A Review Paper

Ceramic Total Hip Arthroplasty in the United States: Safety and Risk Issues Revisited

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Abstract

The advantages of all-alumina bearings are superb wear resistance, stability, and inertness demonstrated over 3 decades. The disadvantage is a small risk for brittle fracture, as described in this paper. Surveying the latest ceramic hip series reported in recent journal articles or presented at the 6th World Biomaterials Congress, we found 11 studies representing more than 35,000 cases followed for 3 to 25 years. There were 24 reported fractures. A unique survey of hip complications in the 1990s found a fracture risk of approximately 1.4 per 1000 ceramic balls used in the United States. A company database holding more than 2.5 million records described the overall fracture risk as 1 per 10,000 cases. Initial use of ceramic cup inserts indicated a 2% to 3% incidence of chipping during surgery. Beginning in 1997, the number of ceramic–metal cup-locking cases entered into a US Food and Drug Administration ceramics database was more than 2400, with no fractures reported by the FDA in July 2003.

Use of ceramics in total hip arthroplasty (THA) began in 1970 with Boutin's introduction of all-alumina bearing surfaces. Thus, ceramic–ultra-high-molecular-weight polyethylene (UHMWPE) and ceramic-on-ceramic (COC) bearings have been in continual use for more than 30 years in Europe (Table I). One unique opportunity came around 1983 with the introduction of the Mittelmeier THA to the United States under the Food and Drug Administration (FDA) premarket approval system using existing European data. Over 3 years in the United States, more than 3500 Mittelmeier THAs were implanted. However, the manufacturer (Smith & Nephew, Memphis, Tenn) then voluntarily removed the implant from the market because of a very high incidence of stem loosening, exceeding 30% within 3 years in some series.[1-4] Only much later did FDA approvals come for ceramic ball–UHMWPE cup combinations (1989) and alumina cup inserts (2003).

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It can be concluded from most clinical[5-8] and laboratory[8-10] reports that alumina–UHMWPE and alumina–alumina combinations conferred a significant reduction in wear on THA bearings.[11-13] Use of COC bearings, with their much reduced risk for osteolysis even after 2 decades of use by active patients, thereby preserved bone stock and enabled easier revisions.[14] However, it is also true that very high wear and osteolysis rates have been sporadically documented over the 35-year history of ceramic implants.[15,16] In a clinical series in Korea, Yoon and colleagues[17] attributed the high failure rate of Mittelmeier ceramic cups (Autophor™, CeramTec Inc., Germany) to "osteolysis" in the pelvis.[17] They also described ceramic debris in retrieved periarticular tissues but did not comment on COC wear rates. A later study of Mittelmeier and Boutin COC implants found that the majority had minimal linear wear (<100 μm) but also that some had the highest wear ever reported (nearly 3 mm).[18] Wear rates in 7 of the 22 cases approached 0.6 mm per year—that is, rates in the same range indicating severe UHMWPE wear.[8] With the exception of some steeper cup angles, there was no

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Table I. History of Alumina Total Hip Arthroplasty (THA)

Year	Development
1970	First ceramic THA introduced by Boutin in France (Ceraver Inc)
1974	Biolox-1 launched in Europe
1980	Biolox-2 underwent gradual transition in late 1970s, early 1980s
1982	Mittelmeier THA concept (Autophor, Xenophor) approved by US Food and Drug Administration (FDA)
1983	Mittelmeier THA introduced in United States
1985	Mittelmeier THA no longer accepted in United States
1989	Ceramic–ultra–high–molecular–weight polyethylene (UHMWPE) combination approved by FDA
1995	Biolox-forte underwent transition in mid 1990s
1997	FDA studies (Stryker, Wright Medical) began in United States
2000	Biolox-delta launched in Europe
2003	Alumina cups (Stryker, Wright Medical) approved by FDA

Table II. Summary of Upgrades to Alumina Implant Technology[20]

Upgrade	Parameter	Decade
1	Replaced engraving with laser markings	1980s
2	Improved quality-control systems	1980s
3	Improved taper models	1990s
4	Hot-isostatic hipping	1990s
5	100% proof-test balls and liners	1990s

Table III. Design Advantages of Alumina Balls 32 mm in Diameter Versus Smaller Alumina Balls

Parameter	Feature	Benefit(s)
Added neck lengths	More surgical options	Improved stability and biomechanics
Larger head diameter	More range of motion	Less risk for impingement, more user-friendly for cups positioned suboptimally
Larger head diameter	More stability	Less risk for dislocation
Length of taper interface	Improved strength	Superior safety record
Alumina wall thickness	Improved strength	Superior safety record

obvious explanation for this high wear. However, in contradistinction to the predictions of Yoon and colleagues,[17] Nevelos and colleagues[18] found no evidence of osteolysis and concluded that ceramic cup loosening was design related. It is also obvious at this time that such high wear has not been reported in any contemporary, metal-backed ceramic cups, use of which began in 1989.

