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Two- to 9-Year Clinical Results of Alumina Ceramic-on-Ceramic THA

Stephen B. Murphy, MD; Timo M. Ecker, MD; and Moritz Tannast, MD

From June 1997 to June 2003 we performed 194 total hip arthroplasties on 173 patients using alumina ceramic-on-ceramic bearings as part of a prospective United States Food and Drug Administration/Investigational Device Exemption study. The average patient age at surgery was 49.9 years. Minimum followup time was 2 years (mean 4.3 years, range 2–9 years). We evaluated survival rate, implant- and non-implant–related complications. Clinical outcomes included the Merle d'Aubigné score. We assessed radiographs for signs of osteolysis, component loosening, and implant wear. No patients had osteolysis and there were no hip dislocations. Implant survivorship for all hips with aseptic revision of any component was 96% (CI, 91–100) at 9 year; survivorship for hips without prior surgery was 99.3%, (CI, 98–100). There was a 1.7% incidence of implant-related complications. Our data help confirm two United States FDA/IDE studies on alumina ceramic-on-ceramic total hip arthroplasty that reported low aseptic revision rates and low revision rates for instability. Total hip arthroplasty using alumina ceramic-on-ceramic implants is a safe and reliable procedure in the comparably young and active patient.

Level of Evidence: Level IV, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

Traditional total hip arthroplasty (THA) using metal-on-polyethylene bearings has been established as a reliable procedure.[6] However, wear and wear debris-associated osteolysis are still among the most common complications affecting these devices. Several alternative bearings have been used clinically to reduce wear and osteolysis.[39] The alternatives include cross-linked polyethylene acetabular liners, metal-on-metal bearings, and alumina ceramic-on-ceramic bearings. Although metal-on-cross-linked polyethylene is most commonly used, these bearings have the shortest clinical experience of the available alternative bearings.[10]

Generally, good results with these improved polyethylene implants have been reported by several authors,[10,27,33] especially compared to the older-generation conventional polyethylene bearings. However, theoretical concerns include a relatively poor resistance to scratching and third-body wear compared with hard bearings. Cross-linked polyethylene bearings may be more susceptible to fracture and dissociation as compared to conventional polyethylene because of their low resistance to crack propogation.[16] Whether these material factors will substantially affect long-term clinical outcomes remains to be seen.

Metal-on-metal bearings have demonstrated substantially improved wear characteristics as compared to metal-on-conventional polyethylene bearings. Long-term clinical studies also suggest these bearings represent a promising alternative method of achieving improved THA longevity.[3,8] Yet, theoretical concerns about wear from these bearings remain because wear debris produces an inflammatory response of the surrounding tissue.[38] Some authors have suggested this response may lead to component loosening or implant-induced osteolysis.[12,22,32] In addition, the significance of elevated serum metal ion concentrations remains unknown.[18,24,34,36] Nonetheless, it is not clear these concerns have had a substantial impact on clinical outcome.

Alumina ceramic-on-ceramic bearings represent another alternative for total hip arthroplasty and have been clinically used for more than 20 years. Interest in alumina ceramic-on-ceramic bearings is largely due to good wear characteristics and relatively low biological reactivity of the wear particles. For example, retrievals have shown linear wear rates 4000-fold less than metal-on-conventional polyethylene bearings of the same era,[11] and

From the Center for Computer Assisted and Reconstructive Surgery, New England Baptist Hospital, Tufts University School of Medicine, Boston, MA.
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Correspondence to: Stephen B. Murphy, MD, Center for Computer Assisted and Reconstructive Surgery, Tufts University School of Medicine, 125 Parker Hill Avenue, Suite 545, Boston, MA 02120. Phone: 617-232-3040; Fax: 617-754-6436; E-mail: tecker@caregroup.harvard.edu.
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have consistently shown low wear rates in clinical and laboratory studies.[4,5,15,28,30] In addition, the biological reactivity of alumina ceramic wear debris seems less than for polyethylene debris[14] and the corrosion level and ion release lower than for metal-on-metal bearings.[35] Yet, early clinical experience using ceramic-on-ceramic bearings demonstrated problems with bearing fracture, impingement, and difficulty with cup fixation of cemented acetabular components.[23,25,40] More recent clinical studies have had the benefit of improved ceramic strength and quality control, and improved fixation of the acetabulum, which has resulted in dramatic improvement in intermediate and long-term results.[7,29,30,41] Further, the absence osteolysis in uncemented alumina ceramic-on-ceramic THA at minimum 18.5-year followup in a study by Hamadouche et al[14] raises the possibility periprosthetic osteolysis may be greatly reduced by the use of these bearings.

