Poor outcome of 44 cemented total hip arthroplasties with alumina ceramic heads

Clinical evaluation and retrieval analysis after 10–16 years

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Submitted 00-10-20. Accepted 01-02-28

ABSTRACT – We evaluated the long-term results of cemented total hip arthroplasty with alumina ceramic heads in 39 patients (44 hips) from 1981 to 1985. The study comprised 8 men (8 hips) and 31 women (36 hips). Their mean age was 54 (37–76) years and mean weight 52 (34–93) kg. The preoperative diagnoses were osteoarthrosis in 34 patients (38 hips), rheumatoid arthritis in 3 (4 hips) and idiopathic osteonecrosis of the femoral head in 2 (2 hips). The mean duration of follow-up was 13 (10–16) years. At this time, 6 cases had been revised because of aseptic loosening (5 hips showed loosening of both components and 1 acetabular loosening alone). Kaplan-Meier survivorship analysis with radiographic loosening as end-point showed 10-year survival rates of 75% for the acetabular component and 86% for the femoral. The mean linear wear rate of polyethylene was 0.10 mm/year radiographically—i.e., about the same as reported for many metal to polyethylene bearings. 5 alumina ceramic heads were retrieved and showed excellent surface roughness and roundness without scratches. However, debris stuck to the gaps was detected. The debris may act as third-bodies and affect polyethylene wear.

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Ultra-high molecular-weight polyethylene (UHMWPE) wear debris is a known cause of osteolysis and loosening in total hip arthroplasty (THA). Femoral heads with improved surface characteristics were introduced to reduce the wear. Alumina ceramics has excellent geometric form, wettable surface, and enhances hardness, which therefore maintains lubrication, and increases resistance to third-body wear.

In 1981, we began using a Bioceram prosthesis (Kyocera, Kyoto, Japan) with a bearing mechanism consisting of an UHMWPE acetabular component and an alumina ceramic femoral head. The quality of the alumina ceramics used from 1981 to 1987 was far from perfect. It contained 7% of yttrium for radioopacity, and the average grain size was 5.6 μm. The average surface roughness was 0.04 μm, and the maximum surface roughness 0.2 μm. In this study, we evaluated long-term clinical results of THA with a Bioceram prosthesis and analyzed retrieved heads. The hypotheses were that the surfaces of alumina ceramic heads would remain intact for more than 10 years and the surface characteristics could help to reduce UHMWPE wear.

Patients and methods

Patients

From December 1981 to June 1985, the senior author (TO) performed 55 primary THAs in 47 patients, using cemented Bioceram prostheses (Kyocera, Kyoto, Japan). 5 patients (7 hips) died before this review, 1 (2 hips) was lost to follow-up, and 2 (2 hips) were bedridden from causes unrelated to hip surgery. All 55 hips were considered for the survival analyses. The remaining 44 hips in 39 patients were reviewed after more than 10 years. The study comprised 8 men (8 hips) and 31

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women (36 hips) having a mean age of 54 (37–76) years and mean weight of 52 (34–93) kg. The preoperative diagnoses were osteoarthrosis (OA) in 34 patients (38 hips), rheumatoid arthritis (RA) in 3 (4 hips) and idiopathic osteonecrosis of the femoral head in 2 (2 hips). The mean duration of follow-up was 13 (10–16) years.

Prosthesis and surgical procedure

A Bioceram Type-5 prosthesis (Kyocera, Kyoto, Japan) consists of a femoral component made of stainless steel containing 20% cobalt and 0.01% phosphorus (COP alloy) with an alumina ceramic head and an acetabular component of UHMWPE. The femoral components had a collar and a tapered neck with a cone angle of 5.7°. In the operating room, the alumina ceramic head, 28 mm in diameter, was fixed in the tapered neck of the femoral component. The UHMWPE sockets were machined from bar stocks and sterilized with ethylene oxide. We used a lateral approach with trochanteric osteotomy and the Bioceram type-5 prosthesis (Kyocera, Kyoto, Japan) with Simplex P cement (Howmedica, Rutherford, NJ). Both components were inserted with cement, which was finger-packed and not vacuum-mixed or centrifuged. We used a medullary plug in 27 hips, structural bone graft from the resected femoral head in 5 hips, to augment the lateral acetabular margin, and in 13 hips, the gap was filled with cement.

