

1.5 Ceramic/Ceramic Total Hip Replacement: The American Experience with Stryker Implants

B. E. Bierbaum

J. D'Antonio, W. Capello, M. Manley and R. Deshmukh

Abstract

A major challenge for total hip arthroplasty is to minimize wear and osteolysis in young, active patients. Alumina ceramic bearings have shown superior wear resistance and lubrication and do not carry the risk of ion release. In a prospective randomized study (ABC), 514 hips were implanted. All patients (average age, 53 years) received the same press-fit hydroxyapatite coated femoral stem; two thirds (345 hips) received alumina ceramic bearings, and one third (169 hips) received a cobalt-chrome-on-polyethylene bearing. A fourth arm (Trident) was included involving use of a metal-backed acetabular component implanted in 209 patients. At a mean follow-up of 35.2 months (range, 24-48 months), there was no significant difference in clinical performance between the patient cohorts. The cohort of patients included in the ABC, Trident, and extended access portion of the study represents a population of 2313 patients with no device related failures attributable to the ceramic on ceramic articulation used in these patients. This new experience involves the use of improved ceramic materials and new design considerations that eliminate the risks and complications of past experiences with ceramic implants and provides a safe bearing option for young patients.

Introduction

Advances in implant design and materials and improvements in surgical technique and instrumentation have made total hip arthroplasty (THA) one of the most durable and successful treatments in medicine [1]. Reproducible high-quality results are attained regularly, with survivorship commonly lasting ≥ 10 to 15 years [2]. The success of this procedure has allowed expansion into a wider, younger and more active patient population [3]. As THA is used in younger and higher demand patients and as life expectancies increase, the orthopaedic community continually is seeking new methods and materials that may extend the useful life of THAs. The challenge today is to develop new bearing surfaces that can function at a high level and prolong the life of well-fixed implants.

Past experiences with alumina ceramic bearings have been met with disappointing results because of increased component loosening, ceramic component fracture, and isolated examples of accelerated wear of the bearing surface [4]. One objective of this clinical study was to evaluate the use of alumina-on-alumina ceramics with proven implants that have had successful track records with regard to fixation (on a prospective randomized basis). These results were compared with the results of cobalt-chrome-on-polyethylene bearings, which is the current standard for THA. A second objective of this study was to compare the complications that are related directly to the alumina ceramic bearing couple with the complications that were seen with previous designs in the 1970s and 1980s.

Materials and Methods

In October 1996, a U.S. IDE prospective randomized study began comparing alumina-on-alumina ceramic bearings with cobalt-chrome-on-polyethylene bearings. Patient enrollment was completed in October 1998, after 514 hips were implanted in 458 patients. A total of 22 investigators at 16 sites participated in this investigational device exemption (IDE) study (see Appendix 1). Approval by the Food and Drug Administration of the protocol and patient informed consent were obtained before study initiation. Each site was required to submit the protocol with consent to the hospital institutional review board. The consent explained that the study was randomized and that the patient would receive the control or the investigational ceramic device based on a randomization scheme, and the patient agreed to participate in the study before determination of which device they would receive. Neither the patient nor the surgeon was aware of the device that was selected randomly for implantation.

There were 3 arms to the study that included 3 cup designs; 2 had alumina-on-alumina bearings (systems 1 and 2), and 1 had the control of cobalt-chrome-on-polyethylene (system 3) (Fig. 1).

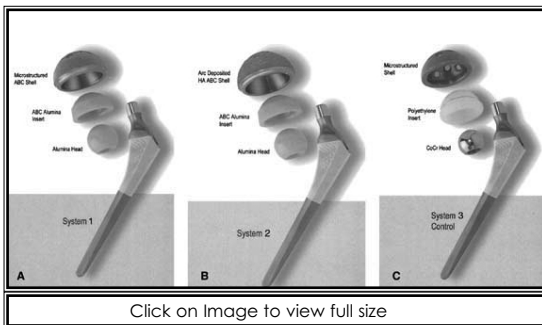


Figure 1:

(A) Porous-coated acetabular shell, alumina ceramic acetabular insert, alumina ceramic femoral head, and hydroxyapatite (HA)-coated titanium femoral stem.