We assessed the clinical and radiographic results of patients treated by alumina ceramic-on-ceramic total hip arthroplasty at 2- to 9-year followup, investigating implant related failure, complication rate, clinical outcome, and occurrence of bearing wear and wear-associated osteolysis.

MATERIALS AND METHODS

We prospectively evaluated 194 hips in 173 patients who underwent total hip arthroplasty using alumina ceramic-on-ceramic bearings from June 1997 to June 2003. The acetabular component was a press-fit, porous-coated titanium shell (TRANSCEND® cup, Wright Medical Technology, Arlington, TN) combined with an alumina ceramic liner (Biolox Forte XLW® bearing, Ceramtec AG, Plochingen, Germany). The alumina ceramic acetabular bearing was fixed into the metal shell using an 18° taper (Fig 1). All patients were treated by the same surgeon (SBM). Patients operated on before February 3, 2003 also were part of a prospective, multicenter United States Food and Drug Administration/Investigational Device Exemption (FDA/IDE) study. We clinically and radiographically evaluated 155 (174 hips) of the 173 patients (194 hips) eligible for minimum 2-year followup (Table 1). Of the other 18 patients, two patients died and 16 were lost to followup. Of the 16 lost to followup, nine were functioning well and had an excellent Merle d'Aubigné scores before the 2-year followup. Patients who had a minimum followup of 2 years had a mean followup of 4.3 ± 1.6 years (range, 2–9 years). Ninety hip arthroplasties (51.7%) were performed in men and 84 (48.2%) were in women.

The surgical approach was a modified direct lateral approach in 149 hips, a two-incision (superior capsulotomy and Watson-Jones) approach in 21 hips, a trochanteric slide approach in three, and a vastus slide approach in one hip (Table 2). The mean age at surgery was 49.9 ± 12.7 years (range, 18–76 years). One hundred thirty-five surgeries (77.6%) were performed in patients 60 years or younger at the time of surgery. There were 85 (48.9%) left hips and 89 (51.1%) right hips. Nineteen patients (12.3%) had bilateral surgery. Preoperative diagnoses included

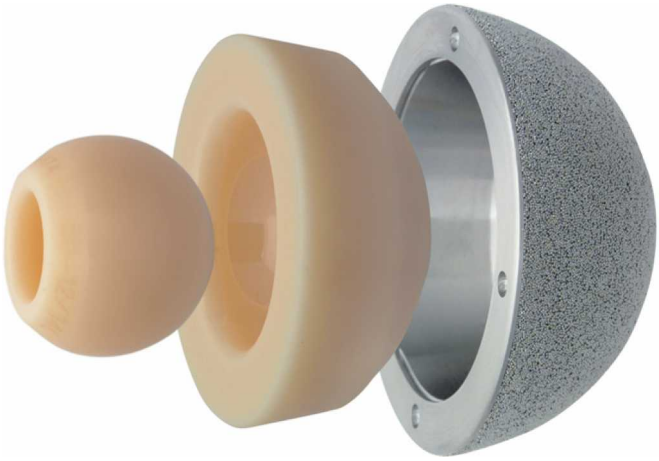

Fig 1. The alumina-on-alumina bearing is shown (Wright Medical Technology, Memphis, TN; Ceramtec AG, Plochingen, Germany).

osteoarthritis (OA) in 118 hips (67.8%), developmental dysplasia of the hip (DDH) in 36 hips (20.7%), osteonecrosis (ON) in 10 hips (5.8%), posttraumatic arthritis in seven hips (4%), rheumatoid arthritis (RA) in one hip (0.57%), slipped capital femoral epiphysis (SCFE) in one hip (0.57%), and Legg-Calvé-Perthes disease in one hip (0.57%). Sixteen patients (19 hips, 10.9%) had previous surgery including eight pelvic osteotomies, nine femoral osteotomies, one shelf procedure, and one surgical dislocation. The mean preoperative Merle d'Aubigné score was 11.1 ± 1.8 points (range, 5–15 points) (Table 3).

