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Isolated Fracture of the Ceramic Head After Third-Generation Alumina-on-Alumina Total Hip Arthroplasty

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Background: While most reports of component fracture following alumina-on-alumina total hip arthroplasty have involved the acetabular liner, few have involved fracture of the alumina femoral head. In the present multicenter study, we investigated ceramic head fractures in a cohort of patients who underwent third-generation alumina-on-alumina total hip arthroplasty.

Methods: We performed a retrospective study of 312 patients (367 hips) who underwent alumina-on-alumina total hip arthroplasty without cement at four participating centers with the use of a 28-mm BIOLOX forte femoral head and a BIOLOX forte liner from July 2001 to October 2003. Three hundred and five patients (359 hips) were evaluated at a mean of forty-five months postoperatively. Clinical follow-up with use of the Harris hip score and radiographic evaluation were performed at six weeks; at three, six, and twelve months; and every six months thereafter. Retrieved ceramic implants were examined by means of visual inspection.

Results: Five hips (1.4%) in five patients were revised because of a ceramic head fracture during the follow-up period. The ceramic head fractures occurred during normal daily activities at a mean of 22.6 months postoperatively. A short neck had been used in all five hips in which a fracture occurred, compared with 121 (34.2%) of the 354 hips in which a fracture did not occur ($p = 0.009$). The fracture involved a circular crack along the circumference of the thinnest portion of the head component at the proximal edge of the bore. The fracture also involved multiple vertical cracks extending radially along the longitudinal axis from the circumference of the circular crack line to the lower edge of the head component.

Conclusions: In the present study, the rate of ceramic head fracture associated with one design of a short-neck modular alumina femoral head was 1.4% (five of 359). The extent to which these findings are generalizable to other designs that utilize this type of femoral head is unknown.

Level of Evidence: Therapeutic Level IV. See Instructions to Authors for a complete description of levels of evidence.

In 1970, Boutin introduced ceramic-on-ceramic total hip arthroplasty[1]. Early generations of ceramic articulations frequently were associated with ceramic implant fracture and excessive wear[1-3]. Although the mechanical properties of ceramic material have improved during the last three decades, fracture of ceramic components remains a problem[4]. Most of the reported ceramic fractures after total hip arthroplasty with use of the third-generation alumina-on-alumina articulation have been fractures of the ceramic liner of so-called sandwich-type acetabular components[5,6].

We conducted a multicenter study of primary total hip arthroplasties that had been performed with a third-generation

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TABLE I Demographic Data

Number of patients	305
Number of hips	359
Male:female ratio *(no. of patients)*	209:96
Age* *(yr)*	49.9 (17 to 80)
Primary diagnosis	
Femoral head osteonecrosis	218 patients (264 hips)
Secondary osteoarthritis	51 patients (55 hips)
Previous infection	19 patients (20 hips)
Femoral neck fracture	7 patients (7 hips)
Primary osteoarthritis	4 patients (4 hips)
Rheumatoid arthritis	5 patients (7 hips)
Ankylosing spondylitis	1 patient (2 hips)

*The value is given as the mean, with the range in parentheses.

alumina-on-alumina articulation and found five instances of isolated ceramic head fracture.

Materials and Methods

The design and protocol of this multicenter retrospective study were approved by the institutional review board at each center, and all patients were informed that their medical data could be used in a scientific study; all patients provided consent preoperatively.

Between July 2001 and October 2003, 319 patients underwent a total of 374 primary total hip arthroplasties at four participating hospitals in South Korea. Of these, 312 patients (367 hips) underwent total hip arthroplasty with a single cementless prosthesis design with use of an alumina-on-alumina articulation.

Of the 312 patients (367 hips), six patients (seven hips) died for reasons that were unrelated to the arthroplasty and one patient (one hip) underwent revision surgery because of deep infection of the hip thirty months postoperatively, leaving 305 patients (359 hips) as the subjects of the study.

