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Long-Term Results of Delta Ceramic-on-Ceramic Total Hip Arthroplasty

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ABSTRACT

Background: Ceramic-on-ceramic (COC) bearings in total hip arthroplasty (THA) have long been considered the coupling with the lowest overall wear. However, concerns about complications such as ceramic breakage and noise, combined with the improved performance of polyethylene, have limited its use in the United States. This postapproval follow-up reports long-term (10 years) results of Delta COC in THA patients primarily enrolled in an Investigational Device Exemption study.

Methods: Patients received Delta COC THA in a prospective multicenter study with either 28-mm (N = 105 hips in 104 patients) or 36-mm (N = 81) articulations. Annual clinical and radiographic evaluations were performed for years 5 to 10, and study patients were asked about hip noises and reproducibility.

Results: There have been 4 additional reports of noise in 4 patients (COC 28, n = 3; COC 36, n = 1). The cumulative incidence rate for squeaking or noise at 10 years is 5.9% for COC 28 and 13.5% for COC 36. There have been 2 additional reports of dislocation in 2 patients (COC 28, n = 1; COC 36, n = 1). The cumulative incidence rate for dislocation at 10 years is 3.7% for COC 28 and 3.5% for COC 36. At 10 years, there were greater than 40 hips available for follow-up. At mean 10-year follow-up, there were a total of 3 ceramic liner fractures, but none since the previous report. There were no revisions in the 28-mm cohort, and 2 revisions in the 36-mm cohort (1 for recurrent dislocation and 1 for pain and noise). Overall Kaplan-Meier survivorship was 95.96% at 10.5 years (28 mm: 97.68% at 10.2 years; 36 mm: 94.11% at 10.4 years.)

Conclusions: At 10-year follow-up, we report excellent results in regard to survivorship, with one patient revised for pain with associated squeaking.

Introduction

The safe introduction of new technology in total hip arthroplasty (THA) may represent a patient care advancement if the technology is proven to be efficacious. The long-term survivorship of THA has been affected by bearing wear and adverse reactions to particulate debris [1,2]. To date, metal-on-highly-crosslinked-polyethylene and ceramic-on-highly-crosslinked-polyethylene have shown excellent results regarding wear reduction [3-5].

Ceramic-on-ceramic (COC) bearing couples have historically shown low wear rates and clinical success [6-8]. Current concerns regarding the use of the bearing material include fracture of either the ceramic head or liner [9-18] and reports of squeaking [19-24]. To address the issues of material fracture, an alumina matrix composite (AMC) ceramic (BIOLOX Delta; CeramTec AG, Plochingen, Germany) was developed. This fourth-generation material is comprised of 82% alumina and 17% zirconia and has a grain size of <0.8 μm. This modification to prior alumina ceramic formulations results in a material with improved toughness and wear characteristics. In a meta-analysis of available literature on COC bearing complications, the authors showed that the Delta material, as compared with the third-generation Forte (BIOLOX Forte; CeramTec AG, Plochingen, Germany) material, reduced the femoral head fracture rate by half [25]. Liner fracture rates were equal with either material.

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In the United States, 2 Investigational Device Exemption (IDE) trials of COC BIOLOX Forte bearings have reported good results at midterm follow-up. In an IDE study, Murphy et al. reported a survivorship of 96% at 9 years (mean 4.3 years, range 2-9), with one mal-seated liner and one liner fracture (Wright Medical, Memphis, TN) [26]. In a study of the Trident (Stryker Orthopedics, Mahwah NJ) system using a ceramic liner encased in a titanium sleeve, the authors reported an overall survivorship of 97% with one revision at 7 years after the surgery for a liner fracture [27].

The IDE trial was initiated in 2003 with 8 sites enrolling patients for the 28-mm COC AMC device. In 2006, an IDE study with 5 sites enrolling patients with the 36-mm COC bearing was begun. The initial early results of the 28-mm IDE were reported in 2010 [16]. Subsequently, we reported the midterm results of the 28-mm and 36-mm IDE studies [28]. In the midterm study, we showed an overall survivorship at a mean 6-year follow-up of 96.9%. In the combined data representing 345 patients, there were 3 postoperative liner fractures (0.9%), and 26 (7.5%) patients reported squeaking. No patient had been revised for squeaking.

