

Poor intermediate-term survival of the uncemented Optan anatomically adapted femoral component

A retrospective study of 432 patients with a mean follow-up of 5 years

Luc J M Heijns, Jelle J Halma, and Steven M van Gaalen, and Arthur de Gast

Clinical Orthopaedic Research Center – midden Nederland (CORC-mN), Department of Orthopaedics, Diaconessenhuis Hospital Utrecht/Zeist, Utrecht, the Netherlands.

Correspondence: jhalma@diakhuis.nl

Submitted 2013-10-22. Accepted 14-03-25

Purpose — We evaluated the 5-year survival of the uncemented Optan anatomically adapted femoral stem, with revision for aseptic loosening as the endpoint.

Methods — Between January 2004 and March 2007, 432 total hip arthroplasties (THAs) were performed in 432 patients. After follow-up for a mean time of 5 years, the patients were evaluated using the WOMAC questionnaire and plain radiography. Patients who were unable to attend the follow-up visit were contacted by telephone to determine whether they had had any revision surgery of their THA.

Results — Within 5 years, 39 patients (9%) had died of unrelated causes and 63 patients (15%) had been lost to follow-up. Of the remaining cohort, 224 patients (68%) had full follow-up while 88 patients (27%) were evaluated with WOMAC only and 18 patients (5%) were evaluated with radiography only. The mean WOMAC score of all evaluated patients was 21 (10–100). At 5-year follow-up, there were 26 stem revisions reported (6%), 14 hips (3%) showed aseptic loosening, and 12 hips (3%) had had a periprosthetic femoral fracture. The 5-year survival to revision for any reason was 94%. Worst-case analysis yielded a 5-year survival of 79%.

Interpretation — The 5-year survival for aseptic loosening of the Optan anatomically adapted femoral component was disappointing. Radiographic evaluation showed evidence of proximal radiolucencies and distal cortical bone hypertrophy, which we attribute to insufficient proximal bone in-growth and increased load transfer at the tip of the stem. We do not recommend the use of the Optan femoral stem.

The Optan femoral stem was designed to reduce proximal femoral bone loss after total hip arthroplasty (THA). It was

designed with a specific geometry, stiffness, and surface roughness (Bieger et al. 2011). It is an anatomically shaped femoral component in the sense that it has an anteversion similar to that of the native proximal femur. The uncemented Optan femoral stem is made of a titanium-based alloy with a porous-coated proximal third. Furthermore, the femoral stem has a ventral rib that should prevent rotation. The distal narrowing, the anatomical shape, and the porous-coated proximal third of the stem are designed to lead to a physiological load transfer and therefore optimal bone in-growth of the femoral stem. Despite the theoretical advantages of the Optan femoral stem, no studies have been published on the survival of this uncemented femoral component. We evaluated the mean 5-year survival of the uncemented Optan femoral stem used in primary THA.

Patients and methods

All 432 patients (303 women) who underwent primary THA and received an uncemented Optan anatomical adapted femoral stem (Zimmer Germany GmbH, Freiburg, Germany) and a Morscher monoblock cup (Centerpulse/Zimmer) between January 2004 and March 2007 were included (432 THAs). Patients aged 30 years or younger were not included. The most frequent diagnosis was primary osteoarthritis. The mean age at evaluation was 71 (32–92) years (Tables 1 and 2). The articulations used were either the 28-mm CoCr alloy metal-on-metal articulation (115 hips (27%)) or the ceramic-on-polyethylene articulation (317 hips (73%)). The operations were performed by 5 experienced orthopedic surgeons who each perform over 150 arthroplasties per year at the same institution. All THAs were performed using a 28-mm femoral head. A lateral (trans-

Table 1. Patient demographics

Demographics	Male	Female	Total
No. of hips	129 (30%)	303 (70%)	432
No. of patients	129	303	432
Age, mean (range)	69 (38–89)	72 (32–92)	71 (32–92)
Right:Left	62:66	154:149	216:215

Table 2. Primary diagnosis of patients

Diagnosis	No. of hips
Primary osteoarthritis	405 (94%)
Post-fracture/AVN	22 (5%)
Secondary osteoarthritis	2 (0.5%)
Acute fracture	2 (0.5%)
Congenital hip dysplasia (CHD)	1 (0.2%)

gluteal) approach was used in all patients. They all received prophylactic antibiotics (cefazolin for 24 h perioperatively).

