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# Good clinical outcomes following total hip arthroplasty using large-diameter ceramic-on-ceramic bearings

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**Large-diameter heads (LDHs) in total hip arthroplasty (THA) enhance range of motion but require thinner liners. Monoblock acetabular components with ceramic liners could reduce liner fracture risks during modular acetabular component assembly. This study aims to confirm the safety and clinical performance of the monoblock Maxera Cup in THA.**

**The study included 198 consecutive patients who received 214 primary monoblock acetabular components with an LDH ceramic-on-ceramic (CoC) bearing between March 2012 and December 2013. We collected Harris hip scores (HHS), Oxford hip scores (OHS), EuroQoL-5D scores (EQ-5D), and conducted radiographic evaluations.**

**Seven patients (3.5%) died for reasons unrelated to the intervention. A single patient (0.3%) underwent cup revision due to recurrent dislocation from trauma. Another patient needed cup revision six years post-surgery due to squeaking. Mean follow-up time was 36.2 ± 27.9 months. Kaplan-Meier survivorship rate at 96 months for any component loosening was 100%, and the cup revision survivorship rate for any reason was 96.8% (95% CI, 87.8-99.5%). At final follow-up, mean HHS was 93.6 ± 9.9, OHS was 16.2 ± 5.9, and EQ-5D was 0.94 ± 0.09.**

**LDH CoC THA using a monoblock cup yielded excellent medium-term functional outcomes. This approach eliminates liner fracture risk during insertion and reduces implant impingement risk.**

**Keywords:** Total hip arthroplasty, tribology, osteoarthritis, hip, ceramic-on-ceramic, observational study.

## INTRODUCTION

Total hip arthroplasty (THA) is one of the most successful orthopaedic interventions[14]. However, although an increasing number of operations are performed successfully, the risks associated with THA remain. Metal-on-polyethylene (MoP) components have been reported to produce debris linked with osteolysis, a serious complication that can lead to pain, periprosthetic fracture, and prosthesis loosening[2]. Furthermore, metal-on-metal (MoM) bearings release corrosion debris associated with adverse local tissue responses[18]. There is also increasing concern regarding metal particles generated from the taper junction in MoP bearings[7]. To address these issues, ceramic-on-ceramic (CoC) bearings have been developed for THA due to their superior tribological properties, such as high hardness, low surface roughness, high wettability, and scratch resistance. Although ceramic bearings still produce debris, the resulting corrosion is of a lesser magnitude than that of other bearing combinations[15]. Research on CoC bearings has shown excellent results, with ample evidence that they display a low rate of wear, which is particularly beneficial for younger patients. However, there is still a paucity of mid- and long-term data.

Large-diameter head (LDH) CoC bearings have recently been introduced to improve range of motion (ROM) and stability, as well as to avoid problems associated with MoM bearings. CoC bearings provide the following benefits: immediate convalescence after THA without restricting ROM, facilitation of bilateral THA, early return to work or leisure activities, and prevention of stem-to-liner impingement. Notably, thin ceramic liners are required for these LDH-CoC THAs. Therefore, to reduce the risk of liner fracture resulting from incorrect assembly of the modular acetabular component[16], the CoC LDH can be preassembled at the manufacturing stage and then implanted as a monoblock component.

Ceramic bearing technology has evolved greatly due to improvements in ceramic materials. The most recent

advance in alumina ceramic technology is represented by BIOLOX® delta. It contains zirconium oxide, which offers basic hardness and wear resistance, as well as strontium oxide and chromium oxide, which offer superior mechanical properties. Therefore, ceramic BIOLOX delta has better mechanical properties, including fracture toughness, than those of pure aluminium oxide[10].

The Maxera™ Cup is sold with both BIOLOX delta and BIOLOX delta Option LDHs. The BIOLOX delta Option LDHs refer to a type of ceramic hip joint component with a detachable sleeve, which provides surgeons with the flexibility to choose between different head sizes without changing the entire implant. LDHs provide superior stability due to their increased displacement distance. Furthermore, they allow a greater technical ROM than conventional small-diameter (28 mm) articulations. Effectively, these characteristics enable improved functionality and stability, while reducing the risk of dislocation[1,13,17]. For example, a recent clinical study revealed that 36 mm CoC coupling provided significantly lower impingement, subluxation, and dislocation (0.9%) than 28 mm femoral heads (4.6%) in total hip replacements[19].

This study aimed to collect medium-term data confirming the safety and clinical performance of the Maxera Cup.

Assessing the safety of the cup was the primary objective of the study. This was achieved by recording and analysing the incidence and frequency of complications, revisions, and adverse events. The secondary objective was to assess the Maxera Cup's clinical performance, as demonstrated by patient-reported outcome measures and radiographic outcomes.

