Does Acetabular Inclination Angle Affect Survivorship of Alumina-ceramic Articulations?

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Abstract

Background Reports in the literature have linked high acetabular inclination angles to increased wear of ceramic-on-ceramic bearings. However, many of these studies were only conducted in vitro and did not address the clinical relevance of such findings.

Questions/purposes We therefore determined: (1) whether the cup inclination angle influences survival or function in patients with ceramic-on-ceramic implants; (2) the incidence of radiolucencies, osteolysis, and subsidence of ceramic-on-ceramic implants; and (3) whether the survival rate higher for ceramic-on-ceramic THAs than for conventional metal-on-polyethylene THAs.

One or more of the authors (MN) have signed agreements with a commercial interest related to this study. 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 Bonutti Clinic.

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Methods We retrospectively reviewed 537 THAs performed in 512 prospectively followed patients having THA between October 1996 and October 2000. Eleven patients (12 hips) were lost to followup before 2 years, leaving 501 patients (525 THAs); of these, 421 were alumina ceramic-on-ceramic articulations and 104 cobalt-chromium-on-polyethylene. The mean age was 54 years. We determined acetabular cup inclination angles, Harris hip scores, Health-Status-Questionnaire-12 scores, and presence and location of any radiolucencies, osteolysis, or radiographic subsidence. We compared survival using the Kaplan-Meier method. The minimum followup was 24 months (mean, 59 months; range, 24–120 months).

Results Twenty-two of the 424 THAs (4.2%) were revised. We observed no difference in clinical or radiographic outcomes with respect to cup inclination angles. Radiographically, two loose acetabular components and two femoral components had subsided. The 5-year survival rate was slightly higher for ceramic-on-ceramic bearings (98%) than for metal-on-polyethylene (92%).

Conclusions Although there may be a link between acetabular inclination angles and wear rates as reported by some authors, we found no differences in patient function or radiographic survivorship using alumina-on-alumina articulations.

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

Introduction

The ideal cup inclination angle has been studied extensively in THA with metal-on-polyethylene (PE) prostheses. Although authors disagree about recommendations for

where the acetabular component should be positioned (for example, some would describe ideal acetabular inclination as $45^\circ \pm 10^\circ$, while others would say $40^\circ \pm 10^\circ$), it is agreed suboptimal acetabular positioning can lead to construct instability and detrimental wear characteristics [4, 11, 19, 23]. Although more horizontal component positioning reportedly reduces the rate of dislocation, there appear to be higher contact stresses when the acetabulum is positioned this way [21, 22], which may lead to increased PE wear [10, 21, 22, 30]. A potential alternative to conventional metal-on-PE bearing surfaces is alumina-ceramic-on-ceramic. Historically, these bearing surfaces were associated with catastrophic failures of the ceramic head or liner, such as component fracture and chipping [17, 18]. Recently, improvements in manufacturing processes have produced ceramics with smaller grain sizes, lower porosity, and higher density, leading to stronger and more fracture-resistant materials [29]. This may lead to component fracture rates as low as one in 25,000 in some reports [35]; however, it remains to be determined whether these design modifications will actually decrease fracture rates [24]. Because the incidence of fracture may have been reduced, the current thought is that the primary cause of failure in ceramic-on-ceramic bearings is now due to increased wear rates related to component malpositioning [31, 32].

Several reports [1, 26, 28] describe how wear rates for ceramic-on-ceramic bearings are affected by cup inclination angles. In vitro retrieval studies have suggested these bearings exhibit extremely low wear rates, ranging from 0.025 to 0.05 μm per year [12, 31]. In vitro experimental studies such as those describe by Nevelos et al. [28] are conducted under ideal conditions; ideal positioning and continuous joint lubrication may create more conservative testing parameters than may be experienced in vivo [28]. Several reports debate whether ceramic-on-ceramic bearings exhibit increased [28] or equal [29] wear at increased acetabular inclination angles. Therefore, it is unclear whether inclination angles affect the durability of ceramic-on-ceramic implants.

We therefore determined: (1) whether cup inclination angles influence survival rates, Harris hip scores (HHS), or Health-Status-Questionnaire-12 (HSQ-12) scores; (2) the incidence of radiolucencies, osteolysis, and subsidence of the ceramic-on-ceramic implants on radiographic analysis; and (3) whether the survival rate of ceramic-on-ceramic THAs was higher than that of conventional metal-on-polyethylene THAs?

