



Short-term Outcomes of Ceramic Coated Metal-on-Metal Large Head in Total Hip Replacement Arthroplasty

Weon-Yoo Kim, PhD, MD, Myung-Sup Ko, MD, Se-Won Lee, MD, Kwang-Sub Kim, MD

Department of Orthopedic Surgery, The Catholic University of Korea, Daejeon St. Mary's Hospital, Daejeon, Korea

Purpose: This study characterizes the short-term outcomes of ceramic coated metal-on-metal (MoM) large head total hip arthroplasty (THA) in prospectively selected patients aged 70 to 75 years.

Materials and Methods: Eighteen patients (18 hips) between the ages of 70 and 75-years old with THA using ceramic-coated MoM large heads between June 2014 and December 2014 were evaluated. We prospectively selected patients younger than 70 years for bipolar hemiarthroplasty and older than 75 years for conventional THA. There were one case of osteoarthritis, 8 cases of femur neck fracture, and 9 cases of intertrochanteric fracture. All patients underwent clinical and radiological follow-up at 6 weeks, 6 and 12 months, and every year postoperatively. The mean duration of follow-up was 24.2 months (range, 18-34 months).

Results: The average Harris hip score at the final follow-up was 81.0, except one case which was ultimately converted to conventional THA due to acetabular cup loosening. Radiographically, mean acetabular cup inclination was 45.8° (range, 38-56°) and anteversion was 20.1° (range, 11-25°). The average femoral head size was 48.7 mm. All stems were neutral-positioned except 1 varus-positioned stem. There was 1 case of a soft tissue infection, 3 patients complained of persistent groin pain, and no dislocations occurred.

Conclusion: Ceramic coated large MOM articulation (ACCIS) have many complications: cup loosening, groin pain, which can lead to fatal outcomes in the elderly patients. Especially in patients with communicated intertrochanter fracture (AO 31-A22, 23), careful attention should be paid to the choice of surgical option.

Key Words: Hip replacement arthroplasty, Metal-on-metal articulation, Large femoral head, Complication

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Address reprint request to

Kwang-Sub Kim, MD (ORCID 0000-0002-6929-5359)

Department of Orthopedic Surgery, The Catholic University of Korea, Daejeon St. Mary's Hospital, 64 Daeheung-ro, Jung-gu, Daejeon 34943, Korea

TEL: +82-42-220-9530 **FAX:** +82-42-221-0429

E-mail: hereksk@gmail.com

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INTRODUCTION

Total hip replacement arthroplasty (THA) is recognized as an effective treatment for degenerative diseases and hip fractures in the elderly. The application range of THA is gradually increasing with the extension of patient's lifespan and lifestyle changes. However, complications of THA in elderly patients can lead to fatal outcomes. One well-known complication is dislocation (reported incidence of 0.4% to 5.8%)^{1,2}.

Large femoral heads have been used in THA to reduce the risk of dislocation and are associated with increased jumping distance and range of motion (ROM). Metal-on-

metal bearings of these large heads provide theoretical advantages of large articulations that improve joint stability and have a low friction rate and increased wear-resistance³⁻⁵. However, some concerns about metal-on-metal articulation have arisen: i) autoimmune and soft tissue diseases⁶, ii) DNA break⁷, and iii) hypersensitivity⁸.

Metal-on-metal surfaces coated with ceramic providing reduced wear and friction rates are theoretically attractive prostheses in terms of large head with a reduction in released ions. We used ceramic-coated large metal heads and ceramic-surfaced cups in THA.

To our knowledge, this study is the first article focused on ceramic-coated metal-on-metal large head THA. The purpose of this study is to present the safety and efficacy outcomes of ceramic coated metal-on-metal large head THA in prospectively selected patients aged 70 to 75 years.

MATERIALS AND METHODS

This study was approved by the institutional review board of The Catholic University of Korea, Daejeon St. Mary's Hospital (DC17RESI0082).

