mm	63	1
EBRA incompatible		1

was observed around seven cups but this was restricted to only one zone (Fig. 1). These were always associated with radiolucencies at the initial radiograph. Radiographs of 86 cups were suitable for assessment of migration. At an average follow-up of 72 months, proximal, medial or combined migration was seen in 55.

Discussion

A number of cemented ti-alloy stems have been developed although clinical reports of their results have been variable. The Triad ti-alloy stem (Johnson & Johnson, New Brunswick, NJ) had poor early clinical results, with reported failure of 4.3% at 4.8 years, and subsequently was abandoned [35]. A ti-alloy version of the McKee-Arden monoblock stem (Zimmer, Swindon, UK) had a 17% revision rate for aseptic loosening at 24 months [41] and again was withdrawn. This stem exhibited gross endosteal lysis, with over two thirds demonstrating some degree of lysis at 5.2 years [36]. The DF-80 monoblock ti-alloy stem (Zimmer, Warsaw, Indiana, USA) had a high rate of revision for aseptic stem loosening, with rates of 4.3% and 3% reported at short follow-up [16, 28]. The ITH modular stem (Smith & Nephew Richards, Memphis, Tennessee, USA) had rapid and progressive aseptic stem loosening, with 7.7% revision rate at 5 years [13]. More recently, the Trios modular stem had only 72% stem survival at 3 years [20].

In contrast, good results were reported for the monoblock cemented STH ti-alloy stem (Zimmer USA, Warsaw, Indiana), with 1.2% revision rate at an average of 52 months [30]. In the presence of an adequate proximal cement mantle, the radiographic results for the cemented STH ti-alloy stem were the same as cemented stainless-steel Charnley stems [7]. The Ceraver-Osteal modular stem had 96–99% stem survival at 10 years [19, 26, 32]. Osorovitz and Goultallier however, noted proximal lucencies around the stem, but distal fixation was well maintained. A cemented modular ti-alloy Furlong stem

Table 1 Cement mantle category, stem early migration and number of stem failures

Mantle grade	Stems	EBRA unsuitable	No migration	< 2 mm	≥ 2 mm	Aseptic failure
A	51	2	32	14	3	0
B	55	6	27	16	6	1
C	13	2	3	4	4	4
D	6	1	1	1	3	3
Total	125	11	63	35	16	8

(JRI, London, UK) also had good interim results [37]. More recently, the BiContact modular stem (Aesculap, Germany) had only a 1.6% aseptic loosening rate at 9.7 years [8].

A retrieval analysis of 28 cemented ti-alloy modular Muller stems (Sulzer, Baar, Switzerland) demonstrated corrosion phenomena at the surface of the stem [39]. The design parameters of the stem were considered crucial in the development of this corrosion. As the stem starts to debond, a conical gap forms between the cement and the implant. Abrasion of the proximal stem surface, when combined with micro-motion, then caused destruction of the soft TiO₂ surface of the stem. At the distal end of this small conical gap, the attempt to re-oxidise the stem surface decreased the local pH and produced crevice corrosion. The stem's longitudinal flutes were implicated by producing a degree of mechanical stability that promoted this crevice creation and resulting corrosion. In two clinical series, the reported revision rates of the Muller stem were 4.6% at 6.9 years and 5.5% at 5 years. However, an alarming 30% demonstrated significant osteolysis [23, 31].

The poor performance of the modular ti-alloy stem version of the Capital hip (3 M Health Care Ltd, UK) has been reported [22]. The use of inadequately sized broaches resulting in thin cement mantle, along with the mechanical properties and surface texture of the ti-alloy, have been implicated in its failure. In the recent report commissioned by the Royal College of Surgeons of England, higher failure rate was observed with ti-alloy Capital stems compared with stainless steel ones with similar geometry [29]. However, irrespective of the material used, the design of this stem did not allow for an adequate cement mantle proximally, leading to early debonding and rotational instability in many cases.

It is therefore increasingly apparent that survival of a ti-alloy stem depends upon the design rather than the alloy itself. Mauer et al. have identified an increased rate of revision with small sizes of ti-alloy stems [23]. They suggested that the higher elasticity of small-sized stems might adversely affect the cement mantle. However, in their study, other confounding factors – including the stem to canal ratio and the quality of cementation – were not analysed. In our study, we were not able to demonstrate a relationship between small stem size and stem failure. Ti-alloy femoral heads are also known to be more prone to third-body abrasion, contributing to increased wear of polyethylene [5, 40]. Thus, any monobloc stem by its very design has an articulating surface that is prone to an increased rate of failure. In addition, any design that used a large diameter head increased the rate of volumetric polyethylene wear due increased contact area and sliding distance [14, 21].

In the present study, the EBRA method was used to assess stem migration. It has been reported as significantly better than conventional radiographs measured visually, where the accuracy is only 2.5–5 mm [25, 34, 38]. The accuracy of EBRA is also the closest to the gold standard Roentgen stereophotogrammetry method [3, 33].

All implants undergo migration. The amount and patterns of migration depends on stem design [24]. Tapered stems are designed to migrate rapidly during the first year, and a highly polished surface is proposed as crucial for this. Loading through a tapered stem increases compression and reduces shear at the stem-cement interface and the cement-bone interfaces [10]. Early migration of non-tapered stem designs has been associated with late failure [15, 18]. The Ultima stem double taper can allow up to 2 mm of migration without loosening in cases with adequate cementing technique. This migration pattern does not appear to promote crevice corrosion, as the rate of osteolysis is low.

In our study, none of the stems with a cement mantle quality category A went onto aseptic failure, and of the stems with cement mantle category B only one failed. Experimental studies have been developed with a three-dimensional finite-element model of the cemented bone implant system [27]. The authors demonstrated that the stiffness of the stem had no significant effect on micro-movement at the cement-bone interface, provided the cement mantle thickness was 3–5 mm. However, if the cement mantle was less than 2 mm and the stem made of ti-alloy, then the shear forces at cement-bone and prosthesis-cement interfaces were drastically increased, leading to cement fracture.

The rate of aseptic loosening in this series using a ti-alloy stem is comparable to other cemented Co-Cr or stainless steel stems, including the current Charnley design [4, 9]. Obviously, further follow-up on the long-term survivorship of the Ultima stem is warranted, but the design of an individual prosthesis appears to be of greater importance than the material used.

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