The study group included 209 male patients (243 hips) and ninety-six female patients (116 hips). The mean age of the patients at the time of the index operation was 49.9 years (range, seventeen to eighty years). The demographic features of the patients, including age, gender, and primary diagnosis, are presented in Table I.

The acetabular component was a hemispherical titanium cup (PLASMACUP SC; Aesculap, Tuttlingen, Germany) with an outer pure titanium plasma-sprayed coating (PLASMAPORE; Aesculap) and an alumina acetabular insert (BIOLOX forte; CeramTec AG, Plochingen, Germany). The femoral component was a slightly tapered, rectangular, collarless titanium stem (BiCONTACT; Aesculap). The proximal one-third of the stem was coated with PLASMAPORE. A 28-mm alumina femoral head (BIOLOX forte; CeramTec AG) was used in all hips (Fig. 1). A short-neck modular femoral head component was used in 126 hips (35.1%), a medium-neck component was used in 132 hips (36.8%), and a long-neck component was used in 101 hips (28.1%).

One senior surgeon at each center (K.-H.K., Y.-C.H., W.H.J. and S.-R.K.) performed all operations with use of a posterolateral approach. All of the acetabular and femoral components were inserted in a press-fit manner. The posterior capsule and the short external rotators were routinely repaired. Postoperatively, patients were instructed to walk with partial weight-bearing with the aid of two crutches for four weeks after surgery. Clinical and radiographic follow-up evaluations were performed at six weeks; at three, six, and twelve months; and every six months thereafter. Patients who had not returned for regularly scheduled visits were contacted by telephone.

In October 2006, we reviewed the follow-up data for our patients. The minimum duration of follow-up was three years for 277 patients (326 hips). The remaining twenty-eight patients (thirty-three hips) had been lost to follow-up before the

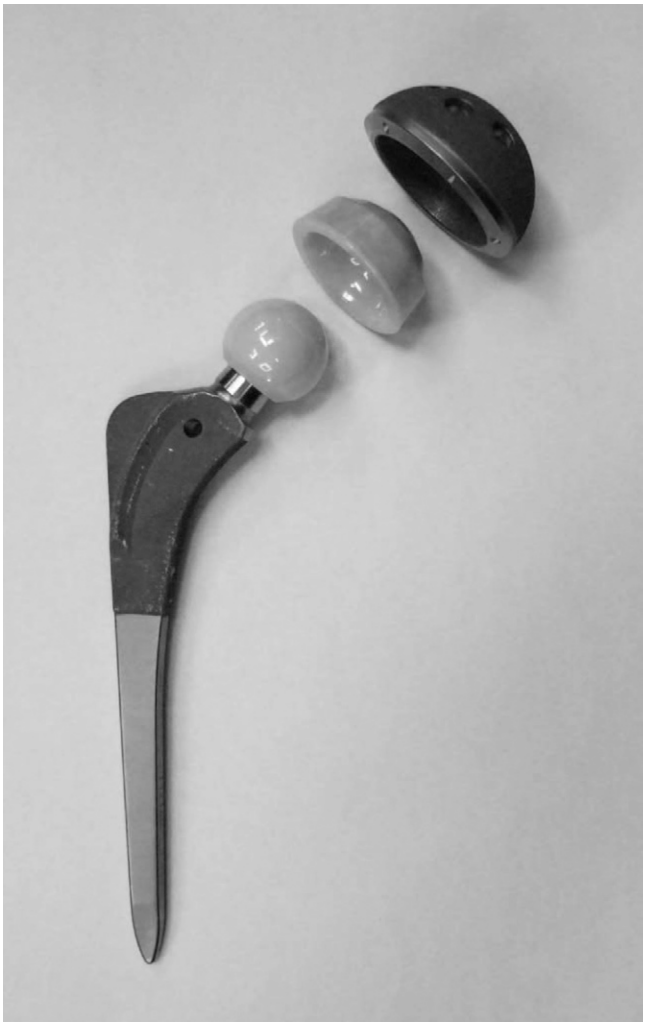

Fig. 1
Photograph showing a PLASMACUP SC-BiCONTACT hip system with a contemporary third-generation alumina-on-alumina bearing surface. The alumina head is secured to the stem with a tapered cone.

