THA With Delta Ceramic on Ceramic

Results of a Multicenter Investigational Device Exemption Trial

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Abstract Although the published studies on the outcomes of total hip arthroplasty (THA) performed with currently available ceramic components show high survivorship and low bearing wear at midterm followup, concern over ceramic fracture and squeaking persist. For these reasons, the use of ceramic is limited. Recently, a new alumina matrix composite material (Delta ceramic) with improved material properties was developed to address these concerns. We report the early outcomes and complications of a prospective, randomized, multicenter trial of 263 patients (264 hips) at eight centers, comparing a Delta ceramic-on-ceramic (COC) articulation with a Delta

ceramic head-crosslinked polyethylene bearing combination (COP). There were 177 COC hips and 87 COP hips. Complications were reported for all patients, whereas clinical and radiographic results were provided for the 233 patients with minimum 2-year followup (average, 31.2 months; range, 21–49 months). The Harris hip scores and clinical, radiographic, and survivorship outcomes were similar in both groups. There were four (2%) revisions in the COC group and two (2%) in the COP group. We encountered three intraoperative ceramic liner-related events. In addition, one patient receiving the COC underwent revision for chipping of the ceramic liner, and a second had ceramic fragmentation on followup radiographs but has not undergone revision. These liner related complications remain a concern. No patient reported squeaking in either group; this leaves us hopeful the new material will lessen the frequency of squeaking. In the short term, the Delta COC articulation provided similar functional scores and survivorship and complication rates with the ceramic head mated with crosslinked polyethylene.

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Introduction

A major long-term problem affecting THA survivorship is polyethylene wear and the resultant wear-induced osteolysis. Alternative bearings in THA have been developed in an attempt to reduce wear and improve implant longevity. Bearing surface combinations consisting of either moderate to highly crosslinked polyethylene with metal or ceramic heads [7, 13, 26], metal-on-metal (MOM) [2], and ceramic-on-ceramic (COC) [6, 9, 11, 14, 16, 23, 29] are currently available for use in the United States.

Crosslinked polyethylene wear rates are substantially less than those for noncrosslinked polyethylene in both simulator studies and clinical trials [13, 26] and ceramic heads reduce wear rates further [7]. Alumina COC couplings also have a long history of use [3, 6, 29] with exponentially lower wear rates than other bearing surfaces [11] and a low incidence of observed osteolysis [6, 16]. Despite this lower wear rate, there are major concerns for adverse events such as head (incidence range 0.004%–1.4%) [1, 21, 30, 34] and liner fracture (incidence range 0.01%–2%) [6, 15, 17, 20, 25, 27, 30, 31, 39, 40, 45]. More recently, squeaking [32, 35, 43] has been reported with an incidence range of 0.48% to 7% [33, 43] and appears to be a multifactorial problem related either to ceramic or metal wear debris, implant design, impingement, or a combination of these factors. Other concerns over the use of COC articulations include the relatively few intraoperative modular options [4], the possibility of femoral head fracture if a new ceramic head is inserted on a used trunion during revision surgery [4], and cost.

A newer alumina matrix composite (AMC) ceramic (BIOLOX® Delta; CeramTec AG, Plochingen, Germany) was developed to hopefully improve wear while reducing the risk of bearing fracture with the alumina-on-alumina design. The AMC material consists of 82% alumina and 17% zirconia based on volume. Chromium oxide (0.5%) is added to improve the hardness and wear characteristics, and strontium crystals (0.5%) are added to enhance toughness and diffuse crack energy. The mechanical properties of this combination result in a bearing that has improved toughness and wear characteristics when measured in a laboratory setting [46]. The material has a smaller grain size (less than 0.8 μm) compared with the grain size of alumina (1–5 μm) [47]. Although it may be difficult to improve the wear characteristics of alumina-on-alumina designs, these improved mechanical properties

should decrease the ceramic fracture rate. The improved mechanical properties allow for the manufacturing of thinner liners and subsequently the use of larger femoral heads, even in smaller-diameter acetabular components. The reduced impingement, improved stability, and lower dislocation rate associated with use of a larger femoral head diameter combined with the low wear rate would provide a major advantage to this bearing combination. Furthermore, one study suggests the material properties of the AMC lead to a different wear response and may decrease or eliminate squeaking [46]. In the United States, the Delta femoral head is currently available for use, but the Delta ceramic liner is not. Outside of the United States, the Delta ceramic head and liner combination has been in use for several years although not reported in the literature.