(B) Titanium arc deposited HA-coated acetabular shell, alumina ceramic acetabular insert, alumina ceramic femoral head, and HA-coated titanium femoral stem.

(C) Titanium porous-coated acetabular shell, polyethylene acetabular insert, cobalt-chrome femoral head (ion bombarded), and HA-coated titanium femoral stem.

All patients received the same femoral stem (Omnifit HA; Howmedica Osteonics, Allendale, NJ). There was a one-third chance of receiving 1 of the 3 cup designs and a two-thirds chance of receiving an alumina-on-alumina bearing surface. System 1 comprised a porous-coated titanium shell and an Alumina Bearing Couple (ABC; Stryker Howmedica Osteonics, Allendale, NJ) insert. System 2 had an arc deposited titanium shell with hydroxyapatite coating and an ABC insert. System 3, the control group, had a porous-coated titanium shell and a polyethylene insert. All of the cups had a peripheral self-locking design with a 1-mm increased peripheral radius over the radius of the dome of the socket. The diameter of head size and the inside diameter of acetabular inserts are outlined in Table 1.

Table 1:
Comparison of femoral head size.

Head Size (mm)	ABC Alumina Components Trident
Control Cobalt-Chrome Femoral Heads	
26	NA NA 20 (12.1%)
28	35 (10.0%) 1 (1%) 136 (82.4%)
32	314 (90.0%) 74 (69%) 9 (5.5%)
36	NA 32 (30%) NA
Abbreviation: NA - not applicable.	

Acetabular components of 32-mm inside diameter and alumina ceramic femoral heads were available for implants that were ≥ 50 mm in diameter. Most (136 cases [82.4%]) of the control implants had 28-mm inside diameter polyethylene inserts and 28-mm cobalt-chrome femoral heads implanted to avoid the potential for increased volumetric polyethylene wear that could occur with the routine use of 32-mm diameter femoral heads. It was believed at the time of the study design that the routine use of 32-mm head size against polyethylene potentially would bias the study against the control group and in favor of the alumina couple, for which the use of 32-mm heads was not an issue.

In the initial study involving 349 ABC alumina ceramic implants, no component fracture was experienced. Nine peripheral chips occurred with the ABC system because of technical problems involving placement of the alumina ceramic insert within the titanium acetabular component. If the ABC shell is canted and wedged in the shell and an impaction force to seat the insert subsequently is delivered, a peripheral chip can occur. After recognizing this technical problem, a fourth study arm (Trident implant; Howmedica Osteonics, Allendale, NJ) was instituted evaluating a metal-backed alumina insert that is placed within the acetabular shell. The alumina ceramic insert of the Trident system has been assembled with a shrink-fit titanium sleeve on the outside that mates with a peripheral taper lock within the acetabular shell. The equatorial edge of the metal sleeve extends past the ceramic liner to prevent articulation of the femoral taper with the ceramic surface. This titanium sleeve also protects the rim of the alumina ceramic from chipping on insertion and increases the burst strength of the alumina ceramic [24]. Six centers from the original ABC study and five additional ones (see Appendix 2) inserted 209 of these implants in a prospective nonrandomized study using system 3 as a control.

The demographics for the combined ABC and Trident study are shown in Table 2.

Table 2:

Patient demographics ABC and Trident Study.

	ABC System 1 ABC System 2 Trident Control
No. cases	172 177 209 165
No. of patients	163 171 194 161
Male/female(%)	66/34 64/36 66/34 60/40
Mean age (y)	53 53 52 53
Mean weight (lb)	187.7 191.8 189.7 188.5
Mean height (in)	68.6 68.6 68.4 68.4
Length of follow-up (mo)	47.7 47.6 30.7 46.6
Diagnosis (%)	
OA	81% 76% 81% 76%
PTA	2% 5% 3% 5%
AVN	14% 18% 11% 16%
Other	3% 1% 4.5% 3%
Abbreviations: OA - osteoarthritis; PTA - post-traumatic arthritis; AVN - avascular necrosis; No - number.	

