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Experience in the United States with Alumina Ceramic–Ceramic Total Hip Arthroplasty

Stephen B. Murphy, MD,[*,†,‡] Timo Ecker, MD,[*,†] Moritz Tannast, MD,[*,†] Benjamin Bierbaum, MD,[†] Jonathan Garino, MD,[§] James Howe, MD,[‖] Eric Hume, MD,[¶] Richard Jones, MD,[**] Kristaps Keggi, MD,[††] Kenneth Kress, MD,[‡‡] Daniel Phillips, MD,[§§] and Robert Zann, MD[‖‖]

Bearing wear and associated osteolysis are the most common problems affecting the long-term results of total hip arthroplasty. Alumina ceramic–ceramic bearings have been introduced as one method of addressing these problems. The current study reviews the clinical outcome of the use of alumina ceramic–ceramic bearings in the United States and specifically reports on the 2- to 8-year results of a prospective FDA–ID. Results demonstrate that the alumina ceramic–ceramic bearings are reliable and show very few early problems. Ceramic fractures do occur rarely and may be similar in incidence to reports of fractures or disassociations of polyethylene components. The incidence of instability is extremely low despite the absence of lipped liners and fewer head-length options.

KEYWORDS alumina, clinica outcomes, bearing wear, osteolysis

Wear debris and debris-associated osteolysis are still among the most common problems affecting total hip arthroplasty and a leading cause for revision surgery.[1,2] Efforts to address this problem have been made by improving the wear characteristics of the bearings used in total hip arthroplasty. Bearings that may have improved wear include metal–polyethylene bearings using cross-linked polyethylene,[3,4] metal–metal bearings,[5] and ceramic–ceramic bearings.[6,7] While cross-linked polyethylene bearings are the most commonly used, they have only been in clinical use since 1998 and, paradoxically, have the least clinical support for their use without any large published studies with long-term follow-up results. Preliminary studies have shown measurable but only slightly improved wear.[8] One prospective study has shown a modest (50%) reduction in wear,[9] whereas hard bearings have shown wear reduction of more than a thousandfold.[10] Cross-linked polyethylene bearings are also still susceptible to scratching and third-body debris,[11,12] and clinical examples of debris-associated osteolysis have been reported for both electron beam[3] and gamma-irradiated polyethylene bearings. By contrast, alumina ceramic bearings have been in clinical use for more than 20 years, and clinical retrievals have shown linear wear rates that are 4000-fold lower than metal-on-polyethylene bearings of the same era.[10] Furthermore, the biological reactivity of alumina ceramic wear particles appears to be lower than that of metal–metal or metal–polyethylene bearings.[13-16] Accumulation of metal ions and inflammatory tissue response to polyethylene debris, as well as dissemination of debris particles, have been investigated in several studies.[13-16] Ceramic–ceramic bearings have consistently shown low wear rates in laboratory evaluations as well as clinically.[17-21] Hamadouche and coworkers[22] had no cases of osteolysis in uncemented ceramic–

*Center for Computer Assisted and Reconstructive Surgery, Boston, MA.
†New England Baptist Bone and Joint Institute, Boston, MA.
‡Tufts University School of Medicine, Boston, MA.
§University of Pennsylvania, Philadelphia, PA.
‖University of Vermont School of Medicine, Burlington, VT.
¶University Orthopaedic Surgeons, Camden, NJ.
**Orthopaedic Specialist, Dallas, TX.
††Orthopaedics Surgery, Waterbury, CT.
‡‡Resurgeons Orthopaedics, Atlanta, GA.
§§Orthopaedic Specialist, Nashville, TN.
‖‖Orthopaedic Specialist, Boca Raton, FL.
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Address reprint requests to Stephen B. Murphy, MD, Center for Computer Assisted and Reconstructive Surgery, 125 Parker Hill Avenue, Suite 545, 02120 Boston, MA. E-mail: stephensmurphy@aol.org.

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ceramic total hip arthroplasties at a minimum 18.5-year follow up. The current study primarily reviews the clinical outcome of the use of alumina ceramic–ceramic bearings in the United States and reports the results a large prospective FDA Investigational Device Exemption (IDE) study with 2- to 8-year follow up.

Materials and Methods

A prospective multicenter IDE study with 22 participating surgeons was undertaken beginning in 1997. All Principal Investigators obtained IRB approval and all participating patients gave informed consent. Investigators agreed to collect and report data necessary for calculation of Harris hip scores (HSS) and radiographic evidence of loosening for a minimum of 2 years after surgery. Patients agreed to return for follow-up as a condition of participation in the study. After closure of the FDA–IDE study in February 2003 some investigators continued following up their patients beyond this point. The resulting data were also included in the study.