A prospective, randomized study was designed to compare a Delta ceramic head and liner (COC) with a Delta ceramic head and moderately crosslinked polyethylene (COP) liner (Marathon®; DePuy, J&J, Warsaw, IN) as a control. Clinical and radiographic results were collected to determine the outcomes, complication rates, implant-related failures, component breakage, noises, or unforeseen complications of the COC bearing combination compared with the COP.

We asked whether this new material provided survivorship, functional scores, and intra- and postoperative complication rates that were at least equivalent to currently available designs. As the study progressed and the issues surrounding ceramics in orthopaedics evolved, we sought to determine if this bearing was susceptible to squeaking.

Materials and Methods

In 2003, we initiated a prospective, multicenter (eight sites), 2:1 randomized, controlled clinical trial comparing a COC bearing with a COP bearing. This was part of a US Food and Drug Administration Investigational Device Exemption (FDA/IDE) study. Approval from the Investigational Review Board was obtained for each of the participating sites before subject enrollment. The power of the study was determined using a 10.08 standard deviation estimate from unpublished data for the primary end point Harris hip score (HHS). Using a ratio of 2:1 for the COC and COP groups, respectively, a noninferiority margin of 5 points, a one-tailed alpha risk of 5%, and statistical power of 95%, the sample size to obtain 95% power was determined to be 134 COC hips and 67 COP hips. The sample size was increased by approximately 30% to account for anticipated protocol violations, deaths, study withdrawals, and patients lost to followup. The final sample size was 177 COC and 87 COP.

We included patients 20 to 75 years of age undergoing primary hip arthroplasty for noninflammatory degenerative joint diseases. All eligible patients were seen by participating surgeons and had the study explained to them and were given the opportunity to enroll, but some patients elected to not enroll in the study. Patients were included in the study only if their preoperative HHS was less than or equal to 70 points and their reported pain level was moderate or worse (ie, marked, totally disabled). We excluded patients with inflammatory arthritis, a previous arthroplasty procedure, bone stock deficiency that precluded the use of a cementless device, communicable diseases (ie, HIV and hepatitis), contralateral hip disease that might have required an arthroplasty within the next year, and any patient who was deemed unable to participate in a study (ie, at high risk for being lost to followup: lived far away, failed to keep appointments, told surgeon they would not followup). We obtained informed patient consent for each patient enrolled in the study.

There were 264 patients (265 hips) enrolled into this study; however, one patient did not receive the appropriate study implant and was removed as a protocol violation, leaving 263 patients (264 hips) with demographics and preoperative diagnoses representative of an average hip arthroplasty population (Table 1). During the study, 31 patients were either lost to followup or had incomplete data at the minimum 2-year followup interval (Table 2), which

was the cutoff for evaluable patients in this study. The final patient cohort consisted of 233 hips, 157 COC hips and 76 COP hips. The minimum followup of the final cohort was 21 months (average, 31 months; range, 21–49 months).

A computer-generated randomization schedule was produced using SAS software, Version 8.02 (SAS Institute Inc, Cary, NC). Random assignment was blocked in three blocks of three patients and four blocks of six patients for a total of 33 study hips (22 investigational COC and 11 control COP) per the eight sites. Treatment assignment was provided to each site using consecutively numbered pull-tabs. Parametric statistical tests were used after normality (Shapiro-Wilks test) and constant variance (folded F-test) were verified.

The investigational device was a ceramic head and liner manufactured from BIOLOX® Delta (CeramTec AG) (Fig. 1), an alumina composite matrix, whereas the control group was implanted with a moderately crosslinked polyethylene liner (Marathon®; DePuy, J&J) and the same BIOLOX® Delta ceramic head. All hips in both groups received the same cementless acetabular cup (Pinnacle® cup; DePuy) and one of five cementless femoral stems (AML®, Prodigy®, Corail®, Summit®, or SROM®; DePuy) (Table 3). This study was limited to 28-mm head and liner sizes. Twenty-eight-millimeter heads were used because it was the only size available at the time of study initiation. Subsequent to this 28-mm study, a 36-mm study was started and is currently ongoing.

The surgical approach and stem design were up to the surgeon's discretion. Each surgeon made slightly different decisions based on their experience and the patient's age and bone quality regarding acetabular bone preparation and underreaming. Screws were used when the investigator believed they would be helpful in acetabular fixation based on the patient's age and bone quality.

