Clin Orthop Relat Res (2015) 473:3796–3802
DOI 10.1007/s11999-015-4428-1

Clinical Orthopaedics and Related Research®
A Publication of The Association of Bone and Joint Surgeons®

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SYMPOSIUM: 2014 INTERNATIONAL HIP SOCIETY PROCEEDINGS

Do Alumina Matrix Composite Bearings Decrease Hip Noises and Bearing Fractures at a Minimum of 5 Years After THA?

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Published online: 1 July 2015

Abstract

Background Ceramic-on-ceramic bearing couples are theoretically attractive in total hip arthroplasty (THA) because of low wear, but concerns regarding ceramic fracture and squeaking have arisen. Improved material properties of newer alumina matrix composite (AMC) materials, known as Delta ceramics, may reduce these risks. In addition, the use of thinner liners and larger femoral heads may be helpful clinically to lower the rate of dislocation. However, limited short-term clinical results are available and intermediate-term effects are unclear.

Questions/purposes (1) What is the frequency of bearing-related complications (dissociation, fracture, and noise) with ceramic-on-ceramic AMC bearings in cementless THA? (2) What other complications arose in patients treated with these bearings? (3) What are the Harris hip scores (HHS) and survivorship free from reoperation and revision at a minimum of 5 years after cementless THA performed with AMC bearings?

Methods Over a 9-month period in 2009, one surgeon performed 125 THAs, of which 100 (80% of the total) were performed with cementless, AMC bearings. During the period in question, the exclusion criteria for this implant were primary THAs with severe acetabular or femoral bone defect and revision THAs. Of these, 94 hips (95%) in 91 patients were available for analysis at a minimum of 5 years (range, 5–6 years), because five patients (six hips) had died. Mean age at the time of arthroplasty was 55 ± 14 years. Prostheses with an identical design and Biolox® Delta ceramics were used in all patients. Noise was classified into squeaking, clicking, grinding, and popping. Ceramic fracture, dislocation, and any other complications associated with the use of AMC ceramics were also investigated. Clinical evaluation included the modified HHS preoperatively and at each followup. Survivorship free from reoperation and revision was calculated using the Kaplan-Meier method.

Results Of 91 patients, four developed bearing-related complications, including one with liner dissociation despite initial square seating and three with clicking. No patients had ceramic fractures. A single event of perioperative dislocation occurred in one patient and postoperative periprosthetic fracture occurred in two hips. Mean HHS improved from 56 to 93 points at the final followup ($p < 0.001$). Survivorship at 5 years free from reoperation and revision was 96.8% and 97.9%, respectively.

Conclusions Improved material properties combined with the possible use of larger diameter heads make AMC ceramics a promising alternative bearing option with

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seemingly comparable clinical outcomes reported by others with conventional ceramic bearings. Despite these encouraging results, however, meticulous technical precautions such as square seating and proper impaction in particular should be taken during liner insertion, because we did observe one liner dissociation and several patients with hip noises.

Level of Evidence Level IV, therapeutic study.

Introduction

Since polyethylene wear and osteolysis became recognized as a major problem affecting long-term survivorship of THA, efforts have been made to reduce wear and improve longevity. Although contemporary THAs with highly crosslinked polyethylene (HXLPE) or hard-on-hard bearings offer great hope for reducing wear, the reduction in wear observed in THAs with HXLPE appears to be not quite as dramatic as seen in those with hard-on-hard bearings [19, 32], and those with metal-on-metal bearings have problematic issues such as hypersensitivity and pseudotumors [34].

Alumina ceramic bearings have been reported to reduce wear [14]. Although the third-generation alumina ceramics have been shown to be superior to those with previous generations in terms of material properties and reducing risk of fractures [18], there still remains a number of concerns such as potential for ceramic fracture [13, 21], noise issues [20], fewer intraoperative options and impingement [3], and decreased positional range of error during liner insertion [22]. These limitations of pure alumina characteristics required the development of improved ceramic materials. The alumina matrix composite (AMC) material, Delta ceramics (CeramTec®, Plochingen, Germany), has been reported to increase ceramic strength with fracture toughness over previous pure alumina in the laboratory setting and thus to allow manufacturing thinner acetabular liners and consequent larger heads [1, 4]. Theoretically, these material improvements would be expected to decrease mentioned concerns associated with previous-generation alumina bearings. However, few short-term clinical results have been published [7, 15, 27] and several questions remain regarding longer term clinical outcomes after THAs using Delta ceramic bearings.