Clinical and radiographic evaluations

Clinical results were assessed with Merle d'Aubigné and Postel's method as modified by Charnley (1972). Radiographic loosening of the acetabular component was evaluated by Hodgkinson et al.'s method (1988). Cases classified as type 3 (complete demarcation) and type 4 (migration and change in position) were considered to be loose. Radiographic loosening of the femoral component was defined by the method of Harris et al. (1982). Definite loosening and probable loosening were viewed as loose. Osteolysis was defined using the method of Mulroy and Harris (1990). Only well-demarcated lytic lesions that were not linear and were more than 2 mm in width were considered. For measurement of linear wear, we used Livermore et al.'s method (1990), including a correction for magnification. All radiographic measurements were made by a single person (MH). Each radiograph was measured three times using a manual caliper. The maximum variation was 0.1 mm.

Statistics

The clinical score was analyzed using Wilcoxon's signed rank test. Kaplan-Meier survivorship curves for the entire population of 55 hips were generated, with radiographic loosening of each component of the hip prosthesis and revision of each component because of aseptic loosening as end-points. Cox regression analysis was done to determine any association between radiographic loosening of the acetabular and femoral component based separately on patient-related, technical and implant-related factors. The patient-related factors for both the acetabular and femoral components included age, gender, weight, and diagnosis. The technical and implant-related factors for the acetabular component included cup-abduction angle, acetabular deficiency filled with bone or cement, UHMWPE thickness, and linear wear rate of UHMWPE. Those for the femoral component included the use of a medullary plug and a linear wear rate of UHMWPE. A p-value of less than 0.05 was considered significant.

Retrieval study

5 pairs of retrieved alumina ceramic heads and UHMWPE sockets were studied. All of them were retrieved at revision surgery because of aseptic loosening after a mean 13 (11–15) years. UHMWPE wear was measured by a shadowgraph technique described by Kabo et al. (1993). The bearing surfaces of the alumina ceramic heads and UHMWPE sockets were evaluated with a scanning electron microscope (JSM-5410LV, JEOL Ltd., Tokyo, Japan). Debris stuck to the bearing surfaces of alumina ceramic heads and UHMWPE sockets was analyzed by energy dispersive analysis of radiographs (EDAX-98001, Edax Japan K. K., Tokyo, Japan). The mean surface roughness value of the bearing surfaces at the equatorial plane was measured with a stylus apparatus (S-405, Kosaka Laboratory Ltd., Tokyo, Japan). The roundness of the alumina ceramic heads at the equatorial plane was measured with a three-dimensional coordinate measuring apparatus (BHN305, Mitutoyo Corp., Tokyo, Japan).