## MATERIAL AND METHODS

The Zimmer® Maxera Cup (Fig. 1) is a monoblock acetabular component that consists of a preassembled shell and liner. The ceramic liner articulates with a ceramic femoral head for CoC LDH articulation.

The exterior geometry of the Maxera Cup is hemispherical, slightly flattened (by 0.9 mm) at the pole. Primary fixation is achieved by under-reaming the acetabulum to attain a press fit. The external surface of the cup includes three pairs of periphery fins placed 120° apart (Fig. 1) that provide supplemental rotational stability and fixation as well as a titanium vacuum plasma spray coating (Ti-VPS) to create a scratch fit. The shell's substrate is manufactured of Tivanium® Ti-6Al-4V alloy and coated with a porous titanium plasma spray. In addition, the Maxera Cup has a BIOLOX delta ceramic liner that is preassembled to lock into the tapered shell's cavity. This liner articulates with standard BIOLOX delta ceramic femoral heads, sized 32, 36, and 40 mm, and with BIOLOX delta Option ceramic femoral heads, sized 32, 36, 40, 44, and 48 mm.

*Figure 1. — The Maxera Cup.*

This was a retrospective study with prospective documentation of the study data and patients included consecutively. We obtained ethics committee approval and written informed consent from all patients prior to commencing the study. Patients requiring primary THA for non-inflammatory degenerative joint disease due to osteoarthritis, avascular necrosis, post-traumatic arthritis, congenital hip dysplasia, or inflammatory joint disease were considered eligible for the study. Exclusion criteria included poor bone quality and active, old, or remote hip infection.

A total of 613 THAs in 572 patients were carried out in the first author's clinics between March 2012 and December 2013. The study device was used in 222 patients (239 hips). Of those, 198 patients (214 hips) were operated for non-inflammatory degenerative joint disease; these patients constituted the population of the current study.

Bilateral THA was performed in a two-stage procedure in 16 (8.1%) patients. The study population's average age was 62.4 years, with a standard deviation (SD) of 8.0 years (range: 33-85). Eighty-eight of the patients (44.4%) were male. The indications for THA were primary osteoarthritis in 207 (96.7%) hips, avascular osteonecrosis in 6 hips (2.8%), and secondary osteoarthritis in 1 hip (0.5%).

We used all the cups in combination with cementless Avenir stem (Zimmer Biomet) and a BIOLOX delta Option CoC bearing (Ceramtec GmbH, Plochingen, Germany). The head sizes used on the patients were 36 mm in 13 hips (6.1%), 40 mm in 66 hips (31.0%), 44 mm in 77 hips (36.20%), and 48 mm in 57 hips (26.8%). The same surgeon performed all implantations using a muscle-sparing posterolateral approach in all cases.

Postoperative rehabilitation consisted of immediate weight bearing on postoperative day 1 and physiotherapy on day 1, with exercises to restore ROM and functional mobility, aiming to establish lower extremity muscle activation and muscle strengthening, as well as proprioceptive training and gait exercises.

In addition to demographic data, intraoperative and postoperative complications were recorded. Kaplan-Meier analysis was conducted for survival analysis, with cup loosening for aseptic or any other reason considered the endpoint of interest. The following clinical data were evaluated both preoperatively and during the follow-up evaluation: the Harris hip score (HHS)[11], the Oxford hip score (OHS)[21], and the five-level EuroQol 5 Dimension (EQ-5D-5L)[12]. Lateral and anterior–posterior (a.p.) radiographs of the proximal femur and an a.p. radiograph of the pelvis were performed preoperatively, immediately after the operation, and during follow-up evaluation. All radiographs were analysed for the presence of radiolucent lines (RLLs), osteolysis, and bone resorption using DeLee classification for the cup[8]. Additionally, Gruen classification was used to analyse the stem[9]. RLLs were defined as zones of regular shape between the implant and the periprosthetic bone, commonly parallel to the implant surface[22]. Osteolytic lesions were defined as radiolucent zones of irregular shape along the interface of the implant and the periprosthetic bone, demarcated irregularly from the surrounding bone, and sometimes showing breaks or signs of resorption[22]. Bone resorption was defined as bone that appears thinner, darker, or more osteopenic on follow-up radiographs than on the immediate postoperative ones[5]. We used Brooker classification to assess periarticular ossification[4]. Leg length discrepancy was measured clinically during follow-up assessment and radiographically using an anteroposterior view of the pelvis in a standing position. Continuous data are presented as mean ± SD, while categorical variables are indicated as frequencies and percentages. A univariate analysis of variance (ANOVA) was employed to assess variations in clinical outcomes based on distinct head diameters. Kaplan-Meier analysis was used to determine implant survival.