The acetabular component used in all cases 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). The demographic and preoperative data are summarized in Table 1. A total of 1709 hips in 1484 patients were entered into the study from April 1997 through February 2003. There were 618 (36.2%) left hips, 659 (38.6%) right hips, and 414 (24.2%) bilateral hips. Fourteen (0.8%) hips were unilateral revision arthroplasties, and 4 hips (0.2%) were bilateral revision arthroplasties. There were 919 (61.9%) men and 565 (38.1%) women. Mean patient age at surgery was 52.1 years (SD 11.0 years; range 17.7-81.1 years) at the time of surgery. 1129 (76.1%) patients were 60 years of age or less. Preoperative diagnoses included osteoarthritis, 1266 (74.1%); developmental dysplasia, 112 (6.6%); avascular necrosis, 274 (16%); traumatic arthritis, 51 (3%); and rheumatoid arthritis, 6 (0.4%).

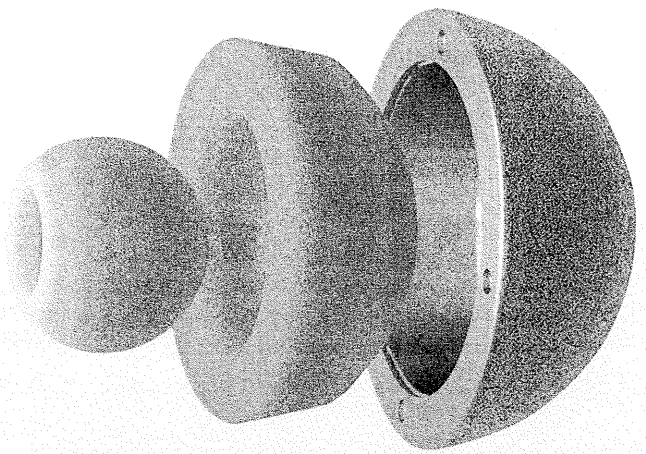

Figure 1 The alumina–alumina bearing (Wright Medical Technology, Memphis, TN and Ceramtec AG, Plochingen, Germany). (Color version of figure is available online.)

Table 1 Demographic and Preoperative Data

Parameter	Study Group
Total number of hips	1709
Total number of patients	1484
Age (years)	52.1 ± 10.8 (17.8–81.1)
Patients below 60 years of age/%	1129/76.1
Gender (m/f/% male)	919/565/61.9
Side (l/r/% right)	618/659/38.6
Bilateral hips (no./% bilateral)	414/24.2
Revision hips	
Unilateral	14
Bilateral	4
Preoperative diagnosis	
Osteoarthritis (%)	1266 (74.1)
Dysplasia (%)	112 (6.6)
Avascular necrosis (%)	274 (16)
Posttraumatic arthritis (%)	51 (3)
Rheumatoid arthritis (%)	6 (0.4)

Results

Of the 1709 total hip arthroplasties, 18 (2.2%) underwent implant-related reoperations. Eleven hips had to be revised because of femoral component loosening; another femoral stem failed to osseointegrate. Two cups had to be revised for loosening. One of the patients had severe osteoporosis and the cup subsequently migrated into the pelvis. There was no case of osteolysis in the study group. Four (0.2%) fractures of the ceramic–ceramic bearings occurred. The acetabular liner fractured three times and the femoral head fractured once. Furthermore, there were 21 (1.2%) revisions that were not implant related. Eight (0.5%) patients needed revision for infection. One (0.1%) patient underwent irrigation and debridement and bearing exchange for suspected infection but did not have an infection. In three (0.2%) patients the bearing diameter of the head and liner were inadvertently mismatched, and the bearings were exchanged to the correct diameters. One (<0.1%) acetabular liner was not seated properly and was revised acutely to properly seat the liner. Two hips that had ceramic bearings implanted were changed to metal–polyethylene bearings during the initial operation for the use of a lipped liner or extended head. One hip was revised for recurrent dislocation (<0.1%). One (<0.1%) patient needed revision because of heterotopic ossification (Brooker III) that led to impingement and limited function There were three (0.2%) postoperative periprosthetic fractures. One patient fractured his pelvis; another patient sustained an acetabular fracture with secondary displacement of the implant. Also, one other patient had a subsiding femoral component after a periprosthetic femoral fracture. There was one trochanteric nonreunion that was treated nonoperatively. The 8-year survival rate (Fig 2) for any implant related complication was 97% (93.3-100%). The acetabular