At follow-up, the patients were examined with plain radiography and the Western Ontario and McMaster Universities index (WOMAC) questionnaire (Roorda et al. 2004). Radiographic evaluation was performed using Rogan software (Oldelft Benelux B.V., Veenendaal, the Netherlands). Patients who were not able to attend the follow-up visit were contacted by telephone and asked questions using the WOMAC questionnaire. Furthermore, we asked whether these patients had had any revision surgery. 63 patients whose telephone number was unknown or who did not respond to telephone calls were categorized as being lost to follow-up.

Radiographic evaluation

Radiographs were assessed for periprosthetic osteolysis and/or radiolucencies. Radiolucencies were defined as a radiolucent line between implant and bone of 1 mm or more. The location of radiolucency was assessed according to the Gruen zones. Radiographic evidence of cortical bone hypertrophy or resorption was also recorded. The first postoperative radiograph was also assessed for varus or valgus malpositioning, i.e. when the femoral component had a varus or valgus orientation of 5 degrees or more on the anteroposterior pelvic radiograph. We also assessed whether the femoral stem was obviously undersized.

Statistics

Statistical evaluations and analysis were performed using SPSS version 19.0. This software was also used for Kaplan-Meier survivorship analysis for aseptic loosening of the femoral stem and revision for any reason. A worst-case survivorship analysis was performed in which all patients lost to follow-up were considered to be revised due to aseptic loosening.

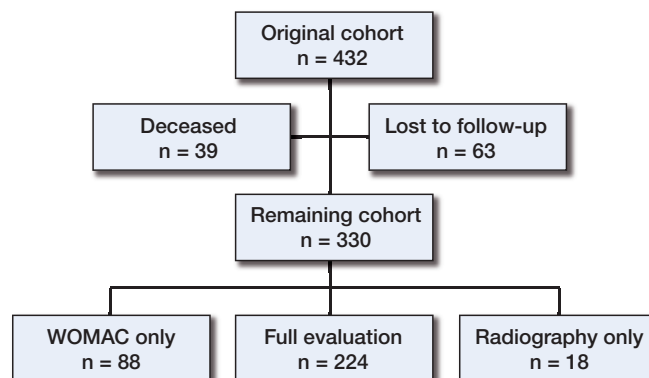


Figure 1. Flow chart of patients in the study.

ing. Welch's t-test was used to compare the mean WOMAC scores of the patients contacted by telephone with the patients who had had full follow-up. Furthermore, chi-square statistics was used to determine the factors that predisposed for periprosthetic fracture. The log-rank test (Mantel-Cox) was used to determine whether there was a significant difference in survival outcome in the different subgroups. We considered p-values of < 0.05 to indicate significance.

Results

The original cohort consisted of 432 hips in 432 patients. At 5-year follow-up, 39 patients (9%) had died of unrelated causes. 63 patients (15%) did not respond for evaluation or could not be contacted and were categorized as being lost to follow-up. The remaining cohort consisted of 330 patients (76%). Of this remaining cohort, 224 patients (68%) underwent the full evaluation, 88 patients (27%) were evaluated with WOMAC only, and 18 patients (5%) were evaluated radiographically only (Figure 1). The mean duration of follow-up was 5.1 (3.7–6.6) years. At the end of follow-up, the stem had been revised in 26 patients (6%), mainly because of aseptic loosening (14 hips) and femoral fractures (9 hips). Other reasons were infection (1 hip) or recurrent dislocation (2 hips). Altogether, 12 patients had had a periprosthetic fracture, leading to revision of the stem in 9 cases. In 1 case, the fracture was managed with cerclage wiring. In another case, the fracture was treated with internal fixation with plate and screws. 1 fracture was treated non-surgically. Periprosthetic fractures had occurred at a mean of 1.6 (0.01–6.3) years after surgery. In 14 hips, symptomatic aseptic loosening had occurred; these had undergone stem revision surgery after mean 2.9 (0.02–6) years. 13 patients had had 1 or more dislocations (3%).

The mean WOMAC score of all patients was 21 (10–100; median 15; 95% CI: 19–24). The patients who were evaluated by telephone had a statistically significantly better outcome than the patients with full follow-up regarding the WOMAC stiffness score and the WOMAC pain score. The mean

Table 3. Comparison of the mean WOMAC scores of patients with full follow-up and patients who were contacted by telephone only

Mean score	Full follow-up (SD)	Telephone contact only (SD)	p-value	95% CI
WOMAC score	22 (21)	19 (20)	0.2	-1.9 to 8.2
WOMAC pain	15 (21)	8 (17)	0.007	1.7 to 11
WOMAC stiffness	26 (27)	14 (23)	0.000	6.3 to 18
WOMAC functional	24 (23)	23 (23)	0.7	-4.7 to 7

WOMAC sum score and the mean WOMAC functional score were similar between the 2 groups (Table 3).

