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High Survivorship With a Titanium-encased Alumina Ceramic Bearing for Total Hip Arthroplasty

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Abstract

Background Although ceramic-on-ceramic bearings for total hip arthroplasty (THA) show promising results in terms of bearing-surface wear, fracture of the bearing, insertional chips, and squeaking remain a concern.

Questions/purposes Our primary objective of this report was to determine overall survivorship of a titanium-encased ceramic-on-ceramic bearing couple. Our secondary objectives were to evaluate for ceramic fracture, insertional chips, osteolysis, and device squeaking.

Methods Six surgeons at six institutions implanted 194 patients (209 hips) with an average age of 52 years with cementless hips and alumina ceramic bearings. One hundred thirty-seven patients (146 hips) have 10-year followup (70%). We determined Kaplan-Meier survivorship of the bearing surface and implant system and collected radiographic and clinical data to evaluate for osteolysis and squeaking.

Results Survivorship using revision for any reason as the end point was 97% at 10 years and survivorship end point bearing surface failure or aseptic loosening of 99%. There was one ceramic insert fracture (0.5%), there were no insertional chips, there was no visible osteolysis on AP and lateral radiographs, and there was a 1% patient-self-reported incidence of squeaking at the last clinical followup. Six hips underwent revision (3.7%).

Conclusions Ceramic bearings for THA with a titanium-encased insert have high survivorship at 10 years followup and a fracture risk of 0.5%. We found at last followup on routine radiographs no evidence of osteolysis, and no patient has been revised for squeaking or has reported dissatisfaction with the clinical result because of noise.

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

Introduction

The major advantages of alumina ceramic bearings for THA include their hardness and scratch resistance, low coefficient of friction, hydrophilic nature and superior lubrication, less reactive particulate debris, and superior wear resistance [2, 5, 7].

One or more of the authors (JAD, WNC) certify that they have or may receive payments or benefits, in any one year, an amount in excess of USD 10,000 from a commercial entity (Stryker Orthopaedics, Mahwah, NJ, USA) related to this work; two authors (JAD, WNC) certify that they have stock in Stryker Orthopaedics. One author (MN) is an employee of Stryker Orthopaedics.

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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 was obtained.

This work was performed at Sewickley Valley Hospital Sewickley, PA, USA; Indiana University School of Medicine, Indianapolis, IN, USA; and Stryker Orthopaedics, Mahwah, NJ, USA.

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Early experiences dating back to the 1970s had failures primarily related to aseptic loosening and ceramic fractures [1, 6, 16]. In the mid-1990s a new generation of alumina ceramic bearings was developed (Biolox Forte; Ceram Tec, Plochingen, Germany) [7]. This new ceramic material is of higher quality, has greater burst strength, and currently is mated with implants that have excellent fixation records and high taper tolerances [4, 7, 13, 16].

In October 1996, a US Investigational Device Exemption (IDE), randomized controlled trial began comparing alumina bearing couples with a chrome cobalt-on-conventional polyethylene control system. At minimum 10-year followup we reported, for the nontitanium-encased ceramic bearings, substantially higher survivorship (96.6% versus 91%), zero osteolysis, one ceramic insert fracture, 1% squeaking, and three intraoperative insertion chips in three patients [4] (Fig. 1).

In 1999 a second prospective IDE multicenter study of ceramic hip bearings (194 patients, 209 hips) began using the same implants with the exception of the ceramic insert component, which was encased in a thin titanium sleeve (Fig. 2). The titanium sleeve was added to in theory improve overall survivorship by reducing ceramic fracture, eliminating insertional chips, and by providing for a greater ease of revision of insert. The primary objective of the second study was to compare the incidence of bearing fracture and insertion chipping with that of the predecessor alumina ceramic bearing design. At a minimum followup of 3 years (mean, 4.2 years; range, 3–5 years) we reported no insertion ceramic chips or ceramic fractures [3].

The present study seeks to provide followup on that earlier report. Our primary objective of this report was to determine the overall survivorship of a cementless THA system that used a titanium-encased ceramic-on-ceramic bearing couple at 10-year followup. Our secondary objectives were to evaluate for insertional chips, ceramic fracture, osteolysis, and device squeaking.