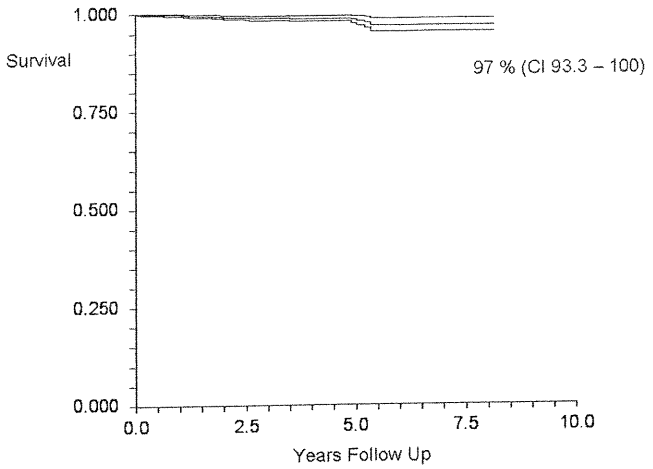

Figure 2 Eight-year Kaplan–Meier survival rate with failure of any component.

component showed an 8-year survival rate of 99.9% (96.6-100%) and the femoral component showed 98 (94.5-100%) 8-year survival. The bearing components had an 8-year survival of 99% (95.7-100%). Of 1709 hips, 1074 (63%) hips had a minimum 2-year follow up. Two patients were lost due to death that was not related to surgery. Six hundred thirty-three patients did not return for a 2-year follow up. Three hundred seventy-one of these patients had good results and were functioning well, with a HSS of 85 or higher at a follow-up before the 2 years. Patients with minimum 2-year follow-up had a mean follow-up of 47.2 ± 20.7 (22-98) months. The minimum of 22 months is because patients were considered to be eligible for "2-year" follow-up at 22 months as part of the IDE protocol. The postoperative and follow-up data are summarized in Table 2.

The average preoperative HHS was 46.6 (SD 12.6; range 8-100) and, in those cases with 2-year minimum follow-up, improved to an average of 93.1 (SD 11.1; range 16.9-100). Of a possible 44 points, the average pain component of the HHS preoperatively was 13.1 ± 6.3 (range 0-44) and improved to 40.9 ± 6.5 (range 0-44). The low postoperative HHS pain score and the low postoperative total HHS occurred in the same patient. This patient had avascular necrosis of the shoulder and knee and severe back pain radiating to the hips. No primary hip problem was identified postoperatively. It was not related to the surgery. The pain from this condition was rather referred to the hip than originating from the hip. In addition the patient scored low in the support and limp section of the HHS. The average preoperative flexion ability was 82.0 ± 23.1° (0-175°) and improved postoperatively to 104.9 ± 11.8° (55-150°).

Discussion

The current study demonstrates that alumina ceramic–ceramic total hip arthroplasty is safe and extremely reliable in a generally young and active patient population. As previously published by D'Antonio and coworkers,[23] reporting on the results of another large FDA/IDE study, this current study demonstrates excellent survivorship of alumina ceramic–ceramic bearings in total hip arthroplasty. The absence of periprosthetic osteolysis and wear in any case as assessed on plain radiographs is extremely promising, especially since wear and wear-associated osteolysis have been the primary cause of failure for total hip arthroplasty.[24] This is in sharp contrast to reports of osteolysis with cross-linked polyethylene bearings at short follow-up intervals.

These data illustrate yet again the excellent properties and characteristics of ceramic–ceramic implants. Current data from other manufacturers of ceramic–ceramic total hip arthroplasty implants have confirmed these promising results. In a series of 380 hips in 348 patients, using Stryker Orthopaedics ceramic–ceramic implants, equally excellent results have been achieved. The Kaplan–Meier survival rates of both studies are equally good. The 8-year survival rate for any component failure in the study group was 97% (93.3-100%), whereas the Stryker implants achieved an 8-year survival of 97.0% (92.8-98.7%) for the failure of any component.

The absence of osteolysis in both series is significant, because osteolysis is among the most common current cause of

Table 2 Operative and Follow-up Data

Parameter	Study Group
Preoperative Harris Hip Score	46.6 ± 12.6 (8–100)
Postoperative Harris Hip Score	93.1 ± 11.1 (16.9–100)
Preoperative flexion ability (degrees)	82 ± 23.1 (0–175)
Postoperative flexion ability (degrees)	104.9 ± 11.8 (55–150)
All complications (%)	39 (2.3)
Complications requiring revision	38
Kaplan–Meier Survival after 8 years (%)	
Any implant failure	97 (93.3–100)
Acetabular component	99.9 (96.6–100)
Femoral component	98 (94.5–100)
Bearing component	99 (95.7–100)
Implant related complications	18
▪ Acetabular loosening	2
▪ Failed osseointegration of stem	1
▪ Femoral loosening	11
▪ Bearing fracture	4
Not implant related complications	21
▪ Deep infection	8
▪ Component mismatch	3
▪ Early dislocation; revised intraoperatively	2
▪ Recurrent dislocation	1
▪ Heterotopic ossification	1
▪ Malseated liner	1
▪ Postoperative acetabular fracture with cup dislocation	1
▪ Postoperative pelvic fracture	1
▪ Postoperative femoral fracture	1
▪ Trochanteric nonreunion	1
▪ Apparent infection without infection in situ	1

failure in total hip arthroplasty. This is clearly because of the improved wear characteristics of the ceramic–ceramic implants, with no patient in our study nor in the *Stryker* database needing revision for signs of implant wear, in contrast to other bearings such as polyethylene that have a much higher incidence of wear.[24]