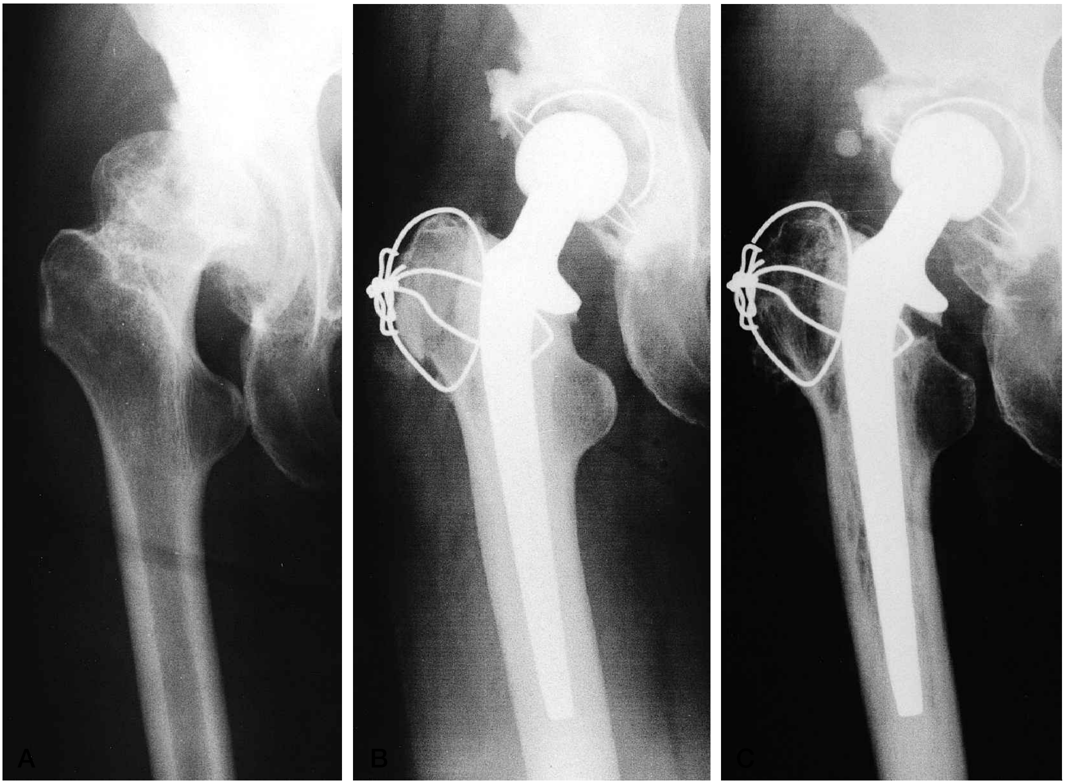

Figure 1. A 52-year-old woman with hip arthrosis. (A) before surgery, (B) 3 weeks after surgery and (C) 15 years after surgery, showing loosening of the acetabular and femoral components.

Results

Clinical results

At the latest follow-up, the mean scores for pain, movement, and walking improved from 2.8, 2.9 and 2.7 preoperatively to 5.7, 4.9 and 5.2, respectively ($p < 0.001$). We found no breakage of alumina ceramic heads, infections, nerve palsies, or dislocations.

Radiographic results

Radiographic evidence of loosening occurred in 18 acetabular and 11 femoral components. In 18 hips with acetabular loosening, 17 hips were type 4 and one type 3, according to the criteria of Hodgkinson et al. (1988). In 11 hips with femoral loosening, 9 hips showed definite loosening and 2 probable loosening (Harris et al. 1982). 6 hips had both the acetabular and femoral components revised for aseptic loosening (5 hips showed loosening of both components and one had isolated acetabular loosening) (Figure 1). All grafts united and only 1 hip loosened after 12 years. 7 of the 13 hips filled with cement at the lateral acetabular margin loosened. Femoral osteolysis occurred in 4 hips and no acetabular osteolysis was detected. We found no significant relation between radiographic loosening of the acetabular component and the patient-related or technical and implant-related factors, such as cup-abduction angle, acetabular deficiency filled with bone or cement, and UHMWPE thickness (Table 1). We found no difference between radiographic loosening of the femoral component and the patient-related factors, such as age ($p = 0.7$), gender ($p = 0.9$), weight ($p = 0.7$), and diagnosis ($p = 0.8$) as well as the use of a medullary plug ($p = 0.4$). On the other hand, grater wear was seen in loose cups ($p = 0.004$) and loose stems ($p = 0.0002$). Radiographically, the mean linear wear rate of UHMWPE was 0.10 mm/year. When the end-point was radiographic loosening, the 10-year survival rates were 75% for the acetabular component and 86% for the femoral component (Figure 2). When the end-point was revision because of

Table 1. Correlation between radiographic loosening of the acetabular component and demographic data

	With loosening n 18	Without loosening n 26	P-value
Age years, mean (SD)	53 (9.4)	54 (10)	0.6
Gender			
Female	15	21	0.6
Male	3	5	
Weight, kg, mean (SD)	53 (9.3)	52 (13)	0.8
Diagnosis			
Osteoarthrosis	17	21	
Rheumatoid arthritis	1	3	0.5
Idiopathic osteonecrosis	0	2	
Cup abduction angle degrees, mean (SD)	45 (6.1)	47 (7.3)	0.8
Acetabular deficiency			
Filled with bone	1	4	0.7
Filled with cement	7	6	
UHMWPE thickness, mm, mean (SD)	7.8 (0.7)	7.4 (1.2)	0.9
Linear wear rate, mm/year, mean (SD)	0.13 (0.10)	0.07 (0.06)	0.004

aspectic loosening, the 10-year survival rates were 100% of both the acetabular and femoral components (Figure 3, Table 2).