third postoperative year. Three home-care nurses and two private locators recruited these twenty-eight patients by telephone and/or direct contact. Thus, the latest follow-up evaluation was performed at an average of forty-five months (range, thirty-six to sixty months) for 305 patients.

Clinical evaluation was performed with use of the Harris hip-scoring system[7].

Baseline radiographic evaluation was performed with use of anteroposterior and cross-table lateral hip radiographs made six weeks postoperatively. The anteversion of the acetabular component was determined on the baseline radiographs with use of the method of Widmer and Zurfluh[8]. Fixation of the femoral component was determined with use of the method of Engh et al.[9], and fixation of the acetabular component was determined with use of the method of Latimer and Lachiewicz[10]. Osteolytic lesions, if present, were defined according the criteria of Engh et al.[11]. The final radiographic analysis was performed at the time of the latest follow-up.

Statistical Analysis

Revision surgery was performed in patients who sustained a fracture of the ceramic femoral head. The retrieved ceramic head and liner were examined by means of visual inspection.

Preoperative Harris hip scores were compared with the scores at time of the latest follow-up with use of the paired t test. The patients in whom a fracture occurred were compared with those in whom a fracture did not occur with regard to the hospital where the procedure had been performed, age, gender, body weight, height, body mass index, the primary diagnosis, the amounts of abduction and anteversion of the cup, and the length of the ceramic head component. Differences between the two groups were examined with the chi-square test for categorized variables and with the Mann-Whitney test for continuous variables. Kaplan-Meier survivorship analysis was used to compare cumulative fracture-free rates between groups that were stratified according to gender, the hospital where the procedure had been performed, neck length, and diagnosis. Multivariate analysis was performed with use of the Cox proportional hazards model with time to fracture as the dependent variable and age, gender, body mass index, cup anteversion, cup abduction, stem size, cup size, and neck length as independent variables. A post hoc power analysis was conducted with use of G*Power (version 3.0.3) to compare the cup anteversion. The level of significance was set at $p < 0.05$.

Results

The mean Harris hip score improved from 48 points (range, 27 to 79 points) preoperatively to 93 points (range, 84 to 100 points) at the time of the latest follow-up ($p < 0.05$). All of the acetabular cups and femoral stems had radiographic evidence of bone ingrowth. All femora had radiographic evidence of proximal cortical thinning, limited to the calcar femorale. The thinning was evident at three months postoperatively and did not progress on serial radiographs. Periprosthetic osteolysis was not detected around any implant.

Five ceramic head fractures occurred in five patients (four men and one woman) with a mean age of 47.2 years (range, thirty-two to seventy-one years). The index total hip arthroplasty had been performed for the treatment of osteonecrosis of the femoral head in four of these patients and for the treatment of secondary osteoarthritis in one. The fractures occurred at a mean of 22.6 months (range, twelve to thirty-one months) after the index total hip arthroplasty. No patient had a history of unusual impact loading or trauma. All patients reported a crunching sensation one day to five days before radiographs confirmed fracture of the ceramic head. The crunch was first noticed during walking in the case of one patient, during stepping down in the case of one patient, and during squatting in the case of one patient. There was no significant difference between the group of patients in whom a fracture occurred and the group in whom a fracture did not occur with regard to the hospital where the procedure had been performed, gender, age, weight, height, body mass index, the primary diagnosis, or the abduction angle or anteversion of the acetabular cup.