Two postapproval studies (PAS) were initiated by the study sponsor, the 28-mm PAS in 2012 and the 36-mm PAS in 2014, to continue to evaluate the AMC material and examine longer term results using this material. The goal of the 2 PAS was to report the minimum 10-year follow-up of both the 28-mm and 36-mm articulations concentrating on survivorship and bearing complications including fracture and squeaking.

Material and methods

The study designer (DePuy Synthes, a Johnson and Johnson Co., Warsaw, IN) initiated voluntary enrollment for further follow-up in the 28-mm PAS, which involved 5 of the original 8 IDE sites, and in the 36-mm PAS, the same 5 IDE sites were used. Of the 345 enrolled patients, 232 had more than 5 years of follow-up in the IDE study, and 186 patients enrolled in the PAS (COC 28, N = 105 hips in 104 patients; COC 36, N = 81). Of this group, 175 patients (COC 28, N = 104; COC 36, N = 71) represent the cohort studied. Demographics, preoperative diagnosis, preoperative Harris Hip Score (HHS), and length of follow-up and the latest postoperative HHS (ie, minimum of 24 months) for the PAS patients are shown in Table 1. Institutional review board approval was obtained for all sites in the IDE and PAS studies. Both PAS were registered on www.clinicaltrials.gov, a registry and results database of publicly and privately supported clinical studies of human participants conducted around the word (COC 28 PAS: NCT01657435, CCO 36 PAS: NCT02096198).

Table 1
Postapproval study (PAS) demographics, n (%) or mean (SD).

Data	COC 28 (N = 104)	COC 36 (N = 81)
Gender		
Men	57 (54.8%)	40 (49.4%)
Women	47 (45.2%)	41 (50.6%)
Age (y)	56.9 (8.99)	59.5 (9.35)
BMI	30.7 (6.57)	29.1 (5.90)
Primary diagnosis		
Osteoarthritis	94 (90.4%)	76 (93.8%)
Avascular necrosis	2 (1.9%)	1 (1.2%)
Posttraumatic arthritis	4 (3.8%)	1 (1.2%)
Missing diagnosis	4 (3.8%)	3 (3.7%)
Preoperative Harris Hip Score[a,b]	50.7 (9.90)	54.2 (10.19)
Years follow-up[a,c]	9.8 (1.29)	10.4 (0.71)
Most recent Harris Hip Score[a,c]	94.5 (9.38)	94.5 (9.80)

[a] Years of follow-up, preoperative and postoperative HHS are based on total hips (COC 28 = 105 and COC 36 = 81).
[b] Three COC 28 Subjects had an incomplete preoperative Harris Hip evaluation.
[c] Follow-up and latest Harris Hip Score were calculated for subjects with Harris Hip Score in the 2-year protocol-defined window or later (N = 167 COC 28, N = 161 COC 36).

Inclusion criteria for rollover into either of the PAS were participation in the previous IDE and consent for continued follow-up through 10 years. Inclusion criteria, at the time of enrollment in the IDE, were patients aged 20 to 75 years undergoing primary THA for noninflammatory degenerative joint disease. The HHS rating was ≤70, with at least a moderate pain rating. Exclusion criteria included inflammatory arthritis, bilateral hip disease requiring staged or simultaneous bilateral THA, an existing THA in the contralateral hip with an HHS pain rating of mild or worse, and patients who had undergone contralateral primary THA within the last 12 months.

All patients received a cementless porous coated acetabular component (PINNACLE; DePuy Synthes, a Johnson and Johnson Co., Warsaw, IN) and 1 of 5 cementless stems based on surgeon preference (AML, PRODIGY, SUMMIT, POROCOAT or DUOFIX, SROM, or CORAIL) from the same manufacturer. The COC 28 group received a ceramic bearing insert (CERAMAX; DePuy Synthes, a Johnson and Johnson Co., Warsaw, IN) with a 28-mm inner bearing. The COC 36 group received a ceramic bearing insert (CERAMAX; DePuy Synthes, a Johnson and Johnson Co., Warsaw, IN) with a 36-mm inner bearing. All ceramic bearings and matching diameter femoral heads were BIOLOX Delta AMC (CeramTec AG, Plochingen, Germany).

