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## Original Article

# No benefit on functional outcomes and dislocation rates by increasing head size to 36 mm in ceramic-on-ceramic total hip arthroplasty



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## ARTICLE INFO

## Article history:

Received 24 November 2014

Accepted 3 July 2015

Available online 10 March 2016

## Keywords:

Ceramic-on-ceramic bearing

Early complications

Functional outcome

Large-diameter femoral head

Total hip arthroplasty

## ABSTRACT

**Background:** Ceramic-on-ceramic (COC) total hip arthroplasty (THA) has gained popularity since improvements in wear characteristics and longevity. Whether large ceramic femoral heads ( $\geq 36$  mm) have increased postoperative range of motion (ROM) and a lower dislocation rate is not clear. This study aimed to compare functional outcomes and early complications between large-head ( $\geq 36$  mm) and smaller-head ( $\leq 32$  mm) COC prostheses with a minimum follow-up of 12 months.

**Methods:** A total of 95 consecutive uncemented COC THAs were performed in 90 patients between January 2012 and July 2013. Of these, 49 patients (smaller-head group) received third generation and 41 patients (large-head group) received fourth generation COC prostheses. Harris hip score (HHS), Western Ontario and McMaster Universities Arthritis index (WOMAC), and ROM of the hip pre- and post-operatively were compared, as well as the presence of early complications.

**Results:** Postoperative HHSs (88.4 vs. 89.3,  $p = 0.34$ ) and WOMAC scores (12.0 vs. 11.0,  $p = 0.111$ ) were not different between the groups. Postoperative flexion ROM was lower in the smaller-head group ( $98.8^\circ$  vs.  $106.1^\circ$ ,  $p < 0.001$ ), but there were no differences in extension, abduction, adduction, internal rotation, and external rotation. One patient in each group reported a grinding noise. There was one dislocation (1.9%) in the smaller-head group, and none in the large-head group ( $p = 0.371$ ). No infections or loosening of the components occurred.

**Conclusions:** Large-head COC articulation provided better flexion, but functional outcomes and early complications are similar to the smaller-head COC.

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Peer review under responsibility of Chang Gung University.

<http://dx.doi.org/10.1016/j.bj.2016.01.005>

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## At a glance commentary

### Scientific background on the subject

Large femoral head could theoretically be used to improve hip range of motion and reduce the dislocation rate. The study was to compare functional outcomes and early complications between large-head ( $\geq 36$  mm) and smaller-head ( $\leq 32$  mm) ceramic-on-ceramic total hip arthroplasty with a minimum follow-up of 12 months.

### What this study adds to the field

Our study demonstrated that the large-head ( $\geq 36$  mm) could provide better flexion of the hip than the smaller-head ( $< 36$  mm) ceramic-on-ceramic articulation. However, functional outcomes and early complications were similar between the two groups at 1-3 years of follow-up.

Total hip arthroplasty (THA) for end-stage hip arthritis is one of the most successful surgical procedures for pain relief and restoration of mobility. Wear debris-induced osteolysis has been reported to be the most important factors that limits THA longevity [1,2]. To reduce wear debris, ceramic-on-ceramic (COC) bearings were developed as a substitute articulation [3]. In comparison to first and second generation of ceramics, third generation alumina ceramic bearings such as the BioloX Forte (CeramTec AG, Plochingen, Germany) have improved manufacturing technology that has resulted in smaller grain size, greater purity, and higher burst strength which reduce crack propagation and improve wear performance [4–6].

The newest, fourth generation, ceramic bearing design is alumina-matrix-composite, represented by the BioloX Delta (CeramTec AG, Plochingen, Germany), which consists of 81.6% alumina and 17% zirconia and other mixed oxides. The difference between the third and fourth generation COC THA is that zirconia was introduced into the design for reduced the risk of ceramic fractures [7]. It has a much higher capacity than other ceramic materials to resist the onset of cracking and to arrest the propagation of cracks. In addition, it allows for the manufacturing of thinner acetabular liner inserts, which allows the use of 36 mm or greater femoral heads. A large head ( $\geq 36$  mm) may decrease the dislocation rate and improve the hip range of motion (ROM) [8–10]. However, recently Allen et al. [11] showed no improvement of functional outcomes by increasing the size of the femoral head 1-year after THA, though the use of a femoral head  $\geq 36$  mm reduced the dislocation rate. Furthermore, Zijlstra et al. [12] reported no difference of postoperative ROM between large metal-on-metal and 28 mm femoral head prostheses. Our report of third generation COC THAs using 28 mm or 32 mm heads showed good clinical outcomes, that is, 92% of patients had a Harris hip score (HSS)  $\geq 90$  and the mean ROM was  $111.32^\circ$  (range,  $60^\circ$ – $140^\circ$ ) [13].