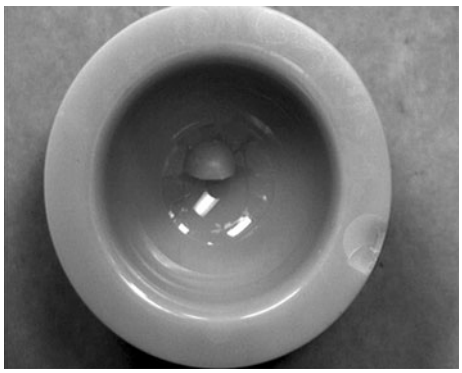

Fig. 1 Ceramic insert developed a peripheral chip on seating and was replaced at the time of surgery.

Fig. 2 The ceramic insert shown is encased in a titanium sleeve.

Materials and Methods

Six surgeons at six institutions implanted 194 patients (209 hips) cementless hip implants with a titanium alloy stem and alumina ceramic bearings (Trident; Stryker Orthopaedics; Mahwah, NJ, USA). Through a shrink-fit process, the acetabular insert was encased in a thin titanium sleeve to reduce the risk of insertional chips that occurred with the previous design (Fig. 2). The titanium sleeve containing the ceramic insert was then secured into a titanium cementless cup through a reverse taper lock. The description of implants and patient inclusion criteria and distribution of head sizes for the original study have previously been reported [3].

Clinical data and radiographs were collected preoperatively, early postoperatively (at 6–8 weeks), at 6 months, at 1 year, and at 1-year intervals thereafter through 5 years and optional to 10 years. An FDA requirement for approval of the device in 2003 was to continue a Post-Approval Study (PAS) through 10 years. The objectives of the PAS were to demonstrate continued safety through reporting incidences of revision and complications through 10 years.

To assess the ongoing status of the hip for those patients, a brief questionnaire was completed annually from 6 to 10 years postoperatively whether or not they returned (Table 1). Optional clinical and radiographic followup at 7 and 10 years was obtained. In addition to the patients who received the questionnaire, 77 patients had a clinical visit with data collection and 60 had radiographs at 10-year followup.

Of the 209 hips in the original study, five were lost to death, four were revised, eight were lost to followup, and three were lost due to patients declining to participate in the PAS. Of the 190 who agreed to participate in the PAS, seven patients died, two were revised and 35 were lost to followup. These 35 patients were lost to followup between 5 and 10 years: 2 at 5 years, 6 at 7 years, 9 at 8 years, and 18 at 9 years. Of those who continued to participate, 152

Table 1. Patient response in percent to questions on postcard followup for postapproval study from 6 to 10 years

Year	(1) Percent yes satisfied	(2) Percent no hip pain	(3) Percent no surgery in the past year
6	N = 161 (97%)	N = 141 (85%)	No = 166 (100%)
7	N = 159 (98%)	N = 136 (83%)	No = 163 (100%)
8	N = 158 (98%)	N = 138 (85%)	No = 162 (100%)
9	N = 147 (99%)	N = 126 (85%)	No = 149 (100%)
10	N = 144 (99.%)	N = 126 (87%)	No = 145 (100%)

(1) Patient satisfaction (Are you satisfied with the THA?); (2) Do you have any hip pain? (3) Have you had surgery in the past year?

