

# Could larger diameter of 4th generation ceramic bearing increase the rate of squeaking after THA?

## A retrospective study

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### Abstract

The present study aimed to evaluate the clinical outcomes and bearing-specific complications in a single center of 135 delta ceramic-on-ceramic (COC) total hip arthroplasties (THAs) and explore the occurrence rate of squeaking in 4th generation COC THAs and collate the risk factors for squeaking.

We retrospectively analyzed consecutive cohorts of 127 patients (135 hips) who had primary THA with delta COC bearings in our hospital between April 2010 and April 2012. Preoperative Harris hip score (HHS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score, and University of California Los Angeles (UCLA) activity score were evaluated preoperatively and postoperatively. We also evaluated ceramic fracture, squeak, mid-term results, and survival.

In our study, the final patient final follow-up date was July 31, 2016. The mean preoperative HHS improved from 39.5 to 93.1 points. Mean preoperative UCLA score was 3.2 points, improving to 8.2 points. The mean preoperative total WOMAC score was 55.5 points and the mean total WOMAC score was 13.3 points at the final follow-up. The Kaplan–Meier survival plot of revision for any reason as the end point was 98.5% and survival with ceramic fracture as the end point was 99.2% at a mean of 70 months' follow-up. One post-operative ceramic liner rim fracture occurred at 50 months after surgery. Thirteen of the 135 hips produced a squeaking sound. There were no significant differences in gender ( $P = .56$ ), age ( $P = .20$ ), body mass index (BMI) ( $P = .11$ ), diagnosis ( $P = .46$ ), cup inclination ( $P = .36$ ), or cup anteversion ( $P = 1.0$ ) between the squeaking and non-squeaking groups. However, the incidence of squeaking in the 36mm COC femoral head bearings was higher than in the 28mm size (13.6% vs 2.1%,  $P = .033$ ).

The 4th generation COC bearing performed well and provides an encouraging rate of survival with no osteolysis or loosening. However, we found that a squeaking sound associated with use of the delta ceramic occurred at a rate of 9.6%, with the larger-diameter heads having significantly higher incidence.

**Abbreviations:** BMI = body mass index, COC = ceramic-on-ceramic, HHS = Harris hip score, THA = total hip arthroplasty, UCLA = University of California Los Angeles, WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

**Keywords:** BIOLOX delta, ceramic fracture, ceramic-on-ceramic, squeaking

## 1. Introduction

Debris-induced osteolysis and aseptic loosening remain major factors that shorten the longevity of hip implants, especially in

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younger and more active patients.<sup>[1]</sup> Ceramic-on-ceramic (COC) bearing surfaces were introduced in an effort to reduce wear and osteolysis. Several studies demonstrated excellent clinical and radiographic results with minimal wear and reduced osteolysis as a result of the ceramic bearing surfaces.<sup>[2–4]</sup> However, concerns persist about adverse events, such as ceramic fracture and squeaking.<sup>[5,6]</sup>

A new BIOLOX delta ceramic (CeramTec AG, Plochingen, Germany), described as a 4th generation ceramics material whose development aimed to improve wear while reducing the risk of bearing fracture with alumina-on-alumina bearings. As observed with zirconia and strontium crystals, this new ceramic material can potentially resist crack propagation, which should reduce the risk of fracture of the ceramic. According to the manufacturer, ceramic fractures rate observed in BIOLOX delta ceramic have been reduced by approximately 10 fold compared to BIOLOX forte ceramic. However, squeaking sounds from ceramic bearings have attracted widespread attention in recent years. Although numerous theories have been posited regarding the cause, the mechanisms or factors responsible for noise generation in COC bearing total hip arthroplasty (THA) bearings have not been identified.

Therefore, the aims of this retrospective study were to

- (1) evaluate the clinical outcomes and bearing-specific complications in a single center of 135 delta COC THAs;
- (2) explore the occurrence rate of squeaking in 4th generation COC THAs and collate the risk factors for squeaking.

