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THE INTERNATIONAL HIP SOCIETY Long-term follow-up of an uncemented proximally hydroxyapatite-coated femoral stem in total hip arthroplasty

A REVIEW OF 165 TOTAL HIP ARTHROPLASTIES AT 20- AND 25-YEAR FOLLOW-UP

Aims

The aim of this study was to evaluate the survival of a collarless, straight, hydroxyapatitecoated femoral stem in total hip arthroplasty (THA) at a minimum follow-up of 20 years.

Methods

We reviewed the results of 165 THAs using the Omnifit HA system in 138 patients, performed between August 1993 and December 1999. The mean age of the patients at the time of surgery was 46 years (20 to 77). Avascular necrosis was the most common indication for THA, followed by ankylosing spondylitis and primary osteoarthritis. The mean follow-up was 22 years (20 to 31). At 20 and 25 years, 113 THAs in 91 patients and 63 THAs in 55 patients were available for review, respectively, while others died or were lost to follow-up. Kaplan-Meier analysis was performed to evaluate the survival of the stem. Radiographs were reviewed regularly, and the stability of the stem was evaluated using the Engh classification.

Results

A total of seven stems (4.2%) were revised during the study period: one for aseptic loosening, three for periprosthetic fracture, two for infection, and one for recurrent dislocation. At 20 years, survival with revision of the stem for any indication and for aseptic loosening as the endpoint was 96.0% (95% confidence interval (Cl) 92.6 to 99.5) and 98.4% (95% Cl 96.2 to 100), respectively. At 25 years, the corresponding rates of survival were 94.5% (95% Cl 89.9 to 99.3) and 98.1% (95% Cl 95.7 to 99.6), respectively. There was radiological evidence of stable bony fixation in 86 stems (76.1%) and evidence of loosening in four (3.5%) at 20 years. All patients with radiological evidence of loosening were asymptomatic.

Conclusion

The Omnifit HA femoral stem offered promising long-term survival into the third decade.

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Introduction

Uncemented femoral stems have been used in total hip arthroplasty (THA) for more than three decades. The long-term performance of various uncemented stems, many with excellent durability and radiological outcomes, has been reported.¹⁻⁷

The Omnifit HA (Osteonics, USA) uncemented stem (Figure 1) was introduced more than 30 years ago. It is made of titanium alloy, is collarless, has a straight stem, and is coated proximally with a 50-micron layer of hydroxyapatite. Proximal normalization steps are present. Arc deposition with titanium increases resistance to abrasion and augments the fit, enhancing osseointegration. The addition of hydroxyapatite coating also enhances bone ongrowth and allows early stable fixation.⁸

The aim of this study was to assess the clinical and radiological outcomes following the use of this stem at between 20 and 25 years, evaluating survival using revision for any indication and aseptic loosening as endpoints, and the radiological evidence of the stability of fixation.

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Omnifit HA stem (Osteonics, USA).

Methods

A total of 138 patients with symptomatic osteoarthritis (OA) who had failed conservative treatment and underwent 165 primary THAs using the Omnifit HA femoral stem were included. Those in whom the stem was used in revision procedures or as a hemiarthroplasty were excluded. There were 107 males (64.8%) and 58 females (35.2%); their mean age at the time of surgery was 46 years (20 to 77). Avascular necrosis in 103 hips (62.4%) was the leading indication for surgery, followed by inflammatory arthropathy including ankylosing spondylitis in 43 hips (26.1%), primary OA in 13 (7.9%), developmental dysplasia in five (3.0%), and tuberculosis in one (0.6%).

The procedures were performed using the posterior approach by eight orthopaedic surgeons at a single centre. One senior surgeon (KYC) was involved in all the operations as either the main surgeon or the supervisor. Cementless Omnifit acetabular components with a HA-coated dual radius design were used in all patients.

The patients were reviewed at six weeks, three and six months, one year, and yearly thereafter. Standard anteroposterior (AP) pelvic and AP/lateral hip radiographs were taken at each visit, all of which were reviewed by a resident orthopaedic surgeon (AHFY), and the results were confirmed by a fellowship-trained arthroplasty surgeon (VWKC). Neither of these surgeons participated in any of the operations. The study had local institutional ethical approval.

During the first 20 postoperative years, 42 patients (47 THAs) died with stems in place, from causes unrelated to the arthroplasty, and five (five THAs) were lost to follow-up. The latest records of these patients revealed that none had undergone revision or showed radiological evidence of loosening. The remaining 91 patients (113 THAs) were available for review, at a mean follow-up of 22 years (20 to 31). A total of 48 patients (56 THAs) had a follow-up of > 25 years (Figure 2).