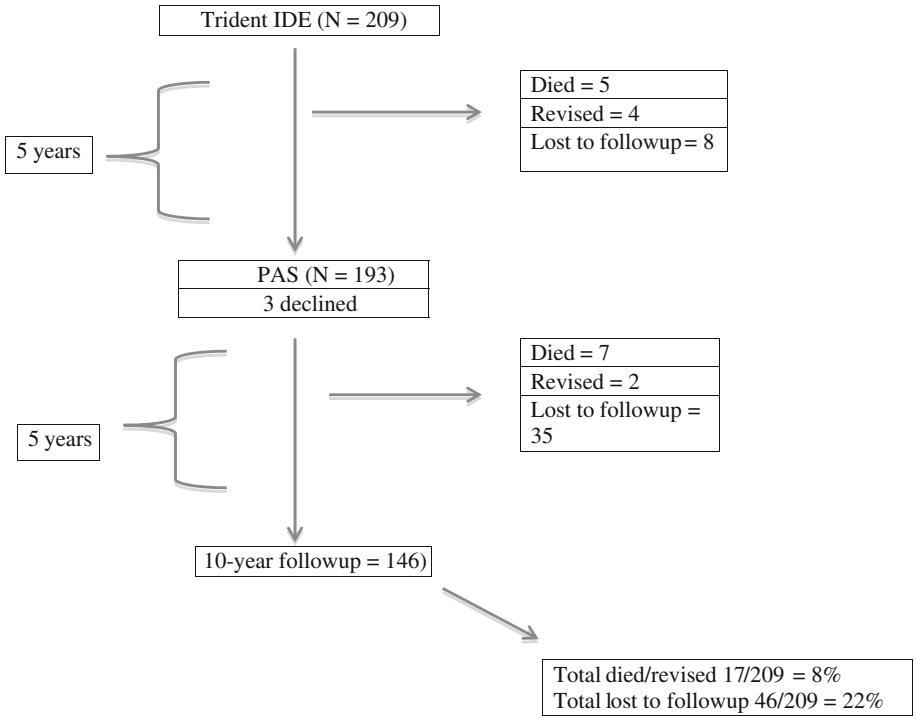

Fig. 3 Flow chart of number of hips followed and reasons for exclusion from onset to 10-year followup is shown.

patients (164 hips [78%]) had 9-year followup and 137 patients (146 hips [70%]) had followup through 10 years. Of the 30% not followed at 10 years, 22% were lost to followup and 8% died or were revised (Fig. 3).

Demographics for the 10-year patient population include average age of 52 years and 65% male patients, which is comparable to the original study cohort of 209 patients (Table 2).

The survival rates, defined as absence of revision for any reason and absence of revision for aseptic loosening or bearing surface failure, were determined using the Kaplan-Meier method [9]. The yearly hip followup questionnaire consisted of three questions: (1) Are you satisfied with the results of your THA? (2) Do you have any pain in your hip? (3) Have you had any surgery on your hip in the past year? If patients were not satisfied with their hip arthroplasty, they were asked for the specific reason or reasons.

The presence of osteolysis was determined by evaluating AP and lateral radiographs at each patient's last visit; CT scanning was not performed in this series.

The presence of squeaking was ascertained by questioning at each clinical visit, which was performed by a member of the team who was not directly involved with patient care. For those patients receiving the yearly hip followup questionnaire, they were asked for specific reasons for lack of satisfaction with the clinical result. They were not asked to report on specific noise.

Categorical variables were summarized as count and percentage, and the chi square test was used to test the distribution difference between two groups. Continuous numeric variables were summarized as mean and SD and Wilcoxon test was used to compare population location parameters between two groups. Survival functions for the absence of revision for any reason and for aseptic loosening or bearing failure were graphed using the Kaplan-Meier

Table 2. The demographics of original population and those followed through 10 years are outlined

Demographics	Total	Trident: minimum 10 years
Number of cases	209	146
Number of patients	194	137
Male/female (%)	66%/34%	67%/33%
Mean age (years)	52 (± 10)	52 (± 10)
Mean weight (pounds)	190 (± 39)	190 (± 39)
Mean height (inches)	68 (± 4)	68 (± 4)
Mean body mass index (kg/m^2)	29 (± 5)	29 (± 6)
Length of followup (years)	9 (1–11)	10 (9–11)
Diagnosis	81% OA, 3% PTA, 11% AVN, 4% SCFE, 1% Fem Fx	84% OA, 2% PTA, 10% AVN, 3% SCFE, 1% Fem Fx

OA = osteoarthritis; PTA = posttraumatic arthritis; AVN = avascular necrosis; SCFE = slipped capital femoral epiphysis; Fem Fx = femoral fracture.