## 2. Patients and methods

### 2.1. Study design and patients

The department database was retrospectively reviewed to identify patients who had received a primary THA between April 2010 and April 2012 using a delta COC bearing, for inclusion in a retrospective study. Patients and investigators were unblinded because of the nature of the study design. For inclusion in the study, all patients who had received THAs were eligible. Exclusion criteria were incomplete radiographic or clinical data with a follow-up period of <48 months. The final patient final follow-up date was July 31, 2016. During this period, ten patients (11 hips) were lost to follow-up because of a change in their address or contact details. Finally, 127 patients with 135 hips were available for complete analysis in this study, which was approved by the Ethics Committee of the Affiliated Hospital of Jiangnan University (JU20161205, April 12, 2016).

### 2.2. Surgical techniques

All patients received a 4th generation COC bearing (BIOLOX delta, Ceramtec AG) using a modified Hardinge approach. The components used were Pinnacle/S-Rom/Tri-lock PBS (Depuy, Warsaw, IN) and BetaCup/Rubber/LCU (Link, Germany). A 36-mm diameter BIOLOX delta ceramic head was used for cup sizes larger than 50 mm and a 28 mm diameter BIOLOX delta ceramic head (Ceramtec AG) for cup sizes smaller than 50 mm. Details are provided in Table 1.

### 2.3. Postoperative management

Antibiotic prophylaxis using a first-generation cephalosporin was administered 30 to 60 minutes before incision and within the first 24 hours postoperatively. Low-molecular-weight heparin was routinely used for thromboembolic prophylaxis. Patients were mobilized on the second postoperative day and progressed to full-weight bearing with a walking frame or crutches as comfort permitted. They were advised to use a walking aid for 6 weeks.

**Table 1**  
Demographic patient data and preoperative diagnosis for this study.

NO. of patients (hips)	127 (135)
Gender (male/female)	68/59
Age ( $\bar{x} \pm s$ , years)	52.1 $\pm$ 13.7 (22~76)
Weight ( $\bar{x} \pm s$ , kg)	63.8 $\pm$ 10.0 (40~92)
BMI ( $\bar{x} \pm s$ , kg/m <sup>2</sup> )	24.5 $\pm$ 2.7 (17.0~32.9)
Preoperative diagnosis (NO. of patients /hips)	
Avascular necrosis of femoral head	48/53
Primary degenerative arthritis	28
DDH	22
Posttraumatic arthritis	12
Ankylosing Spondylitis	9/11
Femoral neck fracture	14
Rheumatoid arthritis	6
Size of femoral head (hips)	
28 mm	50
36 mm	85

BMI = body mass index, DDH = developmental dysplasia of the hip.

### 2.4. Data collection

The collected data incorporated population characteristics and clinical and radiological evaluations. The patients were requested to present for review at 6 weeks, 3, 6, and 12 months and 1 to 2 years thereafter. Each patient was clinically evaluated on the basis of the Harris hip score (HHS),<sup>[7]</sup> Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score<sup>[8]</sup> and University of California Los Angeles (UCLA) activity score.<sup>[9]</sup> All clicks or squeaks caused by the COC bearing were recorded from testimony of the patient. Abduction and anteversion of the acetabular component were measured on 6-week radiographs, in accordance with Murray<sup>[10]</sup> and Widmer.<sup>[11]</sup> A zone of osteolysis was recorded at the acetabulum in accordance with that described by DeLee and Charnley<sup>[12]</sup> and at the femoral component as described by Gruen et al.<sup>[13]</sup> Definite loosening of the acetabular component was diagnosed when a continuous radiolucent line >2 mm could be observed, a change in angle of at least 4° or >3 mm of migration.<sup>[14]</sup> The femoral stems were classified as bone ingrowth, fibrous stable, or unstable according to the system of Engh et al.<sup>[15]</sup>

### 2.5. Statistical analysis

Statistical analysis was performed using SPSS version 22.0 statistical software (IBM, Chicago). For continuous variables, comparison between 2 groups was conducted using an independent *t* test or 1-way analysis of variance. For categorical variables, a chi-square test (or Fisher exact test for small samples) was used. Survival analysis was performed using the Kaplan–Meier technique with revision for any reason as 1 end point and revision due to ceramic fracture at a follow-up point as the other. The level of significance was set at *P* < .05.