Patients and Methods

Between October 1996 and October 2000, 537 THAs were performed in 512 patients as part of a multipart prospective

randomized US Investigational Device Exemption study. In the first portion of the study, patients were randomized into one of three cohorts. The control group received conventional metal-on-PE articulations. The remaining two cohorts received ceramic-on-ceramic articulations. The first cohort was implanted with a porous-coated acetabular shell (113 hips) and the second cohort with an hydroxyapatite-coated shell (109 hips) [8]. In a subsequent study, a further 209 hips were implanted with a modified hydroxyapatite-coated acetabular shell with the addition of a preassembled titanium liner in an attempt to decrease the incidence of chipping [9]. Of the 537 hips, all 431 ceramic-on-ceramic articulations were alumina-ceramic, and the 106 remaining hips were cobalt-chromium-on-PE bearing surfaces. Inclusion and exclusion criteria for the two studies were identical, and patients were considered for inclusion if they (1) agreed to the informed consent; (2) were between the ages of 21 and 75 years at the time of enrollment; (3) were not morbidly obese; (4) clinically qualified for THA; (5) were diagnosed with noninflammatory degenerative joint disease; (6) did not have a hip infection; (7) had not had a prior fusion or THA on the affected side; (8) were physically and mentally able to comply with all postoperative evaluations; (9) did not have a neuromuscular or neurosensory disorder; (10) did not have a systemic disorder (eg, osteoporosis, Paget's disease, or renal osteodystrophy), were not immunosuppressed, and were not receiving corticosteroid therapy; (11) were skeletally mature; (12) were not pregnant; (13) were not a prisoner; and (14) were not planning on relocating to a different geographical region during the study period [8, 9]. All excluded patients received the metal-on-PE articulation. As these were not the subject of the investigation, they were not tabulated. Eleven patients (12 hips) were lost to followup before 2 years, although all of these hips had been functioning well. Eight patients (nine hips) died (two patients in the metal-on-PE matching group), and the remaining three patients could not be contacted or voluntarily withdrew. This left 501 patients with 525 THAs (ceramic-on-ceramic: $n = 421$; metal-on-PE: $n = 104$). All patients had a minimum followup of 2 years. The overall study cohort had a preponderance of men (65%), a mean age of 54 years, and a mean body mass index (BMI) of 28 kg/m^2 . The most frequent diagnoses were osteoarthritis (79%), osteonecrosis (14%), and posttraumatic arthritis (4%). In the ceramic-on-ceramic group, there were 255 men and 166 women with a mean age of 57 years (range, 24–75 years). Their mean BMI was 27 kg/m^2 , and their mean followup was 59 months (range, 24–120 months). In the metal-on-PE group, there were 60 men and 50 women with a mean age of 56 years (range, 24–80 years). Their mean BMI was 28 kg/m^2 , and their mean followup was 59 months (range, 24–120 months). No patients were

recalled specifically for this study; all data were obtained from medical records and radiographs. No a priori power analysis was performed for this study since it reflects a retrospective review of two cohorts originally intended for other purposes. The study had full Institutional Review Board approval at each of the six participating institutions.

The THAs were performed through a posterior approach in 93% of the cases, an anterolateral approach in 7% of the cases, and a lateral transtrochanteric approach in 0.2% of the cases. Because the posterior approach was used in an overwhelming majority of the cases, no meaningful stratification could be performed based upon surgical approach.

According to a strict study protocol, clinical data and radiographs were collected preoperatively, early postoperatively (between 6 and 8 weeks), at 6 months, at 1 year, and at 1-year intervals thereafter, unless the patients had other complications warranting closer scrutiny. The level of pain and functional parameters for each patient, possible walking distance, need for external support, limping, and ROM were evaluated at each postoperative clinic visit, and a HHS was calculated. In addition, a patient satisfaction index was performed (HSQ-12).

Postoperative radiographs were independently reviewed by two of us (PMB, MN) to determine all variables. The acetabular cup inclination angle was ascertained by careful review of postoperative AP radiographs (within 6–8 weeks of surgery). The cup inclination was measured using a standardized technique relative to the ischial tuberosity line, as established by Woo and Morrey [36] for uniplanar measurements. The patients with alumina bearing surfaces were divided into three groups according to acetabular cup inclination angle ($< 40^\circ$, 40° – 50° , $> 50^\circ$). There was no difference in distributions of demographics, diagnoses, and bone type among the three groups (Table 1). The effects of the three different groups of acetabular cup inclination angles on the survivorship and clinical outcomes scores were investigated according to a modified recommendation made by Barrack [4], with acetabular positioning at $45^\circ \pm 10^\circ$ being optimal. Numerous publications have presented evidence for safe acetabular orientation [4, 5, 13, 19, 23, 25, 33, 34, 39]. Recent reports confirmed the recommended safe zone ($45^\circ \pm 10^\circ$) [4, 5, 39]. In this study, the safe zone was tightened to $45^\circ \pm 5^\circ$ since some reports regarded implant placement above 50° as malpositioned [3, 23, 25]. The AP and lateral radiographs at last followup were evaluated for radiolucencies in the modified zones of the femur described by Gruen et al. [16], radiolucencies in the Charnley zones for the acetabulum, calcar resorption, osteolysis, stem subsidence, and stem stability according to a modification of the criteria by Engh et al. [14]. Progressive radiolucencies were defined as an increase of