## RESULTS

The study population had a mean follow-up time of 36.3 ± 27.9 months (range: 1-103 months). Seven patients (3.5%) (7 hips, 3.3%) died during the postoperative course of the study for reasons unrelated to the study procedure. One patient experienced a bilateral dislocation following a fall, which required a reduction under narcosis, 2 years postoperatively, and subsequently a recurrent unilateral dislocation after 4 and 5 years postoperatively, which required cup revision 6.5 years after the index surgery. There were two cases (0.9%) with postoperative squeaking. Of these, one involved a 48 mm head, necessitating cup revision 6 years after the initial operation. The second case, with a 36 mm head, did not require revision. One additional patient was revised for infection following a chronic decubitus wound. During this revision, the femoral head was exchanged. Following the revision, the patient sustained a periprosthetic fracture. No cup loosenings were observed.

No other major complications occurred. At final follow-up, the study population at risk at comprised 189 patients (205 hips). Kaplan-Meier survivorship with revision of any component for loosening was 100% at 96 months. Kaplan-Meier survivorship with revision of the cup for any reason was 96.8% (95% confidence interval, 87.8-99.5%) at 96 months.

The mean HHS was 93.6 ± 9.9 (range: 46-100), and OHS was 16.2 ± 5.9 (range: 12-42) during the final follow-up. The mean EQ-5D at final follow-up was 0.94 ± 0.09 (range: 0.66-1). No statistically significant differences were discerned among distinct head diameters for HHS ($p = 0.897$), OHS ($p = 0.740$), and EQ-5D ($p = 0.711$).

No cases of osteolysis or RLLs around the cup or stem were identified. No patients with periarticular ossification or periprosthetic bone resorption were observed.

## DISCUSSION

The Maxera monoblock ceramic acetabular component with a large-diameter ceramic femoral head exhibited favourable outcomes. The results indicate that the bearing performs well at a mean of 36 months, with two cup revisions due to recurrent unilateral dislocation and squeaking, respectively, but no cup loosening or component fracture. We also noted outstanding functional outcomes, with no statistically significant differences observed among varying head diameters.

In contrast, traditional CoC bearings suffer from multiple disadvantages – risk of fracture, femoral neck – ceramic liner impingement, chipping on insertion, and squeaking[3,6]. However, the diameter of the femoral head may be constrained by the liner thickness required for a modular acetabular component[3]. A thinner ceramic liner and metallic shell combination increases the bearing diameter ratio. To this end, preassembled monoblock acetabular components result in a larger head diameter and a smaller acetabular component. CoC LDH acetabular systems are designed to mitigate the risk of liner fracture occurring due to incorrect surgical assembly and to optimize the taper connection in the titanium shell[3]. Notably, no implant fractures occurred in the current study. However, the study did not have sufficient statistical power for definitive conclusions on this issue. Adequate primary pressure fixation is critically important for this implant design, as it prevents supplemental screw fixation. Notably, there was no acetabular loosening in this series.

Our study results align with a recent Australian registry study that found the monoblock ceramic cup to display remarkable durability compared to other commonly used bearing options[20]. The revision rate for the monoblock cup was significantly lower. Notably, the study revealed that large-diameter femoral heads contributed to a reduction in dislocation rates and improved range of movement. Specifically, patients with a smaller head size (predominantly 36 mm in diameter) exhibited a significantly lower revision rate for dislocation. This is noteworthy, as smaller head sizes are inherently at risk. Additionally, the study showed that larger ceramic head sizes demonstrated a lower risk of ceramic breakage, a concern predominantly observed in patients with a modular CoC acetabular component[20].

Our findings are also consistent with the results of Blakeney et al., who assessed 264 patients using a Maxera Cup through a minimally invasive posterior approach, with a mean follow-up time of 67 months[3]. They reported a lower revision rate (1%) compared to our study, with 0.4% of the cups being revised for early loosening and no reported hip dislocation. However, they did find a substantial proportion of patients (23%) who reported squeaking, which was observed in only 0.9% of the operated hips in our study.

This study has certain limitations. All uncontrolled studies carry a risk of selection bias and confounding; thus, causal inferences from this study should be made with caution. We mitigated the disadvantages of an uncontrolled study through the consecutive enrolment of patients, alongside the prospective documentation of study data. Other limitations of this study were the relatively short follow-up period and the small sample size, which rendered it insufficient statistical power to reach definitive conclusions on rare events, such as dislocation and implant fracture.

## CONCLUSION

The functional outcomes of LDH CoC THAs at medium-term follow-up were excellent, with no cases of loosening. This suggests that LDH CoC with a monoblock acetabular component can provide long-term implant survivorship, while also offering the advantages of eliminating the risk of liner fracture during insertion and implant impingement. Further research is encouraged to confirm the findings of this study.

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