The follow-up included 349 alumina-on-alumina hips (318 patients), with 335 hips (307 patients) at 24 months, 243 hips (227 patients) at 36 months, and 72 hips (71 patients) at 48 months (mean, 35.2 months' follow-up). For the 165 hips (161 patients) included in the control group, follow-up included 149 hips (147 patients) at 24 months, 111 hips (111 patients) at 36 months, and 26 hips (26 patients) at 48 months (mean, 33.6 months' follow-up). All groups had a preponderance of males (60-66%), a young mean age of 52 to 53 years, and a predominant diagnosis of osteoarthritis (76-81%). All patients in all study groups suffered from noninflammatory disabling arthritis.

Data coordinators collected radiographic and clinical data preoperatively, early postoperatively (6-8 weeks), at 6 months, at 1 year, and at 1-year intervals thereafter. The level of pain and functional parameters, including distance the patient could walk, stair climbing, need for external support, sitting, limp, and participation in recreational activities were evaluated at each visit, and a composite Harris hip score (HHS) was calculated for each patient [5]. The postoperative radiographs were evaluated by an orthopaedic surgeon who was not part of the investigator group. Anteroposterior and lateral radiographs of the patients were obtained at each visit. The postoperative radiographs were evaluated for radiolucencies, implant fixation, implant migration, and erosion of cortical bone (osteolysis). The acetabulum was divided into 3 zones based on DeLee and Charnley [6], and femoral components were evaluated using Gruen zones 1 through 14 [7]. Component stability was determined using the criteria described by Engh et al [8].

Results

Clinical data for the ABC system with minimum 2-year follow-up are shown in Table 3.

Table 3:
Clinical data.

	ABC System 1 (2-4 y; mean, 3 y) (n = 166) ABC System 2 (2-4 y; mean, 3 y) (n = 172) Trident (2-3 y; mean, 2.5 y) (n = 193) Control (2-4 y; mean, 3 y) (n = 151)
Pain none/slight (%)	91 92 94 93
Limp none/mild (%)	98 96 99 97
Mean Harris hip score	95.4 96.6 97.2 95.9

Harris % G/E (%)	94
	94
	97
	96
Patient satisfaction ("Are you satisfied with results?") (%)	95
	98
	97
	97
Abbreviation: G/E, Good/Excellent scoring for the Harris hip score. G = Harris hip score of 80-89 and E = Harris hip score of 90-100.	

Complications for the ABC and Trident groups are reported in Table 4.

Table 4:
Complications.

Complication	System 1 System 2 Trident Control
Revision	
Acetabular	0 1 (0.6%) 1 (0.5%) 2 (1.2%)
Femoral	1 (0.6%) 0 1 (0.5%) 2 (1.2%)
Both	1 (0.6%) 2 (1.1%) 0 0
Insert and/or head only	0 0 2 (1.0%) 5 (3.0%)
Deep Joint Infection	1 (0.6%) 1 (0.6%) 0 2 (1.2%)
Intra op Fem Fx	6 (3.5%) 7 (4.0%) 4 (1.9%) 7 (4.2%)

Postoperative femoral fracture	5 (2.9%)
	2 (1.1%)
	1 (0.5%)
	2 (1.2%)
Dislocation	4 (2.3%)
	6 (3.4%)
	4 (1.9%)
	7 (4.2%)
Heterotopic bone	6 (3.5%)
	7 (4.0%)
	8 (3.8%)
	10 (6.1%)
Intraoperative insert chip	5 (2.9%)
	4 (2.3%)
	0
	NA
Abbreviation: NA - not applicable	

Four (1.2%) revisions have taken place for the entire study group (349 cases) implanted with alumina ceramic bearings, 1 in system 1 and 3 in system 2. Eight revisions were reported in the control group (system 3). In ABC systems 1 and 2, 1 revision of the femoral stem and head was for postoperative femoral fracture; 1 revision of the acetabular component, insert, and head was for recurrent dislocation; 1 revision of all components was for sepsis; and 1 revision of all components was for suspected, but not confirmed sepsis. For the cobalt-chrome-on-polyethylene control group, 1 revision of the stem and head was for postoperative femoral fracture; 1 revision of the stem and head was for leg-length discrepancy; 1 revision of the acetabular shell insert and head with retention of the femoral component was for acute sepsis; 1 revision of the acetabular shell, head, and insert was for loosening of the acetabular component; and 4 revisions of the insert and head were for recurrent dislocations. Peripheral chips (2.6%) occurred in 9 hips of the ABC alumina ceramic study group at the time of insertion. In all but 1 case, the alumina ceramic liner or shell or both were replaced. In 1 hip, the chipped insert was seated, impacted, and left in place without any known secondary complications. No complications have been reported related to these events in these 9 cases, and none of the revised cases had insertional chips. No alumina ceramic fractures or bearing surface-related failures have occurred in the 318 patients (349 hips) who received the ABC alumina ceramic bearing inserts.