Serial radiographs were evaluated and compared for change or progression. Patients who underwent revision of the stem were not included in the radiological evaluation. The Engh classification was used to assess the stability of fixation of the stems.⁹ Findings suggestive of unstable fibrous ingrowth or loosening, including migration (subsidence, varus/valgus tilt), progressive radiolucent lines (RLLs), and pedestals were noted; those indicating stable bony ingrowth, including spot welding and stress shielding without evidence of loosening, were also documented.

Statistical analysis. Long-term survival was analyzed using the Kaplan-Meier (KM) method. Two endpoints were adopted: revision of the stem for any indication; and for aseptic loosening alone. SPSS Statistics v. 18.0 (SPSS, USA) and R v. 4.0.3 (R Foundation for Statistical Computing, Austria) were used for analysis.

Results

The stem was revised in seven THAs (4.2%). The indications and timing postoperatively of revision included aseptic loosening (one; 15 years), periprosthetic fracture (three; seven, 13 and 23 years), infection (two; four and 14 years), and recurrent dislocation (one; six years). One stem (0.6%) required revision for aseptic loosening.

A total of 32 THAs (19.4%) required acetabular revision for aseptic loosening, 28 (17.0%) required revision of the polyethylene liner for wear, and seven (4.2%) required revision of both the acetabular component and the liner (Figure 3). The stems were well fixed in all of these patients.

Kaplan-Meier survival at 20 years was 96.0% (95% confidence interval (CI) 92.6 to 99.5) using revision of the stem for any indication as the endpoint (Supplementary Figure a). It improved to 98.4% (95% CI 96.2 to 100) considering revision for aseptic loosening as the endpoint (Supplementary Figure b). At 25 years, the corresponding figures were 94.5% (95% CI 89.9 to 99.3) and 98.1% (95% CI 95.7 to 99.6).

Standard AP and lateral radiographs were available for all the remaining patients at 20 and 25 years. Stable bony fixation was seen in 86 (76.1%) of 113 hips at 20 years (Figure 4). Pedestals were found in four hips (3.5%), and migration with subsidence of > 1 cm in one (0.9%). Parallel RLLs were identified in 17 hips (15.0%), all < 2 mm wide. These changes were all identified in the first five postoperative years and did not subsequently progress. These patients were all asymptomatic. At 25 years, stable bony fixation was found in 46 (82.1%) of 56 THAs, while an unstable fibrous union or loosening was seen in five (8.9%).

Discussion

Uncemented components for THA were developed following reports of high rates of aseptic loosening with cemented components using first-generation cementing techniques,¹⁰⁻¹² a particular problem with young, active patients. The concept of biological fixation with porous-coated femoral stems has since attracted increasing interest. Earlier uncemented designs were associated with thigh pain postoperatively, failure of fixation, and osteolysis, without universally improved survival.^{13,14} Durable fixation and extremely low rates of aseptic loosening



Fig. 2

The cohort showing the breakdown of the number of patients available at 20 and 25 years' follow-up. Seven stems were revised.



Fig. 3

Anteroposterior radiographs of a 61-year-old female who underwent total hip arthroplasty using an Omnifit HA femoral stem (Osteonics, USA). There was evidence of polyethylene wear and aseptic acetabular loosening seven years postoperatively (left side). The stem was well fixed. Revision of acetabular component and liner was performed (right side).

have, however, been reported with later designs.¹⁻⁷ The addition of hydroxyapatite coating further enhances stability through osseointegration.⁸ We reported early promising clinical and radiological results of the Omnifit HA stem.¹⁵ Evidence of osseointegration was found in 66 of 77 hips (86%) at a mean follow-up of two years, and it was identified as early as three months postoperatively. One patient had septic loosening. Geesink and Hoefnagels⁸ reported a 100% survival rate in a series of 118 THAs using the same stem, at a minimum follow-up of six years. There was also evidence of osseointegration in all hips by two years. In the current study we found satisfactory long-term outcomes and survival of the same stem in 113 hips, which were assessed at a mean of 20 years postoperatively, constituting 68.5% of the original cohort. This, therefore, represents one of the most robust and well-retained cohort of patients in a long-term study of any uncemented stem, considering the high rate of mortality and loss to follow-up in many studies.

