THA Using an Anatomic Stem in Patients With Femoral Head Osteonecrosis

Yong-Chan Ha MD, Hee Joong Kim MD,
Shin-Yoon Kim MD, Tae-Young Kim MD,
Kyung-Hoi Koo MD

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Abstract Treating young patients with femoral head osteonecrosis (ON) remains challenging. Anatomic stems were introduced in the 1980s and 1990s to improve the proximal canal fit in an attempt to enhance long-term implant survival, an important aspect of treating young patients. We began using one design in 1993 and asked three questions to confirm whether the design criteria improved outcomes in patients with ON: (1) What is the long term survivorship of these implants?; (2) What is the amount and rate of wear?; and (3) What is the incidence of osteolysis? We retrospectively reviewed 56 patients (69 hips) who underwent THA for femoral head ON with

a cementless anatomic stem proximally coated with hydroxyapatite. Four patients (four hips) were lost to followup and 16 patients (19 hips) died. In the remaining 36 patients (46 hips) the minimum followup was 10 years (mean, 11.2 years; range, 10–13 years). The mean age at operation was 48.6 years. The average Harris hip score at last followup was 87 points. Worst-case survivorship was 58.1% at 13 years and best-case was 93.3%. The average linear wear of the polyethylene liner was 2.02 mm and the average annual wear was 0.18 mm per year. Thirty-seven hips (80%) had femoral osteolysis and 14 (30%) had acetabular osteolysis. One patient who had extensive femoral osteolysis and stem loosening was revised at 11.2 years postoperatively. The high rates of polyethylene wear and osteolysis are of concern.

Level of Evidence: Level IV, therapeutic study. See the Guidelines for Authors for a complete description of levels of evidence.

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Each author certifies that his or her institution has approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

Y.-C. Ha, H. J. Kim, K.-H. Koo
Department of Orthopaedic Surgery, Seoul National University
College of Medicine, Seoul, South Korea

S.-Y. Kim
Department of Orthopaedic Surgery, Kyungpook National
University College of Medicine, Daegu, South Korea

T.-Y. Kim
Department of Orthopaedic Surgery, Korea University College
of Medicine, Seoul, South Korea

K.-H. Koo (✉)
Department of Orthopaedic Surgery, Seoul National University
Bundang Hospital, 300 Gumi-dong, Bundang-gu, Seongnam
463-707, South Korea
e-mail: khkoo@snu.ac.kr

Introduction

Femoral head osteonecrosis (ON) occurs in young patients with a mean age of younger than 50 years [19, 29, 31] and treating these young patients remains a major therapeutic challenge [5, 18, 22, 34].

Cementless THA was developed to obtain biologic fixation and increase the longevity of the implant. Short-term results of various types of cementless THA were encouraging [3, 4, 7]. However, THA using the first-generation straight femoral stems was associated with high rates of failure as a result of thigh pain, subsidence of the femoral stem, aseptic loosening, proximal loss of bone attributable to stress shielding, and polyethylene particle-induced osteolysis [1, 2, 8, 13, 21, 24, 28, 32, 33, 35].

Anatomic stems were designed to maximize the proximal fit in both the coronal and the sagittal planes and hopefully enhance implant survival compared to that of the first-generation stems. Implant survival would, of course, be particularly important for the younger patients with ON. However, the effectiveness of the anatomic stem remains controversial and it is not known whether the design criteria solved the problems with the first-generation straight stems [3, 20, 28].

We therefore asked three questions: (1) What is the long term survivorship of these implants?; (2) What is the amount and rate of wear?; and (3) What is the incidence of osteolysis?

Materials and Methods

We retrospectively reviewed 56 patients (69 hips) with femoral head ON treated with an anatomic cementless stem design between July 1993 and December 1995. Of the 56 patients (69 hips), 16 patients (19 hips) died because of problems unrelated to the operation and four patients (four hips) were lost before a minimum followup of 10 years. These 20 patients (23 hips) were followed for an average of 4.7 years (range, 1–9 years). The causes of death in the 16 deceased patients were chronic liver disease in seven, chronic renal failure in two, heart disease in two, malignant neoplasm in two, traffic accident in two, and unknown in one. None of the 16 deceased patients (19 hips) and four lost patients (four hips) had a revision or a reoperation at last followup. Their mean Harris hip score was 91.4 (range, 82–98) at the last followup. None of these patients used support and one patient (one hip) had a mild limp; one patient had mild thigh pain. None of the 20 hips had loosening at last followup but femoral osteolysis was seen in one hip in Gruen zones 1 and 7 and acetabular osteolysis was seen in one hip in DeLee and Charnley zone I. Of the 36 surviving patients there were 30 men (39 hips) and six women (seven hips). The mean age of these 36 patients was 48.6 years (range, 22–65 years) at the time of the index operation. Twenty-two (61%, 27 hips) of 36 patients were less than 50 years old. On preoperative radiographic classification with the system of Ficat [11], six hips were in stage II-B, 29 in stage III and 11 in stage IV. Nine patients (11 hips) were sedentary workers, eight patients (10 hips) moderate workers, 16 patients (20 hips) intermediate workers, and three patients (five hips) intensive workers [12] (Table 1). In the remaining 36 patients (46 hips), the minimum followup was 10 years (mean, 11.2 years; range, 10–13 years). The study was approved by our Institutional Review Board; all patients were informed his or her medical data could be used in a scientific study and provided consent preoperatively.