The aim of this study was to compare functional outcomes including hip ROM and early complications between patients who received THA with large-head ( $\geq 36$  mm) and smaller-head ( $\leq 32$  mm) COC prostheses with a minimum follow-up of 12 months.

## Methods

Between January 2012 and July 2013, a total of 104 consecutive uncemented COC THAs were performed in 99 patients by two senior surgeons (JWW and CJW). The inclusion criteria were patients between 18 and 75 years of age undergoing primary third- (Wright Medical Group, Inc.) or fourth- (Zimmer Biomet Holdings, Inc.) generation COC THA because of end-stage arthrosis of the hip. Because ceramic bearing materials were not covered by our official health care system, the selection of a third- or fourth-generation ceramic prosthesis depended upon the patient's preference, economic situation, or their insurance policies. The exclusion criteria were patients who had received a girdlestone procedure for infected hip, a previous THA, had a stiff hip (such as ankylosing spondylitis), or a body mass index (BMI)  $> 40$  kg/m<sup>2</sup>, in whom, an inferior hip ROM may be expected after THA reported by Murgatroyd et al. [14]. The THAs with 32 mm femoral head in fourth generation COC THA were excluded as well to make distinct head size differences between the two groups. There were three patients with ankylosing spondylitis and six that received a fourth generation 32 mm femoral head there were not considered eligible for the study. The remaining 90 patients (95 hips) had complete data for statistics analysis. Of them, 49 patients (53 hips) received a third generation COC (BioloX-Forte) THA (smaller-head group, head size  $\leq 32$  mm) and 41 (42 hips) received a fourth generation COC THA (BioloX-Delta) (large-head group, head size  $\geq 36$  mm).

All operations were performed via a posterolateral approach with posterior capsulotomy and posterior capsular repair under general anesthesia. This study was approved by our Institutional Review Board (registration number 103-5960B) and regarded as a retrospective review.

All patients had preoperative and postoperative functional evaluations using the Harris hip score (HHS) [15] and Western Ontario and McMaster Universities Arthritis index (WOMAC) [16]. Patients were also evaluated with questionnaires which included the presence of noise in the hip and other complications. Postoperative radiographic examinations including an anteroposterior radiograph of the pelvis and a lateral radiograph of the hip performed at 4 weeks, 3 months, 6 months, and then annually. Acetabular cup inclination angle was determined on the anteroposterior radiograph of the pelvis as an angle in degrees, between a line drawn along the angle from the rim of the cup and the transischial line [Fig. 1]. Each individual arc of motion was also measured preoperatively and at the latest follow-up. Radiolucencies were recorded in the zones described by DeLee and Charnley [17] around the acetabular component and around the femoral component as described by Sarmiento and Gruen [18]. The stability of the femoral component was assessed using the method described by Engh et al. [19].

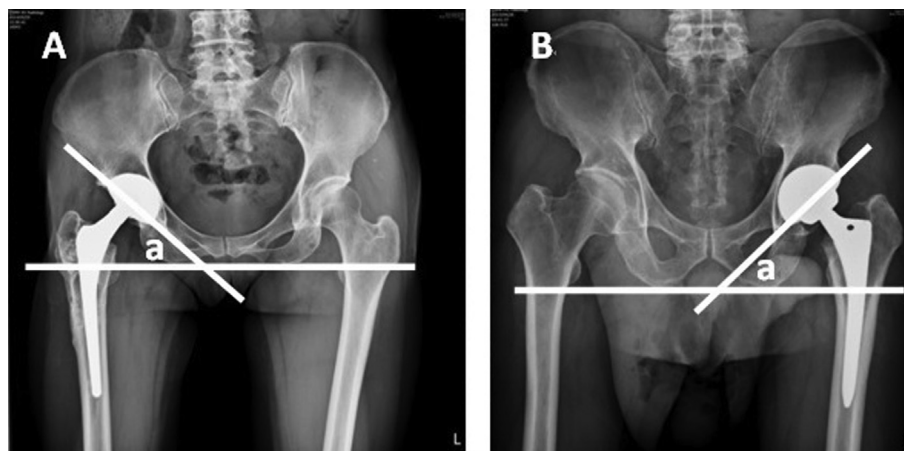


Fig. 1 – Illustration of cup inclination angle (a). (A) Postoperative anteroposterior view of the pelvis of a 65-year-old female who received a right ceramic-on-ceramic (Bilox Forte) total hip arthroplasty using a 28 mm head.  $a = 40.9^\circ$ . (B) Postoperative anteroposterior view of the pelvis of a 66-year-old male who received a left ceramic-on-ceramic (Bilox Delta) total hip arthroplasty using a 36 mm head.  $a = 40.3^\circ$ .