Table 1. Demographic data of study groups

Data	COC	COP	p value
Number of hips	177	87	
Gender			
Men	90 (51%)	47 (54%)	See below
Women	87 (49%)	40 (46%)	0.7
Age (years)	56.4	57.3	0.54
Weight	194.8	193.5	0.83
Diagnoses			
Osteoarthritis	155 (89%)	78 (90%)	
Avascular necrosis	12 (7%)	4 (5%)	
Posttraumatic arthritis	5 (3%)	2 (2%)	
Developmental dysplasia	5 (3%)	1 (1%)	
Epiphyseal defect	0 (0%)	2 (2%)	
Months followup (range)	31.1 (21–49)	31.5 (21–49)	
Preoperative Harris hip scores	50.6*	50.7	0.96
Postoperative Harris hip score	94.4	93.8	

* There were four hips that had a postoperative Harris hip score but incomplete preoperative evaluation that prevented the calculation of a preoperative score; COC = ceramic-on-ceramic; COP = ceramic-on-polyethylene.

Table 2. Reasons for not being included in the final patient cohort

Reason	COC count	COP count
*Protocol violation	5	4
Death	1	1
Withdrawn consent	3	0
No 24-month clinical followup	8	3
No 24-month radiographic followup	3	3
Total	20	11

* The nine protocol violations in this study included three patients with preoperative Harris hip scores above 70 points, two patients with urinary tract infections before surgery, one patient who had a 32-mm head implanted instead of the required 28-mm head, one patient who used corticosteroids before surgery, one patient who had bilateral arthritis disease at time of surgery, and one patient who was older than 75 years old at the time of surgery; COC = ceramic-on-ceramic; COP = ceramic-on-polyethylene.

Fig. 1 The investigational device is shown, including the Pinnacle acetabular cup and the BioloX Delta liner and head (DePuy, Warsaw, IN; CeramTec AG, Plochingen, Germany).

Table 3. Distribution of stem type and surgical approach used

Stem type	COC	COP
AML	30 (17%)	15 (17%)
Corail	5 (3%)	2 (2%)
Prodigy	20 (11%)	10 (12%)
SROM	96 (54%)	48 (55%)
Summit Duofix	26 (15%)	12 (14%)
Surgical approach		
Lateral	36 (20%)	16 (18%)
Posterior	141 (80%)	71 (82%)

COC = ceramic-on-ceramic; COP = ceramic-on-polyethylene.

We evaluated patients clinically and radiographically preoperatively, at 6 weeks, 6 months, 1 year, and annually thereafter. Interim visit forms were used when patients had visits outside of these prescribed time intervals. Patients completed questionnaires regarding pain severity, location, and satisfaction and surgeons completed the remainder of the HHS assessing limp and range of motion. Any and all adverse events were reported at all study intervals and interim visits. Squeaking or other hip noises were not initially asked about on the study followup forms. However, once reports of squeaking with other designs were published, careful attention was paid to any sounds, and careful examination and additional questioning were conducted. All reports of sounds were recorded as adverse events.

A single radiographic reviewer (JPG) evaluated all study radiographs. Patients were considered to have a radiographic failure if any of the following four criteria were met at any time after surgery: radiolucencies greater than 2 mm observed in any zone; acetabular cup migration greater than 4 mm; acetabular cup inclination change of more than 4° when compared with the immediate postoperative angle; or any osteolysis observed around any of the implanted components. No attempt was made to measure radiographic wear in this study. A cup was defined as stable if there was no measured migration or inclination change as described.

The primary end point used in the IDE study was the HHS. The HHS means were then tested with a noninferiority t-test comparing covariate-adjusted mean scores for patients in the final cohort. Covariates tested to potentially adjust the mean HHS included age, preoperative HHS, weight, and duration of followup. All covariates were entered into an analysis of covariance model and reduced stepwise using an alpha p value level of 0.05. The noninferiority margin for measuring the primary end point was 5 points based on precedence of use by the FDA for hip studies using HHSs as the primary end point.

Any hips that underwent a reoperation in which any of the device components (ie, femoral head or stem, acetabular liner, or shell) was removed at any time were considered a revision and a survivorship failure. A hip meeting any of the failure criteria was considered a failure regardless of the other success/failure outcomes. Fisher's exact test was used to test for differences in proportions between the COC and COP groups. A comparison of adverse events between the two groups was another secondary end point. We used Fisher's exact test to determine whether the proportion of complications was different between the COC and COP groups. Complications were separated into intraoperative and postoperative events. Kaplan-Meier survivorship was conducted for each group in which revision for any reason was the event of interest. The log rank test was used to compare the survivorship of the two groups [10]. SAS statistical software, Version 9.1 (SAS Institute Inc) was used for all analyses.