Table 1. Demographic data

Variable	Data
Number of patients	36
Number of hips	46
Gender (male/female)	30 (39 hips) / 6 (7 hips)
Age (years)	mean, 48.6; range, 22–65
< 50 years (%)	22 (61.1%)
≥ 50 years (%)	14 (38.9%)
Body weight (kg)	mean, 64.8; range, 49–89
Height (cm)	mean, 167.2; range, 151–183
Body mass index	mean, 23.9; range, 22.1–25.8
Preoperative Harris hip score	mean, 44.2; range, 20–62
Duration of followup (years)	mean, 11.2; range, 10–13
Risk factors for osteonecrosis	
Idiopathic	17 patients (23 hips)
Alcohol abuse	13 patients (16 hips)
Steroid	4 patients (5 hips)
Femoral neck fracture	2 patients (2 hips)
Ficat stage	
Stage IIB	6 hips
Stage III	29 hips
Stage IV	11 hips
Occupational activity	
Sedentary workers	9 patients (11 hips)
Moderate workers	8 patients (10 hips)
Intermediate workers	16 patients (20 hips)
Intensive workers	3 patients (5 hips)

The stem design was a cementless anatomic metaphyseal fitting titanium stem. The stem had a rough surface with an average roughness of 1.2 micron and the proximal 50% of the stem was coated with hydroxyapatite in a thickness of 100 micron (Profile, DePuy, Leeds, UK) (Fig. 1).

All operations were performed by one surgeon (K-HK) using the posterolateral approach. All of the acetabular and femoral components were inserted in a press-fit manner. The surgeon tried to position the acetabular cup at the abduction of $40^\circ \pm 10^\circ$ as suggested by Lewinnek et al. [26]. A porous-coated hemispheric cup (Duraloc 1200; DePuy, Warsaw, IN), an ultrahigh-molecular-weight polyethylene liner (Enduron; DePuy), and a 28-mm cobalt-chromium head (DePuy) were used in all hips.

Patients were instructed to walk with partial weight-bearing with the aid of two crutches for 4 weeks after surgery.

We performed followup evaluations at 6 weeks; at 3, 6, 9, and 12 months; and every 6 months thereafter. Patients who had not returned for regularly scheduled visits were contacted by telephone. Two nurses and one doctor located and visited nonresponders. These three individuals performed a clinical evaluation using the Harris hip scoring system [15].

Fig. 1 The cementless anatomic Profile stem, shown from three angles, has a large proximal segment to obtain a maximized fit into the endosteal cavity of the proximal part of the femur. The proximal part of the stem is coated with hydroxyapatite.

We considered the 6-week anteroposterior and cross-table lateral radiographs the baseline study for radiographic comparison. Two of us (Y-CH and S-YK) measured the abduction and anteversion angles of the acetabular component using the method of Widmer and Zurfluh [36] and the offset of femur before and after the total hip arthroplasty using the method of Jolles et al. [16]. On the final radiographs we assessed fixation of the femoral and acetabular components, polyethylene liner wear, osteolysis, and heterotopic ossification. The fixation of the femoral component was classified with use of the method of Engh et al. [10] and the fixation of the acetabular component with use of the method of Latimer and Lachiewicz [25]. The wear of the polyethylene liner was calculated according to the method developed by Livermore et al. [27]. Volumetric wear was calculated with the equation $V = [\pi]r^2w$, where V = volumetric wear, r = the radius of the femoral head, and w = measured linear wear [23, 27]. Osteolytic lesions were defined according to the criteria of Engh et al. [9]. The lesions were recorded according to the three zones described by DeLee and Charnley [6] on the acetabular side and the seven zones described by Gruen et al. [14] on the femoral side.