Mean composite Harris hip scores for all ABC groups were consistently >90 out of 100 points (excellent range). At a mean 3 years postoperatively, the mean composite Harris hip scores for the ABC systems 1, 2, and 3 were 95.4 (158 hips), 96.6 (163 hips), and 95.9 (142 hips). Patients were asked if they were satisfied with the results of the surgery at each follow-up evaluation. At a mean 3 years postoperatively, patient satisfaction with the surgery was reported as 95% (157 hips), 98% (169 hips) and 97% (145 hips) with ABC systems 1, 2, and 3.

In evaluating revisions in the Trident study arm, one case involved revision of the femoral stem and head due to post-op femoral fracture which occurred at the 7 week postoperative visit as the patient descended from the exam table. One acetabular component, Trident insert, and alumina head were revised approximately 9 months postoperatively to an all-polyethylene cup with a 32 +5mm head due to acetabular component loosening. In one instance of chronic instability, the acetabular insert only was revised 19 months postoperatively to a Trident Crossfire polyethylene insert. Another case involved subluxation and led to revision of the acetabular insert and head at 22 months postoperatively.

Table 5 provides a summary of the radiographic results of the ABC and Trident study arms.

Table 5:
Radiographic results.

Radiographic Parameter	System 1 (2-4 y, mean, 3 y) (n = 162) System 2 (2-4 y; mean, 3 y) (n = 169) Trident (1-3; mean, 2 y) (n = 185) Control (2-4; mean, 3 y) (n = 149)
Femoral RLL zone 1	8 (6.0%) 3 (2.3%) 4 (2.3%) 11 (8.8%)
Femoral RLL zone 7	2 (1.5%) 1 (0.8%) 0 1 (0.8%)
Stem subsidence	0 1 (0.8%)* 0 0
Unstable stem fixation	1 (0.8%) 1 (0.8%)* 0 1 (0.8%)
Acetabular RLL	
Zone 1	10 (6.2%) 1 (0.6%) 1 (0.5%) 10 (6.7%)
Zone 2	3 (1.9%) 0 0 7 (4.7%)

Zone 3	25 (15.4%) 0 6 (3.3%) 35 (23.5%)
Acetabular RLL	
3 Zone	0 0 0 2 (1.6%)
Acetabular shell migration	1 (0.7%) 0 0 1 (0.8%)*†
Unstable acetabular component	2 (1.5%) 0 0 3 (2.4%)†
Abbreviation: RLL - radiolucent line. * Same femoral component. † Same acetabular component.	

One case (0.6%), implanted with ABC system 2, was reported to have an unstable femoral component. The same case was reported to have femoral subsidence. The investigator reported that the patient fell, and a postoperative femoral fracture was suspected, although it was not evident on radiographs. The patient has not been revised at this time. Two cases (systems 1 and 3) were reported to have unstable acetabular components. One case (system 1—microstructured surface treatment) was determined to have radiographic evidence of the acetabular shell loosening with radiolucent lines in zones 1 and 3 on evaluation of the 3-year radiographs. The patient is asymptomatic at this time. One case implanted with control system 3 was reported to have shell migration at the 3-year radiographic review. The patient is pending revision of a loose acetabular component. No cases of acetabular loosening were reported for system 2, which has an arc deposited titanium surface with hydroxyapatite treatment. At a minimum 2-year follow-up for 169 cases evaluated for ABC system 2, only 1 cup (0.6%) exhibited a radiolucent line in any zone. This case was reported to have a 1-mm radiolucent line in zone 1 at 2 years postoperatively. For the 162 cases evaluated for ABC system 1, 33 cups (20.4%) exhibited a radiolucent line in any zone, and 25 cups (15.4%) were reported as having a radiolucent line in zone 3. For the 149 cases evaluated for control system 3, 45 cups (30.2%) exhibited a radiolucent line in any zone, and 35 cups (23.5%) were reported as having a radiolucent line in zone 3. No hip was reported to have radiolucencies in all 3 acetabular zones (Fig. 2).