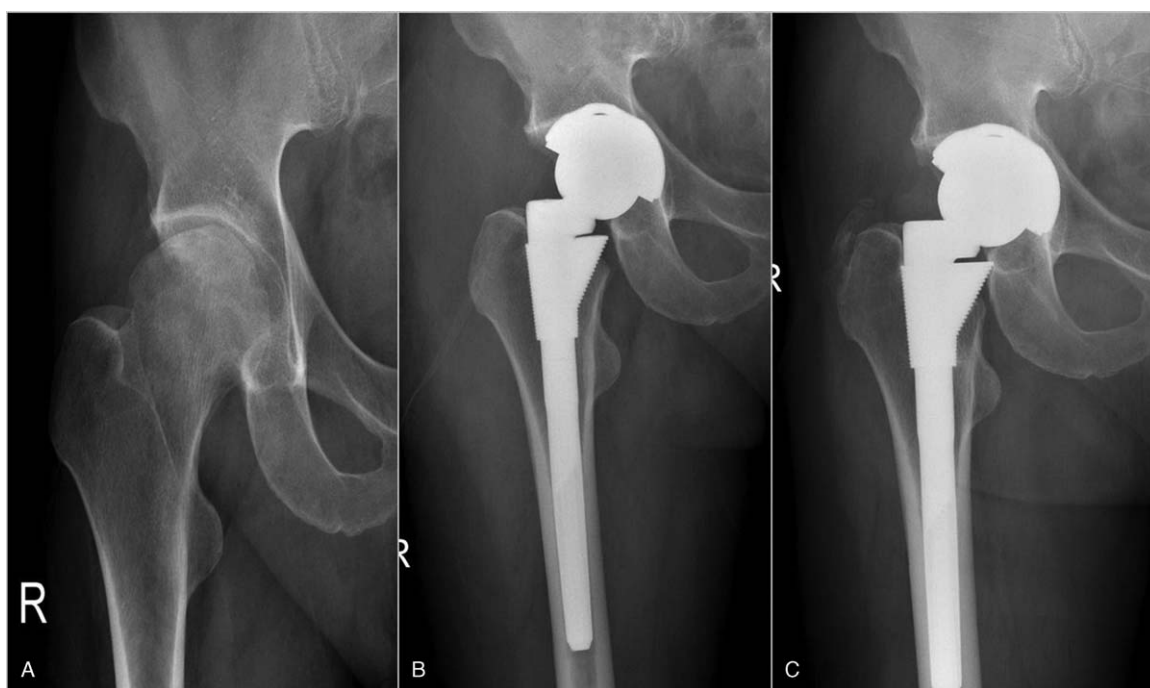
## 3. Results

### 3.1. Demographics

One hundred twenty-seven patients had adequate follow-up data in this study. Sixty-eight (53.5%) patients were male and 59 (46.5%) were female with a mean age of 52.1 years (range: 22–76 years) and a mean follow-up period of 70.1 months (range: 50–86 months). The mean body weight was 63.8  $\pm$  10.0 kg (range: 40–92 kg), with a mean body mass index (BMI) was 24.5  $\pm$  2.7 kg/m<sup>2</sup> (range: 17.0–32.9 kg/m<sup>2</sup>). Pre-operative diagnostic reasons are listed in Table 1.

### 3.2. Clinical outcomes

The clinical outcomes were reflected by the HHS, WOMAC score, and UCLA activity score. All scores were significantly improved at the final follow-up. The mean preoperative HHS was 39.5  $\pm$  5.7 points (range: 28–56 points) and improved to 93.1  $\pm$  5.5 points (range: 75–100 points) at the final follow-up. The mean preoperative total WOMAC score was 55.5  $\pm$  12.0 points (range: 34–84 points), increasing to 13.3  $\pm$  5.8 points (range: 5–26 points) at the final follow-up. Mean preoperative UCLA score was 3.2  $\pm$  1.1 points (range: 2–4 points), improving to 8.2  $\pm$  1.3 points (range: 6–10 points) at the final follow-up. Sixteen of the 127 patients (12.5%) changed their work duties from heavy labor prior to surgery to light manual work thereafter. Ten patients (7.8%) were unemployed following surgery. The remaining 101 patients (79.7%) remained in their previous occupation, mostly engaged in sedentary work, such as office or manual work.