Therefore, we investigated: (1) What is the frequency of bearing-related complications (fracture, noise, and dissociation) with ceramic-on-ceramic AMC bearings in cementless THA? (2) What other complications arose in patients treated with these bearings? (3) What are the Harris hip scores (HHS) and survivorship free from reoperation and revision at a minimum of 5 years after cementless THA performed with AMC bearings?

Materials and Methods

The current retrospective study is a case series and we collected the data in a prospective manner. This study was approved by institutional review board and all patients provided informed consent.

Over a 9-month period in 2009, one surgeon (S-YK) performed 125 THAs, of which 100 (80% of the total) were performed with cementless, AMC bearings. During the period in question, the general indications for this implant were all primary THAs without severe acetabular or femoral bone defect and revision THAs were excluded. Of these, 94 hips (94%) in 91 patients were available for analysis at a minimum of 5 years (range, 5–6 years), because five patients (six hips) had died.

There were 47 male and 44 female patients with a mean age of 55 ± 14 years at the time of arthroplasty. The mean body mass index (BMI) was 23 ± 3 kg/m^2. The mean followup was 5 ± 0.3 years (range, 5–6 years). The primary diagnosis for THA was osteonecrosis of the femoral head in 47 (50%), hip dysplasia in 16 (17%), primary osteoarthritis in 15 (16%), femoral neck fracture in eight (9%), posttraumatic osteoarthritis in four, ankylosing spondylitis in two, rheumatic arthritis in one, and sequela after pyogenic arthritis in one hip.

Prostheses with an identical design were implanted and so-called fourth-generation ceramics, Biolox® Delta (CeramTec®), without a metallic sleeve were coupled as the bearing surface in all patients (Fig. 1). Because 36-mm-sized femoral heads could be implanted only in cups larger than 50 mm according to the product specifications, the diameter of the femoral head was 32 mm in 19 (20%) and 36 mm in 75 hips (80%). The length of the femoral neck was short in 20 (21%), medium in 70 (75%), and long in four hips (4%). Biolox® Delta inserts have a Morse taper angle of 18.5° and were self-secured into cementless Bencox® Cups (CorenTec®, Cheon-An, Korea). Although the angled conical shape made it difficult to calculate the thickness of the liner, the mean thickness of outer conical fit according to the manufacturer was 3.9 ± 0.53 mm (range, 3.4–5.9 mm). The hemispheric titanium alloy cup was plasma-sprayed with microporous pure titanium with more than 30% porosity. The mean size of the acetabular cup was 53 ± 4 mm (range, 46–62 mm). The femoral component was a cementless Bencox® stem (CorenTec®), a grit-blasted tapered double-wedge stem with a rectangular cross-section.

We evaluated questionnaires on the history of ceramic fracture, dislocation, reoperation, and the noise around the hip, which was classified into squeaking, clicking, grinding, and popping [17] at each followup and snapping was excluded through physical examination or ultrasonography. These complications were investigated by routine radiographs as well. The serial radiographs were analyzed regarding component loosening [11, 33], osteolysis [24], periprosthetic fracture [6], and joint infection.

The modified HHS [16] was also evaluated at each followup and survivorship with any reoperation and revision as the endpoint at 5 years was calculated using the Kaplan-Meier method. Statistical analysis was conducted using the SAS (Version 9.3; SAS Institute Inc, Cary, NC, USA). Student's/paired t-test and chi-square test were used to compare variables. A p value of < 0.05 was considered to be significant.

Results

Of 91 patients, four developed bearing-related complications, including one with liner dissociation and three with hip noises. No patients sustained ceramic fractures. The single liner dissociation without fracture was noted immediately after surgery and was revised with a new acetabular shell, Delta ceramic liner, and head. Three patients (three hips) reported subjective clicking, which was not associated with pain or functional limitation, and no patients reported squeaking. Noise occurred in younger age (p = 0.009), but was not associated with sex (p = 0.583), BMI (p = 0.334), head and cup size (p = 0.565 and p = 0.963, respectively), neck length (p = 0.832), inclination and anteversion angle of the cup (p = 0.338 and p = 0.661, respectively), and final HHS (p = 0.642) (Table 1).