Critical evaluation of the Trident arm of the study With a 1- to 3-year follow-up, this study group has performed from a clinical standpoint equal to systems 1, 2,

and 3. There have been no peripheral chips because of the protective metal backing of the Trident, and there have been no ceramic fracture or ceramic bearing surface-related failures.

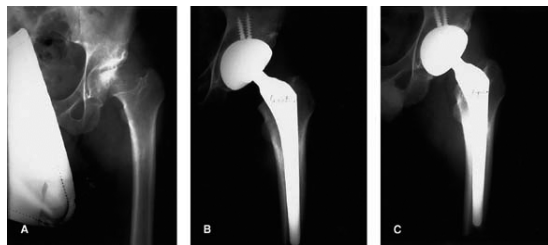


Figure 2A-C:

A 41-year-old laborer with Perthes's disease and secondary degenerative joint disease. Anteroposterior radiographs of (A) preoperative, (B) 6-week postoperative, and (C) 4-year postoperative views.

Discussion

In the 1970s and 1980s, emphasis was placed on achieving a high degree of fixation for THAs. In the 1990s, it became obvious that a major challenge to long-term success was to minimize wear and osteolysis. The most common mode of long-term failure for THA is aseptic loosening, and it has been recognized that particulate debris, in particular, polyethylene particulate debris, is responsible in many cases for the inflammatory response that leads to bone resorption and loosening of the implants over time [9-14]. Many patients are undergoing reoperation without revision of components in the form of liner or head exchange with or without bone grafting secondary to osteolytic periprosthetic bone loss. The actual biologic event is caused by macrophage-induced resorption of bone at the prosthesis-bone interface secondary to the presence of particulate polyethylene debris [15,16]. If the life expectancy of implants is to be improved significantly, better bearing surface materials are needed for the future.

Two approaches are being pursued simultaneously to minimize wear of THA bearing surfaces. The alternatives to traditional metal-on-polyethylene include improved cross-linked polyethylene components and hard-on-hard bearings, including metal-on-metal and alumina-on-alumina ceramic. Although new cross-linked polyethylene components offer great hope for reduced wear, long-term follow-up is necessary to determine their true potential for long-term success. With regard to hard-on-hard bearings, of the 2 alternatives, metal-on-metal versus alumina-on-alumina ceramic, the alumina ceramic bearing couples have several theoretical advantages. One is the elimination of polyethylene. Retrievals from alumina-on-alumina ceramic implants have indicated that alumina ceramic debris is less biologically reactive than particulate metal or polyethylene debris [17-20]. The extremely low coefficient of friction and superior wear resistance of alumina ceramics promises wear rates that are appreciably less than those of polyethylene-on-metal and metal-on-metal couples [11,17,20]. Alumina ceramics are extremely hard, scratch resistant, and stable at high temperatures, and their hydrophilic nature provides for improved lubrication over other

bearing surfaces [21]. Alumina ceramic bearings have no potential for ion release, a distinct advantage over metal-on-metal couplings. However, Alumina-on-alumina ceramic bearings have their own unique limitations, such as higher rigidity, the consequences for neck-socket impingement, the potential for fracture, and a history of early loosening revealed in previous clinical experiences reported from Europe and the United States [4,22,23]. As a result of these complications and past experiences, the alumina ceramic materials and prosthetic designs have evolved and improved.