We performed Kaplan-Meier survival analysis for all hips with a minimum ten-year followup with revision of either component as an endpoint [17]. We did two analyses: a best-case scenario (in which all 23 hips with less than 10 year followup were considered to have had no revision through the 13 year followup) and worst-case scenario (in which all 23 hips were considered to have required revision before the 13 year followup). For all analyses we used SPSS version 11.0 (Chicago, IL).

Results

In the 36 patients (46 hips) who had a minimum followup of 10 years, the mean Harris hip score was 87 (range, 56–95)

at the final followup. No patient used support and three patients (three hips [7%]) had a mild limp. Thigh pain was present in three patients (three hips [7%]).

Worst-case survivorship was 58.1% (95% confidence interval, 41.8%–71.3%) and best-case survivorship was 93.3% (95% confidence interval, 80.7%–100%) at 13 years (Fig. 2).

The average linear wear of the polyethylene liner was 2.02 mm (range, 0.3–4.7 mm), and the average amount of volumetric wear was 1243.43 mm³ (range, 184.6–2892.6 mm³). The average linear wear rate was 0.18 mm per year (range, 0.03–0.48 mm per year), and the average annual rate of volumetric wear was 110.87 mm³ (range, 18.5–295.4 mm³).

Femoral osteolysis was seen in 37 hips (80%); 19 hips (41%) had osteolysis in Gruen zone 1 and 17 hips (37%) in zones 1 and 7. These osteolytic lesions were small (less than 1 cm²) and were not progressive on serial radiographs. Forty-five stems (98%) had bone on growth stability (Fig. 3). However, one stem (2%) had diffuse extensive

Fig. 2 The Kaplan-Meier survival curve including 95% confidence interval estimates with implant revision as the endpoint. Excluding patients lost to followup (best-case scenario) there was only one failure of the femoral stem at 11.5 years (straight line). The dotted line shows the worst-case scenario presuming all 23 hips lost to followup had failed.

Fig. 3A–B A 28-year-old man underwent THA resulting from ON of the femoral head with use of a Profile stem. **(A)** An anteroposterior radiograph obtained 6 weeks postoperatively shows radiolucent line in DeLee and Charnley zones II and III as well as screw sites. No remodeling changes are seen around the stem. **(B)** On anteroposterior radiograph obtained 13 years postoperatively, the line disappeared in DeLee and Charnley zone III. Focal osteolysis (less than 1 cm^2) is seen in Gruen zone I (arrows) around the stem and a shelf pedestal at the tip of the stem.

osteolysis and loosening, which was revised 11 years 2 months after the index operation (Fig. 4) (Table 2). Acetabular osteolysis was identified in 14 hips (30%); two hips (4%) in DeLee and Charnley zone I, eight hips (17%) in zone II, three hips (7%) in zones I to II, and one hip (2%) in Zones II to III (Fig. 4) (Table 2).

Reactive radiolucent line formation was found around the uncoated distal tip of the stem in nine hips (20%) at nine to 24 months after the operation. The line was seen in only lateral radiograph (Gruen zones 10, 11 and 12) in eight hips and in both anteroposterior and lateral radiographs (Gruen zones 3, 4, 5, 10, 11 and 12) in one hip. The line was parallel to the distal tip and the thickness was less than two millimeters. It was not associated with the formation of a halo pedestal and was not progressive. Thus, it was not thought to be osteolysis. Three hips (7%) had a shelf pedestal at the tip of the stem. Cortical hypertrophy was observed in the distal zone (Gruen zones 3, 4 and 5) in nine hips (20%). All hips had cortical thinning and cancellization of the cortex in the calcar femorale (Fig. 3).

No acetabular component had loosening. We observed radiolucent lines around the acetabular cup in 29 hips

(63%) at 6-week radiographs, which was presumed to be polar gap or peripheral gap. No line had progressed on serial radiographs. The line disappeared at six to 12 months after the operation in 20 hips and persisted until the latest evaluation in nine hips (20%) (Fig. 3).

There was an intraoperative linear fracture of the calcar femorale in one hip, which was treated with a cerclage wire and healed completely. One hip dislocated at postoperative day one, which was treated successfully with closed reduction and an abduction brace for 3 months. One patient sustained a periprosthetic fracture of the proximal femur because of a traffic accident 57 months postoperatively. The fracture was treated with open reduction and internal fixation using cerclage wires. The fracture united uneventfully and the stem was still well-fixed 7 years later (Fig. 5).

Discussion

Treating patients with femoral head ON is a challenge owing to their relative young age and anticipated many decade survival. Owing to disappointing survival rates of

Fig. 4A–C A 53-year-old man underwent THA because of ON of the femoral head with use of a Profile stem. (A) An anteroposterior radiograph obtained 6 weeks postoperatively shows no remodeling changes. (B) An anteroposterior radiograph and a (C) lateral

radiograph obtained 11 years postoperatively show extensive femoral osteolysis (arrows). Cavitary osteolysis (arrowheads) is also seen around the acetabular cup in DeLee and Charnley zones I and II.