The downside of alumina implants has been the small but finite risk for fracture resulting from ceramics "brittleness." Over the first 2 decades of clinical studies with COC bearings, fracture rates were 0.4% to 0.5%.[19] Two clinical studies found fracture rates as high as 5% and 13%, but these were pioneering designs made before 1980.[19,20] For ceramic–UHMWPE, the ball fracture rate was less than 1.6% over the same 2 decades.[21] The difference may have been partially related to the lower tensile stress field in the ceramic ball when combined with a UHMWPE cup. In contrast, the rigid ceramic cup created smaller contact areas and hence higher ball stresses.[22] It was also well recognized that use of structured trunnion surfaces and use of Ti6Al4V minimized stress concentrations and thereby increased the safety factor.[23,24] In contrast, most fracture rates in the 1980s and 1990s were less than 0.02%.[9,19] In addition, "long-neck" ball designs increased the risk for fracture due to the reduced area of contact of ball on metal trunnion.[25,26] The strength of long-neck balls could be reduced 30% to 40% over that of the standard-neck design.[26]

As we enter a new era of ceramics use in the United States, we decided to review the safety and fracture records of alumina implants. This review paper is divided into 4 parts. The first summarizes the enhancements made to alumina implant technology by the 1990s. The second provides an overview of published fracture cases from 1970 to 1995.[19] The third examines a paper by Heck and colleagues,[27] who in 1995 conducted a poll regarding implant problems in the United States. And the fourth examines the latest clinical publications on ceramic THA use around the world. Especially relevant to US surgeons are the reports on the FDA-monitored, randomized, and blinded clinical studies.[28-30] Four FDA studies have been completed, and 2 more are in progress, each representing the most rigorous and detailed examination of ceramic THA performance (>3000 cases).

Enhanced Technology for Alumina Implants

Alumina implant technology has been improving over the past 3 decades. Most of the alumina implants used today are from CeramTec (Germany), Ceraver (France), Morgan Matroc (United Kingdom), and Kyocera (Japan). These companies

Table IV. Latest Clinical Reports Published in Journals or Presented at 6th World Biomaterials Congress (2000–2003)

Year	Congress/Journal	Author	Country	Follow-Up (y)	Total Hip Arthroplasty N	Total Hip Arthroplasty Type	Fractures (N)
2000	6th World Biomaterials Congress	Ueno[50]	Japan	>10	27,738	COC, CPE	9
2000	*Clin Orthop*	Boehler et al[48]	Austria	6	243	COC	0
2000	*Clin Orthop*	Bizot et al[47]	France	>5	234	COC	1
2000	*Clin Orthop*	Garino[28]	USA	1-3	333	COC	0
2001	*J Bone Joint Surg Am*	Urban et al[51]	USA	17-21	64	CPE	0
2001	*J Arthroplasty*	Delaunay et al[49]	France	5-10	133	CPE	0
2001	*Clin Orthop*	Bizot[52]	France	<3	96	COC	1
2002	*J Bone Joint Surg*	Hamadouchel[46]	France	>18	118	COC	0
2002	*J Arthroplasty*	D'Antonio[63]	USA	3	345	COC	0
2002	*Clin Orthop*	Bierbaum et al[30]	USA	4	514	COC	0
2003	*Clin Orthop*	Hannouche et al[45]	France	25	5500	COC, CPE	13

[a]COC, ceramic-on-ceramic; CPE, ceramic-on-polyethylene.

Table V. Six Companies Involved in Ceramic-on-Ceramic FDA-Monitored Clinical Studies, in Order of Study Initiation

Company	C–M Taper	Cup Type	Cases (N)	Fracture (N)
Howmedica/Osteonics	Yes	Rigid	843	0
Wright Medical Technology	Yes	Rigid	959	0
Encore Medical	Yes	Rigid	300	0
Smith & Nephew	Yes	Rigid	350	0
Implex	No	Porous-metal back	300	4/5 (1.3%)
Biomet	No	Sandwich/metal back	250	0
Total no. total hip arthroplasties			3002	

have substantially refined grain size, improved density, and significantly reduced inclusion levels. For example, the bending strength of the Biolox™ implant (CeramTec Inc., Germany) has been improved 40% over 3 decades (Figure 1).