**Figure 1.** The Delta ceramic-on-ceramic bearing THA in a 61-year-old man with osteonecrosis of the right femoral head. (A) Preoperative view; (B) Right AP roentgenograms of the seventh operation day. (C) A 86 months' follow-up right hip radiograph demonstrated implants stable fixation and no evidence of osteolysis or loosening around them. THA=total hip arthroplasty.

### 3.3. Radiological outcomes

Mean abduction angle and anteversion of the acetabular component were  $40.2^\circ$  (range:  $26^\circ\sim 56^\circ$ ) and  $15.4^\circ$  (range:  $8^\circ\sim 26^\circ$ ), respectively. All acetabular and femoral components showed radiographic evidence of osseointegration at the last follow-up (Fig. 1). No periprosthetic osteolysis was observed around any acetabular or femoral component.

### 3.4. Adverse events

**3.4.1. Squeaking.** Thirteen (9.6%) of the 135 hips produced a squeaking sound. There were no significant differences in gender ( $P=.56$ ), age ( $P=.20$ ), BMI ( $P=.11$ ), diagnosis ( $P=.46$ ), cup inclination ( $P=.36$ ), or cup anteversion ( $P=1.0$ ) between the squeaking and non-squeaking groups. However, the incidence of squeaking was higher in the large-diameter heads (36 mm) ( $P=.033$ ) (Table 2). Among them, ten patients reported that they heard squeaking when the hip was placed under a heavy load or when they performed a sudden squat (flexion  $>90^\circ$ ). However, no patients required revision due to the annoyance of squeaking.

**3.4.2. Ceramic fracture.** One post-operative ceramic liner rim fracture occurred at 50 months after surgery (Fig. 2). However, the patient was asymptomatic and refused revision. This patient experienced squeaking when he squatted suddenly.

**3.4.3. Others complications.** Three of the 135 hips dislocated postoperatively. Two were treated by closed reduction, with no further dislocation being reported. One of 3 hips suffered recurrent dislocation and in this case the cup was revised.

### 3.5. Survival

Two of the 135 hips were revised, and thus the revision rate for whatever reason was 1.48% (2/135 hips). One hip was revised

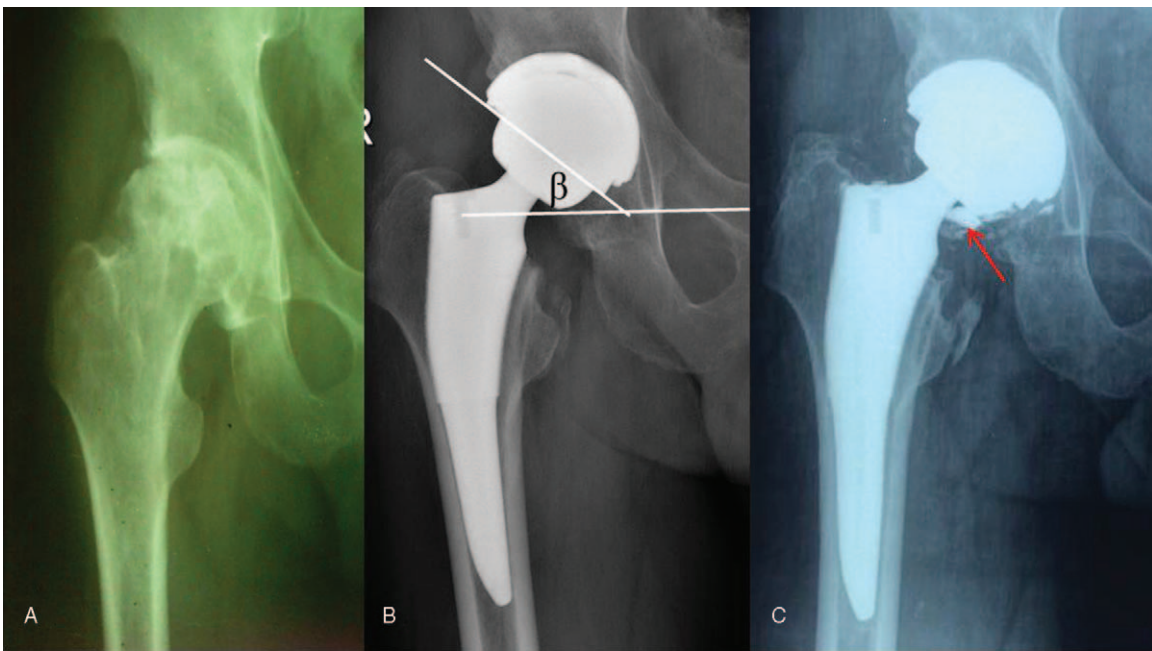
due to postoperative infection, and another hip due to recurrent dislocation, as detailed above. There were no cases of revision due to aseptic loosening or osteolysis. The Kaplan–Meier survival plot of revision for any reason as the end point was 98.5% (95% CI: 96.5%~100%) (Fig. 3) and survival with ceramic fracture as the end point was 99.2% (92.5%~100%) (Fig. 4) at a mean of 70 months' follow-up.