Retrieved materials

The mean linear wear rate measured directly in the 5 retrieved sockets was 0.22 mm/year, and similar to the radiographic wear rate (mean 0.21 mm/year). The mean surface roughness of the bearing surfaces at the equatorial plane was 0.04 µm and the mean roundness of the bearing surfaces at the equatorial plane was 0.44 µm—i.e., similar to the values seen in new heads (0.04 µm and 0.17 µm, respectively) (Table 3). None of the alumina ceramic heads had macroscopic damage. The scanning electron microscopic study of the alumina ceramic heads showed smooth surfaces without scratches. However, some gaps were detected on the surfaces. The gaps were a little larger than those in the new head; furthermore, debris had stuck to the gaps (Figure 4). Energy-dispersive analysis of radiographs of debris showed the peaks for copper, sulfur, calcium, and potassium. Some scratches were detected on the bearing surfaces of the UHMWPE sockets. Debris also stuck to the surface of the UHMWPE. Energy-dispersive analysis of radiographs of debris showed the peaks for sulfur, calcium, potassium, chlorine, and silicon.

Discussion

UHMWPE wear is one of the important factors

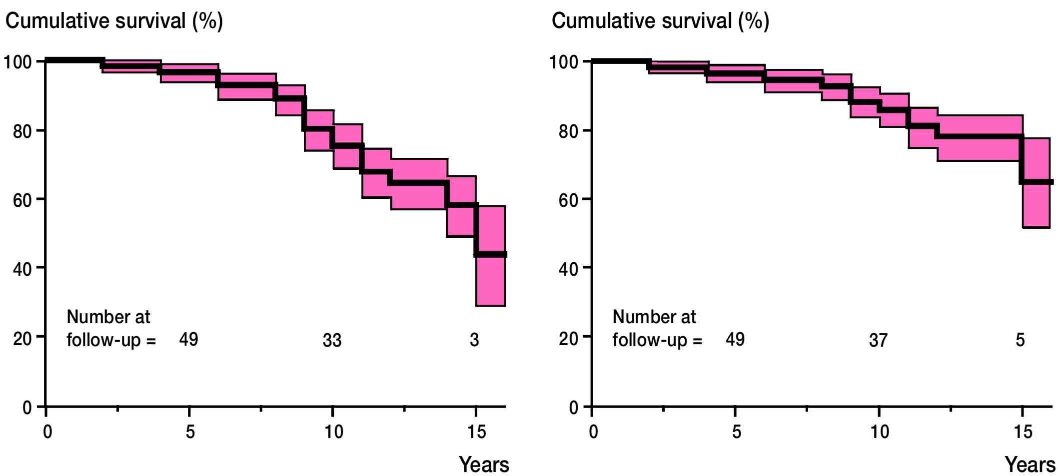

Figure 2. Kaplan-Meier survivorship curves with radiographic loosening as the end-point (left) for the acetabular component and (right) femoral components. The colored area indicates the 95% confidence intervals.

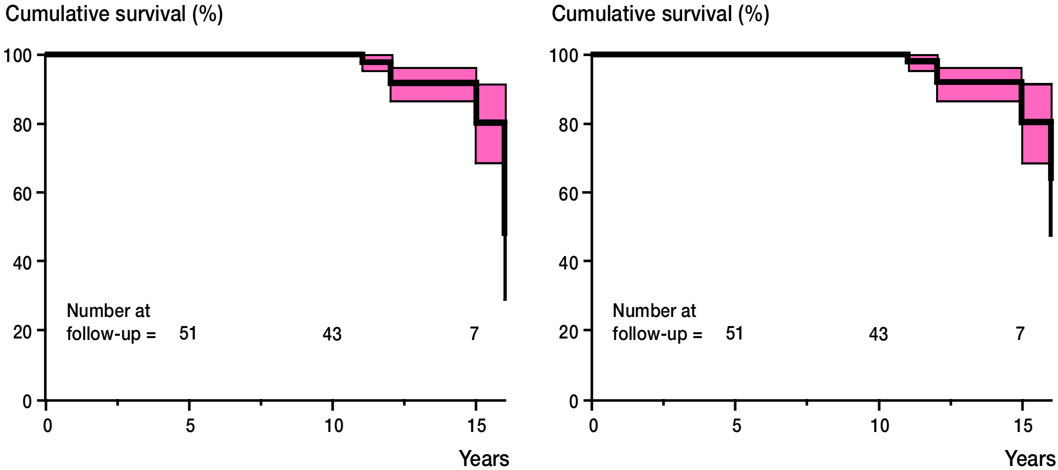

Figure 3. Kaplan-Meier survivorship curves with revision (left) of the acetabular component because of acetabular loosening as the end-point and (right) of the femoral component because of the femoral loosening as the end-point. The colored area indicates the 95% confidence intervals.