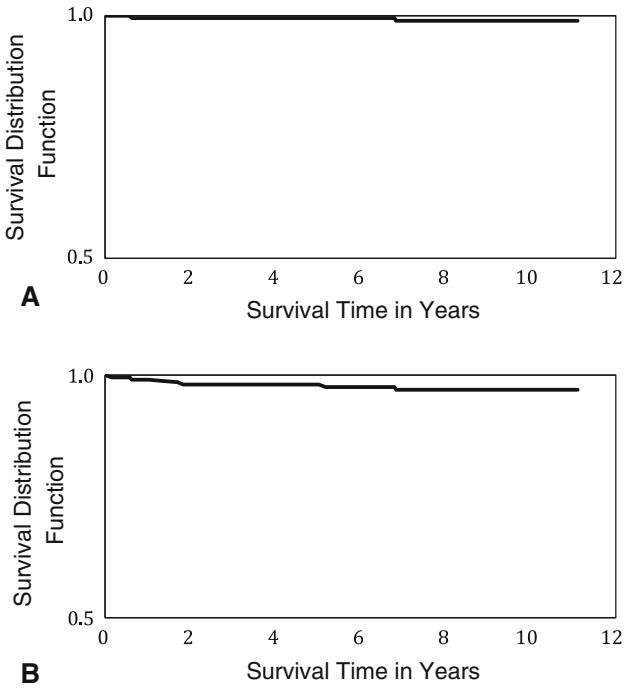

Fig. 4A–B (**A**) The Kaplan-Meier survivorship end point aseptic loosening and or bearing surface failure (99%). (**B**) The Kaplan-Meier survivorship end point revision for any reason (97%).

method. All statistical tests were two-sided with a significance level of 0.05. SAS/STAT software Version 9.1.3 (SAS Institute, Cary, NC, USA) was used for all data analyses.

The demographic data were summarized and reported by group with 10 years followup; comparisons were performed to identify potential differences between those lost to followup compared with either the original 209 hips or 10-year cohort. Statistical analysis demonstrated no differences in patient sex, height, weight, or body mass index between those lost to followup compared with either the original 209 hips or 10-year cohort.

Results

For the entire population, the survivorship using revision for any reason as the end point was 97% (Fig. 4A), and for revision for aseptic loosening or bearing surface failure, it was 99% (Fig. 4B). The major complications in this series included six revisions (3.7%), four dislocations (2%), and one fractured ceramic insert (0.5%) (Table 3). Revisions have occurred postoperatively for the following reasons: two (1%) revised at 2 years for recurrent instability; one (0.5%) at 7 years for acetabular insert fracture; one (0.5%) revision at 5 years for groin pain and tendonitis; one (0.5%) at 1 year for acetabular component loosening; and one (0.5%) revision at 0.2 years for postoperative femoral fracture. This last patient continued to be followed for 8 years.

No osteolysis has been found on routine radiographs at the last followup visit.

Table 3. Hip-related postoperative complications for total population of patients

Complication	Number (%)
Revision for instability (insert only)	2 (1)
Revision for insert fracture (insert only)	1 (0.5)
Revision acetabular loosening (shell, head, liner)	1 (0.5)
Revision periprosthetic femoral fracture (tem and head)	1 (0.5)
Revision (groin pain) (insert and head)	1 (0.5)
Dislocations	4 (2)
Squeaking noise (no revisions)	2 (1.0)

Although two patients reported squeaking (1%), neither was revised for noise and no patient reported dissatisfaction with the clinical result because of squeaking.

Discussion

The primary objective of this followup report was to determine the overall survivorship at 10 years of a cementless THA system that used a titanium-encased ceramic acetabular bearing with a ceramic-on-ceramic bearing couple. Our secondary objectives were to evaluate for insertional chips, ceramic fracture, osteolysis, and device squeaking. The titanium sleeve was added to theoretically increase survivorship by reducing ceramic fracture

Table 4. Published studies with minimum 10-year followup using Biolox Forte aluminum ceramic bearings for THA