The revision rate for early as well as recurrent dislocations and instability in this study is extremely low compared with the literature.[25] There were only two reoperations for early dislocation and another one for recurrent dislocation out of more than 1700 hips in the current study (Wright Medical Technology implants). Similarly, only three early and three recurrent dislocations were reported with the Stryker implants. These data from both series suggest that concerns about fewer available modular options (such as lipped liners and/or extra-long heads or extra-large bearing diameters) leading to a greater incidence of instability may be exaggerated. In fact, the incidence of instability and revision for instability are lower than those previously reported in the literature.[26]

Although catastrophic ceramic bearing failure has been a concern in the past, this study demonstrates that, with only four bearing failures per manufacturer, modern ceramic–ceramic total hip arthroplasty implants are a safe alternative. While high-impact activities have not been recommended for ceramic total hip arthroplasty bearings, the resilience of the devices to these demands is encouraging. In contrast, catastrophic failure of polyethylene bearings may occur much more frequently. The low incidence of ceramic bearing fracture in both series is promising. While ceramic bearing fractures do still occur, fractures and dissociations of polyethylene bearings may actually be more common. Heck and coworkers[27] have reported the incidence of polyethylene liner fracture or complete wear-through at approximately 5 cases per 1000. While some of the polyethylene locking mechanism problems may have been improved in recent designs, the more common use of extremely thin polyethylene liners and the use of cross-linked polyethylenes with a lower resistance to crack propagation may result in continued reports of polyethylene fractures and dissociations at a rate that is equal to or higher than the incidence of fracture of ceramic bearings. The incidence is currently unknown since no clinical series of metal-on-cross-linked polyethylene hip reconstructions that are the size and follow-up duration of the current study have been reported.

We do not have an explanation as to why three hips had incorrect bearing diameters implanted, especially since there are fewer implant options to choose from when ceramic bearings are used. Improved hospital protocols for confirming correct implant selection before wound closure may address this issue.

The current study is limited by the large number of patients failed lost to follow-up. This has been frustrating to the investigators. Intense efforts to gather these missing data are currently under way. This finding may be due to several factors. Many of these patients sought surgeons who were performing ceramic–ceramic total hip arthroplasty and therefore often traveled great distances for the surgery. Patients who are highly motivated to travel before surgery are often less motivated to travel the same distance after surgery, especially if the hip is functioning well. Many of the patients were also not fully aware or concerned about their responsibility to return for reevaluation.

While these two large clinical studies demonstrate excellent survivorship of alumina ceramic–ceramic bearings, much remains to be learned about the long-term management of these hips. More experience must be gained with revision of alumina ceramic bearings. Issues associated with revising a ceramic–ceramic bearing to another ceramic–ceramic bearing, a metal–metal bearing, or a metal–polyethylene bearing remain undefined. Preventing wear of revision total hip arthroplasty, performed in the presence of preexisting alumina ceramic particles, will require further experience. Revision of an alumina ceramic bearing to another one may result in the low wear. By contrast, revision of an alumina ceramic bearing to a metal–metal bearing may be simpler and be less likely to require revision of components that are well fixed to bone. The risk of using new ceramic bearings on previously used taper junctions has also not been well defined.

Another interesting issue concerns acetabular component design. The acetabular liner in the current study is designed to seat in a position that is flush with the surrounding acetabular component. By contrast, the acetabular liner in the Stryker series is recessed within a surrounding metal sleeve. Recessing the bearing reduces range of motion and causes metal–metal impingement and wear,[28] whereas metal–ceramic impingement may be better tolerated.[29] Nonetheless, impingement-related revisions did not occur in the Hamadouche series[22] (where the ceramic shell was not protected by a metal rim) and were rare in the study reporting on the Stryker design[23] and the current study. Therefore, based on clinical data, it is not yet clear whether an acetabular liner should seat evenly with the surrounding metal or should be recessed within it.

Conclusion

The current prospective FDA–IDE study demonstrates that alumina ceramic–ceramic bearings are very reliable in a diverse patient group with an average age of 51 years and with more than three-fourths of the patients being 60 years or less at the time of surgery. These findings confirm the findings of another prospective FDA–IDE study of alumina ceramic–ceramic bearings previously reported.[10] The complete absence of osteolysis in this series is very promising, because wear-related osteolysis and associated bone loss and loosening has been the most common cause of failure of total hip arthroplasty to date. The combination of alumina ceramic–ceramic bearings with uncemented titanium acetabular components offers many advantages for younger patients with osteoarthrosis of the hip.

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