In the PAS, all enrolled 28-mm-group patients were seen at clinic visits at their rollover interval at a minimum of 5 years and then annually until 10 years postoperatively. The 36-mm-group patinets were seen at clinic visits at their rollover interval at a minimum of 5 to 7 years and then at a minimum of 8 and 10 years. The two COC PAS groups had different follow-up intervals, and not all visits were required to be in clinic: The 28-mm group allowed for postal follow-up for years 6-10, and the 36-mm group allowed for telephone interviews for years 8 and 10. If in-clinic visits occurred, the HHS were obtained. Any reoperation that resulted in removal of any index total hip component, for any reason, was considered a revision. Patients were asked about noise or squeaking, and this was recorded as an adverse event. If a patient reported noise, the patient was asked to describe the quality, frequency, and factors that caused the noise. The patients were asked to try to reproduce the noise in the clinic.

For all in-clinic visits, radiographs included supine anteroposterior (AP) pelvis and AP and lateral views of the proximal femur. At the initial in-clinic rollover visit in the COC 36 group, a cross-table lateral view was also collected to assess acetabular cup inclination. All radiographs (IDE and PAS) were evaluated by an independent radiographic review vendor (MMI, Inc., Houston, TX). Radiographs were examined for radiolucencies, interface gaps, acetabular migration, or inclination change and osteolysis. Radiolucencies were defined as gaps between the surface of the prosthesis and the surrounding bone [29]. If present, the maximum width and location of any radiolucencies were noted. Osteolysis was defined as an area of localized loss of trabecular bone or cortical erosion and classified as linear or expansile [30]. Linear osteolytic lesions were measured in millimeters, and the regions where they appeared were noted. Linear osteolytic lesion measuring 2 millimeters or less was considered insignificant. Expansile lesions with a ballooning appearance were noted in the pelvis and femur. If present, expansile pelvic osteolysis was recorded as extending into the ilium, ischium, or pubis. Cup abduction angle was measured on an AP pelvis radiograph as the angle between a line tangent to the inferior edges of both teardrops and another line tangent to the long axis of the ellipse projected by the rim of the acetabular shell [31]. The following were deemed to be clinically meaningful radiographic findings: radiolucencies >2 mm, acetabular cup migration >4 m, change in cup inclination >4 degrees, and any osteolysis around the stem or cup.

Descriptive statistics include mean values ± standard deviations. The HHS aggregate score was examined at the latest follow-up. Given the limited rollover enrollment, the PAS had the potential for longer follow-up than patients originally in the IDE. Thus, a direct comparison of proportions would be biased. To overcome this bias, the cumulative incidence rates (CIRs) were compared postoperatively using Kaplan-Meier (KM) time-to-event methodology. The time variable was time to first observation of the event (ie, squeaking/noise or dislocation) or last clinical follow-up or death if there was no event. CIR was defined as 100% minus KM (absence of the event) estimate. KM CIR was estimated for 10 years, which had at least 40 or more patients with follow-up available. Squeaking was evaluated using a post-hoc univariate Cox proportional hazards model for both the COC 28 and COC 36 groups to evaluate the following factors for possible association with squeaking: age, gender, BMI, acetabular inclination angle, cup size, cup diameter, and HHS at the latest follow-up. A *P* value of .05 was defined as the threshold for statistical significance. A KM survivorship analysis using revision of any component for any reason as an endpoint was performed.

Results

From the initial enrollment of 186 hips (COC 28, N = 105 hips in 104 patients; COC 36, N = 81) at more than 10 years of follow-up, 175 patients (COC 28, N = 104; COC 36, N = 71) were examined. There was one death in the COC 28 group and no revisions, and none were lost to follow-up. In the COC 36 group, there was 1 death and 2 revisions, 6 patients were lost to follow-up, and 1 patient withdrew consent (Fig. 1).