Table 2. Survivorship according to Kaplan-Meier with radiographic loosening of the acetabular or femoral component and revision as end points

End-point, years	Survival rate (%)	95% confidence intervals (%)	Number at risk
Loosening			
Acetabular component			
5	96	94–99	49
10	75	69–81	33
15	43	29–58	3
Femoral component			
5	96	94–99	49
10	86	81–91	37
15	65	52–78	5
Revision			
Acetabular component			
5	100		51
10	100		43
15	80	69–92	7
Femoral component			
5	100		51
10	100		43
15	80	69–92	7

influencing component loosening. The surface characteristics of the femoral head play an important role in generating UHMWPE wear debris after THA (Cuckler et al. 1995). Laboratory tests in a hip simulator showed that the UHMWPE wear rate against alumina ceramic heads was less than that against metal heads (Saikko et al. 1993). In previous studies, radiographically, alumina ceramic heads articulating against UHMWPE have shown wear rates equivalent to or less than metal to polyethylene bearings. Sychterz et al. (1997) compared alumina ceramic heads to metal heads against UHMWPE and found an insignificant reduction in wear. Other authors have found that the wear decreased with alumina ceramics (Schüller and Marti 1990, Zichner and Willert 1992, Wroblewski et al. 1999, Oonishi et al. 2000). Furthermore, wear rates were reduced by use of highly cross-linked polyethylene (Wroblewski et al. 1999, Oonishi et al. 2000). In the present study, the mean UHMWPE linear wear rate, measured on radiographs, was 0.10 mm/year. The rate was similar to that reported by Sugano et al. (1995), who used the same prostheses as we did. However, these rates were somewhat higher than the 0.08 mm/year reported for a Trapezoidal-28 prosthesis with a metal head (Livermore et al. 1990) (Table 4). Laboratory tests can not accurately reproduce the complex environment in vivo. Joint replacement components in situ are exposed to more third-body debris than the components used in well-controlled laboratory simulations. Minakawa et al. (1998) showed that alumina

Table 3. Comparison between the linear wear rate as determined by radiographic and direct measurements, roughness and roundness values of retrieved and unused alumina ceramic heads

Case	Time in vivo (years)	Radiographic measurement (mm/year)	Direct measurement (mm/year)	Surface roughness (μm)	Roundness (μm)
1	10.7	0.08	0.08	0.04	0.21
2	11.3	0.09	0.08	0.04	0.42
3	10.9	0.18	0.13	0.04	0.63
4	14.1	0.28	0.36	0.04	0.31
5	15.3	0.16	0.18	0.04	0.38
unused head				0.04	0.17

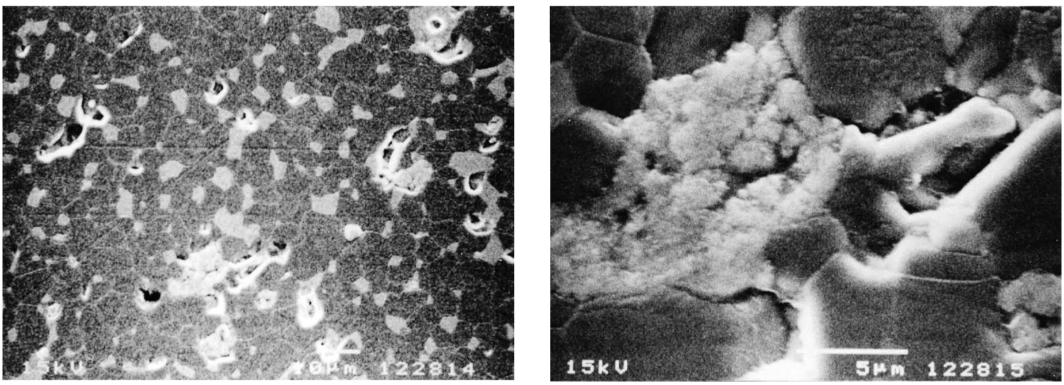

Figure 4. Scanning electron micrograph of a surface of an alumina ceramic head after 15 years in situ (left) showing a smooth surface. The white area contains yttrium. Higher magnification (right) shows debris stuck to the gap.