Results

The survivorship estimate at 3.2 years followup was 97.6% in the COC group and 97.7% in the COP group. There were six revisions, four of 177 (2.3%) in the COC group and two of 87 (2.3%) in the COP group (Table 4).

The percentage of patients with an HHS greater than 80 was 90.2% in the COC group and 90.5% in the COP group. The mean adjusted HHSs were similar ($p < 0.0001$) in the two groups (94.4 for the COC and 93.8 for the COP). We

Table 4. Complication incidence and proportion for group and Fisher's exact test

Complication	COC	COP	Fisher's exact p value	Comment
Intraoperative				
Femur fracture	5 (2.8%)	1 (1.1%)	0.667	
Nerve damage	1 (0.6%)	0 (0%)	1	
Chipped liner (insertional)	2 (1.1%)	0 (0%)	1	
Other	5 (2.8%)	2 (2.3%)	1	
Operative site				
Acetabular liner failure	2 (1.1%)	0 (0%)	1	One revised
Deep infection	2 (1.1%)	0 (0%)	1	One two-stage reimplantation, one repeat I&D with component retention
Dislocation	5 (2.8%)	4 (4.6%)	0.483	2 in COP group revised
Femoral component loosening	3 (1.7%)	0 (0%)	0.553	2 revised, one fibrous stable
Fracture	2 (1.1%)	0 (0%)	1	
Wound problem	9 (5.1%)	2 (2.3%)	0.349	

COC = ceramic-on-ceramic; COP = ceramic-on-polyethylene; I&D = incision and drainage.

observed no radiographic failures, cup migration, or change in inclination during the first 24 months. All cups were classified as stable, and no osteolysis was observed in either of the two groups. No differences in intraoperative and operative site complication rates were seen between the COC and COP groups (Table 4).

There were three intraoperative events involving the ceramic liner. In the first patient, the surgeon had difficulty symmetrically seating the ceramic liner. On impaction, the liner fractured and was removed. The cup was retained and a 32-mm polyethylene liner and a ceramic femoral head were implanted. In the second patient, a surgeon at a different site had difficulty seating the acetabular liner and on initial impaction found the liner was not symmetrically seated in the cup. The surgeon attempted to remove the liner by tamping the edge of the metal cup, but the process of doing so fractured the ceramic liner. The cup, fractured liner, and ceramic fragments were removed and replaced with a new cup and ceramic liner without difficulty. In the last patient, the same surgeon had difficulty seating the ceramic liner. The cup and liner were removed and replaced with a new cup and ceramic liner without difficulty. The liner did not fracture in this case. The overall rate of insertional liner fracture was 1.1% (two of 177).

The overall rate of postoperative ceramic liner fracture was 1.1% (two of 177). One patient with an SROM stem reported postoperative events suggestive of subluxation but never dislocated the hip. On a routine 12-month radiograph, findings consistent with fragmentation of the ceramic liner were observed (Fig. 2). Despite being asymptomatic, revision surgery was performed. At the time of surgery, the liner was eccentric in the cup, and peripheral chipping of the liner was observed (Fig. 3). One

Fig. 2 Anteroposterior radiograph demonstrates fragmentation of the ceramic liner (arrow).

Fig. 3 The retrieved liner and head show the fractured rim of the liner and ceramic fragments retrieved from the wound.

Fig. 4 Anteroposterior radiograph of a patient with a chipped ceramic liner. A small ceramic fragment (arrow) can be visualized.

additional patient had similar ceramic fragmentation on a followup radiograph (Fig. 4). Revision has been recommended but has not been performed as of this writing. A flow chart depicting the revisions and reoperations for the entire study cohort is included (Fig. 5).

Squeaking has not been reported for the COC investigational group or the COP control group. One COP subject did report a single episode of clicking 69 days after surgery, but, in the opinion of the investigator, it was not related to the orthopaedic device.