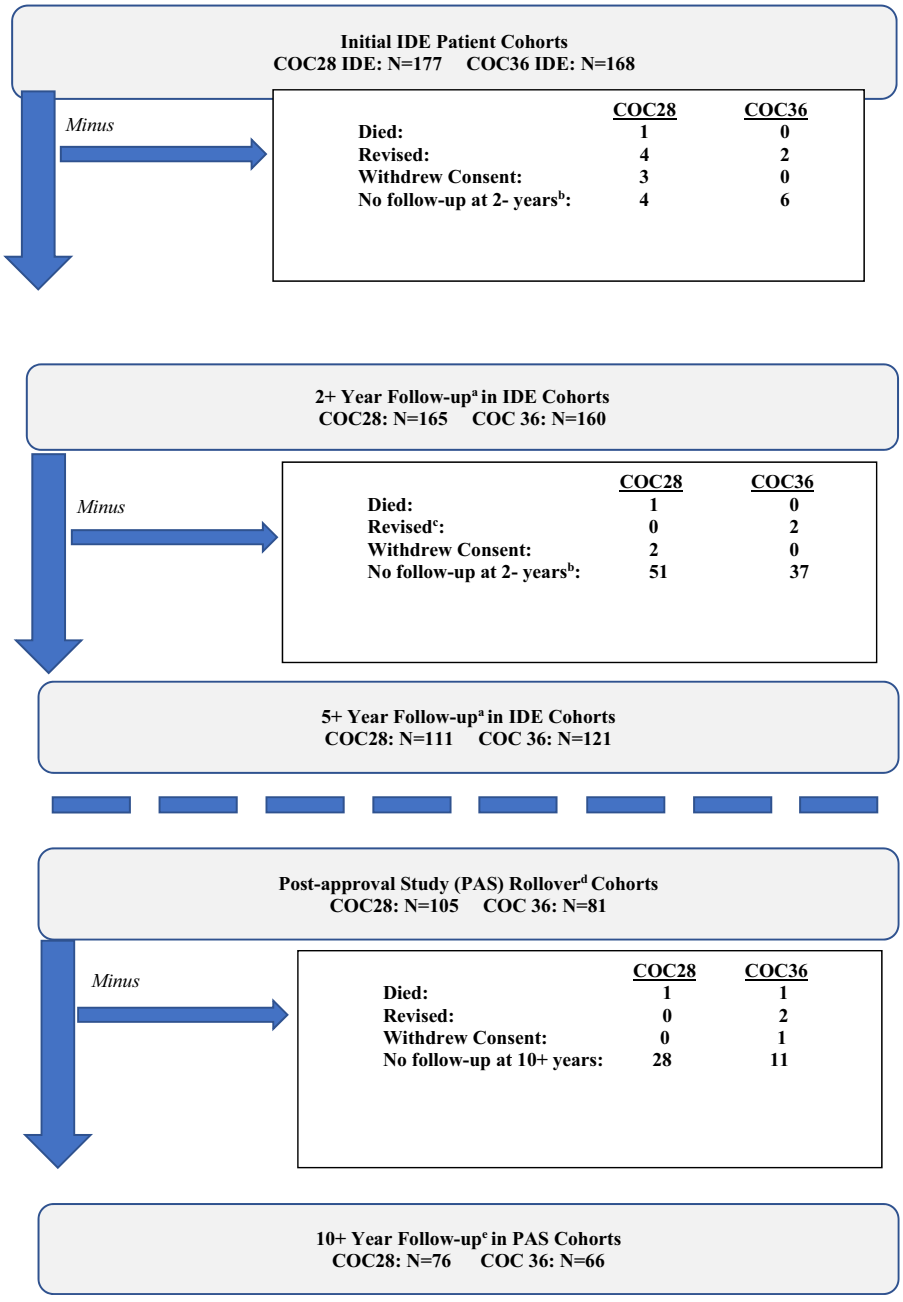

Figure 1. Flow diagram of IDE and PAS study enrollment over time.

Comparing the COC 28 and COC 36 groups at mean 10.5-year follow-up, the latest recorded HHS were similar (COC 28, 94.5 ± 9.83; COC 36, 93.9 ± 9.82, $P = .5757$). The KM survivorship overall at 10.5 years was 96.0% (95% CI: 92.7, 97.8). Survivorship in the COC 28 group was 97.7% at 10.2 years (95% CI: 93.9, 99.1), and in the COC 36 group, 94.1% at 10.4 years (95% CI: 87.7, 97.2).