The prevalence of component fracture in hips that had a short prosthetic femoral neck was 4.0% (five of 126), whereas no ceramic head fractures occurred in the group of 233 hips that had either a medium or a long neck ($p = 0.009$) (Table II). Survivorship analysis revealed that patients with a short prosthetic femoral neck had a significantly shorter fracture-free period than those with a longer neck ($p = 0.0023$) (Fig. 2). In the group of 126 hips that had a short neck, there was no significant difference between the patients in whom a fracture occurred and those in whom a fracture did not occur with regard to the hospital where the procedure had been performed, gender, age, weight, height, body mass index, the primary diagnosis, or the abduction angle or anteversion of the acetabular cup (see Appendix). Multivariate analysis with use of the Cox proportional hazards model revealed no variable that had a significant association with ceramic head fracture. Only cup anteversion had a marginally significant association with ceramic head fracture ($p = 0.052$, odds ratio 1.137 [95% confidence interval, 0.999 to 1.295]) (see Appendix). A post hoc power analysis revealed that the comparison of anteversion has a statistical power of 0.55.

At the time of revision surgery in the five hips that sustained a fracture of the femoral head, all acetabular cups and femoral stems were well fixed. The original acetabular shell was intact and was retained in all hips. The original femoral stem was retained in four hips. In one hip (Case 5), the femoral stem was revised because of severe damage on the trunion (Table III). In one hip (Case 1), the fracture occurred twenty-three months after the primary total hip arthroplasty (Table III). At the time of revision surgery, a new ceramic head and a new ceramic liner were implanted although the trunion of the stem was damaged with scratches. Four weeks after the revision, the new ceramic head fractured. At the time of the second revision, the fractured ceramic head was replaced with a 28-mm cobalt-chromium head and the ceramic liner was replaced with a polyethylene liner. The second ceramic head fracture in that patient was excluded from our series because

TABLE II Comparison Between the Fracture Group and the Non-Fracture Group

Factors	Fracture Group (N = 5)	Non-Fracture Group (N = 354)	P Value
Hospital of treatment (*no. of hips*)			0.522
Hospital 1	1	128	
Hospital 2	2	80	
Hospital 3	1	119	
Hospital 4	1	27	
Male:female ratio (*no. of hips*)	4:1	239:115	0.553
Age* *(yr)*	47.2 ± 16.6	49.8 ± 14.02	0.535
Weight* *(kg)*	65.6 ± 8.51	63.6 ± 10.39	0.609
Height* *(cm)*	166.1 ± 8.65	162.9 ± 10.56	0.495
Body mass index*	23.7 ± 1.36	24.3 ± 8.28	0.917
Primary diagnosis *(no. of hips)*			0.707
Femoral head osteonecrosis	4 (80.0%)	260 (73.4%)	
Secondary osteoarthritis	1 (20.0%)	54 (15.3%)	
Miscellaneous	0 (0.0%)	40 (11.3%)	
Cup position* *(deg)*			
Abduction	37.6 ± 7.7	38.8 (6.5)	0.697
Anteversion	22.2 (9.1)	15.9 (7.0)	0.106
Neck length (*no. of hips*)			0.009
Short	5 (100.0%)	121 (34.2%)	
Medium or long	0 (0.0%)	233 (65.8%)	

*The values are given as the mean and the standard deviation.

