Delta Ceramic-on-Alumina Ceramic Articulation in Primary THA

Prospective, Randomized FDA-IDE Study and Retrieval Analysis

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Published online: 3 November 2009
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Abstract Wear and osteolysis continue to be major reasons for revision surgery in THA. Ceramic-on-ceramic bearings eliminate polyethylene wear debris. The newest generation of these bearings incorporate nanosized, yttria-stabilized tetragonal zirconia particles producing an alumina matrix composite. We asked whether this new material would perform as well as a conventional bearing

One or more of the authors (AVL, KRB) receive royalties and institutional research support from and have consulting agreements with Biomet, Inc (Warsaw, IN). One author (KRB) has consulting agreements with Synvasive Technology, Inc (El Dorado Hills, CA) and Salient Surgical Technologies (Portsmouth, NH) and owns stock in Angiotech Pharmaceuticals, Inc (Vancouver, BC). One author (AVL) receives royalties from Innomed, Inc (Savannah, GA). Each author certifies that his or her institution has approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained. This work was performed at Joint Implant Surgeons, Inc.

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in terms of functional hip scores, radiographic migration and osteolysis, complications and survival. As part of a US FDA investigational device exemption study (G000075), we conducted an initial prospective safety study of 21 alumina matrix composite femoral heads articulating on alumina liners followed by a prospective, randomized study with 44 more of these articulations and 45 zirconia femoral heads on polyethylene liners. The minimum followup for all patients was 26 months (mean, 73 months; range, 26–108 months). Harris hip scores and radiographic findings were similar in the two groups as was survivorship (trial 95% versus control 93%). There were three reoperations in the trial group and three in the control group. A fractured head retrieval showed a 33% monoclinic transformation with an increase in surface roughness from 3 to 5 nm at the main wear zone. While our numbers were insufficient to compare device-related complications, the trial device performed as well as the control device in terms of reoperation, and clinical and radiographic outcome. The alumina matrix composite femoral head on an alumina liner provided high survivorship.

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

Introduction

Ceramic modular heads articulating with highly cross-linked polyethylene reportedly have reduced wear rates compared to cobalt-chrome heads on polyethylene in THA, but wear and its debris still occur [21, 38, 45]. Ceramic-on-ceramic articulations are one proposed solution for reducing or eliminating polyethylene wear and its associated osteolysis. Ceramic-on-ceramic THA has progressed to the

currently approved alumina-on-alumina designs, and several studies have reported improved wear properties and reduced osteolysis and ceramic fracture in short-term followup with these devices [3, 7, 53].

Various techniques in production have led to the newest generation of ceramics, incorporating zirconia into the alumina matrix (marketed as Biolo[®]x delta by CeramTec, Plochingen, Germany). Nanosized, yttria-stabilized tetragonal zirconia particles improve the mechanical properties by preventing the initiation and propagation of cracks [8]. Oxide additives produce plateletlike crystals that dissipate energy by deflecting cracks. The addition of chromium oxide further increases the strength and toughness by composite hardening. The final product is a mixture of roughly 75% aluminum oxide, 25% zirconia, and less than 1% chromium oxide and strontium oxide. The result is a composite ceramic with improved mechanical properties and reduced wear as shown on scanning electron microscopy (SEM) and a predicted longer lifespan [29]. These improved mechanical properties reduce overall wear rates of 28-mm heads in a hip simulator wear test from 1.84 mm³ per million cycle to 0.16 mm³ per million cycle, comparing alumina-on-alumina versus alumina matrix composite-on-alumina matrix composite, respectively [40]. While the US FDA approved alumina-on-alumina (Biolo[®]x forte) articulations in 2003 and alumina matrix composite (Biolo[®]x delta) ceramic heads on polyethylene in 2005, the safety and effectiveness of alumina matrix (Biolo[®]x delta) ceramic heads coupled with alumina (Biolo[®]x forte) liners are unknown.

As part of a sponsored FDA investigational study, we therefore asked whether the survival, Harris hip scores, and osteolysis and component migration would be comparable with the new ceramic-on-ceramic bearing and a ceramic-on-polyethylene bearing. We also analyzed one retrieved fractured alumina matrix composite femoral head from the trial group to evaluate the characteristics including surface roughness, phase transformation, and resistance to wear of this new-generation ceramic.