1. Demographics and Clinical Measurements

Between June 2014 and December 2014, THA in patients with modified Koval index stage of greater than 3 (under 70-years old) and bipolar hemiarthroplasty (patients over 75-years old) were performed^{9,10}. During that period, 18 patients (18 hips) aged between 70 and 75 years were enrolled to be operated on with ceramic-coated metal-on-metal large heads^{9,10}.

There were 8 men and 9 women (mean age of 72.0 years; range, 70-75 years) at the time of surgery. There was one case of osteoarthritis, 8 cases of femur neck fracture, and 9 cases of intertrochanteric fracture.

Basic clinical details included age, gender, etiology, pre & postoperative modified Koval indices, complications and bone mineral density were collected. Patient activity was recorded with the modified Harris Hip Score (mHHS)¹¹.

2. Implant

The THA implant consisted of acetabular and femoral head components made of Cobalt-Chromium-Molybdenum alloy. A ceramic titanium-niobium-nitride coating is applied on the articular surfaces of both components. Cementless acetabular components of the advanced ceramic coated implant system

(ACCIS; Implantcast GmbH, Buxtehude, Germany) have three radii with three distinct areas: i) polar area with no contact between the bone and the component, ii) fit area in contact with the porous coated surface for bone ingrowth, and iii) press fit area with circumferential press fit at the equator (Fig. 1). Femoral components have three parts: i) 12/14 mm cone, ii) cone adapter, and iii) modular head (Fig. 2). The ACCIS guide recommends that if hard bone (e.g., subchondral sclerosis) is encountered, preventing proper seating of the component, an acetabulum reamer larger than 1 mm is needed. Each adapter is available in three different neck lengths in 4 mm increments and suited for three head sizes¹².

3. Radiologic Measurements

All patients underwent clinical and radiological follow-up at 6 weeks, 6 and 12 months, and every year postoperatively. The mean duration of follow-up was 24.2 months (range, 18-34 months).

Standard anteroposterior pelvic X-rays were used to measure acetabular cup version and inclination. Acetabular inclination was defined as an angle between the line

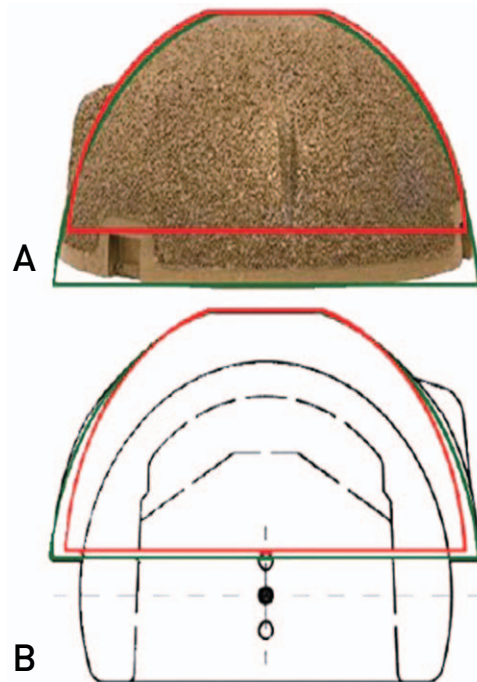


Fig. 1. Acetabular component design. Polar area: no contact between the bone and the component. Fit area: contact with the porous coated surface for bone ingrowth. Press fit area: circumferential press fit at the equator for primary implant stability.