**Table 2**

**Comparison between squeaking group and non-squeaking group.**

Factors	Squeaking (13 hips)	Non-squeaking (122 hips)	P value
Male: female	9:4	69:53	.56
Age (Mean $\pm$ SD)	47.7 $\pm$ 6.2	52.8 $\pm$ 13.8	.20
BMI (Mean $\pm$ SD)	26.4 $\pm$ 4.2	23.8 $\pm$ 2.8	.11
Diagnosis			.46
Avascular necrosis of femoral head	4	46	
Primary degenerative arthritis	3	24	
DDH	3	17	
Femoral neck fracture	2	11	
Rheumatoid arthritis	1	5	
Ankylosing Spondylitis	0	7	
Posttraumatic arthritis	0	12	
Inclination			.36
Normal range	13	107	
Outlier	0	15	
Anteversion			1.00
Normal range	13	127	
outlier	0	0	
Size of femoral head			.033
28 mm	1	46	
36 mm	12	76	

BMI=body mass index, DDH=developmental dysplasia of the hip.

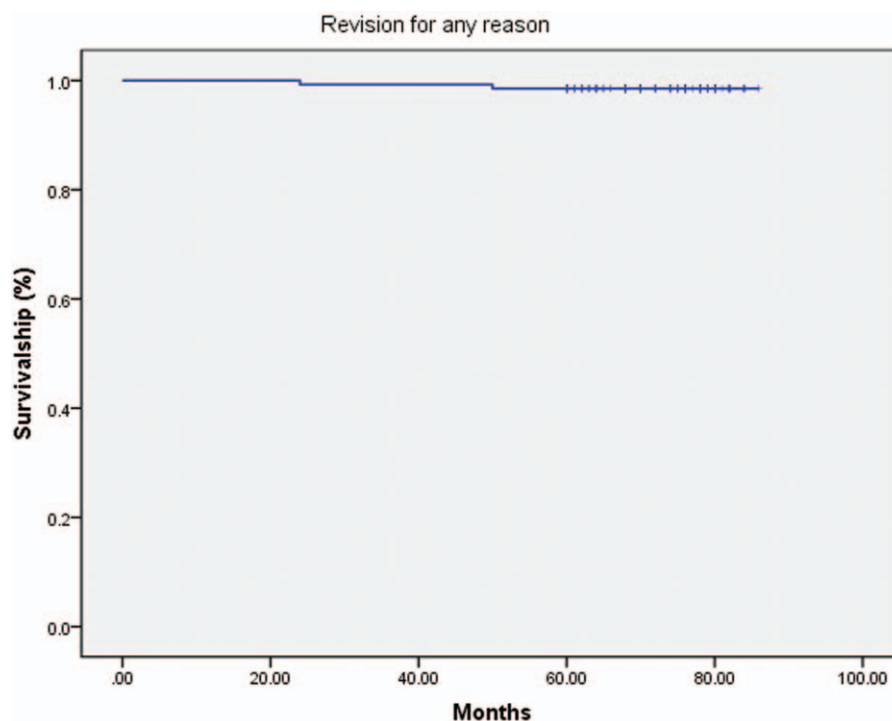


**Figure 2.** A 46-year-old male patient with the right femoral head osteonecrosis. (A) Preoperative radiograph (B) Immediate postoperative radiograph and acetabular component inclination ( $\beta$ ) of  $39^\circ$  (C) After 50 months of follow-up, ceramic liner fracture occurred (red arrow).