### Statistical analysis

Differences in age, BMI, diagnosis, cup inclination angle, mean ROM, HHS, and WOMAC, and complications were compared using the Mann–Whitney test. Differences in gender were examined using the Chi-square test. Differences in preoperative and postoperative ROM, HHS, and WOMAC were compared using the Wilcoxon Signed Ranks test. All the statistical analyses were performed with Statistical Package for Social Science (SPSS) version 16 software (SPSS Inc., Chicago, IL, USA).

### Results

The mean follow-up period of all patients was 20.3 months (range, 12–34 months). Patients in the smaller-head group had a mean age of 59 years (range, 18–74). Patients of the large-head group had a mean age of 50 years (range, 23–69). The preoperative diagnoses included primary osteoarthritis, avascular necrosis of the femoral head, developmental dysplasia, posttraumatic arthropathy, and rheumatoid arthritis [Table 1]. In the smaller-head COC group, nine patients received a 28 mm femoral head and 44 a 32 mm femoral head. In the large-head COC group, 30 patients received a 36 mm head and 12 a 40 mm femoral head [Table 1]. There was no difference between the two groups in the degree of cup inclination ( $40.1^\circ$  s.  $41.6^\circ$ ,  $p = 0.163$ ). The HSS improved to 88.4 at the latest follow-up from a preoperative value of 41.0 in the smaller-head group and from preoperative value of 42.0–89.3 at the latest follow-up in the large-head group (both,  $p < 0.001$ ). WOMAC improved from a preoperative value of 82.8 to 12.0 at the latest follow-up in the smaller-head group and from 80.4 to 11.0 in the large-head group (both,  $p < 0.001$ ). There were no statistical differences of the postoperative HHS ( $88.4$  vs.  $89.3$ ,  $p = 0.34$ ) and WOMAC ( $12.0$  vs.  $11.0$ ,  $p = 0.111$ ) between the smaller-and large-head group [Table 2].

Postoperative flexion ROM was lower in the smaller-head than the large-head group ( $98.8^\circ$  vs.  $106.1^\circ$ ,  $p < 0.001$ ), but no differences in extension ( $13.9^\circ$  vs.  $14.8^\circ$ ,  $p = 0.054$ ), abduction ( $38.3^\circ$  vs.  $39.6^\circ$ ,  $p = 0.062$ ), adduction ( $21.0^\circ$  vs.  $21.2^\circ$ ,  $p = 0.776$ ), internal rotation ( $30.8^\circ$  vs.  $30.4^\circ$ ,  $p = 0.661$ ), and external rotation ( $38.5^\circ$  vs.  $38.8^\circ$ ,  $p = 0.34$ ) were noted [Table 2].

No patients had squeaking of the hip, but one patient in each group reported a grinding noise [Table 3]. Further questioning revealed that the noise only occurred intermittently at

Table 1 – Preoperative patient data.

Variable	Smaller-head group (n = 53)	Large-head group (n = 42)	p
Male/female	24/25	21/20	0.486
Mean age, years (range)	59 (18–74)	50 (23–69)	<0.001
Mean BMI, kg/m <sup>2</sup> (range)	25.2 (17.4–33)	25.0 (17–34.6)	0.476
<b>Diagnosis</b>			
Osteoarthritis	16	11	0.548
Osteonecrosis	16	21	0.075
Posttraumatic arthritis	8	5	0.579
Rheumatoid arthritis	1	1	0.898
Developmental dysplasia	12	4	0.069
<b>Ceramic femoral head size</b>			
28 mm	9		
32 mm	44		
36 mm		30	
40 mm		12	
<b>Mean ROM, degrees (SD, range)</b>			
Flexion	48.6 (3, 43–57)	48.9 (5, 40–58)	0.608
Extension	9.1 (2, 5–14)	10.0 (2, 6–15)	0.059
Abduction	27.5 (4, 16–35)	28.8 (4, 22–36)	0.323
Adduction	13.6 (3, 8–22)	13.8 (3, 10–22)	0.945
Internal rotation	20.7 (4, 14–28)	20.6 (4, 14–30)	0.748
External rotation	27.3 (5, 15–36)	28.8 (3, 22–34)	0.126
Mean HHS (SD, range)	41.0 (6, 32–52)	42.0 (9, 22–58)	0.237
Mean WOMAC (SD, range)	82.8 (4, 72–91)	80.4 (6, 71–90)	0.059