Discussion

Bearing surface wear and resultant particulate-induced osteolysis and component loosening have been a major factor limiting the survivorship and performance of traditional THA [12]. COC is accepted as the coupling that produces the lowest wear, and early to midterm reports

demonstrate less osteolysis [9]. The drawbacks of ceramic bearings include component breakage, the poorly understood issue of squeaking, cost, and the lack of large-diameter heads. The alumina matrix composite material examined in this study was developed to address some of the drawbacks of currently available alumina designs. Our primary question was to determine if this new material was safe and provided outcomes that were at least equivalent to designs currently available. As the study progressed and the issues surrounding ceramics evolved, we sought to determine how the complication rate in this study of component fracture and squeaking compared with the published literature. Furthermore, we attempted to identify factors that may have contributed to the divergence of this complication rate with that in the literature. By doing so, we hoped to provide guidance for practicing surgeons using this new material.

There are several shortcomings of this study that should be recognized. First, the duration of followup is relatively short with a minimum followup of 2 years and an average of 3.1 years. We cannot conclude whether this ceramic material will outperform other bearing couplings in the long term. Longer-term followup will answer this important question. Second, the FDA-approved study design was multicenter and multisurgeon, and practice patterns regarding stem type used and surgical approach used were surgeon-dependent. Although this induces variability in the study, given that we were primarily studying the bearing surface, we did not believe allowing these variables would negatively influence our primary study objective. The multi-institutional nature of the study may make the results more generalizable to the orthopaedic community. Third, although there were slight differences in the trunion geometry of the different stems, there was no difference in the proportion of stems used in the COC or COP groups. Fourth, because the study was powered using the gold standard measurement tool available at the time (HHS), the

Fig. 5 Flow chart details revisions and reoperations. All of the nonrevision reoperations were in the COC investigational group. The component revisions were divided between COC and COP groups. COC = ceramic-on-ceramic; COP = ceramic-on-polyethylene; (C) = control; (I) = investigational; I & D = incision and drainage.

Table 5. Comparisons of revisions/survivorship and liner fractures in literature

Study	Number of hips	Average followup (range)	Revision rate (RR)/survivorship	Ceramic liner fractures	Product
Ha et al. [15]	157	3.8 years (3–5.7)	RR: 3.2%	5 (3.2%)	Biolox Forte poly sandwich
Capello et al. [6]	475	8 years (6.5–8.6)	RR: 1.8%	2 (0.42%)	Biolox Forte-Trident alumina
Murphy et al. [29]	194	4.3 years (2–9)	Survivorship: 96%	1 (0.52%)	Biolox Forte-Trident alumina
Hamadouche et al. [16]	118	19.7 years (18.5–20.5)	Survivorship: 85.6% for cementless cups 61.2% for cemented cups 84.9% for cementless stems 87.3% for cemented stems RR: 21.2%	0	Ceraver Osteal
Park et al. [30]	357	3.9 years (3–6)	RR: 1.8%	6 (1.7%)	Poly-ceramic composite liner and alumina
Lusty et al. [23]	301	6.5 years (5–9.2)	Survivorship: 96%	0	Biolox Forte
Yoo et al. [47]	100	5.7 years (5–6.5)	RR: 1%	1 (1%)	Biolox Forte
Sugano et al. [38]	180	6 years (5–8)	RR: 1.2%	1 (0.56%)	Cremascoli (Biolox Forte)
Hamilton et al. [current study]	264	2.6 years (1.8–4.1)	Survivorship: 97.6%	2 (1.1%)	Biolox Delta

study is underpowered to detect subtle differences in performance, fracture rates, or squeaking. Lastly, although our dislocation rate is consistent with reported rates in the literature [5, 8], the use of only 28-mm heads likely increased our rate of dislocation. The 36-mm head option, when available, should lower the dislocation rate, and the mechanical properties of the AMC allow manufacturing of the 36-mm liner starting at 52-mm cups.

Fracture of a ceramic head and/or liner remains a major disadvantage for this bearing combination compared with metal on polyethylene or MOM. However, all bearing surfaces have the potential to break, including polyethylene. Heck reported a polyethylene fracture or dissociation rate over a 5-year period of 0.45% [18]. More recent case reports of fractured highly crosslinked polyethylene have similarly raised concern with that material [28, 41]. Femoral head fractures with modern COC are rare with a reported incidence of alumina femoral head fractures of 0.004% [44]. Reasons for this include the processing of the material yielding better tolerance between the femoral head and trunion, smaller grain size and fewer impurities, and the process of implants undergoing regular proof testing before release [19, 24]. Still, sporadic reports showing modern COC designs breaking do exist. One study reported a rate of alumina head fracture of five of 359 (1.4%) [21]. No ceramic head fractures were observed in this study. Regarding ceramic liner fractures, Sedel's experience with the all alumina Ceraver THA (Ceraver, Paris, France) [17, 39] reported a fracture rate of 2% in the 1970s, which decreased to 0.05% with improvements in materials and processing [39, 45]. Early results using the BIOLOX® forte alumina-on-alumina ceramic from an FDA multicenter study in the United States revealed no ceramic