Nine revisions were previously reported [28]. In the COC 28 cohort, there have been no revisions. In the COC 36 group, there were 2 revisions, one performed for dislocation at 8.5 years after the index THA and one revision for pain and squeaking at 9.0 years after the index THA. There have been 4 additional reports of noise in 4 patients (COC 28, n = 3; COC 36, n = 1). The CIR for squeaking or noise at 10 years is 5.9% for COC 28 and 13.5% for COC 36. There have been 2 additional reports of dislocation in 2 patients (COC 28, n = 1; COC 36, n = 1). The CIR for dislocation at 10 years is 3.7% for COC 28 and 3.5% for COC 36. At 10 years, there were more than 40 hips available for follow-up.

We previously reported the 5-year radiographic review [28]. At that time, no acetabular component or femoral component was loose. There were 2 patients (n = 1 COC 28, n = 1 COC 36) with femoral stem radiolucencies.

For the 28-mm group, the PAS did not require radiographs for the 6- to 10-year intervals as the protocol allowed for postal follow-up. However, if radiographs were submitted for years 6-10, including unscheduled visits, they were reviewed by the independent radiographic review. For this group, there were no interval changes in the radiographic findings.

For the 36-mm group, the PAS required radiographic evaluations at the 5- to 7-year interval, but at the 8- and 10-year intervals, they were required only if the visits are conducted in the clinic. Acetabular findings during the PAS include 1 report of osteolysis at 8 years and 1 report at 10 years. Femoral findings include 1 report of radiolucency at 8 years, 1 report of "tilt" at 8 years, and 2 reports of sclerotic lines at 10 years.

In our prior report, there were 3 postoperative ceramic liner fractures, 2 in the COC 28 group, and 1 in the COC36 group. There were no femoral head fractures at that time. There are no ceramic fractures in the PAS groups.

There have been 4 additional reports of noise in 4 patients (COC 28, n = 3; COC 36, n = 1). The CIR for squeaking or noise at 10 years is 5.9% for COC 28 and 13.5% for COC 36. For the COC 28 group, one patient reported a "clicking" sound at 10-year follow-up, one patient reported "popping" when walking at the 10-year follow-up, and one patient reported a squeaking sound that was possibly related to the ceramic articulation but was not reproducible in clinic. No patients have undergone revision surgery, and all events were deemed mild in severity. In the COC 36 group, one patient reported occasional "squeaking" related to sitting and stair-climbing at 8-year follow-up. This patient had an HHS of 100 at 8-year follow-up and was not revised; the adverse event was mild. No association was found between the complaints of noise and age, BMI, acetabular inclination angle, acetabular component size, and latest HHS (Table 2).

Table 2
Cox proportional hazards univariate models—initial time of squeaking event.

Data	Hazard ratio	Chi-square *P* value
36 mm and 28 mm		
Age	0.982	.3277
Gender (F)	2.697	.0312
BMI	1.013	.7357
Inclination angle	1.029	.2032
28 mm vs 36 mm (28 mm)	0.524	.0292
Cup diameter	0.917	.1677
Last Harris Hip Score	1.026	.2429
28 mm		
Age	0.968	.3639
Gender	3.034	.3579
BMI	1.086	.0740
Inclination angle	0.983	.7276
Cup diameter	0.940	.6094
Last Harris Hip Score	1.013	.5366
36 mm		
Age	0.985	.4633
Gender	2.753	.0402
BMI	0.977	.544
Inclination angle	1.071	.0897
Cup diameter	0.832	.0573
Last Harris Hip Score	1.038	.2808

Discussion

While advances in polyethylene manufacturing techniques have led to a significant reduction of wear and osteolysis, there remains a role for bearings such as COC that offer potential for even further wear reduction. In these PAS, we have reported excellent survivorship with this specific COC articulation, while detailing the complications and causes for revision with this device. Because choosing a bearing for a specific patient depends on the interplay of patient age, bearing-specific complication concerns, and cost, these data can help surgeons in determining the appropriate bearing for their patient.