Contemporary alumina ceramic material is of higher quality than earlier alumina ceramics. As a result of hot isostatic pressing, currently used alumina ceramics are produced with a dense fine grain alumina with a grain size $<2 \mu$ and limited grain boundaries and inclusions. The grain size of these materials has been reduced for Biolox material (CeramTec, Plochingen, Germany) from a high of 4.2 μ m in 1984 to 1.8 μ m for Biolox forte in 1995. Corresponding to the reduction in grain size, burst strength has increased from 46 kN in 1984 to 65 kN in 1995 [24]. Minimal Food and Drug Administration standards for burst strength for alumina ceramic components are 46 kN and no failures at 20 kN. These material improvements have increased greatly the toughness and strength of alumina ceramics. High tolerances for mating of the alumina ceramic to the implant have been established, eliminating a major cause for stress risers and fractures that occurred in the past [24]. Laser etching instead of mechanical engraving is used now, which minimizes stress risers. Proof testing also has been introduced. All modern components are subjected to a burst strength examination before sterilization and shipping [25,27]. Current alumina ceramic bearing implants benefit from the advantages gained as a result of improvements in the preparation of the alumina ceramics and new design features, such as improved manufacturing tolerances for mating of the alumina ceramics to the implants. Also, the alumina ceramic bearings now are used with femoral stems and acetabular components that have had a successful track record with regard to fixation. These combined improvements provide for a new approach to alumina-on-alumina ceramic bearings and hold great promise for prolonged fixation of implants, particularly in young and more active patients.

The clinical experience in Europe with alumina-on-alumina ceramic acetabular components began in 1970. Clinical experience in the United States began in the early 1980s with the introduction of the Autophor and Xenophor devices (threaded alumina ceramic cup designs developed by Mittelmeier in Europe) (Smith & Nephew, Richards, Memphis, TN). These ceramic-on-ceramic devices had disappointing results primarily because of design issues [4]. The primary design concerns were neck socket impingement, which could lead to femoral neck wear, cup rim fracture, debris degeneration, and loosening [17]. The use of these implants in the United States eventually was abandoned. Although these were alumina ceramic bearings, device failures were in large part design related rather than material related [4]. The implants that were used in the early 1980s were inferior to today's designs with regard to achieving lasting fixation and to mating of the alumina ceramic to the implants. The goal of current ceramic-on-ceramic components is to resolve design and fixation limitations and deficiencies revealed in earlier ceramic-on-ceramic designs.

An important feature of the ABC system is the protection of the alumina ceramic acetabular liner from impingement on the femoral neck. The components used in this study are recessed within the metal shell, avoiding the

possibility of impingement on the periphery of the alumina ceramic, which can lead to chipping and fracture. Perhaps the greatest concern with the use of alumina ceramics today is the issue of fracture. A review of the literature reveals a progressive decline in the incidence of component fractures as the quality of alumina ceramic materials improves with continued use of alumina ceramic bearings in Europe [22,25]. A report published in 1995 on the use of alumina ceramic femoral heads in the United States indicated a fracture rate of 1.9% in 4 of the 189 alumina ceramic femoral heads used. All alumina ceramic heads fractured within the first 2 years after implantation [23]. These femoral heads were used on femoral stems that were manufactured in the hospital, and there was a mismatch between the alumina ceramic femoral head and the trunnion of the femoral stem. This is an important issue, which has been resolved by appropriate design modifications. Precise matching of the taper-locking interface between the alumina ceramic and femoral or acetabular components is crucial to minimize the risk of stress risers and fracture. A recall of zirconium femoral heads (St. Gobain, Cedex, France) occurred because of reported fractures. The alumina femoral heads used in this study (ABC system) are of a completely different composition, are produced by a different manufacturer (CeramTec), and have not experienced a fracture.

To date, >7,000 ABC implants have been implanted in Europe and Australia. Two fractures of the acetabular liner have been reported. In both cases, the components intentionally were left in a canted nonseated position. Both of these implants failed through fracture in a short period. When an acetabular component of the ABC design is fully seated and when a femoral component from these systems is fully seated on a clean and appropriate trunnion, the risk of fracture is estimated to be 1 in 20,000 [24]. The risk of fracture of a metal component used in THA has been reported to be 27 in 10,000 [26].

Critical evaluation of the Trident arm of the study demonstrates that with a 1- to 3-year follow-up, this study group has performed from a clinical standpoint equal to systems 1, 2, and 3. There have been no peripheral chips because of the protective metal backing of the Trident, and there have been no ceramic fracture or ceramic bearing surface-related failures. The cohort of patients included in the ABC, Trident, and extended access portion of the study represents a population of 2313 patients with no device related failures attributable to the ceramic on ceramic articulation used in these patients.