Another development is improved manufacturing processes, including use of laser markings instead of the earlier engraving method, which may have been a source of stress risers (Table II). Refinement of 3-dimensional stress models also brought better understanding of the trunnion taper design elements and the various stress states in ceramic ball designs. In 1995, the hot-isostatic hipping (HIP) process was introduced, and the latest alumina implant was marketed as Biolox-forte™ (CeramTec Inc., Germany). Another significant development was the introduction of the "proof test." The goal of the proof test is to eliminate the weakest balls in each lot by temporarily loading them to a stress state above the physiologic requirements.[24] Before this test was introduced, only 2% to 3% of each lot were studied in a destructive "burst test." This meant that 97% of the balls in each lot were installed in patients with no other mechanical testing. With the proof test, 100% of alumina implants can be mechanically tested before leaving the factory—a major advance over previous methods.

The latest development was the introduction of alumina–zirconia composites for orthopedic implants.[31-33] Mechanical testing of femoral balls made of Biolox-delta™ (CeramTec Inc., Germany) showed strengths more than twice those of standard alumina. Thus, such composite ceramics have the excellent stability and hardness features of alumina plus the superior strength and fracture toughness of zirconia-type ceramics.

1990s Survey of Ceramics Fractures

For our review, we exclude all reference to implants made by ceramics companies that left the medical field (eg, Friedrichsfeld, Rosenthal). We also exclude reference to zirconia, a complex ceramic unique from alumina.[34-36]

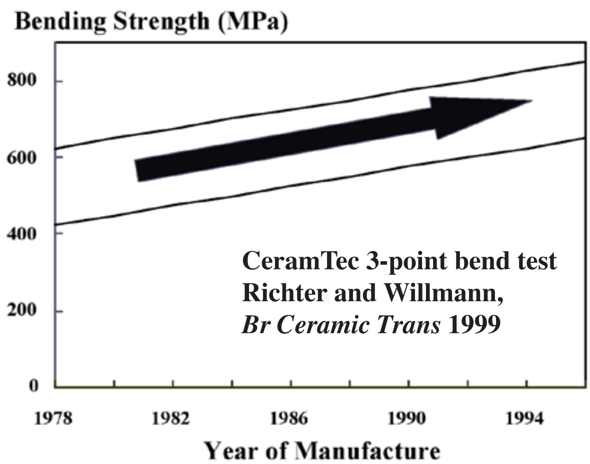

Figure 1. Bending strengths improved in successive grades of alumina (Biolox™). Data from Table 1 in: Richter HG, Willmann G. Reliability of ceramic components for total hip endoprostheses. *Br Ceramic Trans.* 1999;98:29-34.[24]

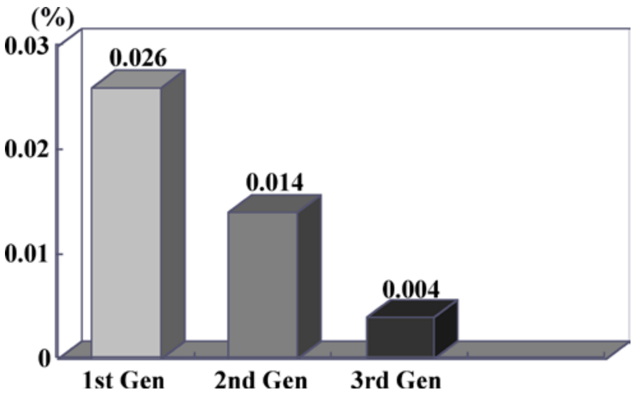

Figure 2. Manufacturer (CeramTec) statistics for decreasing incidence of ball fractures from 1970s. Third-generation alumina (Biolox-forte™) was introduced around 1995.[32]

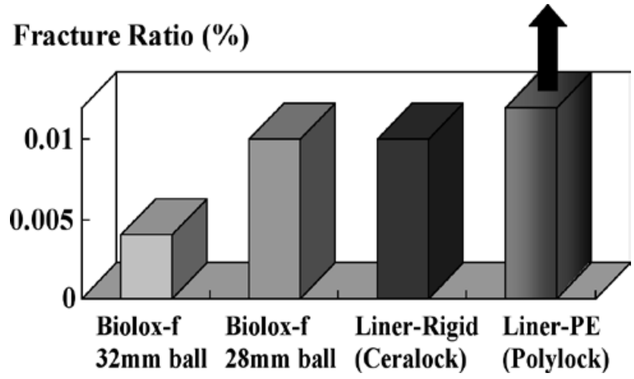

Figure 3. Comparison of fracture rations for third-generation alumina (Biolox-forte™) implants from 1995 to 2002.[33]