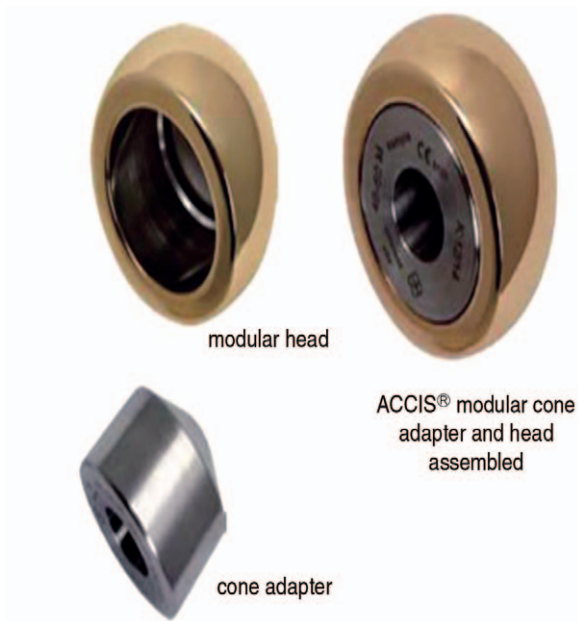


Fig. 2. Femoral heads and cone adapters. Each adapter is available in three different neck lengths in 4 mm increments and adapters are suited for femoral components with a 12/14 mm cone.

connecting both tear drop and acetabular cup measured on anteroposterior radiographs. Acetabular anteversion was measured on anteroposterior radiograph using Widmer's method¹³. Femoral stem positioning was measured on anteroposterior radiographs (varus and valgus less than 5° was considered as a neutral position).

4. Surgical Technique

The modified Gibson approach was used and after routine approach, the short external rotators were exposed. The insertion of the quadratus femoris was identified and used the quadratus femoris osteotomy approach¹⁴. After implanting the prosthesis, the decision to use a cemented or noncemented stem was determined based on bone quality. The bone fragment detached by flap osteotomy was reattached with wires. In cases of proximal femur fractures, Greater Trochanteric Reattachment Devices (DePuy Synthes, Westchester, PA, USA) or wires were used for greater trochanter fixation.

5. Post-operative Treatment

In the immediate postoperative period, the hip is positioned in abduction with a triangular pillow to maintain abduction, and deep breathing exercises, pneumatic pumps and isometrics

exercise of lower extremity are begun. On the first postoperative day, if not limited by discomfort, patients can sit up. Gait practicing usually can begin after removal of drain in the physical training (PT) center. Practicing gait without help in older patients has additional risks, (e.g., fall from height), so most gait trains started in the PT room. Most elderly patients required a gait-assistance device to maintain balance. To prevent venous thromboembolic disease, active exercises and intermittent pneumatic compression boots of both lower extremities were applied immediately after surgery. The peak incidence of deep vein thrombosis varies among studies, with a range of 4 to 17 days after surgery. We used low-molecular-weight heparin daily for two weeks postoperatively¹⁵⁻¹⁷.

The statistical analyses were performed using IBM SPSS Statistics ver. 19.0 (IBM Co., Armonk, NY, USA).

RESULTS

1. Clinical Outcomes and Demographics

Among the 18 patients included in this study, there was 1 case of osteoarthritis, 8 cases of femur neck fracture, and 9 cases of intertrochanteric fracture. No patients presented with anatomical hip deformity (Table 1).

The modified Koval index scores decreased slightly from average pre-operative 1.38 (range, 1-3) to 2 (range, 1-5) at the final follow-up after surgery. For pre-operative and post-operative modified-Koval score evaluation, Wilcoxon signed rank test was performed. The *P*-value 0.009 (*P*<0.05) on the test showed that the postoperative Koval score was significantly improved. Ambulatory function was unchanged after THA in 10 cases and deteriorated in 8 cases. In case of deterioration, the patients showed a 1- or 2-stage decline. The average mHHS at the final follow-up was 81.0. The mHHS distribution was bimodal and the difference appears to depend on the degree of fracture. In the mHHS, the pre-trauma ROM was not directly measurable, and the scores were measured according to the bus and stair availability. The reason for this was that the flexion in the HHS had the greatest effect on the score. The mHHS above 80 points except a femur neck fracture were intertrochanter fractures of Müller AO Classification 31-A21 (Simple). The mHHS below 80 points were Müller AO Classification 31-A22 or 23 (Comminuted) in the intertrochanter fracture. Three patients complained of persistent hip pain and their femur head size were 46 mm (n=1) and 50 mm (n=2). They did not experience a reduction in pain without treatment; pain