Patients and Methods

Beginning June 2000 as part of a multicenter FDA Investigational Device Exemption study (G000075), we obtained IRB approval and conducted an initial, prospective safety study of 21 patients undergoing primary THA with alumina matrix composite (Biolo[®]x delta) modular femoral heads articulating on liners of pure alumina ceramic (Biolo[®]x forte) inset on polyethylene (Fig. 1), followed by a prospective, randomized study with 44 more primary THAs using these articulations and 45 primary THAs with zirconia ceramic modular heads (Biomet, Inc, Warsaw, IN) articulating on highly crosslinked polyethylene liners

Fig. 1 The study device consisted of a Biolo[®]x delta ceramic head (pink) articulated with a liner of Biolo[®]x forte ceramic (yellow) inset in polyethylene (white).

(ArCom[®], Biomet). A single surgeon (AVL) performed all the procedures. We included patients with degenerative joint disease, 18 years or older, undergoing either unilateral or bilateral (simultaneous or staged) THA, with a preoperative Harris hip score of less than 70 and at least moderate pain. We excluded patients with inflammatory arthritis and those undergoing revision surgery. The study was offered to all patients who met the inclusion criteria. Patients who enrolled were similar in terms of clinical and demographic characteristics to those who refused. After the patient signed the informed consent agreement to participate in the study, the investigator's study coordinator notified the sponsor's (Biomet) study manager, who then assigned the patient to one of the two groups using investigator-designated blocks of a random digit table of 100 numbers corresponding to four sequences of A/B. Power analyses conducted using the method of Blackwelder [4] determined a sample size of 28 for each group to determine no difference in Harris hip scores with 10% correction for bilateral cases to 31 and 15% correction for lost to followup cases to 37, and a sample size of 92 for each group needed to demonstrate no difference in complications rates, with 10% correction for bilateral cases to 102 and 15% correction for lost to followup cases to 120. Therefore, the overall study enrollment goal was 240 cases, with a limit of 120 cases for any one center participating.

There were 29 women (45%) and 35 men (55%) in the trial group and 21 women (47%) and 24 men (53%) in the control group. The mean age of the trial group was 57 years (range, 33–76 years) and the mean age of the control group was 60 years (range, 35–79 years). The minimum followup was 26 months (mean, 73 months; range, 26–108 months) in the trial group and 31 months (mean, 72 months; range, 31–98 months) in the control group. No patients were lost to followup; two patients died before the minimum 24-month followup period, one at 3 weeks postoperatively due to pulmonary embolism and one at 7.5 months due to prostate cancer. Six other patients

(seven hips) died for reasons unrelated to the surgery but after 2 years.

The Charnley classification was similar between the two groups, with 55% Class A, 31% Class B, and 14% Class C in the trial group versus 52% Class A, 36% Class B, and 11% Class C in the control group. The average body mass index was 29.9 kg/m² in the trial group and 28.8 kg/m² in the control group, again without difference. Of the 64 hips in the trial group, 55 (86%) were diagnosed with osteoarthritis, six (9%) with avascular necrosis, one (2%) with Legg-Calvé-Perthes, one (2%) with posttraumatic arthritis, and one (2%) with slipped capital femoral epiphysis. Of the 44 hips in the control group, 37 (84%) had a diagnosis of osteoarthritis, four (9%) had avascular necrosis, and three (7%) had developmental dysplasia. Five patients underwent simultaneous bilateral surgeries with one hip in the trial group and one in the control group. Three patients underwent staged bilateral surgeries, again with one hip in each group. One patient underwent staged bilateral surgeries 1 year apart with both hips randomly assigned to the trial group.

All surgeries were performed via the modified direct lateral approach previously described [10]. Head sizes included 28 and 32 mm. All cups were Porous Plasma Sprayed (PPS[®]) titanium shells, either Mallory-Head[®] RingLoc[®] or Universal[®] RingLoc[®] (Biomet). The trial group liner was composed of a Biolox[®] forte insert molded into an ArCom[®] polyethylene liner. The control group liner was ArCom[®]. All stems were a press-fit PPS[®] titanium Mallory-Head[®] prosthesis (Biomet). A standard postoperative protocol was administered to all patients including immediate full weightbearing.