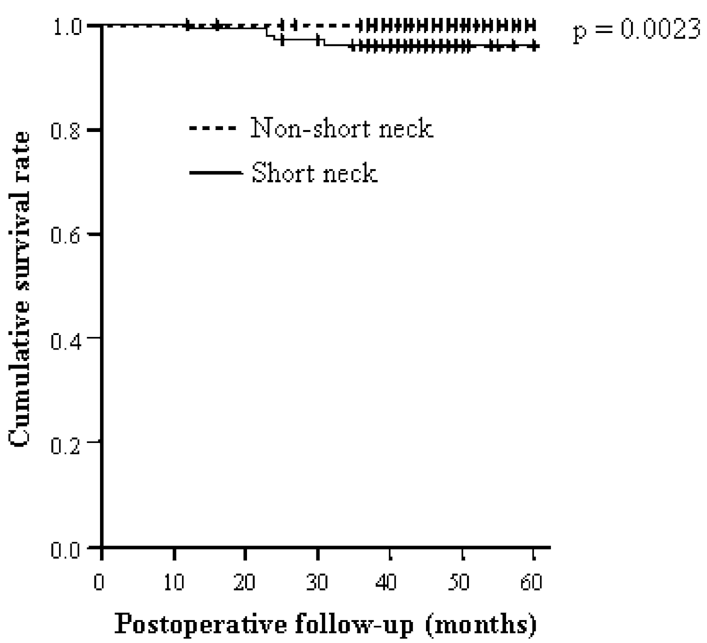

Fig. 2

Kaplan-Meier survival curves comparing the cumulative fracture-free rates between the group of hips with a short-neck component and the group of hips with a non-short-neck component.

TABLE III Data on the Five Patients with Fracture of the Ceramic Head

Case	Gender	Age *(yr)*	Final Harris Hip Score *(points)*	Body Mass Index	Time of Fracture After Surgery	Position at Fracture	Revised Articulation
1*	M	34	94	21.7	23 months	Stepping down	Ceramic liner/ceramic head
					4 weeks	Walking	Polyethylene liner/metal head
2	M	41	93	24.6	12 months	Unknown	Polyethylene liner/metal head
3	F	71	95	23.1	31 months	Unknown	Polyethylene liner/metal head
4	M	32	92	23.9	24 months	Walking	Polyethylene liner/metal head
5†	M	58	90	25.2	23 months	Squatting	Polyethylene liner/metal head

*In Case 1, fracture of the revised ceramic head occurred four weeks after revision. †In Case 5, the trunion of the stem was severely damaged, and the stem was replaced.

it was deemed to be secondary to the damaged trunion. For the subsequent four revisions (Cases 2 to 5), we used a polyethylene liner and a 28-mm cobalt-chromium head (Table III).

Retrieval Analysis

All five ceramic head fractures demonstrated a similar pattern. A circumferential crack measuring 9 to 15 mm in diameter was found at the dome of the head, corresponding to the thinnest portion of the head adjacent to the proximal edge of the head bore. Three to five vertical cracks radiated from the circular crack to the lower edge of the head component. Consequently, the head component was fractured into one apical segment and several lateral segments (Fig. 3). In two cases (Cases 3 and 4, Table III), the apical segment was comminuted into several pieces. In all five cases, dark metallic-like smears were visible on the fracture surface and the inner surface of the fractured ceramic head (the surface abutting the metal taper) (Fig. 3). In addition, in all five cases, dark metallic-like smears and multiple scratches were visible on the articular surface and the lip of the ceramic liner. Also, chip fractures were found at the peripheral rim of the ceramic liner in all five cases. The number of fracture sites ranged from one to three. The fractures measured 3 to 14 mm in length, 1 to 4 mm in width, and <1 mm in height. The trunion of the femoral stem was damaged with multiple scratches in all five cases.

Discussion

The mechanical properties of ceramic materials have been improved by hot isostatic pressing, laser marking, and nondestructive proof-testing[12], yet the fracture of such com-

Fig. 3

Photograph of the fractured ceramic head component from one of our patients (Case 2), showing a circumferential crack at the dome and three vertical cracks. The fracture pattern suggests that the mechanism of ceramic head fracture was a brittle fracture at the thinnest circumferential portion of the head component. Dark metallic-like smears are seen on the fracture surface and the inner surface of the ceramic head.