Table 1. Demographic Data

NO	Sex/Age (yr)	Diagnosis	Head size (mm)	BMD	Classification*	mHHS pre-trauma	mHHS final FU
1	F/73	Fx ITC femur Lt	46	-2.6	31-A22	84.5	76
2	F/73	Fx neck femur Rt	44	-2.8	31-B2	90.2	88
3	M/76	Fx ITC femur Rt	50	-3.2	31-A22	84.4	73.8
4	M/75	Fx ITC femur Rt	50	-2.8	31-A22	80	68.8
5	F/73	Fx ITC femur Lt	46	-2.7	31-A22	90	88
6	F/72	Fx ITC femur Lt	46	-2.4	31-A22	76.8	66.8
7	F/76	Fx ITC femur Rt	50	-3.3	31-A22	92	75
8	M/78	Fx neck femur Lt	50	-2.6	31-B2	92	79.9
9	M/71	Fx ITC femur Lt	54	-1.7	31-A21	92	92
10	F/71	Fx ITC femur Rt	46	-2.5	31-A21	92	92
11	M/53	OA hip Lt	54			47.5	92
12	F/70	Fx neck femur Lt	46	-1.4	31-B3	92	92
13	F/72	Fx neck femur Lt	46	-1.7	31-B2	92	54
14	M/72	Fx neck femur Rt	54	-2.4	31-B3	92	92
15	M/72	Fx ITC femur Rt	54	-2.9	31-A22	84.9	74.9
16	M/73	Fx neck femur Lt	50	-3.0	31-B2	92	89
17	F/75	Fx neck femur Rt	46	-2.7	31-B3	92	92
18	F/72	Fx neck femur Lt	46	-3.4	31-B2	89	89

BMD, bone mineral density, mHHS, modified modified Harris Hip Score, FU: follow-up, M: male, F: female, Fx: fracture, ITC: intertrochanter, Lt: left, Rt: right, OA, osteoarthritis.

* Müller AO Classification.

Table 2. Clinical Outcomes and Radiologic Outcomes

Variable	Outcome
mHHS (avg)	80
Modified Koval index score (avg)	
Pre-operative	1.38
Post-operative	2.0
Complication (<fair results)	
Infection	1
Persistant inguinal pain	3
Acetabular loosening	1
LLD (cm)	1 (1.5)
General condition aggravation	1
Spinal stenosis aggravation	1
Acetabular component	
Anteversion (°)	20.1 (11-25)
Inclination (°)	45.8 (38-56)
Femoral component*	
Head size (avg, mm)	47.8 (44-54)

Data are presented as value only or value [range].

mHHS: modified Harris Hip Score, avg: average, LLD: leg length discrepancy.

* Neutral, except one 8° varus.

P=0.009 for pre-operative modified Koval index score.

relievers were used as necessary, along with rest and non-steroidal anti-inflammatory drugs. One patient experienced a soft tissue infection which required subsequent cement

bead and debridement, and was cured within postoperative 2 months (Table 2). In case of osteoarthritis (male, n=56), acetabular-component loosening occurred by un-pressure fitted acetabular cup without screws. As recommended by the ACCIS guide, if subchondral sclerosis due to arthritis occurred, a reamer one size larger than expected acetabular cup size should be used. In this case after revision operation with screw fixation, good results were achieved. Importantly, no dislocations occurred. At the final follow-up, there were no cases of clinical hypersensitivity or allergic reactions.

2. Radiological Findings

Radiography indicated a mean acetabular cup inclination of 45.8° (range, 38-56°) and mean anteversion of 20.1° (range, 11-25°). The average femoral head size was 48.7 mm. All stems were positioned neutrally except 1 (varus). Four cases of progressive acetabular osteoporotic changes throughout the follow-up period occurred; however, these radiographic signs were not associated with patients complaints. The mHHS were an average 85 points (range, 84-95). Limb length discrepancy more than 1.5 cm was observed in one case of intertrochanteric fracture and no dislocations occurred (Table 2).

DISCUSSION

This study helps show that even with ceramic-coated metal-on-metal heads, the results of THA are not always positive, and when choosing between THA or bipolar hemiarthroplasty, the patient's systemic condition, disease characteristic and fracture degree should be carefully considered. Importantly, however, the use of large head femoral components provides a clear advantage of reduced dislocation rate¹⁸⁻²⁰.