Radiographic evaluation (n = 239) showed cortical bone hypertrophy at the distal end in 106 hips (45%). In 17 hips, there was radiolucency at the proximal end of the femoral stem. Of these cases, the radiolucency was located in Gruen zone 1 in 10 hips and in 5 hips a radiolucency was seen in Gruen zones 1 and 7. A pedestal, i.e. the formation of bone at the tip of the stem—which usually closes the medullary canal—was found in 18 hips. In 47 hips, there was an undersized femoral component; the femoral component was in varus malpositioning in 13 hips and it was in valgus malpositioning in 5 hips.

Survivorship analysis

Survivorship analysis with stem revision for any reason as the endpoint revealed an overall survival of 94% at the 5-year follow-up (Figure 2). 5-year survival with aseptic loosening as the endpoint was 97% (Figure 3). The type of articulation (either ceramic-on-polyethylene or 28-mm metal-on-metal), age, varus/valgus malpositioning, or undersizing of the femoral component did not significantly affect survival with stem

Table 4. Survival to revision for any reason and survival to aseptic loosening of the different subgroups categorized by sex, articulation, undersizing, varus/valgus malpositioning, and patient age (log-rank/Mantel-Cox test)

	Revision for any reason Survival (%)	p-value	Revision for aseptic loosening Survival (%)	p-value
Sex				
Male	92	0.3	94	0.03
Female	95		98	
Articulation				
Metal-on-metal	97	0.2	97	0.6
Ceramic-on-polyethylene	93		97	
Undersized				
Yes	87	0.06	96	0.8
No	95		97	
Malpositioned				
Varus	85	0.7	92	0.6
Valgus	100		100	
Age				
32–54	94	0.6	97	0.6
55–74	93		96	
75–92	95		98	

loosening or stem revision for any reason as the endpoint (Table 4). Male patients had relatively more cases of aseptic loosening (survival 94%, p = 0.03).

The worst-case scenario, in which all 63 patients who were lost to follow-up were considered to have had a revision of the femoral component, would yield a survival rate of 79% with revision for any reason as the endpoint. With aseptic loosening as the endpoint, the survival rate would be 82%.

Patient age, sex, varus or valgus malpositioning, and undersizing of the femoral component did not significantly affect

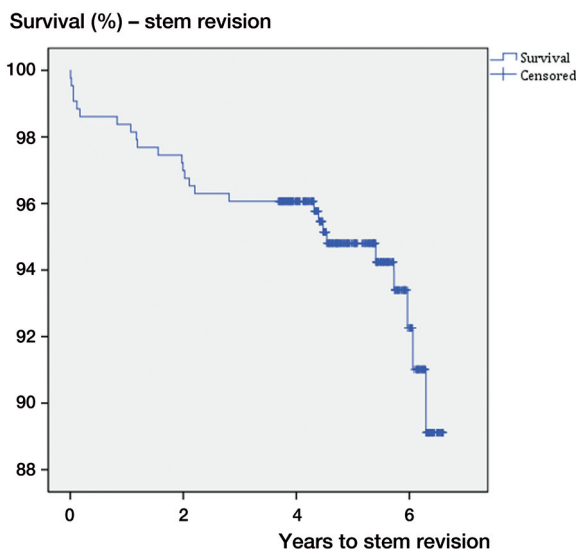


Figure 2. Kaplan-Meier survival analysis with revision for any reason as the endpoint.

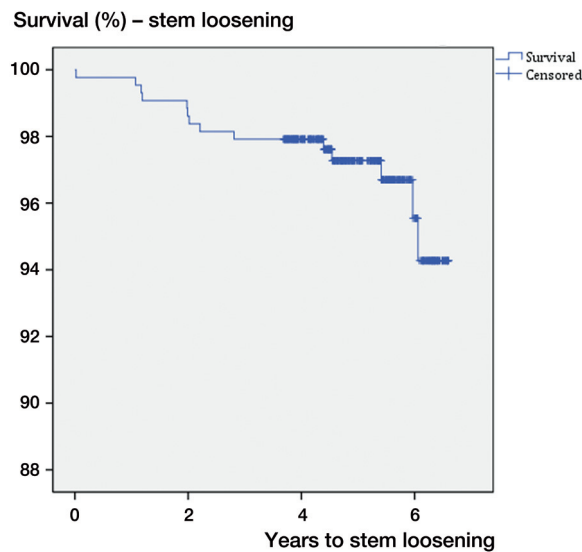


Figure 3. Kaplan-Meier survival analysis with revision due to aseptic loosening as the endpoint.

the frequency of periprosthetic fracture. The frequency of periprosthetic fracture was higher in the patients with a ceramic-on-polyethylene articulation ($p = 0.03$).