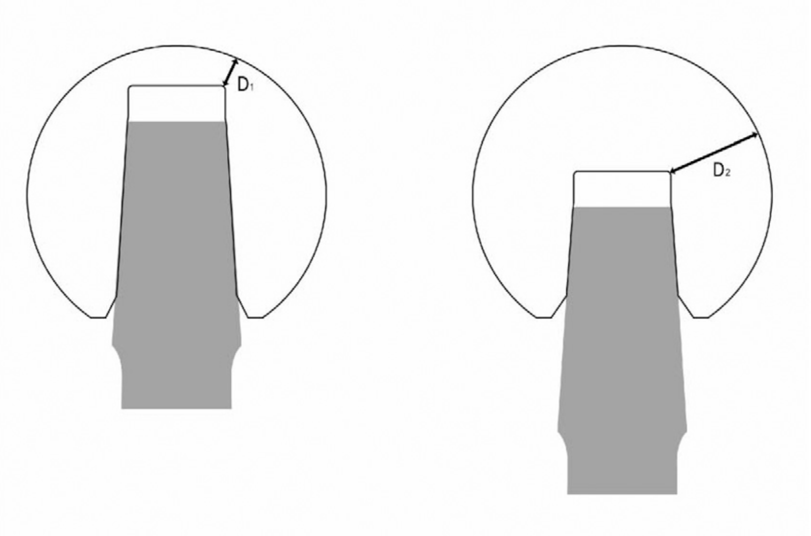

Fig. 4
Head bore is a tapered hole in the modular femoral head, which is inserted onto the Morse taper of the femoral stem. When using a short-neck taper (left image), the contact area between the bore of ceramic head and the trunion of the femoral stem is located high, nearest to the dome. The distance between the bore corner and the outer surface (D_1) is 2.4 mm. When using a medium-neck or long-neck ceramic head (right image), the contact area is located lower. The distance between the bore corner and the outer surface (D_2) is 3.9 mm for the medium-neck taper and 6.3 mm for the long-neck taper.

ponents remains a problem. Most reported fractures associated with contemporary third-generation ceramic material have been chip fractures of the ceramic liner[13,14] or fractures of the ceramic liner after the use of sandwich-type acetabular component[5,6].

We are aware of only three ceramic hip fractures that have been reported after total hip arthroplasty with use of third-generation ceramic-on-ceramic components. One was a traumatic fracture that occurred following a motor-vehicle accident[15], and the other two occurred in association with sandwich-type ceramic liner fractures[6].

We can only speculate about the cause or causes of the alumina ceramic head fractures in our series. Possible causative factors include component design; the material properties of the ceramic components; and manufacturing defects, including cone-trunion mismatch and ceramic material deterioration[16-19]. The ceramic head contact area with the trunion taper is an important aspect of component design, and the modularity of different neck lengths presents an important variable to the head-trunion interface.

In the present study, all five ceramic fractures occurred during normal daily activities in patients who had received a 28-mm short-neck ceramic head. The fracture involved the thinnest circumferential portion of the head adjacent to the proximal edge of the head bore, with several vertical cracks extending from the circular crack to the lower edge of the head component. The fracture pattern suggests that the mechanism of ceramic head fracture was a brittle fracture. A brittle fracture is characterized by rapid crack propagation with low energy release and without substantial plastic deformation.

Our findings agree with those of Callaway et al., who reported a fracture rate of 2.2% (four of 184) in association with the use of a second-generation alumina head-on-polyethylene liner articulation[16]. The fractures occurred five to nine months after surgery, during normal daily activities, and the neck length was short in all instances.

In contrast, Masonis et al. reported on fractures of modular zirconia ceramic heads that had been used in association with long necks[18]. The authors hypothesized that, with longer neck designs, the contact area and hoop stresses occur lower in the bore, thereby raising the tensile stress at the superior rim of the bore and potentially increasing the risk of head fracture.