Clinical and radiographic followup was performed by an attending surgeon at 6, 12, and 24 months and annually thereafter. We obtained Harris hip scores [14] both preoperatively and at the followup period. We recorded subsequent surgeries and device-related complications for all patients. Two of us (AVL, KRB) radiographically identified femoral and acetabular osteolysis, using the zones of Gruen et al. [11] and DeLee and Charnley [9], respectively, noting any periacetabular bony destructive lesion that was progressive in nature, or a radiolucency of more than 2 mm in width not present on the immediate postoperative radiographs, or both. We measured subsidence of the stem, noting change from the immediate postoperative radiograph of 4 mm or more, or a radiolucency of more than 2 mm in all Zones 1 to 7 on the AP or lateral views. For the cup, we measured angle of inclination, noting change of 4° or more from the immediate postoperative radiograph; migration, noting change of 4 mm or more; and a radiolucency of 2 mm or more in Zone A, B, or C. The device was considered successful if the incidence of device-related complications in the experimental group was no worse than the control group

(delta = 0.08) and if the proportion of experimental group patients with clinical and radiographic success and the original device still in place at followup was no worse than that of the control group (delta = 0.08).

We computed Kaplan-Meier survivorship curves [22] using revision as an end point. Statistical differences in survivorship were measured using log-rank and Wilcoxon analyses. All patients enrolled were included in Kaplan-Meier analyses. Patients were censored by date of last followup, including those without the minimum 2-year followup. A two-tailed homoscedastic Student's *t* test was performed to compare differences in mean Harris hip total scores, pain scores, and radiographic assessment of angle of inclination between the two groups.

Though fracture of an alumina matrix composite head was unexpected, such a fracture did indeed occur in one patient in the experimental group. To investigate this occurrence further, the recovered fracture components were analyzed by the Peterson Research Center and the Donaldson Arthritis Research Center at Loma Linda University (ICC). The analysis included reflected light microscopy, mapping of wear stripes and metal transfer layers, SEM imaging of the surfaces (Zeiss, Oberkochen, Germany), energy-dispersive spectroscopic (EDS) analysis of surface contamination, laser study of surface roughness (Zygo Corp, Middlefield, CT), xray diffraction analysis of zirconia transformation, and study of worn implant geometries (Legex; Mitutoyo, Neuss, Germany). Seven fragments were identified. The surface areas examined on the fractured ball included the main wear zone, the stripe wear zone, the transition wear zone, and the nonwear zone. In addition, the fracture planes and the revealed internal bore taper were also examined.

Results

The average Harris hip score improved from 51 (range, 6–68) to 90 (range, 50–100) in the trial group and from 48 (range, 6–69) to 92 (range, 49–100) in the control group. These scores were similar between the two groups preoperatively (*p* = 0.34) or postoperatively (*p* = 0.40). Pain scores from the HHS improved from an average of 14 preoperatively to 39 postoperatively in the trial group and from 13 to 42 in the control group; these pain scores were similar in the groups preoperatively (*p* = 0.62) and postoperatively (*p* = 0.10). We identified no cases of squeaking in either group.

We observed stem migration and a radiolucency in Zone 3 of the acetabulum in one (2%) patient in the trial group at 20-month followup. He subsequently underwent revision of the femoral stem and placement of a standard polyethylene liner and cobalt-chrome head. The cup was stable and we believed the failure related to lack of bone ingrowth and

not an issue with the ceramic-on-ceramic articulation. We observed osteolysis in Zone 2 of the acetabulum in one (2%) patient in the control group at 82-month followup and have recommended revision of the acetabular liner. There were no other radiolucencies, component migration, or incidence of osteolysis throughout the followup period in either group. The average cup angles of inclination were similar for the two groups immediately postoperatively and at final followup with no differences over the followup time: 45.4° in the trial group versus 46.1° in the control group at immediate postoperative visit ($p = 0.5$) and 44.9° in the trial group versus 46.0° in the control group at the most recent followup ($p = 0.27$).