Patients were clinically and radiographically examined preoperatively, at two postoperative visits (0–9 weeks and 9–24 weeks, respectively), and annually thereafter. The patients completed a questionnaire rating all non-examination–related parameters including pain severity and location, walking distance, use of support, chair rising, stair climbing, and ability to put on socks and shoes. The operating surgeon (SBM) assessed limp and range of motion (ROM). Radiographs included an anteroposterior (AP) pelvis and AP false-profile and frog lateral views of the affected hip (Fig 2). The radiographs were screened for any sign of osteolysis or loosening by one examiner (TME) according to the recommendations of DeLee and Charnley[9] for the acetabular implant and Gruen et al[19] for the femoral component. Hip function was measured using the Merle d'Aubigné score.[28] We evaluated implant failure, complications, and revision rates. Implant failures were calculated for the entire construct and for each individual component. The complications and revisions were divided into implant-related and technique-related revisions and into non-implant–related and non-technique–related revisions.

We analyzed survivorship of the entire construct and for the single components using Kaplan–Meier survival analysis with implant failure as the endpoint.

RESULTS

Overall survival after 9-year followup (mean 4.3 years) was 96% (CI, 91–100) (Fig 3). Survival in patients without

TABLE 1. Operative and Followup Data of the 174 Hips (155 patients) in the Study Group

Parameter	Study Group (n = 174)
Cup abduction (degrees)	41.4 ± 4 (range, 26–54)
Abduction outliers (< 30° and > 50°)	5 (2.9%)
Merle d'Aubigné score (preoperative)	11.1 ± 1.8 (range, 5–15)
Merle d'Aubigné score (first followup)	13.1 ± 2 (range, 8–18)
Merle d'Aubigné score (second followup)	16.5 ± 1.5 (range, 10–18)
Merle d'Aubigné score (third followup)	17.6 ± 0.7 (range, 15–18)
Complications	13 (7.4%)
Kaplan–Meier survival in patients without previous surgery	99.3% (CI, 98–100)
Stem	99.5% (CI, 98.5–100)
Cup	99.5% (CI, 98.4–100)
Bearing	97.1% (CI, 92.3–100)
All components	96% (CI, 91–100)
Implant-related complications	3 (1.7%)
Failed osseointegration of cup	1
Bearing fracture	1
Malseated liner	1
Non-implant–related complications	10
Trochanteric wafer non-reunion	5
Intraoperative femoral fracture	2
Postoperative greater trochanteric fracture	1
Irrigation and débridement for infection	1
Irrigation and débridement for suspected infection without infection in situ	1

previous surgery was 99.3%, (CI, 98–100). At 9 years, stem survival was 99.5% (CI, 98.5–100), acetabular component survival was 99.5% (CI, 98.4–100), and bearing survival was 97.1% (CI, 92.3–100). There were three (1.7%) implant-related complications in the 174 hips of the study group. One cup failed to osseointegrate. One liner was malseated during the index operation, which led to immediate reoperation to properly seat an acetabular liner. The third implant-related complication was a liner fracture which occurred in a multiply operated patient with a trochanteric nonunion. After analysis of the radiographic images using the DeLee and Gruen recommendations, no patient had signs of osteolysis on plain radiographs. The mean cup abduction measured on plain AP pelvis radiographs was 41.4° ± 4° (range, 26°–54°).

Repeat surgery other than revision for implant failure included ORIF of a postoperative greater trochanteric fracture and ORIF of two trochanteric nonunions. Two patients underwent acute irrigation and débridement with incidental bearing exchange for suspected infection. One had an acute infection, and the other did not. There were no hip dislocations. Two patients sustained femoral cracks during implantation and were treated by cerclage (Table 1).