The point of highest tensile hoop stress during impaction in the ceramic head is located at the superior corner of the bore[18]. The stress at the taper-bore interface is decreased with a short-neck femoral head. However, the distance between the corner of the bore and the surface of the head is shortest for short-neck femoral components (2.4 mm), larger for medium-neck components (3.9 mm), and greatest for long-neck components (6.3 mm) (Fig. 4).

In our study, dark metallic-like smears were visible on the articular surfaces and the lips of the retrieved ceramic liners, and the trunions of the retrieved femoral stems were damaged with multiple scratches. Previous studies of retrieved ceramic femoral heads have demonstrated that metal was transferred to the ceramic head when the head was scratched on the metal shell during femoral head reduction or dislocation of the total hip replacement. Transferred metal appeared as dark smears on the surface of the ceramic liner[20-22]. We believe that the dark metallic-appearing smears on the surface of the ceramic liners in our patients were caused by contact of the ceramic liner with the trunion of the femoral stem after ceramic head fracture. The trunion was probably scratched by the sharp edges of the ceramic fracture fragments.

The present study had several limitations. The findings of our study are exploratory as they are based on descriptive data. The cup anteversion in the five hips in which a fracture occurred was greater than that in group of hips in which a fracture did not occur. The difference was not significant, but the calculated statistical power was not sufficient to differentiate two groups because of the small number of hips in the fracture group. Theoretically, a minimum sample size required to achieve a power of 0.80 is 208 (200 for the group without a fracture and eight for the group with a fracture) with the p value set at 0.05. In the present study, the primary diagnosis was femoral head osteonecrosis (264 hips; 73.5%). The mean age of our patients was 49.9 years, and four of the five patients in whom a fracture occurred were less than sixty-five years old. Thus, our subjects were younger and presumably were more active than typical recipients of total hip replacements in Western countries. In addition, we did not evaluate the physical activity of our patients, which may have had an effect on the development of ceramic head fracture.

Technically, several options could be considered for revision of a fractured ceramic head and trunion-damaged stem: revision of the stem and head, insertion of a new ceramic head on the retained stem, or replacement with a metallic head and polyethylene liner without changing the stem. In one of our patients (Case 1), we did not change the trunion-damaged stem because it was well-fixed and we would have risked fracture of the proximal part of the femur during removal of the stem. We implanted a new ceramic head on the damaged taper, and the new ceramic head fractured shortly after the revision procedure. Currently, we do not recommend retention of a damaged trunion if a ceramic head has to be used. In subsequent revisions, we replaced the articulating components with a metal head and polyethylene liner and did not revise the stem. Even though our five patients who underwent revision surgery with a metallic head and retention of the stem were doing well at the time of the latest follow-up, we cannot conclude at this time that this is a satisfactory technique. A longer follow-up study of a large number of patients must be conducted to determine the best treatment guidelines for revising hips with a ceramic head fracture.

An important question is to what extent our findings related to this specific design are generally applicable to other alumina-on-alumina articulations. Since 1994, CeramTec AG has supplied 28-mm BIOLOX forte femoral heads and acetabular inserts to many manufacturers of total hip implants in Europe and the United States, including Aesculap, Zimmer, DePuy, and Stryker. Acetabular metal shells and femoral stems from these manufacturers have been used in combination with the ceramic heads and ceramic liners from CeramTec AG. The geometries of other BIOLOX forte ceramic heads that are currently in use are similar to the geometry of ceramic heads used in the present study. Thus, other 28-mm short-neck BIOLOX forte heads also might be at risk of fracture.

Our findings suggest that patients should be informed thoroughly about the potential risk of the component fracture before total hip arthroplasty with use of alumina-on-alumina articulation.

Appendix

eA Tables showing a comparison between these short-neck heads with and without fracture and showing the result of the multivariate analysis with use of Cox proportional hazards model are available with the electronic versions of this article, on our web site at jbjs.org (go to the article citation and click on "Supplementary Material") and on our quarterly CD-ROM (call our subscription department, at 781-449-9780, to order the CD-ROM). ■

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