Fig. 1 Photograph demonstrates the Bencox® hip system with the Biolox® Delta ceramic head and liner.

One hip dislocated in a 61-year-old woman 9 days after surgery; after closed reduction, she has not experienced any further dislocations. When an intraoperative femoral fracture was suspected, simultaneous cerclage wiring was performed in seven hips (7%). In addition, postoperative periprosthetic fractures occurred in two hips (2%): one hip with type B_2 fracture according to the Vancouver classification system underwent stem revision with an extensively porous-coated stem and plate fixation, whereas the other with Vancouver type AL was treated with cerclage wires. There was no loosening, osteolysis, or periprosthetic joint infection at the final followup.

Mean HHS improved from 55.5 ± 16.3 to 93.2 ± 6.8 points at the final followup ($p < 0.001$). Two hips were revised as a result of liner dissociation and postoperative periprosthetic fracture, respectively. Survivorship with any reoperation and revision as the endpoint at a minimum of 5 years was 96.8% (95% confidence interval [CI], 90.45–98.96) and 97.9% (95% CI, 91.75–99.46), respectively (Fig. 2).

Discussion

AMCs, also known as fourth-generation ceramics, provide superior strength with fracture toughness and allow manufacturing thinner liners with larger heads compared with earlier ceramic materials [1, 4]. Although these material improvements would be expected to decrease clinical concerns associated with previous-generation alumina bearings such as ceramic fracture and squeaking, little is known about this new bearing material and intermediate-term effects are unclear [7, 15, 27]. Therefore, we evaluated complications associated with the use of ceramic-on-

Table 1. Details of patients reporting noise around the hip

Case number	Type of noise	Gender	Age (years)	Height (cm)	Weight (kg)	Onset of noise (months)	Final HHS (points)	Cup size (mm)	Cup inclination (degrees)	Cup anteversion (degrees)	Neck length
1	Clicking	Male	48	162	53	40	96	56	51	3	Short
2	Clicking	Male	30	182	76	35	90	56	52	19	Medium
3	Clicking	Female	22	163	58	2	96	48	42	35	Medium

HHS = modified Harris hip score.

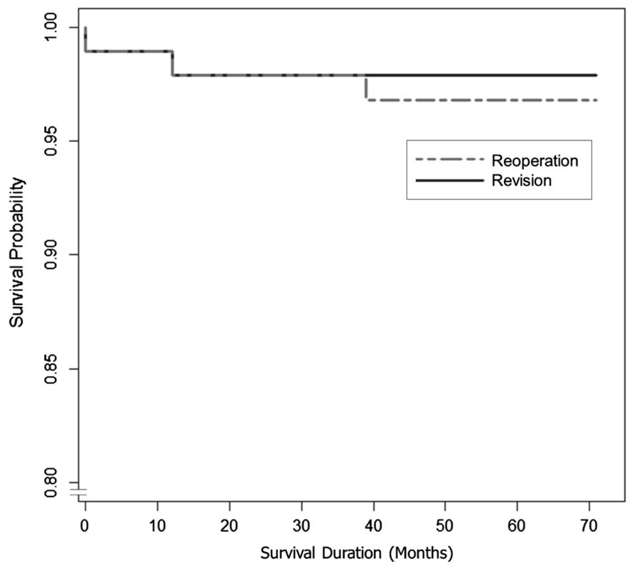

Fig. 2 Survivorship with any reoperation and revision as the endpoint using the Kaplan-Meier method is shown.

ceramic AMC bearings and clinical outcomes including HHS and survivorship.