Abbreviations: BMI: Body mass index; ROM: Range of motion; HHS: Harris hip score; WOMAC: Western Ontario and McMaster Universities Arthritis Index; SD: Standard deviation.

**Table 2 – Postoperative patient data.**

Variable	Smaller-head group (n = 53)	Large-head group (n = 42)	p
Mean cup inclination angle, degrees (SD, range)	40.1 (3, 29.6–51.5)	41.6 (5, 31.5–54.7)	0.163
<b>Mean ROM, degrees (SD, range)</b>			
Flexion	98.8 (6, 85–110)	106.1 (10, 90–120)	<0.001
Extension	13.9 (2, 10–20)	14.8 (2, 10–20)	0.054
Abduction	38.3 (3, 32–45)	39.6 (3, 34–45)	0.062
Adduction	21.0 (3, 14–28)	21.2 (4, 14–28)	0.776
Internal rotation	30.8 (3, 24–38)	30.4 (5, 22–39)	0.661
External rotation	38.5 (3, 30–43)	38.8 (4, 32–45)	0.568
Mean HHS (SD, range)	88.4 (6, 63–98)	89.3 (7, 65–98)	0.340
Mean WOMAC (SD, range)	12.0 (4, 4–21)	11.0 (5, 6–28)	0.111
Abbreviations: ROM: Range of motion; HHS: Harris hip score; WOMAC: Western Ontario and McMaster Universities Arthritis Index; SD: Standard deviation.			

maximum flexion, and was not associated with pain or functional disability. A 69-year-old male in the smaller-head group using 32 mm head experienced twice dislocation postoperatively. There was no mal-position of the acetabular component (45° inclination, 25° anteversion). The dislocation was treated by open reduction and iliotibial band tension release to maintain soft tissue balance. The patient experienced no recurrent dislocation at 2 years follow-up. There were three intraoperative periprosthetic calcar fractures in the large-head group and one periprosthetic greater trochanteric fracture in the smaller-head group. All were fixed by cerclage wiring techniques, and good bony union was noted during follow-up. No cases of ceramic material fracture, postoperative periprosthetic fractures, nerve damage, deep vein thrombosis, pulmonary embolism, or deep infection were observed in either group. Postoperative radiographs showed no radiolucencies or osteolysis adjacent to the acetabular or the femoral components or loosening of the components. No patients in either group required a revision surgery because of component failure [Table 3].

**Table 3 – Complications.**

	Smaller-head group (n = 53) (%)	Large-head group (n = 42) (%)	p
Noise (grinding)	1 (1.9)	1 (2.4)	0.868
Squeaking	0	0	
Dislocation	1 (1.9)	0	0.371
<b>Periprosthetic fracture</b>			
Intraoperative	1 (1.9)	3 (7.1)	0.318
Postoperative	0	0	
Ceramic material fracture	0	0	
Nerve damage	0	0	
Aseptic loosening of the components	0	0	
Deep vein thrombosis	0	0	
Deep infection	0	0	
Revision surgery	0	0	

## Discussion

Instability remains the most common early complications after THA, and the reported incidence of dislocation ranges from 0.4% to 5.8% [20]. Some dislocations (30%–65%) after THA become recurrent [21–24]. The causes of early dislocations include patient, surgical technique, and implant design factors. A posterior surgical approach is associated with a high dislocation rate [25,26]. Our traditional surgical approach for THA, hoping to reduce postoperative dislocations, is a posterolateral approach with posterior capsular repair and reinforcement. However, there was a substantial rate of early dislocation (3.6%, 4/111) in our previous report of 111 THAs using third-generation COC prostheses with femoral-head sizes of 28 mm and 32 mm [13]. The dislocation rate in the 28 mm head group was 6.3% (3/48) and 1.6% (1/63) in the 32 mm head group. However, there was no difference in dislocation rate between the two groups ( $p = 0.314$ ). The current study compared the early dislocation rate of a large-diameter femoral head ( $\geq 36$  mm) COC with that of a smaller head ( $\leq 32$  mm) COC operated on during the same period. The results showed only one dislocation (1.9%) in the smaller-head group and no dislocations in the large-head group ( $p = 0.371$ ), though the number of patients was small.