Addressing our secondary research question, we evaluated the patients clinically at each followup visit using the Merle d'Aubigné score for quantification of their hip function (Fig 4). There was an improvement ($p < 0.05$) in the Merle d'Aubigné score, from 11.1 ± 1.8 points preoperatively (range, 5–15 points) to 17.6 ± 0.7 points (range, 15–18 points) at the most recent followup (Fig 4).

DISCUSSION

Our study demonstrates THA using alumina ceramic-on-ceramic implants can be reliable in a generally young and active patient population at short and intermediate followup. The absence of osteolysis and aseptic loosening in this patient population at a mean followup time of 4.3 years and a maximum followup time of 9 years is promising because osteolysis subsequent to implant wear is one of the most common causes of THA failure.

We also note several limitations in our study design. Comparison to at least one other study group using, for example, metal on polyethylene or metal on metal bearings, would have strengthened the report. Another concern is the 18 patients lost to followup. Following the recommendations of Murray et al,[31] a worst case Kaplan-Meier

TABLE 2. Surgical Approach and Implant Sizes of the 174 hips (155 patients) in the Study Group

Parameter	Number of Hips in Study Group
Surgical Approach	
Modified direct lateral	149
Two-incision minimal invasive (superior capsulotomy and Watson Jones)	21
Trochanteric slide	3
Vastus slide	1
Head size	
28	53
32	121
Cup size	
46	26
48	18
50	9
52	60
54	40
56	19
58	2
Femoral component	
Wright® Perfecta IMC*	15
Wright® Perfecta RS*	155
Wright® Profemur R*	1
DePuy® SROM†	1
DePuy® Stability†	2

*Wright Medical Technology, Arlington, TN

†Depuy, Warsaw, IN

TABLE 3. Demographic and Preoperative Data of the 174 Hips (155 patients) in the Study Group

Parameter	Study Group
Total number of hips	174
Total number of patients	155
Age (years)	49.9 ± 12.7 (range, 18–76)
Gender (male/female/percent male)	90/84/51.7%
Side (left/right/percent right)	85/89/51.1%
Patients with bilateral surgery (number/percent bilateral)	19/12.3%
Preoperative diagnosis	
Osteoarthritis	118 (67.8%)
Dysplasia	36 (20.7%)
Osteonecrosis	10 (5.8%)
Post traumatic arthritis	7 (4%)
Other	3 (1.7%)
Height (cm)	172 ± 10.4 (range, 147–198)
Weight (kg)	81.2 ± 18.9 (range, 45–144)
Body mass index (kg/m^2)	27.3 ± 5.2 (range, 18.1–49.9)
Number of hips with previous surgery	19 (10.9%)
Pelvic osteotomy	8
Trochanteric osteotomy	9
Surgical dislocation	1
Shelf	1
Mean duration of hospital stay (days)	4.2 ± 1.3 (range, 2–11)
Preoperative Merle d'Aubigné score (points) (174 hips)	11.1 ± 1.8 (range, 5–15)

survival defining each missing patient as a failure, should be noted. In this case, survival would be 76.7% (CI, 63.8–89.6). Because nine of the 18 missing patients had excellent clinical performance at the last followup before their 2-year visit, the assumption that all these patients failed is unlikely, but should be mentioned.

The absence of hip dislocation in this series compares to the literature.[26] This is reassuring since alumina ceramic-ceramic bearings have fewer modular options (such as extended heads or offset or lipped liners) and this had raised a concern that the use of these bearings might result in an increased incidence of instability.[2] However, all of these surgeries were performed with preservation of the short external rotators and posterior capsule, therefore a low incidence of dislocation with alumina ceramic-on-ceramic bearings may not be expected for all surgical exposures.