The present study has a number of limitations. First, this is not a comparative study. Comparison with those with different bearings would provide stronger evidence to our study. Second, it included a relatively small number of patients, which makes the statistical power of the study relatively weak. According to the manufacturer, fractures seen in third- and fourth-generation ceramics are as rare as 0.021% and 0.002% [25]. If the clinical performance of these bearings matches these laboratory findings, the number needed to treat to prevent a single ceramic fracture is as many as 4762 (range, 4351–5259) and 50,000 (range, 36,823–77,862), respectively. Nevertheless, as of the time of this writing, this is the first intermediate-term study after THA performed with AMC ceramic bearings conducted at a single institution by the same surgeon. We believe that our findings are valuable because, when new bearing materials are introduced, studies should be performed to look for unexpected complications unique to them. Third, we are unable to report long-term outcomes, because our study addresses intermediate-term outcomes with a minimum followup of 5 years. However, 90% of in vivo failures of AMC ceramics have been reported to occur within 24 months (80% at 12 months) after implantation [12]. Thus, different from third-generation ceramics, the fracture of fourth-generation ceramics appears to be rare after 5 years postoperatively. Fourth, average BMI is 23 ± 3 kg/m^2; thus, we could not extend our conclusions to obese patients.

Liner dissociation is a concern. The rate of incorrect liner positioning has been reported as high as 16% in some studies and is thought to be the result of difficulty in seating along the axis of the Morse taper interior to the metal cups [15, 22]. As a result, instead of using a taper angle less than 10°, which generates a smaller window for engagement like in earlier designs, most manufacturers have adopted a taper of approximately 18°. Although increasing taper angle facilitates correct liner insertion into the shell, this change can complicate liner-cup engagement and lead to problems of secondary micromotion of the ceramic insert [18, 25]. Concerning the brittle nature of ceramics, we applied manual pressure with a plastic pusher on all ceramic liners and did not impact them after confirming square seating by tactile feeling with a finger [26]. A suction force acting at the instant of separation of the 28-mm-diameter head and liner was reported up to 30 N [10]. This force acts against the static friction between them and failure to impact the liner with sufficient force during assembly may contribute to liner dissociation [18]. Moreover, suction force between the head and liner and micromotion between the liner and cup secondary to joint torque force may increase as head size increases. Thus, a modular ceramic liner can introduce potential liner dissociation even after correct positioning. Indeed, special technical considerations, impacting the liner in particular, should be paid during the whole process of ceramic insertion [26]. We have not experienced ceramic bearing fracture. Although manufacturers reported a stable fracture rate of third- and fourth-generation ceramic liners going from 0.032% to 0.028% [25], this very low rate has not been supported by previous studies, which reported a higher rate of AMC ceramic liners ranging from 1.9% to 2% [7, 15] (Table 2). Most of those liner fractures were intraoperative insertional chipping [15] or postoperative fracture resulting from improper initial seating of the modular liner within the metal cup [7, 15]. Thus, liner fractures in vivo reported in earlier studies can be explained by technical errors rather than mechanical properties of the AMC ceramics. No patient reported squeaking, whereas three younger patients (3.2%) reported clicking in this study. Baek and Kim [2] reported squeaking in 1.4% and clicking in 18.3% after THAs using 28-mm-sized third-generation ceramic bearings at a mean followup of 7.1 years and attributed this to higher activity in younger patients and cultural habits like frequent squatting in Asian people. Hamilton et al. [15] hypothesized that absence of squeaking might result from smaller grain size in the AMC material leading to a lesser effect on the articular fluid film layer and avoidance of an elevated metallic rim. Other theoretical causes of squeaking include impingement, microseparation, or metal transfer. These might be reduced by the use of a larger head, but further comparative studies are necessary [12, 30].

Table 2. Previous studies regarding results after THAs using AMC ceramic bearings