Table 4. Linear wear rates of alumina-on-polyethylene and metal-on-polyethylene

Study	Diameter of head (mm)	Linear wear rate with alumina (mm/year)	Linear wear rate with metal (mm/year)	Material of metal
Schüller and Marti (1990)	32	0.03	0.10	cobalt chrome
Livermore et al. (1990)	28		0.08	stainless steel
Zichner and Willert (1992)	32	0.10	0.20	cobalt chrome
Sugano et al. (1995)	28	0.10		
Sychterz et al. (1997)	32	0.16	0.17	cobalt chrome
Wroblewski et al. (1999)	22	0.04 [a]	0.16	stainless steel
Oonishi et al. (2000)	28	0.10	0.25	stainless steel
	28	0.05 [a]		
present study	28	0.10		

[a] highly cross-linked polyethylene was used.

ceramics was more resistant to simulated third-body damage than metal in laboratory studies. The scratches on damaged heads dramatically increase the polyethylene wear. Some authors reported that retrieved metal heads had more surface damage and rougher surfaces than did retrieved alumina ceramic heads (Jasty et al. 1997, Sychterz et al. 1999). In our retrieval study, the mean surface roughness of the bearing surfaces at the equatorial plane was 0.04 μm, the same value as with new heads. Scanning electron microscopic analysis showed no scratches on any of the heads. However, debris stuck to the gaps on the bearing surfaces of the heads. The elements detected by energy dispersive analysis of radiographs exist in the living body, and these elements may be derived from joint fluid. These particles may affect polyethylene wear as third-body wear. The large gaps on the surface of the head to which debris stuck must be reduced in size. Such gaps were seen between the grains of alumina ceramics.

Reductions in grain size might be useful in reducing large gaps. Since 1987, considerable changes have been made in the material and geometry of the alumina ceramic component (Kyocera, Kyoto, Japan). The average grain size has been reduced from 5.6 µm to 1.4 µm. The average surface roughness has been reduced from 0.04 µm to 0.01 µm, and maximum surface roughness from 0.2 µm to 0.06 µm. The new alumina ceramic heads are 22, 26, and 28 mm in diameter. These improvements may reduce UHMWPE wear. However, the problem of third-body wear remains, despite improvements in the qualities of UHMWPE and the femoral head.

Alumina ceramics entail the risk of breakage. Fracture of alumina ceramic heads in the early postoperative period has been reported (Griss and Heimke 1981, Hølmer and Nielsen 1993). In our study, we found no fractures and no debris from the alumina ceramics. Fractures may be initiated by small foreign bodies, such as cement or bone, which will prevent proper placement of the ball, and induce local stress concentration.

Zirconium oxide ceramics have been introduced as femoral heads to prevent femoral head fractures observed with alumina ceramics. The ability of zirconium oxide ceramics to withstand fractures is at least twice that of alumina ceramics. Like alumina ceramics, it has high biocompatibility and high resistance to scratching. However, this material entails problems with radioactivity and stability, which have been studied in detail. Aging of zirconium oxide ceramics induces a transformation of the tetragonal phase into monoclinic phase with an associated reduction in its ability to withstand a fracture (Piconi and Maccauro 1999, Cales 2000). An yttria-stabilized tetragonal zirconia (Y-ZTP) with a grain size smaller than 0.5 µm is used today for bearing-surfaces. Blaise et al. (2000) showed that the phase transformation did not affect the mechanical- and wear-performance of zirconia femoral heads. UHMWPE wear against zirconia and alumina ceramics were similar in laboratory tests (Piconi and Maccauro 1999). The clinical results of wear behavior of zirconia-on-polyethylene have aroused increasing interest.

In conclusion, retrieved alumina ceramic heads had no scratches and the hypothesis that their surfaces would not be damaged for more than 10 years was borne out. However, some gaps were detected on the surfaces with debris, which might act as third bodies and affect polyethylene wear. Using early-generation alumina ceramic heads, the linear wear rate of 0.10 mm/year was similar to that expected if a metal-on-polyethylene articulation had been used, despite third-body wear. The characteristic of a high resistance to third-body damage of alumina ceramic heads was not entirely responsible for the reduction in UHMWPE wear in vivo. More recently, we have used improved alumina ceramic heads or zirconia ceramic heads with cross-linked polyethylene. Further evaluation is needed to determine whether these new materials can substantially reduce wear.

No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subjects of this article.

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