Bearing fracture has been a concern with alumina ceramic-on-ceramic bearings and one bearing fracture (0.52%) did occur in the current study. Comparing this incidence to that of metal-on-polyethylene, Heck et al[21] reported fracture or dissociation of polyethylene occurred at a combined rate of [45/10,000 in a 5-year period. Similarly, 18 cases of fracture or dislodgement of polyethylene liners has also been reported.[17] Thus, the fracture incidence in this small series (0.52%) seems similar to the fracture/dissociation rate of polyethylene (0.45%). Because trochanteric nonunion is a risk factor for an increased incidence of hip instability after revision total hip arthroplasty, trochanteric nonunion may have played some role in the etiology of the one ceramic liner fracture in this series, even though this hip did not dislocate. By contrast, there are many exceedingly active patients in this study group who have not sustained bearing fracture (Fig 2), suggesting bearing fracture may be more random than simply impact-activity related.

The 96% 9-year Kaplan-Meier survival for all components in our study of patients with a mean age of less than 50 years confirms the positive results with ceramic implants presented by D'Antonio et al.[7] Further, the implant survivorship in patients without previous surgery (99.3%;

Fig 2. An AP radiograph shows a total hip arthroplasty 7 years, 5 months after implantation. The patient was 46 years at the time of surgery, and the hip has been exposed to mostly high-impact activities, including over 20,000 miles of running.

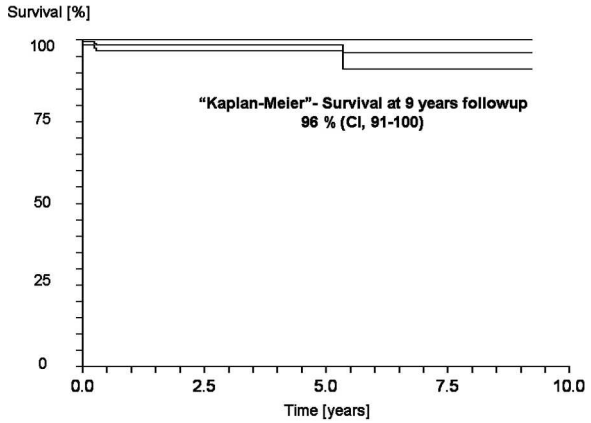

Fig 3. A survival curve shows the Kaplan-Meier survival at a maximum followup of 9 years for all components of the prosthesis system.

CI, 98–100) is promising given the very young average age of this patient group.

Despite these encouraging results, we need specific information about the use of alumina ceramic-on-ceramic bearings, particularly issues related to revision. Potential complications after revision of ceramic THA have been reported by Allain et al,[1] but comparison to revision results with other implants is needed to show substantial differences regarding complication rates. Similarly, results of revision THA in the small subpopulation of patients who sustain a ceramic bearing fracture is not known. Whether it is better to position a ceramic bearing flush with a shell or recessed within a shell is another unresolved issue. Recessing the bearing reduces ROM and causes metal-on-metal impingement and wear,[13] whereas as metal-on-ceramic impingement may be better tolerated.[39]

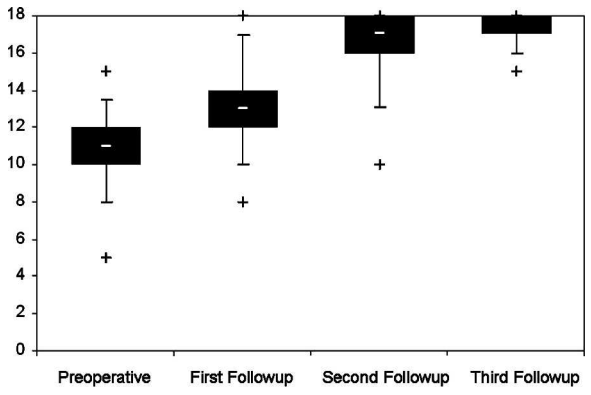

Fig 4. A box and whisker plot shows the improvements in the average Merle d'Aubigné score (maximum 18 points) as a measure of hip function and clinical performance at different times of followup.

We found alumina ceramic-on-ceramic bearings reliable and safe in a diverse patient population, with an average patient age younger than 50 years and with more than 75% of the patients aged 60 years or younger at the time of surgery. The absence of osteolysis was very promising, and implant-related problems were infrequent. Using alumina ceramic-on-ceramic bearings with uncemented titanium acetabular components offers many advantages for younger patients with osteoarthritis of the hip.

Acknowledgments

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