Several authors have reported results of the use of uncemented stems beyond 20 years (Suppementary Table i). Belmont et al⁷ reported a 20-year survival of 98% in 223 Anatomic Medullary Locking (AML) (Depuy) uncemented stems. Lombardi et al⁶ reported a 20-year rate of survival of 96% in 196 Mallory-Head stems (Biomet, USA); six were revised for periprosthetic fracture. Corten et al⁴ reported a 20-year rate of survival of 99% in 126 Mallory-Head stems. Streit et al¹⁶ reported a 22-year rate of survival of 86% in 354 Cementless Spotorno (CLS) stems (Zimmer, USA); 12 were revised for periprosthetic fracture. McLaughlin and Lee⁵ reported a 29-year rate of survival of 90% in 145 Taperloc stems (Biomet); none was revised for periprosthetic fracture. Jacquot et al² reported a 27-year rate of survival of 94% in 347 Corail (Depuy) stems. Our study yielded comparable rates of survival, with an extremely low rate of aseptic loosening (0.6%) and a 20-year rate of survival of 96% and 98.4% with revision for any indication and for aseptic loosening as the endpoint, respectively. Direct comparison,



Serial anteroposterior radiographs of a 48-year-old female who underwent total hip arthroplasty using an Omnifit HA femoral stem (Osteonics, USA). The initial surgery was performed for avascular necrosis in 1997. a) One year postoperatively (1998). b) 13 years postoperatively (2010). c) There were no signs of loosening 25 years postoperatively (2022).

however, is not recommended in view of the heterogeneity of the patients, differences in the designs of stem, and different lengths of follow-up.

Late periprosthetic fracture has been reported to be a significant mode of failure in the long term for uncemented stems.¹⁶ The incidence increased after the eighth postoperative year and continued to rise into the second decade. Minor trauma accounted for about 75% of late periprosthetic fractures.¹⁷ We found similar rates with three stems (1.82%) being revised for late periprosthetic fracture, the earliest of which occurred seven years postoperatively. This remained the most common cause of failure in our series. Rates ranged from 1.2% to 3.1% in studies involving other stems.^{2,6,16}

One phenomenon that we observed was the wide discrepancy in the performance of Osteonics' acetabular component and its femoral counterpart. We found that the acetabular component failed due to aseptic loosening at a much higher rate than the stem, with 32 THAs (19.4%) requiring revision for this indication. The actual rate of aseptic acetabular loosening could be higher, as some patients might have been asymptomatic, or did not require revision. Another 28 THAs (17.0%) required revision for polyethylene wear. Acetabular osteolysis was likely to have been caused by polyethylene wear. Only one patient required femoral revision for aseptic loosening. Jacquot et al² reported a rate of revision of 32.2% using the Kaplan-Meier method, considering revision of the acetabular component as the endpoint. Similarly, polyethylene wear was the indication but did not lead to significant rates of femoral loosening. D'Angelo et al¹⁸ reported mid-term results of the same Dual Radius Osteonics' acetabular component that we used, with a mean follow-up of ten years. Aseptic loosening, requiring revision, occurred in 17 (9.3%) of 183

acetabular components. It was suggested that these unsatisfactory results were attributed to fatigue failure between the metal and the hydroxyapatite coating caused by prolonged distractional stress imposed by the patient's activity. Another possible cause was thought to be "degradation or loss" of the hydroxyapatite coating.

Strengths of the current study include a large cohort with a long follow-up, and the retention of nearly 70% of the patients up to 20 years postoperatively. All available patients, except five who were lost to follow-up, were seen regularly at one- or two-year intervals postoperatively, with radiographs available from each visit. This allowed close monitoring of their progress and the timely identification of complications. The decision to undergo uncemented THA for each patient was made with consensus among arthroplasty specialists in our centre, ensuring the strict selection of patients. All the operations were either performed or supervised by a single senior surgeon, with a consistent surgical technique. Limitations of the study include the high rate of acetabular loosening and polyethylene wear, which could have confounded the radiological results, and the inevitable loss of some patients to follow-up, which could have led to a minor underestimation of the incidence of complications. Clinical scores and risk factors for revision were not evaluated.

In summary, a hydroxyapatite-coated femoral component offered promising results into the third decade after THA. While the overall results were comparable to those of some other uncemented stems, the exceptionally low rate of revision for aseptic loosening was better than that of others.



Take home message

 This study offers insight into the long-term performance of an uncemented femoral stem with hydroxyapatite coating.

Supplementary material



Kaplan-Meier survival curves with femoral revision as the endpoint (either from all causes or from aseptic loosening).

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Data sharing:

The datasets generated and analyzed in the current study are not publicly available due to data protection regulations. Access to data is limited to the researchers who have obtained permission for data processing. Further inquiries can be made to the corresponding author.

Ethical review statement:

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