Study	Implants	Number of hips	Mean age (years)	Mean followup (years; range)	Head size (mm; %)	Ceramic head fracture (number; %)	Ceramic liner fracture (number; %)	Squeaking (number; %)	Dislocation (number; %)	Last HHS	Survivorship (endpoint)/RR
Fourth-generation ceramics											
Hamilton et al. [15]	Identical cup Five stems	177	56	2.6 (1.8–4.1)	28 (100%)	0	4 (2.2%)	0	5 (3%)	94.4	97.6% (revision)
Cai et al. [7]	Identical cup and stem	51	42	3.3 (3.0–3.7)	36 (100%)	0	1 (1.9%)	2 (4%)	1 (2%)	84.3	RR: 3.8%
McDonnell et al. [27]	Preassembled cup Four stems	208	59	1.8 (1.0–2.9)	42–66 (median 54)	0	0	43 (21%)	1 (0.5%)	NA	100% (reoperation)
Current study	Identical cup and stem	100	55	5.4 (5.0–5.7)	32 (20%) 36 (80%)	0	0	0	1 (1%)	93.2	97.9% (revision) 96.8% (reoperation)
Third-generation ceramics											
Yoo et al. [35]	Identical cup and stem	100	41	5.7 (5.0–6.5)	28	1 (1%)	1 (1%)	NA	0	97.0	RR: 1%
Sugano et al. [31]	Identical cup and stem	180	53	6 (5–8)	28	0	1 (0.6%)	NA	7 (4%)	NA	RR: 1.2%
Lusty et al. [23]	Identical cup and stem	301	58	6.5 (5.0–9.2)	28 (8%) 32 (92%)	0	1 (0.3%)	NA	1 (0.3%)	95	96% (revision)
Baek and Kim [2]	Identical cup and stem	71	39	7.1 (6.0–9.0)	28	0	0	1(1%)	0	97.0	96.0% (worst case)
Koo et al. [21]	Identical cup and stem	367	50	3.8 (3.0–5.0)	28	5(1.4%)	0	NA	NA	93	RR: 1.6%
Choi et al. [9]	Two cups Identical stem	173	53	7.3 (5.6–9.4)	28 (78%) 32 (22%)	0	1 (0.6%)	8 (5%)	1 (0.6%)	94	RR: 0.6%
Restrepo et al. [29]	Two cups Identical stem	1486	50	5.5 (2.5–7.9)	28 (16%) 32 (61%) 36 (23%)	0	0	95 (6%)	NA	91.3	RR: 0.7% (squeaking)
Porat et al. [28]	Six cups Ten stems	1757	50	4.2 (0.5–8)	28–36	1	NA	4 (0.2%)	NA	NA	RR: 2.2%
Capello et al. [8]	Three cups Identical stem	380	53	7.4	NA	0	6(1.6%)	3 (1%)	NA	96.0	95.9 (revision)
Keurentjes et al. [20]	Identical cup and stem	43	57	3.9 (3.3–4.7)	NA	0	0	9 (21%)	1 (2%)	NA	RR: 4.7%

AMC = alumina matrix composite; HHS = modified Harris hip score; RR = revision rate; NA = not available.

In addition to the decrease in the risk of ceramic head fracture, another potential advantage of a larger head is that it may reduce the risk of dislocation and result in improved stable range of motion [21]. In THAs using AMC ceramics, when the acetabular cup size is large enough (> 50 mm in particular), a larger ceramic head (≥ 36 mm in particular) can be used. In our study, a 61-year-old woman with severe pelvic deformity by past trauma had a single event of perioperative dislocation. Although this result was comparable to those of previous intermediate-term studies using earlier generation ceramics ranging from 0% to 4% [9, 31, 35], dislocation is so multifactorial and the data available in this study are too small to draw any definite conclusions (Table 2). The risk of intraoperative femoral fractures has been shown as high as 5.4% during cementless primary THA [5]. Our rate appears higher than this. Because placement of a cerclage wire is a rapid procedure with little morbidity, when we suspected an intraoperative fracture, particularly in elderly females, we performed prophylactic cabling, which may account for this increase.

The HHS at the final followup in our study was 93.2 points, similar to those of previous studies ranging from 91 to 96 [8, 29] (Table 2). The 5-year survivorship free from revision was 97.9% and this result is also comparable to the survival rate of 95.9% to 96.0% in intermediate-term studies using third-generation ceramics [8, 23] and 97.6% in a short-term study using fourth-generation ceramics [15]. When new bearing materials are introduced, it is important to document patient-reported outcome and survivorship.

In conclusion, improved material properties combined with possible use of larger diameter heads make AMC ceramics a promising alternative bearing option with no evidence of increased early failure such as ceramic fracture, squeaking, and dislocation. Despite these encouraging midterm results, however, meticulous technical precautions such as square seating and proper impaction in particular should be taken during the whole process of liner insertion.

Acknowledgments We thank Martin Zimmermann PhD, and Tae-Jin Shin PhD, for providing materials and information associated with Delta ceramics and professor Won Kee Lee for statistical analysis.

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