Three patients in each group underwent revision surgery. One patient in the trial group had an atraumatic fracture of his femoral head while simply rising from a commode at almost 6 years postoperatively (Fig. 2). He had a 28-mm (−3-mm neck) femoral head and was revised to a polyethylene liner with a standard-neck 32-mm cobalt-chrome head. One patient in the trial group underwent a cup revision due to recurrent instability with multiple dislocations. She subsequently became infected and underwent successful two-stage revision. The third revision was the one mentioned above performed for subsidence. In the control group, one patient had a trochanteric avulsion and underwent open reduction internal fixation and conversion to a cobalt-chrome head. He later underwent formal cup revision due to feelings of instability without frank dislocation. Two other patients underwent cup revisions due to recurrent dislocations.

Survivorship was similar ($p = 0.44$ and $p = 0.716$, for log-rank and Wilcoxon analyses, respectively) in both

groups: 95% in the trial group and 93% in the control group at 6 years (Fig. 3).

The analysis of the fractured alumina matrix composite femoral head demonstrated the surface roughness increased minimally from new condition (3 nm) to the main wear zone (5 nm) (Table 1, Figs. 4, 5). The stripe wear zone showed elevated roughness (55 nm). Zirconia phase transformation to monoclinic was present at 33% level. This tetragonal to monoclinic transformation seemed to equilibrate at the 33% level throughout the entire construct. The SEM and roughness mapping demonstrated the

Fig. 3 Kaplan-Meier survivorship estimates with time with reoperation for any reason as the end point are shown. Tick marks represent censored patients. The dotted lines represent 95% confidence intervals. The survivorship was similar between groups at 90 months' followup.

Fig. 2A–E (A) A preoperative radiograph of a 40-year-old male patient shows osteoarthritis of the left hip. (B) A radiograph taken immediately postoperative to THA with a ceramic-on-ceramic articulation shows components in satisfactory position and alignment. (C) A radiograph at 70 months postoperatively reveals atraumatic fracture of the ceramic head and liner. (D) A radiograph taken

immediately postoperative to revision THA confirms the use of a 32-mm-diameter cobalt-chrome femoral head with standard neck on crosslinked polyethylene liner with retained acetabular shell and femoral stem. (E) A radiograph at 14 months postoperative to revision of the head and liner demonstrates excellent fixation.

Table 1. Summary of analyses of zirconia transformation data for delta ball fracture

Description	Zygo roughness Sa (nm)	XRD (monoclinic %)	EDS (Ti weight %)
Nonwear	3		
Main wear	5	32.0	
Stripe wear	55	33.3	5.6
Bore surface		32.8	
Fracture surface	682	39.7	

Zygo = laser study of surface roughness, XRD = xray diffraction; EDS = energy-dispersive spectroscopic imaging of surface contamination.

Fig. 4A–C Overview of fracture fragments from a 28-mm delta ball from (A) polar view, (B) view of the base, and (C) side view of the stripe wear zone. The dominant fracture plane is indicated by dashed lines in the polar and basal views. The large stripe wear zone crosses over three of the fragments at the angle indicated by the dashed ellipse on the side view.

Fig. 5A–E Photographs show five of the largest of seven fragments (A–E) from a fractured 28 mm 'Delta' ball. The circles indicate sites of analysis for polished main wear zone (MWZ), stripe wear zones (SWZ), metal contamination, machined taper bore and fracture cleavage regions (CZ).

alumina matrix ceramic had superior resistance to wear. Titanium contamination was noted at the stripe wear zone at a level of 5.6% by the EDS.

Discussion

As new materials are developed for biomedical implants used in human subjects, thorough clinical study is necessary to ensure that change is a benefit rather than a detriment to the patient. We evaluated a new alumina matrix composite ceramic on alumina liner in comparison with zirconia ceramic on polyethylene, with success of the

study device defined as incidence of device-related complications in the experimental group no worse than the control group and proportion of experimental group patients with clinical and radiographic success and the original device still in place at followup no worse than that of the control group.