fractures at 3 years followup in 333 cases [14]. In a more recent multicenter IDE study using the Trident insert (Stryker, Mahwah, NJ), Capello et al. reported a fracture rate of three in 1382 (0.2%) [6]. Using the same ceramic liner in a series of 301 patients, apart from one insertional chipped liner, no ceramic failures were observed [23]. One notable exception to this low fracture rate was with the ceramic polyethylene sandwich design (thin alumina ceramic articular surface embedded within a modular polyethylene liner) (Table 5) [15, 30, 31].

Given the reported results, the presence of the two ceramic liner insertional fractures and the two postoperative ceramic device failures in our study remains a major concern. We presume most liners failed as a result of eccentric or incomplete seating of the modular ceramic liner within the metal acetabular shell. Improper positioning and impaction may generate uncontrolled peak stresses in the ceramic, which may lead to fracture [27]. There are reports in the literature of difficulty seating COC liners both with [25] and without a metal encasing with rates of improper positioning as high as 16.4% [22]. Like with all hard bearings, proper seating of the liner at the time of surgery is critical. Surgeons should be aware that titanium cups can deform as much as 0.16 mm at the rim, especially when impacting into hard bone [36]. Attempting to insert a hard bearing into an elliptical opening can be quite difficult and may contribute to incomplete seating, edge loading, or chipping of these inserts. If the rim of the titanium cup has deformed even slightly, it can be difficult to get the liner to symmetrically seat. In cases in which dense, sclerotic bone is encountered, or if difficulty is encountered with cup or liner insertion, we believe consideration should be given to reaming line to line to prevent major cup deformation.

Furthermore, it is critical to confirm the liner is seated appropriately before impaction. Surgeons may be inclined to lightly impact this liner given the notion that ceramic is a fragile material with the potential to break. However, firm impaction of the liner into the cup is necessary to make sure the liner is locked into the cup. Careful inspection of postoperative anteroposterior and lateral films of the acetabular rim is important to confirm proper seating of the ceramic insert. The soft tissues adjacent to the acetabular cup should also be examined for ceramic debris on postoperative radiographs to rule out ceramic liner failure.

Interest in the topic of the squeaking ceramic hip has increased over the past several years. Squeaking, however, is not unique to ceramic bearings. A 3.9% rate of transient squeaking was reported with MOM resurfacing replacements [2]. The reported incidence of squeaking with modern ceramic bearings ranges from 0.48% [43] to 7% [33]. Major differences exist in all of the studies that report noises from hips, including the types of ceramic used, the geometry of the liner and neck, and the methods used to detect squeaking. Possible etiologies include microseparation associated with impingement and stripe wear [42], edge loading, cup malposition [43], and entrapment of third-body wear debris. Restrepo et al. reported an incidence of squeaking of 28 of 999 (2.7%); four of these underwent revision, all with stripe wear observed from the retrievals (Trident; Stryker) [33]. Using the same component, Ranawat and Ranawat reported squeaking in 11 of 143 (7%) patients [32]. In these cases, the use of an elevated metal rim to protect the ceramic liner from neck impingement may have contributed to this increased rate of squeaking because neck rim impingement could cause microseparation and entrapment of third-body wear debris. To date, no squeaking has been reported in this study. We hypothesize that this is the result of two specific advantages of this AMC material. One, the locking mechanism used avoids an elevated metal rim. Two, the characteristics of the material property of the AMC may lead to the absence of squeaking. Simulator studies show that in severe microseparation, the AMC material produces shallower wear stripes with less grain loss compared with alumina ceramic. The smaller grain size in the AMC material may contribute to this difference. This may lead to lesser disruption of the fluid film layer and lessen the risk of squeaking [37, 46].

This study should be of interest as a result of the continuing need for bearing couplings with an improved performance profile. Although we cannot conclude from these short-term data superiority of either COP or COC bearing surfaces, we believe the early results justify ongoing use of the AMC material in THA. The improved material properties of this ceramic combined with the ability to use larger-diameter heads and liners to reduce instability and impingement make this bearing an attractive alternative.

The fractured liners remain a concern, and careful attention to the technical points mentioned is warranted.

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