Discussion

The present study had several important limitations. Because of the retrospective design, it suffered from a substantial number of patients being lost to follow-up (63 patients, 15%), which could have influenced our results. The high number of patients who did not attend the full follow-up (106 patients, 25%) was also a limitation. Radiographic follow-up was completed in only 242 patients (56%). We believe, however, that the telephone-based interview using the WOMAC questionnaire and determining whether patients had had any revision surgery of their THA was an adequate form of follow-up for patients who were unable to attend for full clinical follow-up. Furthermore, the WOMAC sum scores were similar in the full-evaluation group and the WOMAC-only group, indicating that these groups were comparable regarding clinical outcome.

Of the 432 patients, 115 (27%) received a metal-on-metal articulation. Thus, it is possible that patients who experienced pain after their THA actually had symptoms of pseudotumors or aseptic lymphocyte-dominated vasculitis-associated lesions (ALVAL) (Pandit et al. 2008). Advanced diagnostics in the form of ultrasonography, magnetic resonance imaging, or blood-cobalt screening were not routinely performed. Nevertheless, there were no signs of metal debris-induced pseudotumors or ALVAL—either clinically or by plain radiography—in our patients. Furthermore, in the present study the type of articulation did not significantly affect the survival rate of the stem.

The overall survival rate of 94% for the Optan femoral stem at 5-year follow-up is a poor result. For reference, the tenth annual report of the National Joint Registry of England and Wales shows that uncemented total hip implant combinations with a metal-on-polyethylene bearing have a mean 5-year all-cause revision rate of 2.5% (CI: 2.4–2.7). We found 14 hips with aseptic loosening (3.2%). Compared to other studies, the frequency of aseptic loosening after 5 years of follow-up in our study was high. For example, Wittenberg et al. (2013) reported a prevalence of 1.2% for aseptic loosening in cementless femoral stems. Worst-case analysis of our cohort yielded a 5-year survival of 79% with revision for any reason as the endpoint and 82% with aseptic loosening as the endpoint. This indicates that the Optan femoral component may not be able to meet the NICE recommendations for THA.

The specific geometry of the Optan femoral component, with a smooth surface at the distal end of the stem and a porous-coated proximal third, is designed to facilitate proximal bone in-growth. Nevertheless, we found radiolucencies in the proximal femur, Gruen zones 1 and 7, in 50% and 25% of cases. Other studies on the Optan stem (Decking et al. 2006, Bieger

et al. 2011) have demonstrated bone loss medially and laterally in the proximal femoral regions, mainly affecting Gruen zones 1 and 7, and a progressive decline in bone mineral density (BMD) over the first 12 months after surgery (Bieger et al. 2011). In the latter study, the most pronounced decrease in BMD, after 12 months, was found to be in Gruen zones 7 and 1. Furthermore, in a large number of patients (106 patients (45%)) we observed cortical bone hypertrophy around the distal end of the stem. The frequency of distal cortical bone hypertrophy that we found was high compared to other studies with medium-term follow-up (Mallory et al. 1996, Christie et al. 1999, Sinha et al. 2004).

We attribute these phenomena—radiolucencies in the proximal femur and cortical hypertrophy around the tip of the stem—to a non-physiological loading pattern, which was previously described by Decking et al. (2006). In their study, these authors observed a change in the strain pattern after implantation of the Optan femoral stem, with a major principal strain reduction of 43% in the medial part of the proximal femur and 69% in the lateral part. We attribute this to insufficient proximal bone in-growth due to the stiffness of the Optan stem and the insufficient roughness of the proximally porous-coated part. Furthermore, we consider that the cortical bone hypertrophy is the result of an increase in load transfer around the tip of the stem. We hypothesize that insufficient proximal bone in-growth leads to more load transfer at the distal end of the femoral stem, subsequently leading to distal cortical bone hypertrophy and/or the formation of a pedestal. Furthermore, the mechanical mismatch between the Optan stem and the femoral bone leads to stress shielding and subsequent bone resorption in the proximal femur. These implant properties offer poor conditions for osseointegration. We believe that these properties caused the high frequency of aseptic loosening at medium-term follow-up that was observed in the present study.