Indications for the use of large femoral heads (i.e., larger than 36 mm) are increasing in THA. Importantly, implants with large articulation decrease the risk of dislocation²¹, particularly in elderly patients with weak neuromuscular muscle control, weakness and hip fractures. This decrease in risk of dislocation appears to be the result of the large head size (i.e., large head:neck ratio and increased jump distance of larger articulation leading to an increased range of motion without impingement)²².

Crowninshield et al.²³ demonstrated in 2004 that a larger femoral head size can provide the more hip stability by increasing the prosthetic impingement-free range and the inferior head displacement required for hip dislocation. If femoral head size is increased from 22 mm to 40 mm, the required displacement for dislocation is increased by roughly 5 mm with the acetabular inclination at 45°. But increasing acetabular component abduction above 45° considerably decreases this conferred benefit to hip stability by larger femoral heads. The use of large femoral heads has demonstrated the greatest benefit when applied with appropriate acetabular inclination.

Rodriguez and Rathod²⁴ reported in 2012 that there are advantages of THA with large femoral heads (e.g., hip stability and reduced dislocation rates). However, acetabular component alignment is a critical factor in THA stability. Clinical studies have not demonstrated any benefit of large heads (38 mm or 40 mm) and using a large head in THA is associated with a higher incidence of groin pain. Even in our study, the number of subjects was small, but there were no dislocations with an average head size of 49 mm.

However, there are potential risks associated with the use of large heads. There are concerns related to the release of metal ions due to corrosion of the head-neck junction leading to adverse local tissue reactions²⁵. Dyrkacz et al.²⁶ demonstrated higher corrosion scores in patients with a 36-mm bearing compared with a 28-mm bearing. Elkins et al.²⁰ reported that a femoral head larger than 40 mm provides a minimal benefit for joint safety; however, trunnion corrosion seems to increase significantly. Importantly, corrosion of the head-neck junction

is a multifactorial problem and cannot be explained as the single factor resulting from the use of a larger head²⁶.

Another problem associated with larger diameter femoral heads is the possibility of groin pain, which is considered to be associated with soft-tissue impingement^{27,28}. One recent study demonstrated that larger-diameter heads were associated with a higher rate (18% vs. 7%) of groin pain compared with regular size implants. In the case reports of Browne et al.²⁸, using a larger diameter than the native femoral head was stated to cause anterior iliopsoas and capsular impingement. In this study, 3 patients complained of persistent inguinal pain which was relieved using conservative care.

The advantage of a metal femoral head component minimizes dislocation by using the large head, and since a dislocation can produce fatal results in older age patients with weakness and decreased compliance, reducing dislocation is particularly important.

There is some controversy about the side effects of metal-on-metal, because the potential effects of elevated levels of metal ions are poorly understood. Some authors claim there are concerns (e.g., hypersensitivity, carcinogenicity, and DNA damage) by the use of metal-on-metal articulations^{7,8,29}. But other authors report benefits (e.g., reduced renal insufficiency, malignancy, and even serum metal levels that do not differ from short- and intermediate term follow-up⁴).

Except for metal ion release from trunnion in older THA patients, large metal-on-metal articulation may be a good mechanical benefit and lower volumetric wear⁵.

In this study, there are some limitations. First, this was a retrospective study. Second, this is small size study including several etiologies for THA. It means that there is heterogeneity in terms of patient etiology. Thus, the finding of this study must be accepted and generalizing the results should be minimized without further study relating to etiology. Finally, there was no control group and we did not measured the metal ion concentration but only clinical issues and related factors.

CONCLUSION

Ceramic-coated large metal-on-metal articulations (ACCIS) are associated with a number of complications in elderly patients (e.g., cup loosening, groin pain, and even fatalities). In cases of communicated intertrochanter fracture (AO 31-A22,23) particularly, careful attention should be paid to the surgery approach selected.

CONFLICT OF INTEREST

The authors declare that there is no potential conflict of interest relevant to this article.

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