Combining advances in material and design provides for a new approach to alumina-on-alumina ceramic bearings that hold great promise for increasing durability of implant fixation, particularly in young, active patients (Fig. 2). By combining new, high-quality alumina ceramic acetabular and femoral bearing heads with THA systems that have achieved long-term stable fixation, we believe a substantial increase in the fixation longevity of implants can be achieved. Current alumina-on-alumina ceramic bearing systems feature high-quality, fine grain alumina ceramic heads and inserts and hip stems and acetabular shells with clinically established successful fixation histories. We believe the use of alumina-on-alumina ceramic bearings, when properly designed, is indicated for younger and more active patients.

References

1. Papatheofanis F: Technology report: prosthetic hip and knee arthroplasty. University Hospital Consortium (UHC) Technology Advancement Center, Oakbrook, IL, 1994
2. Black J: Prospects for alternate bearing surfaces in total replacement arthroplasty of the hip. In: Proceedings of the 2nd Symposium on Ceramic Wear Couple, Stuttgart, Germany, 1997
3. Capello WN, D'Antonio JA, Feinberg JR, et al: Hydroxyapatite-coated total hip femoral components in patients less than fifty years old: clinical and radiographic results after five to eight years of follow-up. *J Bone Joint Surg Am* 79:1023, 1997
4. Mahoney OM, Dimon JH: Unsatisfactory results with a ceramic total hip prosthesis. *J Bone Joint Surg Am* 72:663, 1990
5. Harris WH: Traumatic arthritis of the hip after dislocation and acetabular fractures: treatment by mold arthroplasty: an end result study using a new method of result evaluation. *J Bone Joint Surg Am* 51:737, 1969
6. DeLee JG, Charnley J: Radiological demarcation of cemented sockets in total hip replacement. *Clin Orthop* 121:20, 1976
7. Gruen TA, McNeice GM, Amstutz HC: Modes of failure of cemented stem-type femoral components: a radiographic analysis of loosening. *Clin Orthop* 141:17, 1979
8. Engh CA, Massin P, Suthers KE: Roentgenographic assessment of the biologic fixation of porous-surfaced femoral components. *Clin Orthop* 257:107, 1990
9. Dumbleton J: Wear and prosthetic joints. Churchill Livingstone, New York, 1991
10. National Institute of Health: Total hip replacement. NIH Consensus Statement 1994. 12(5):1, 1994
11. Saikko VO, Paavolainen PO, Slatys PS: Wear of the polyethylene acetabular cup, metallic and ceramic heads compared in a hip simulator. *Acta Orthop Scand* 64:391, 1993
12. Harris WH: Osteolysis and particle disease in hip replacement. *Acta Orthop Scand* 65:113, 1994
13. Geesink R, Hoefnagels N: Six-year results of hydroxyapatite-coated total hip replacement. *J Bone Joint Surg Br* 77:534, 1995
14. Schmalzried T, Kwong L, Jasty M: Periprosthetic bone loss in total hip arthroplasty: the role of polyethylene wear debris and the concept of the effective joint space. *J Bone Joint Surg Am* 74:849, 1992
15. Goldring SR, Schiller AL, Roelke M, et al: The synovial-like membrane at the bone-cement interface in loose total hip replacements and its proposed role in bone lysis. *J Bone Joint Surg Am* 65:575, 1983
16. Shanbhag AS, Jacobs JJ, Glant TT, et al: Composition and morphology of wear debris in failed uncemented total hip replacement. *J Bone Joint Surg Br* 76:60, 1994
17. Clarke IC: Role of ceramic implants: design and clinical success with total hip prosthetic ceramic-to-ceramic bearings. *Clin Orthop* 282:19, 1992
18. Sedel L, Kerboull L, Christel P, et al: Alumina-on-alumina hip replacement: results of survivorship in young patients. *J Bone Joint Surg Br* 72:658, 1990
19. Lerouge S, Huk O, Yahia LH, et al: Ceramic-ceramic and metal-polyethylene total hip replacements: comparison of pseudomembranes after loosening. *J Bone Joint Surg Br* 79:135, 1997
20. Fisher J, Besong AA, Firkins PJ, et al: Comparative wear debris generation in UHMWPE on ceramic metal on metal and ceramic on ceramic hip prostheses. Presented at 46th Annual Meeting, Orthopaedic Research Society, Orlando, FL, 2000
21. Skinner HB: Ceramic bearing surfaces. *Clin Orthop* 369:83, 1999
22. Fritsch E, Gleitz M: Ceramic femoral head fractures in total hip arthroplasty. *Clin Orthop* 328:129, 1996