The frequency of periprosthetic fractures in our study was within the range reported for other (uncemented) femoral components, ranging from 2.3% to 3.5% at an average of 6.9 and 3 years of follow-up, respectively (Wu et al. 1999, Wal et al. 2005). We found that varus or valgus malpositioning or undersizing of the femoral component did not affect the frequency of periprosthetic fractures ($p = 0.2$ and 0.7). Furthermore, we did not observe periprosthetic fractures without an adequate trauma. We therefore believe that the prevalence of periprosthetic femoral fractures is not related to the geometry or to the degree of osseointegration of the femoral component. We hypothesize that the frequency of periprosthetic fractures is related to the low BMD and frailty of the patients. This is supported by the fact that we observed fewer periprosthetic fractures in patients with a metal-on-metal articulation, which was used in young and active patients only.

In summary, the survival of the Optan anatomically adapted femoral stem at 5-year follow-up was disappointing in terms of the high frequency of aseptic loosening. We observed a high

number of cases with evidence of insufficient proximal bone in-growth and distal cortical bone hypertrophy. We attribute this to the high stiffness of the implant and to the inadequate surface roughness of the porous-coated proximal part.

LJH gathered and analyzed the data and wrote the initial draft of the manuscript. JJH gathered and analyzed the data and revised the manuscript. SMG ensured the accuracy of the data and the analysis, and revised the manuscript. AG conceived the study, ensured the accuracy of the data and the analysis, and revised the manuscript.

No competing interests declared.

Bieger R, Martini F, Reichel H, Decking R. Changes of periprosthetic bone density after implantation of an anatomical femoral stem with cemented and cementless fixation. *Hip Int* 2011; 21 (3): 317-24.

Christie M J, DeBoer D K, Trick L W, Brothers J C, Jones R E, Vise G T, Gruen T A. Primary total hip arthroplasty with use of the modular S-ROM prosthesis. *J Bone Joint Surg (Am)* 1999; 81 (12): 1707-16.

Decking R, Puhl W, Simon U, Claes L. Changes in strain distribution of loaded proximal femora caused by different types of cementless femoral stems. *Clin Biomech* 2006; 21 (5): 495-501.

Gruen T A, McNeice G M, Amstutz H C. "Modes of failure" of cemented stem-type femoral components: a radiographic analysis of loosening. *Clin Orthop* 1979; (141): 17-27.

Mallory T H, Head W C, Lombardi A V, Emerson R H, Eberle R W, Mitchell M B. Clinical and radiographic outcome of a cementless, titanium, plasma spray-coated total hip arthroplasty femoral component. Justification for continuance of use. *J Arthroplasty* 1996; 11 (6): 653–60.

National Joint Registry of England, Wales and Northern Ireland, 10th Annual Report 2013, <http://www.njrcentre.org.uk>.

Pandit H, Glyn-Jones S, McLardy-Smith P, Gundle R, Whitwell D, Gibbons C L, Ostlere S, Athanasou N, Gill H S, Murray D W. Pseudotumours associated with metal-on-metal hip resurfacings. *J Bone Joint Surg (Br)* 2008; 90 (7): 847-51.

Roorda L D, Jones C A, Waltz M, Lankhorst G J, Bouter L M, van der Eijken J W, Willems W J, Heyligers I C, Voaklander D C, Kelly K D, Suarez-Almazor M E. Satisfactory cross cultural equivalence of the Dutch WOMAC in patients with hip osteoarthritis waiting for arthroplasty. *Ann Rheum Dis* 2004; 63 (1): 36-42.

Sinha R K, Dungy D S, Yeon H B. Primary total hip arthroplasty with a proximally porous-coated femoral stem. *J Bone Joint Surg (Am)* 2004; 86 (6): 1254-61.

Wal van der B C H, Vischjager M, Grimm B, Heyligers I C, Tonino A J. Periprosthetic fractures around cementless hydroxyapatite-coated femoral stems. *Int Orthop* 2005; 29 (4): 235-40.

Wittenberg R H, Steffen R, Windhagen H, Bucking P, Wilcke A. Five-year results of a cementless short-hip-stem prosthesis. *Orthop Rev* 2013; 5 (1): e4.

Wu C C, Au M K, Wu S S, Lin L C. Risk factors for postoperative femoral fracture in cementless hip arthroplasty. *J Formos Med Assoc* 1999; 98 (3): 190-4.