#### 4. Discussion

Patients in this study had good clinical, radiographic and wear results at the final follow-up. Mean HHS improved from 39.5 to 93.1 points, with no cases of osteolysis. Furthermore, cementless THAs using 4th generation alumina COC bearings (BIOLOX delta) demonstrated a high survival rate of 98.5% at a mean 70

months' follow-up. Previous studies demonstrated similar results. Lim et al<sup>[16]</sup> reported that delta COC THAs had a survival rate of 98.6% with no radiographic evidence of osteolysis at a 6.5-year follow-up. In the present study, however, we found 9.6% of cases produced a squeaking sound and 0.76% suffered a ceramic line fracture associated with the use of delta ceramic. The incidence of



**Figure 3.** Kaplan-Meier survivorship curves with the end point of revision for any reason at 70-month follow-up.



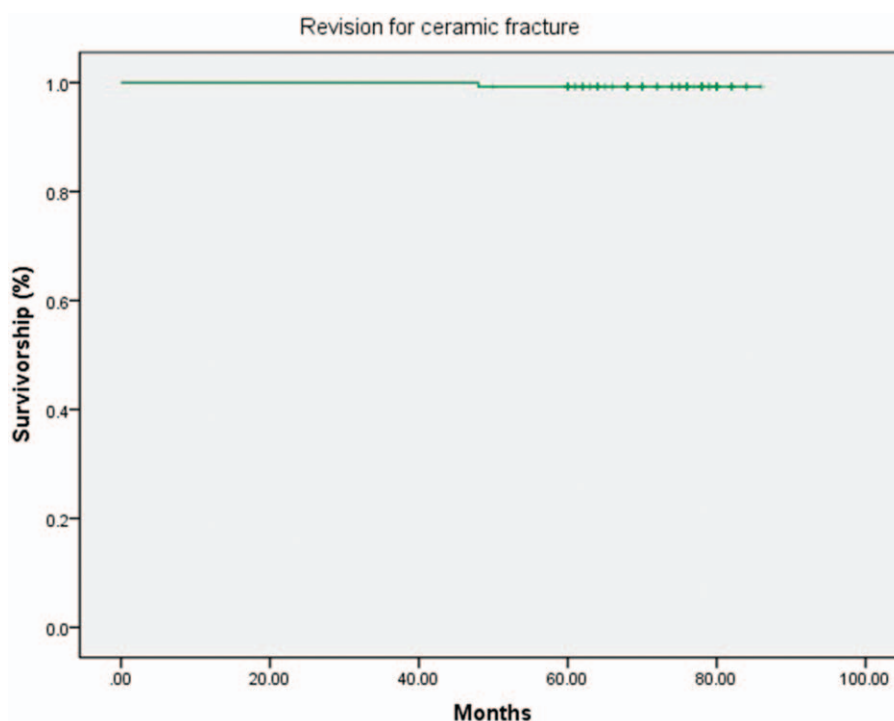


Figure 4. Kaplan–Meier survivorship curves with the end point of revision for ceramic fracture at 70-month follow-up.

squeaking was experienced in larger-diameter heads at a significantly greater rate than the small heads.