There are a few limitations to our study. First, due to the short followup period, we are unable to form conclusions regarding the prevention of osteolysis, the ultimate goal of an alternative bearing. However, multiple studies have reported decreased wear rates and reduced osteolysis and aseptic loosening with earlier-generation ceramic-on-ceramic bearings [12, 18, 25, 32, 53]. Longer followup with new-generation ceramic-on-ceramic bearing is needed to draw similar conclusions. Second, our control group had zirconia ceramic heads, which has subsequently been found to undergo monoclinic phase transformation and possess an increased risk of fracture [24, 26]. To date, none of the patients who received a zirconia femoral head have had a fracture. Third relates to the modular ceramic-polyethylene sandwich acetabular liner used in this study, wherein the alumina insert is molded into a polyethylene liner. Ravasi and Sansone [34] reported satisfactory 5-year followup of a ceramic cup sandwich and noted the benefit of reduced stiffness by adding a layer of polyethylene, reducing the dynamic stresses transmitted to the acetabular bone/component interface. However, another ceramic polyethylene sandwich device was withdrawn from the Japanese market after reports of up to 3% alumina liner fractures and 6% alumina/polyethylene liner dissociation with 3933 sandwich cups implanted [1, 15, 17, 51]. We observed no cases of fracture or dissociation of the ceramic liner from within the polyethylene insert. The lack of liner dissociation may be in part due to the superior design of the RingLoc® liner locking mechanism [44, 49]. Finally, the potential for backside polyethylene wear leading to osteolysis still exists in the current polyethylene sandwich model and a mechanism that completely eliminates polyethylene from the equation would be ideal.

We believe a ceramic-on-ceramic articulation represents an ideal bearing surface from the standpoint of its wear characteristics. With the use of today's improved implant designs, we found the new ceramic coupling to have a revision rate of 4.7% at an average of 6 years. There are many mechanical characteristics that make alumina ceramic bearings ideal in THA. Alumina is 10 times harder and zirconia seven times harder than cobalt-chrome [20]. Alumina has a hardness of approximately 2000 VH (Vickers Hardness), compared to cobalt-chrome at 240 to 450, and other than diamond, is the hardest material available [6]. This hardness provides for improved scratch resistance. Another key to improved wear properties is the improved lubrication found with ceramics due to its lower

wetting angle, which is the angle formed between the material and a bead of fluid (ie, synovial fluid). This permits better wettability, especially when coupled with the formation of a microfilm of lubrication on the surface of ceramics due to the van der Waals forces between water and aluminum oxide crystals. Finally, strong bonding between the oxygen and aluminum ions provides extremely good corrosion resistance, leading to better biocompatibility, and because they are inert, there is no concern about allergic reaction [20, 39].

Some important disadvantages of ceramic-on-ceramic articulations are reported in the literature. The highest rates of component fracture, up to 13%, occurred mainly with early-generation ceramics, although CeramTec reports a rate of only 0.026% [40]. Second-generation ceramics showed improvements in the purification of alumina powder, leading to smaller grain size. This, along with refined manufacturing, increased the density, resulting in decreased fracture rates to 0.014% [20, 28, 42]. Third-generation BioloX® forte fracture rates were reduced to 0.004% [20, 28, 42]. This reduction was made possible by further improvements in processing, such as the implementation of a three-stage sintering process that includes hot isostatic pressing during the second stage, laser etching versus engraving to reduce points of high stress, and finally proof testing of all components to ensure consistently high quality. While it is believed crack propagation in early-generation ceramics allows fractures to occur, BioloX® delta prevents this through the insertion of nanosized, yttria-stabilized tetragonal zirconia particles [8]. A recent article reports no fractures at 6-year followup with more than 65,000 ball heads and 40,000 inserts of alumina matrix composite implanted [27]. While no specific fracture rates are present for zirconia-toughened alumina, there is one recent report of a BioloX® delta liner rim fracture in a patient with a BioloX® forte ceramic head [19]. We encountered one alumina matrix composite femoral head fracture in a 40-year-old moderately active man with a body mass index of 25.1 kg/m² suffered in an atraumatic fashion while rising from a commode at 6 years postoperatively. At his initial surgery, he received a size 56-mm solid acetabular shell with a 28-mm head with a -3-mm neck. Cup position was at a 45° angle of inclination and stem position was neutral. Followup plain radiographs at 2 years showed no osteolysis or change in component positioning. He was subsequently revised to a standard 32-mm cobalt-chrome femoral head with a crosslinked polyethylene liner. There is debate in the literature with regard to which type of femoral head is best used for revision of a ceramic component fracture. While there is strong evidence against using stainless steel femoral heads in the revision setting, some studies support placing cobalt-chrome heads on retained femoral components [2], while