There are several other studies that have reported on the results and complications of COC devices. Amanatullah et al. reported on the 5-year follow-up of 220 patients of an IDE which compared COC (n = 196) to a ceramic-on-polyethyelene (COP) (n = 161) with the use of 28-mm and 32-mm articulations (Smith and Nephew, Memphis, Tenn) [32]. There were 2 intraoperative (1.0%) liner fractures and 3 postoperative fractures liner fractures (2 liner and 1 head). There were no differences in dislocation rates or revision rates between the groups. In another report on 94 COC total hips at minimum 5-year follow-up, there was one revision for liner dissociation noted immediately after surgery, no ceramic fractures, and 3 reports of noise [33]. Buttaro et al. reported one liner fracture and one femoral head fracture in 939 COC total hips performed by 4 surgeons and attributed the liner fracture (incompletely seated) and femoral head fracture (excessively inclined acetabular component) to surgeon error [34]. Lim et al. reported 2 liner fractures and no femoral head fractures in 749 total hips using a 32-mm (227, 37%) or 36-mm (472, 63%) articulation [35]. The authors identified that at the time of revision surgery, both liners showed peripheral chipping at the posterior-inferior quadrant. Specifically looking at results in patients younger than 50 years at the time of surgery in a single surgeon series of 334 COC total hips at mean 7.8-year follow-up (range 6-9), there were no bearing fractures [36]. Using the Medicare 100% fee-for-service claims database for hospital stays over a period of 9+ years (2005-2014), Kurtz et al. compared 3 different bearing articulations [N = 70,495 COP; 9497 COC; 235,792 metal-on-polyethyelene (MOP)] [37]. For the COC cohort as compared to MOP, there were no differences in dislocation rate or mortality risk. Peters et al. reported on the outcomes stratified by bearing type in the Dutch Arthroplasty Registry examining 209,912 THAs from 2007 to 2016 (n = 70,175 COP, 37,351 MOP, and 17,625 COC articulations) [38]. In subcategorizing all revisions (N = 5464), revision for dislocation and infection were lowest for COC (dislocation = 20% [91/454], infection = 11% [51/454]) compared with those for COP (dislocation = 30% [498/1694], infection = 20% [330/1649]) and MOP (dislocation = 28% [248/890], infection = 19% [165/890]). The findings of lower dislocation rates with the use of a COC bearing in 2 are encouraging. The studies show that bearing fractures, predominantly of the liner, do occur postoperatively. In our study, bearing fracture (liner) only occurred intraoperatively.

Squeaking remains an issue with any COC articulation and is multifactorial. We have shown that bearing size does not make a difference with this specific implant (Table 2) and that for this cohort, age, BMI, acetabular inclination and acetabular component size, and HHS are unrelated to squeaking with the numbers available. While acetabular inclination likely plays a role in the development of squeaking, femoral stem type and acetabular anteversion may also be important factors. In a report comparing the Accolade stem (titanium-molybdenum-zirconium-iron alloy with V-40 neck geometry) to a titanium-aluminum-vanadium alloy with C-taper neck geometry, the incidence of squeaking was 7-times greater with the Accolade stem [39]. Revision surgery for squeaking resulted in no complications. In a report using third-generation AMC (BIOLOX Forte) with 28-mm or 32-mm articulations, noise was reported in 22% of hips at the first screening (3.8 years, range 3-5), with 2 patients (1.5%) reporting squeaking [40]. At the second screening (10.5 years, range 5-13), noise was slightly less at 19%. There was no association with age, gender, or BMI, and no patient was revised for noise. However, noise was correlated with decreased acetabular anteversion (mean 18.5 ± 8.5 degrees) compared to patients without noise (mean 22.3 ± 11.5 degrees). Pierrepont et al. matched 18 COC total hips with squeaking heard in deep flexion to 36 COP patients and evaluated component anteversion [41]. The mean anteversion for a squeaker was 5 degrees less using computed tomography (CT) evaluation in the supine position (squeaker anteversion 16.5 degrees [range 5-31.5]; nonsqueaker anteversion 21.3 degrees [range 8.4-31.8]). When orientation was adjusted to represent the pelvis in a flexed seated position, the functional anteversion for a squeaker was 8.1 degrees (−10.4 to 36.0) compared with the nonsqueaker anteversion of 21.1 degrees (range −1.9 to 38.4). McDonnell et al. in a report on 208 THAs using the monobloc acetabular Delta Motion bearing with 4 different stem types showed no association (DePuy Synthes, Warsaw, IN) between stem type, age, sex, BMI, and functional outcomes and squeaking [42]. However, both acetabular inclination and anteversion were significantly decreased in the patients that reported squeaking. No patient was revised for squeaking. In the single surgeon series reported by Baek et al., there was no association between the finding of noise and acetabular inclination or anteversion [33]. In our series, we saw no association between femoral stem type, acetabular inclination, and squeaking. We did not evaluate the influence of component anteversion. The reported literature suggests that squeaking occurring with activities involving high hip flexion may be secondary to loss of functional anteversion.