Squeaking arising from a COC THA was first reported by Charnley in 1979 and has been reported sporadically to be associated with bearing failure. In recent years, hip squeaking associated with COC THA has surfaced as a common concern among surgeons and patients. Overall, the reported prevalence of squeaking has been reported to range from 2% to 21%.<sup>[17,18]</sup> In our study, we found the incidence rate of squeaking to be 9.6% as reported by patients. Several factors, including age, gender, clinical diagnosis, and cup orientation have been known to influence the incidence of squeaking. Moreover, a number of studies have considered acetabular orientation an important cause of the origin of the squeaking. In our study, however, the prevalence of the squeaking sound was not significantly associated with inclination ( $P=.36$ ) or anteversion ( $P=1.0$ ). Ten patients who suffered squeaking reported that they heard the noise when placed under a heavy load or performed a sudden squats (flexion  $>90^\circ$ ). Those specific movements might lead to increased edge loading, which was deemed responsible for the squeaking heads with previous COC bearing.<sup>[19–21]</sup> Interestingly, our results indicated that the incidence of squeaking in the 36 mm COC femoral head bearings was higher than in the 28 mm size (13.6% vs 2.1%,  $P=.033$ ). Hamilton et al<sup>[22]</sup> reported on a series of delta ceramic THAs, finding that patients fitted with a 36 mm head size experienced the highest incidence of squeaking (11.3%) compared to a head size of 28 mm (4.0%). Tai and their coauthors<sup>[20]</sup> also found the similar results. One possible explanation is that a larger head might reduce the frequency of the resonating waves to the audible range for humans.<sup>[20]</sup> Goldhofer et al<sup>[23]</sup> also observed in a cohort of 206 COC hip patients that the rate of squeaking rose from 7.3% at a 2-year follow-up to 17.4% at a 5-year follow-up. They speculated that

the etiology of squeaking was most likely multifactorial, including edge loading, greater pelvic anterior tilt with bending and improvements in hip ROMs.<sup>[23]</sup> In a number of recent reports, the authors have suggested that the squeaking may be an early sign of ceramic fracture.<sup>[24]</sup> In our cohort, the patient who suffered a ceramic liner fracture experienced squeaking, however, such fractures were not detected in other squeaking hips, although this may change in long-term follow-up.

Although third-generation COC bearing THAs have been demonstrated to be superior to those of previous generations in terms of material properties and reduced risk of component fracture, failure of ceramic remains a serious issue, with an incidence in the range 0% to 5.7%.<sup>[5,6]</sup> The 4th generation ceramic was introduced to reduce the risk of bearing fracture using alumina-on-alumina. However, sporadic reports of the failure of delta COC bearings have emerged. Cai reported a rate of fracture in delta ceramic THAs of 1 in 51 (1.9%) at a mean of 3.3 years' follow-up.<sup>[25]</sup> McCourt has subsequently reported 5 cases of early delta ceramic liner fracture in UK between 2011 and 2012.<sup>[26]</sup> In our current cohort of 135 hips, we did observe 1 ceramic liner rim that was damaged, which occurred when the patient suddenly squatted. We speculate that squatting led to repetitive impingement between the rim of the ceramic liner and the stem adjacent to the femoral neck, which might be an important factor in the fracture of the ceramic liner. To decrease the chances of failure, designs with an extended titanium rim on the acetabular component have been constructed as an attempt to prevent metal-on-ceramic contact.<sup>[27]</sup> However, in a recent report, Chotai observed that the elevation created by the metal rim decreased the available range of motion and created neck-socket rim impingement, resulting in ceramic liner fracture.<sup>[28]</sup> In our experience, contact between the ceramic liner rim and the metal neck of the femoral stem at the extremes of motion can be

avoided if sequential acetabular reaming is performed to an additional depth of 1~2 mm to elevate the rim of the acetabulum that might impinge against the femoral component. In addition, this procedure can ensure symmetrical seating of the liner in the cup. As a result, we are able to report a 99.2% survival rate without further ceramic fractures. A number of other researches also believe that ceramic fracture can be attributed to insertion error of the component within the cup, rather than as a result of the mechanical properties of the delta ceramics per se. Thus, as surgery with this newest ceramic develops, our belief is that the incidence of the ceramic component fracture will be decline.

The present study has several shortcomings that should be recognized. First, it was a retrospective study of a small cohort with a short follow-up of an average of 70 months. Second, it included a relatively small number of patients, which makes the statistical power of the study relatively weak. Third, multiple implants were included in the study (different stems and acetabular cups) and this may influence the outcome independently of the bearing surface used.

## 5. Conclusions

Our mid-term data indicate that the 4th generation COC bearing performed well and provides an encouraging rate of survival with no osteolysis or loosening. However, we found that a squeaking sound associated with use of the delta ceramic occurred at a rate of 9.6%, with the larger-diameter heads having significantly higher incidence.

## Author contributions

**Conceptualization:** Yuan Luo, Tao Wang.

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**Supervision:** Jin Chen.

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**Writing – original draft:** Yuan Luo.

**Writing – review & editing:** Tao Wang.

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