Unlike ROM after total knee arthroplasty [27–29], hip ROM after THA has not been extensively studied [30,31]. Scoring systems of hip function have only a small contribution of hip motion as compared to measures of functional activity and pain [15,16]. Davis et al. [32] analyzed postoperative hip ROM and HHS after primary THA and concluded that hip motion was correlated with postoperative hip function. Lavigne et al. [33] reported that a large diameter THA group had significantly greater hip ROM compared with a group that received a 28 mm prosthesis, and hip ROM showed a significant correlation with the WOMAC index, especially with respect to the flexion arc. However, Zijlstra et al. [12] reported no difference of postoperative ROM between a large diameter THA group and a 28 mm THA group in a randomized clinical trial. After the introduction of a large diameter ceramic femoral head, Cai et al. [34] reported that a large-diameter Delta COC articulation group had a greater ROM improvement (6.1° more) than that of a common-sized ceramic-on-polyethylene articulation group. However, HHS and early complication rates were similar between the two groups. In the current study, the large-head ( $\geq 36$  mm) articulation group had a higher postoperative ROM, mainly in flexion as compared to the smaller-head COC ( $\leq 32$  mm) articulation group ( $106.1^\circ \pm 10^\circ$  vs.  $98.8^\circ \pm 6^\circ$ ,  $p < 0.001$ ). There were no significant difference in HHS and WOMAC index between the two groups, similar to the report by Cai et al. [34], indicating that the improvement of hip ROM does not truly reflect functional improvement of daily activities.

The importance of ROM after THA has been stressed by Davis et al. [32] who considered that ROM is more useful in evaluating postoperative hip function than the current hip rating system, including HHS. The HHS only assigns 5% of the overall score to hip motion [15]. In another study investigating the correlation of measured ROM after THA and responses to a questionnaire, there were no significant correlations of

WOMAC pain, stiffness, and physical function scores to ROM after THA [35]. Similar results have been reported by Allen et al. [11] who found that a large femoral head ( $\geq 36$  mm) failed to improve functional outcomes at 1-year after THA. Taken together, these data suggest that hip ROM improvement may be more important than previous thought in evaluating outcomes after THA.

Audible noise is another complication that can occur after COC THA. Our previous review of 99 patients who received a third generation COC bearing surface (BioloX, Forte) showed that noise was present in 7% of hips, and included a click in three, grind in two, and a snap in two [13]. No patients had squeaking of the hip. In the current study, one hip in each group had a grinding noise, but no squeaking was observed in either group. The grinding noise did not affect the outcome, and no revision surgery was required. A squeaking noise is more problematic after COC THA, and an incidence of 2.4% was reported in a recent meta-analysis of 6137 alumina-on-alumina THA [36]. The etiology of squeaking is multifactorial, and believed related to patient age, size, implant position, edge loading, postoperative ROM, and implant design [37–40]. A longer clinical follow-up and a larger cohort of patients may be necessary to delineate a difference in the incidence of audible noise between the two groups of patients.

We acknowledge several limitations of this study. First, the patient cohort was small and the follow-up period was short. However, there has been only 3 years since the introduction of the fourth-generation of COC at our institution. Based on a prior study of functional outcomes and hip motion improvement at 1-year after THA [11], a follow-up period >1-year may be adequate. Second, the study was a retrospective review, not a prospective randomized trial. Because ceramic materials in THA surgery are not covered by our government health care system and are most costly than other devices, a clinical trial of different sized ceramic heads is difficult. However, the study periods of two groups of patients were the same, and all the operations were performed by the two senior surgeons with the same modern technique.

## Conclusion

A large-head ( $\geq 36$  mm) COC articulation provides better flexion of the hip than a smaller-head (<36 mm) COC articulation, but functional outcomes and early complications are similar at 1–3 years of follow-up. Longer-term follow-up is necessary to determine differences in clinical outcomes and late complications between large and smaller-head ceramic bearing surfaces when used for THA.

## Source of support

Nil.

## Conflict of interest

None declared.

## Acknowledgment

We thank MS Ya Ju Yang for assistance with the statistical design and analysis.

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