23. Callaway GH, Flynn W, Ranawat C: Case report: fracture of the femoral head after ceramic-on-polyethylene total hip arthroplasty. *J Arthroplasty* 10:855, 1995MEDLINE
24. Willmann G: Ceramic ball retrieval data. In: *Proceedings of the 4th Symposium on Ceramic Wear Couple*, Stuttgart, Germany, 1999
25. Heros RJ, Willmann G: Ceramics in total hip arthroplasty: history, mechanical properties, clinical results, and current manufacturing state of the art. *Semin Arthroplasty* 9:114, 1998
26. Heck DA, Partridge CM, Reuben JD, et al: Prosthetic component failures in hip arthroplasty surgery. *J Arthroplasty* 10:575, 1995MEDLINE
27. Guarino J: Ceramic-on-ceramic total hip replacements: back to the future. *Orthopedic Special Edition* 6, 2000

APPENDIX 1

Investigators and Co-Investigators in the ABC Study (Excluding Authors)

Paul Pongor, MD, New England Baptist Hospital, Boston, MA
 Edward Hellman, MD, Orthopaedics of Indianapolis, Indianapolis, IN
 Clifford W. Colwell, MD, Scripps Clinic, LaJolla, CA
 Steven Copp, MD, Scripps Clinic, LaJolla, CA
 Richard Walker, MD, Scripps Clinic, LaJolla, CA
 Joseph H. Dimon, III, MD, Peachtree Orthopaedic Clinic, Atlanta, GA
 John D. Henry, MD, Peachtree Orthopaedic Clinic, Atlanta, GA
 Jonathan Hottenstein, MD, Sewickley Valley Hospital, Moon Township, PA
 William Hozack, MD, Rothman Institute, Philadelphia, PA
 William L. Jaffe, MD, Hospital for Joint Diseases, Orthopedic Institute, New York, NY
 Paul DiCesare, MD, Hospital for Joint Diseases, Orthopedic Institute, New York, NY
 Patrick Meere, MD, Hospital for Joint Diseases, Orthopedic Institute, New York, NY
 Ormonde Mahoney, MD, Athens Orthopedic Clinic, PA, Athens, GA
 Kenneth E. Marks, MD, Cleveland Clinic Foundation, Cleveland, OH
 J. Wesley Mesko, MD, Ingham Medical Center, Lansing, MI
 James R. Roberson, MD, Emory Sports Medicine & Spine Center, Decatur, GA
 Sean P. Scully, MD, PhD, Duke University, Durham, NC
 Scott Siverhus, MD, Flower Hospital, Sylvania, OH
 Robert Zann, MD, Boca Raton Hospital, Boca Raton, FL

APPENDIX 2

Investigators and Co-Investigators in the Trident Study (Excluding Authors)

Joseph McCarthy, MD, New England Baptist Hospital, Boston, MA
 Arnold Scheller, MD, New England Baptist Hospital, Boston, MA
 Donald Reilly, MD, New England Baptist Hospital, Boston, MA
 Jonathan Hottenstein, MD, Sewickley Valley Hospital, Moon Township, PA
 James R. Roberson, MD, Emory Sports Medicine & Spine Center, Decatur, GA
 Scott Siverhus, MD, Flower Hospital, Sylvania, OH
 Robert Zann, MD, Boca Raton Hospital, Boca Raton, FL
 William Hozack, MD, Rothman Institute, Philadelphia, PA
 William L. Jaffe, MD, Hospital for Joint Diseases, Orthopedic Institute, New York, NY
 Patrick Meere, MD, Hospital for Joint Diseases, Orthopedic Institute, New York, NY
 Ormonde Mahoney, MD, Athens Orthopedic Clinic, PA, Athens, GA
 Clifford W. Colwell, MD, Scripps Clinic, LaJolla, CA
 Richard Walker, MD, Scripps Clinic, LaJolla, CA
 Steven Copp, MD, Scripps Clinic, LaJolla, CA
 J. Wesley Mesko, MD, Ingham Medical Center, Lansing, MI