A milestone report on alumina fracture incidence in THA was published by Heros and Willmann[19] in 1998. They reviewed the results from 35 ceramics publications, predominantly from European surgeons and representing the 1970s, 1980s, and early 1990s. According to their table of clinical data published in the early 1990s (representing the 1980s), fracture incidence ranged from 0% to 0.8% (ie, 8 fractures per 1000 cases).[37] A confounding factor was that the majority represented small series of cases and were of the Mittelmeier design pioneered in the early 1970s.[4,37-39] This THA design, with its limited, skirted head mated with a bulky, monoblock screw cup, was abandoned by CeramTec in 1991. Overall statistics from CeramTec, with its database of more than 1 million sales, indicated a fracture incidence of 0.02% in the early 1990s—that is, 2 ball fractures per 10,000 cases.[40]

The Sedel group in Paris has issued many reports on its 26-year experience with the all-alumina Ceraver THA (Ceraver, Paris, France). This group's experience now includes more than 5500 cases. Its pioneering studies showed a 1970s fracture rate of 2%, which dropped to 0.1% in the 1980s. The estimate for the most recent decade is 0.05% (ie, 5 per 10,000). The confounding factor in this series was unreliable fixation methods used for the ceramic cups, and subsequent cup design issues were explored. Sedel[41] also reported 2 liner fractures in his newest metal-backed cup design. The latest CeramTec statistics from a database of more than 2.5 million ball sales demonstrated a dramatically decreased incidence (Figure 2) of fractures over 3 generations of alumina[42]—representing more than a 6-fold decrease from the 1970s to the 1990s, with current incidence being 0.004% (ie, 1 in 25,000 cases).

With regard to the Biolox-forte alumina implant introduced in 1995, incidence of fracture problems after 7 years of sales was 0.01% for both balls and liners—that is, 1 per 10,000 cases (Figure 3).[43] The 1 exception (higher incidence) was the "sandwich" design, with its adaptive layer of UHMWPE.[40] Compared with the smaller, 28-mm ball, the larger, 32-mm ball had a demonstrably lower fracture risk (ie, 0.004%, representing 1 in 25,000 cases). Thus, the 32-mm ball had considerably more optimal features than the 28-mm ball (Table III). Sedel has always made the case for using balls with a minimum diameter of 32 mm for alumina ceramics in his practice.[14]

One exception, apparently rising above the 0.01% fracture level in the CeramTec database, was the "sandwich" cup design with its adaptive layer of UHMWPE.[40,43] However, the number of cases is much smaller, so it is important to monitor this design concept carefully, as is discussed below for the FDA-monitored studies.

Implant-Related Problems in the United States

Heck and colleagues[27] conducted a poll regarding more than 60,000 implants used in the United States over 5 years in the 1990s. Eleven fractures were reported among 5023 ceramic balls used, but the survey documented only 10 fracture cases, and 3 of these were from a set mounted on femoral stems manufactured at the Hospital for Special Surgery (HSS). HSS data should probably be excluded, as they represent a hospital group's unique manufacturing environment.[44] Thus, the fracture rate in this poll was 7 fractures among 5023 cases, for a ratio of 1.4 per 1000. To put this in perspective, the same poll documented the combined risk of wear-through and fracture in cemented UHMWPE cups as 24 per 1000 and fractures of the femoral stem as 2.7 per 1000. In other words, fracture of ceramic balls was a somewhat rare complication overshadowed by the fracture incidence for femoral stems and gross failures with the cemented UHMWPE cups.

Latest Reports on Ceramic THAs (2000-2003)

Surveying the latest ceramic THA series reported in recent journal articles or presented at the 6th World Biomaterials Congress, we found 11 studies representing more than 35,000 cases (Table IV). From the Paris group, Hannouche and colleagues,[45] who reported on 5500 cases followed for 25 years, found 8 head fractures and 5 cup fractures. Hamadouche[46] and Bizot,[47] presenting various developments in ceramic implants, found no fractures in their selected series followed for 20 years. From Austria, Boehler and colleagues[48] reported on 243 cases followed for 6 years (no fractures). From the FDA multicenter studies recently conducted in the United States, Garino[28] reported on 333 cases followed for 3 years (no fractures). Delaunay and colleagues[49] from France reviewed 133 cases followed for 5 to 10 years (no fractures). From Japan, the Kyocera group[50] presented 27,738 cases (9 head fractures, 0.032%). In the United States, Urban and colleagues[51] reported on 64 cases followed for a minimum of 17 years (no fractures). Also in the United States, D'Antonio and colleagues[29] and Bierbaum and colleagues[30] reported on 345 and 514 cases followed for 3 and 4 years, respectively (no fractures in each series). Thus, in this recent international set of presentations involving more than 35,000 cases with follow-ups from 3 to more than 20 years, there were 24 fractures.