Citations	Followup (years)	Number of hips	Average age (years)	Survival of revision for any reason	Survival of aseptic loosening	Ceramic fracture	Osteolysis	Squeaking
Sugano et al. [20]	11–14	100	56	96%	97%	1% 1 insert	1%	N/R
Solarino et al. [18]	13	68	50	97%	99%	0%	0%	0%
Yeung et al. [21]	10+	244	58	98%	99%	0%	0%	0.3%
Kim et al. [10]	10–13	93	38	100%	100%	0%	0%	2%
Lee et al. [11]	10+	88	41	97%	100%	2% 2 heads	0%	1%
D'Antonio et al. [4]	9–11	289	54	97%	100%	0.4% 1 insert	0%	1%
Yoon et al. [22]	10+	75	24	99%	100%	1.3% 1 insert	0%	3%
Current study	10	146	52	97%	99%	0.5% 1 insert	0%	1%

N/R = not reported.

and eliminating insertional chips. Although the sleeve did eliminate the insertional chips seen with the previous design, it was unknown what affect the sleeve would have on overall survivorship.

Our study has limitations. First, 46 patients (22%) were lost to followup over the 10-year period. As of the last evaluation on these patients, the implants were still in service and the patients were doing well; however, the possibility exists that some could have been revised since then or developed complications since the last visit. Statistical analysis demonstrated no differences in sex, height, weight, or body mass index between those lost to followup compared with either the original 209 hips or 10-year cohort, suggesting that the 10-year patient cohort was representative of the study population. However, it is not possible to be certain that the population with complete followup is entirely comparable to those who are lost to followup. Although we have 70% followup of the original cohort of patients, our followup percent is similar to those studies recently reported with 10-year followup that range from 70% to 93% (average 82% followup) [4, 10, 11, 18, 20–22]. The incidence of squeaking is probably underestimated in this report. Although patients were asked about noise on return visits, the postcard survey did not specifically ask the question. We know that this results in an underestimation of the prevalence of hip noise [8]. Although only two patients have reported squeaking, no patient has reported dissatisfaction because of noise. Another limitation is with the determination of osteolysis. In our study, routine radiographs were used and not all patients had radiographs through 10 years. We believe that routine radiographs are sufficiently sensitive to detect clinically important osteolytic lesions, but we agree with literature that suggests CT scans offer more accuracy; we consider the CT to be indicated when surgical intervention is considered [12, 17]. Finally, the six surgeons in this study were experienced with the implant systems used, and the results may not be similar to a wider, less experienced surgeon population.

When considering survivorship, osteolysis, ceramic fracture, and squeaking, our results with a titanium-encased ceramic liner agrees with our previous prospective study and with six other current reports using nontitanium-encased inserts, cementless implants with titanium alloy stems, all with minimum 10-year followup [4, 10, 11, 18, 20–22]. Combining our current study results with those seven reports, 1166 ceramic hip bearings are included and found to have high survivorship, a 0.5% ceramic fracture rate, rare osteolysis, and no known significant squeaking issues (Table 4). The relatively young average age of our patient of 52 years was similar to these reports (range, 24–58 years). Our survivorship using revision for any reason of 97% and for aseptic loosening of 99% was the same with their range, respectively, of 96% to 100% and 97% to 100%.

We experienced one insert fracture (0.5%), which is similar to the three reported studies that had an insert fracture (0.4%–1%) [4, 20, 22], One of the studies reported two femoral head fracture (2%) [11], and three reported no ceramic fractures.

Osteolysis when assessed with plain radiographs is rarely seen with contemporary ceramic implants and our experience agrees with the rare finding (0%–1%) in other reports with minimum 10-year followup. Although our incidence of squeaking may be underestimated because patients were not specifically screened beyond 5 years, it does agree with these reports (1%–3%) and also with a meta-analysis covering 6137 patients (2.4%) [19] and is in contrast to reports of 10% to 18% squeaking [8, 14, 15].

Although the presence of a titanium sleeve for the acetabular insert has prevented insertional chips, it has not resulted in any apparent improvement regarding survivorship, osteolysis, ceramic fracture, or squeaking when compared with those reports with 10 years followup that

did not use a titanium-encased insert. We determined no complications that can be related to the addition of the titanium sleeve.

The use of Biolox Forte titanium-encased inserts with alumina ceramic bearings for THA with cementless implants and a titanium alloy stem has high survivorship at 10 years of followup. Although ceramic fracture is rare, it remains a risk for both the femoral head as well as the socket insert. We believe that an alumina ceramic bearing continues to provide an option for the young and more active patient.

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