others recommend ceramic heads [16, 36]. The latter usually requires removal of a well-fixed stem, as placement of a new ceramic head on a used metallic taper with any defects may predispose to refracture [16, 17, 33]. CeramTec is in the early stages of providing adapters to fit over a used trunion, thus providing a defect-free taper for a new ceramic head and the ability to retain a well-fixed femoral component [27]. The retrieval analysis of the fractured alumina matrix composite ceramic head revealed an extremely wear-resistant surface. The stripe wear zone showed elevated roughness (55 nm), but this is still in the same low level as any good chromium-cobalt ball retrieval and the orientation of the main stripe wear was consistent with that seen with other ceramic-on-ceramic retrievals [41, 46, 50]. The stability of this composite was further reinforced by the fact that there was only 33% phase transformation of the zirconia. This correlates with previous studies on phase transformation of pure zirconia ceramic heads, which found phase transformation was associated with increased surface roughness [13, 24, 26]. However, the constraint offered by the surrounding alumina matrix will limit further monoclinic transformation. Since zirconia represents 20% of the content of the femoral head, this actually represents approximately 8% of the surface. The alumina present in the composite serves to prevent further zirconia transformation. This is a completely different process from that seen in zirconia balls in which massive surface disintegration was observed in retrieved balls [5]. To date, there have been no other reported analyses of fractured alumina matrix composite femoral heads. Further retrieval analysis is needed to definitively document durability of this matrix ceramic.

Of recent concern in the literature is the risk of squeaking associated with ceramic-on-ceramic bearings, with rates reported between 0.3% and 20% [23, 25, 35, 37, 47, 48]. The etiology of this squeaking phenomenon remains a mystery. Keurentjes et al. [23] found a higher risk of squeaking with a neck length of -4 mm or shorter and they concluded this may lead to multiple issues including neck-socket impingement or increased joint laxity resulting in microseparation. Microseparation is a known risk factor for stripe wear and both are reported as potential causes of squeaking [31, 35, 39, 43]. Others found the mismatch of zirconia on alumina as a cause of squeaking [30]. Of note, we did have a mismatch of ceramics and still did not observe any cases of squeaking. The debate as to whether component malpositioning is a direct cause of squeaking remains unsettled [35, 49]. Thus, the final etiology is most likely multifactorial, the result of a combination of issues ranging from hard-on-hard bearing surfaces, microseparation and subluxation associated with impingement and secondary stripe wear, entrapment of

third-body wear debris, disruption of fluid film lubrication, and mismatched ceramic bearings [50, 52].

In conclusion, we believe the new articulation of an alumina matrix composite ceramic articulating on an alumina liner is a safe option with improved wear characteristics. While we cannot comment on a reduced rate of late osteolysis, we found no cases of osteolysis in the study group versus one case in the control group. The experimental device had a comparable rate of early revision, high survivorship in the short term, and no instances of squeaking. The fractured alumina matrix composite femoral head showed evidence of monoclinic transformation, but because the overall composition of zirconia is considerably less compared to pure zirconia balls, massive surface disintegration is less likely to occur. While the number of cases from our center was insufficient for a comparison of device-related complications rates, the trial device performed as well as the control device in terms of reoperation rates, functional scores, and radiographic complications.

Acknowledgments We thank Tom Donaldson, MD, and Koseki Kubo, MD, PhD, for their assistance in analysis of the delta head fracture. We also thank Tawnya L. Tucker, MT, for her assistance with the collection of data in this study.

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