Contemporary Alumina-Liner Inserts

The history of alumina inserts used in rigid metal shells is fairly recent and therefore not nearly as comprehensive as for alumina balls. However, European surgeons have described occasional rim chipping and fracture of ceramic inserts.[52-54]

Recently in Japan, some authors reported alumina bearing surface (ABS) cup fracture.[55-58] Amino[57] reported on 5500 cases of ABS cup (January 1998–July 2000) with 16 fractures by January 2002. Kitajima and Hotokebuchi[58] reported more than 60 fractures by January 2003. In the United States, cases in the FDA database have numbered more than 3000 since 1997[59,60](Table V).

In the US market, there are 2 distinct design concepts. The cup design with the most experience worldwide is the direct taper-lock of alumina liner to metal shell (C–M taper, Table V), which constitutes major reinforcement of the inner ceramic bearing. Such cups have more load-bearing capacity than the mating ceramic ball does. No fractures have been reported in this "rigid" cup series (>2400 cases are being followed in the FDA database). However, with the other cup design, alumina bearing cup (ABC™, Osteonic, Mahwah, NJ), there were 9 intraoperative reports of chipping of the outer rim of the cup liner during impaction (incidence, 2.6%).[61] Under the FDA study guidelines, such chipped liners and their metal-backed cups were discarded during surgery. The ABC insert was then superceded by the metal-lined alumina insert (Trident™, Stryker, Mahwah, NJ), and that evolution in liner design eliminated the rim-chipping phenomenon.

The so-called sandwich cup, which has the ceramic liner locked into an adaptive layer of polyethylene, also comes in 2 design concepts. Biomet sandwich cups (Biomet, Inc., Warsaw, IN) are conventional, metal-backed cups; no fractures have been reported in this series. The other design, Implex (Zimmer, Inc., Warsaw, IN), incorporates the ceramic liner/polyethylene adaptor into a more flexible, fiber–metal cup. As reported in FDA studies, 5 of 300 liners disassociated, and 4 of the 5 fractured, resulting in a 1.3% fracture incidence (Table V). At the 2003 American Academy of Orthopaedic Surgeons annual meeting, the manufacturer announced it was voluntarily stopping its clinical studies.

Thus, the data for alumina–metal cup constructs used in the United States indicate a 2% to 3% incidence of chipping during surgery[54,59-61] and a fracture rate of 0% (Table V).

Discussion

The clinical advantages of all-alumina (COC) bearings are superb wear resistance (even while under attack by various 3-body wear particles) and demonstrated stability and inertness over 3 decades of continual use. Their disadvantage is their brittleness, which is common to this class of materials, and their resulting small risk for fracture. On the other hand, the alternative design, all-metal (MOM) bearings, demonstrates excellent wear resistance (given the right conditions) and no fracture risk. The disadvantages of MOM bearings are their unknown vulnerability to 3-body wear and their known systemic distribution of trillions of Cobalt (Co) and Chromium (Cr) particulates plus their dissolution into ionic form.

Another candidate is the highly cross-linked polyethylene cup, which has excellent wear characteristics in the laboratory (50-100 kGy radiation dose). In the past, however, clinical experience with "new and improved" polyethylenes has seldom been exemplary, and current clinical experience is but a blip on the radar screen. It is also likely that the adverse conditions in the hips of our high-activity patients will severely challenge even the newest cross-linked polyethylene cups.

Major advances have been made in all-alumina bearing technology. Alumina material has been significantly improved, and today's designs of ceramic inserts are in most instances reinforced with metal backing. In this regard, the porous-coated, hemispherical shell has represented a significant advance in noncemented hip surgery. The small but disturbing incidence of ceramic rim chipping may have disappeared with improved teaching and attention to surgical details. One ceramic insert design, with its addition of a protective metal sleeve, has eliminated that risk. However, will some small risk for fracture always remain? We know that stringent attention to detail is required during surgery—and also vigilance in monitoring these continuing series of ceramic hip joints. Fortunately, for the first time we have access to data from large multicenter clinical studies being conducted under stringent FDA guidelines, and we may finally see introduced into orthopedics the composite alumina ceramics that bring twice the strength of today's alumina.

Authors' Disclosure Statement

The authors report no actual or potential conflict of interest in relation to this article.

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