Table 2. Periprosthetic bone change along the implants

Bone change type	Percentage
Radiolucent line	
Femoral	9 (19.6%)
Acetabular	9 (19.6%)
Osteolysis	
Femoral	37 (80.4%)
Acetabular	14 (30.4%)
Shelf pedestal	3 (6.5%)
Cortical hypertrophy	9 (19.6%)
Calcar atrophy	46 (100%)

some straight stems, anatomic stems were developed in the 1980s and 1990s to improve the proximal canal fit and presumably long-term survival. We began using one design in 1993 and asked three questions to confirm whether the design criteria improved outcomes in patients with ON: (1) What is the long term survivorship of these implants?; (2) What is the amount and rate of wear?; and (3) What is the incidence of osteolysis?

We note several limitations to our study. Among the 56 patients (69 hips), 16 patients (19 hips) died and four patients (four hips) were lost before the 10 year minimum followup; additionally, the followup rate was 64%, which

might have influenced the long-term results. The unexpectedly high death rate in our patients seemed related to causes of ON including alcohol abuse and steroid use, which might be potentially confounding comorbidities.

The effectiveness of the anatomic stem remains controversial and the long-term followup results have not yet been determined. One previous study [3] reporting 2-year results of 50 cementless THAs with the use of Porous-Coated Anatomic (PCA) stems (Howmedica, Rutherford, NJ), the clinical results were encouraging. However, progressive radiolucency femoral lines developed in 41%, progressive loosening of beads from the stem in 24%, and thigh pain in 16%. In another study [28], 52 THAs with the use of the PCA stem were evaluated and a high failure rate was reported. At a mean of 2.4 years followup, four (8%) femoral components were revised because of subsidence and persistent thigh pain was reported in 33%. Kim et al. [20] reviewed 108 patients (116 hips) who were followed for 10 to 12 years after THA using a PCA hip prosthesis. The rate of revision of the femoral component was 11%, the rate of revision of the acetabular component was 15%, and the incidence of thigh pain was 28%. Moskal et al. [30] evaluated 107 PCA arthroplasties at an average of 12.4 years. The failure rate was 13% in the acetabular components and 4% in the stems. The design of the Profile stem used in our study has a similar design to a PCA stem.

Fig. 5A–B A 59-year-old man underwent THA because of ON of the femoral head with use of a Profile stem. The patient sustained injury resulting from a traffic accident 57 months postoperatively. **(A)** An anteroposterior radiograph shows a periprosthetic fracture of the proximal femur. The fracture was treated with open reduction and internal fixation using cerclage wires and the fracture united uneventfully. **(B)** On an anteroposterior radiograph obtained 7 years after the fracture operation, the stem is still well fixed.

Both stems are cementless anatomic metaphyseal fitting stems with a circumferential coating on the proximal one-third. However, the proximal portion of the Profile stem is larger than that of the PCA stem and has a closer match to the endosteal cavity of the proximal part of the femur and a better surface coating.

We observed only one patient with a loose stem (2%) and three with thigh pain (7%) at a mean of 11.2 years followup. Our findings agree with those of Kim et al. [23] who evaluated 118 THAs with the use of the Profile stem. DePuy supplied two versions of the Profile stem. The two versions are identical with regard to geometry and stem material. The two versions differed only with regard to the surface treatment of the proximal portion; one was porous-coated and the other was hydroxyapatite-coated. Although we used hydroxyapatite-coated Profile stems, Kim et al. [23] used porous-coated Profile stems. At a mean of 9.8 years followup they had no aseptic loosening and the incidence of transitory thigh pain was 10%. We believe the improved design features of the Profile stem might lead to the better results with the Profile stem compared to the PCA stem.

We observed a femoral osteolysis rate of 80% and an acetabular osteolysis rate of 30%. These rates were much higher than rates in the study of Kim et al. [23] who reported 12% femoral osteolysis and 9% acetabular osteolysis. Their low incidence of osteolysis around the acetabular and femoral components might be related to the

relatively low rate of volumetric wear of polyethylene because they used a 22-mm head. The different surface treatments, hydroxyapatite coating and porous coating, might have influenced the rate of osteolysis.

Our data suggest the anatomic fit cementless Profile stem had durable fixation in young, active patients who had femoral head ON. However, a high wear rate of the polyethylene liner and a high incidence of osteolysis are concerning.

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