The average time to the report of squeaking was 3.9 ± 2.40 years for all patients originally enrolled in the IDE including additional data from the PAS (n 345). Restrepo et al. reported on the use of the Stryker system (Stryker Orthopedics, Mahwah, NJ) in 1284 patients (61% male, average age 49.9 years) and showed a 6% incidence of squeaking [43]. The time to onset of squeaking after surgery was 19.7 months (range 1.7-48.2 months). In a review of 939 COC total hips consecutively performed by 4 surgeons at a minimum 2-year follow-up (range 2-10 years), there was one report of squeaking occurring at 23 months postoperatively in a 50-year-old female with a 36-mm articulation who did not require surgical intervention [34]. Lim et al. described clicking in 29 (3.8%) of 749 COC total hips and squeaking in 19 (2.5%), with 25 of the 48 patients reporting that the sound developed within 6 months of surgery [35]. In examining 336 COC total hips, Salo et al. reported an incidence of 16% (54/336) of audible noise in patients with a 36-mm Delta bearing and a SUMMIT femoral stem and Pinnacle acetabular component [44]. Prior reports documented prevalence rates of noise of 0.3% to 12% [28,33,34,36]. We report a combined CIR of noise generation (clicking, squeaking) of 9.6% at 10 years with no association with stem type used. The time to onset of squeaking and prevalence is multifactorial and likely represents an interplay of component type, placement, and implant impingement.

The limitations to this study are that the longer term follow-up was voluntary, which reduced our original cohort size. There could be a bias regarding those patients that wished to remain in the study. Our follow-up using the same PAS approach was similar in length and patients lost to follow-up as that of the IDE of D'Antonio et al. [27]. We used a multisurgeon multicenter design with the surgeon determining the surgical approach and the use of 1 of 5 FDA-approved femoral stems. We used 5 different stems, which may bias our reporting on noise, yet with the numbers available, we could not identify a specific stem involved. We measured cup abduction yet did not measure anteversion of either the cup or the stem. We did not measure patient-reported outcomes other than HHS. Finally, the use of 28-mm bearings is limited in current practice.

In conclusion, at long-term follow-up, both the 28-mm and 36-mm AMC show excellent function and HHS. We have had no additional fractures using this specific material and implant combination. We have yet to identify an etiology for the squeaking reported, which is seen in all reported series. We caution that squeaking alone is not a cause for revision; squeaking associated with pain is. The need for a strict surgical technique particularly during liner insertion has been previously emphasized. Component position appears to influence later bearing fracture.

Conflicts of interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this article.

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

T.J.B. receives royalties and research support from Depuy Synthes, Warsaw, IN. J.P. receives royalties and research support from, is in the speakers' bureau of, and is a consultant for Depuy Synthes, Warsaw, IN. S.C. and T.O'D. are paid employees of Depuy Synthes, Warsaw, IN. W.H. receives royalties from, is in the speakers' bureau of, and is a consultant for Depuy Synthes, Warsaw, IN, and Total Joint Orthopedics, Salt Lake City, UT.W.H. also receives research support from Depuy Synthes, Warsaw, IN, and Zimmer Biomet, Warsaw, IN.

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