Table 1. Acetabular cup inclination angle, implant frequencies, diagnosis, bone type, preoperative body mass index, and age

Variable	Cup inclination group			Total
	< 40°	40°–50°	> 50°	
Cup inclination				
Mean	36.0°	45.7°	54.9°	
SD	3.2°	3.1°	3.7°	
Range	24°–39°	40°–50°	51°–69°	
Implant frequency				
Alumina ceramic-on-ceramic	53	227	141	421
Metal-on-polyethylene	15	50	39	104
Total	68	277	180	525
Diagnosis frequency				
Osteonecrosis	8	38	26	72
Osteoarthritis	52	226	145	423
Other	8	13	9	30
Total	68	277	180	525
Bone type				
Type A	42	182	128	352
Type B and C	26	95	52	173
Total	68	277	180	525
Preoperative body mass index				
Mean	26.4	28.1	29.5	
SD	3.9	4.7	5.3	
Range	19.8–41.7	18.2–47.3	14.2–46.3	
Age (years)				
Mean	52.5	54.0	53.5	53.7
SD	10.8	10.4	10.7	
Range	21.9–73.7	22.4–75.9	18.3–75.0	

more than 2 mm in comparison to previous films (Table 2). After dividing all patients into one of the three study groups based on acetabular inclination angle, the groups were compared between the two reviewers (PMB, MN) to evaluate for any interobserver variability. Any radiographs that were borderline between two groups were reevaluated jointly until a consensus was reached regarding how to stratify the patient.

We performed a multivariate ANOVA for all patients comparing the effects of incremental acetabular cup inclination ($< 40^\circ$, 40° – 50° , $> 50^\circ$) on HHS and HSQ-12 scores. Kaplan-Meier survivorship analyses were performed with 95% confidence intervals (CIs) calculated, and log-rank tests were used to compare survivorship between the two study groups. The end point for implant survivorship was considered revision for any reason. All statistical analyses were performed using SAS® Statistical Analysis Software (SAS Institute, Inc, Cary, NC).

Table 2. Radiographic results of ceramic-on-ceramic bearings

Results	7 week	1 year	Latest
Femoral RL Zone 1	0	4 (0.8%)	34 (6.4%)
Femoral RL Zone 7	0	2 (0.4%)	8 (1.5%)
Femoral subsidence	0	2 (0.4%)	2 (0.4%)
Unstable stem fixation	0	2 (0.4%)	0
Acetabular RL (> 1 mm)			
Zone 1	4 (0.7%)	1 (5.0%)	0 (0%)
Zone 2	19 (9.3%)	0 (0.2%)	0 (0%)
Zone 3	0 (0%)	0 (0%)	0 (0%)
Acetabular shell migration	0	1 (0.2%)	1 (0.2%)
Unstable acetabular component	0	0	2 (0.4%)
Mean cup inclination (°)	47.4 (range, 24–69)		

RL = radiolucency.

Fig. 1 The 5-year Kaplan-Meier survival curves indicate no difference (log-rank statistic $p = 0.51$) among the three study groups based on acetabular inclination angle: inclination angles of less than 40° , 95.6% (95% CI, 86.9%–96.8%); 40° to 50° , 98.2% (95% CI, 95.8%–99.3%); greater than 50° , 95.4% (95% CI, 91.0%–97.7%).

Results

The 5-year Kaplan-Meier survival curves indicated no difference (log-rank statistic $p = 0.51$) among the three study groups based on acetabular inclination angle (Fig. 1). There were no differences in postoperative HHS or HSQ-12 scores. In total, 22 revision surgeries were performed in the study cohort for an overall revision rate of 4.2% (Table 3). In the first group (cup inclination $< 40^\circ$, $n = 68$), there were four revisions. The estimated 5-year survival was 96% (95% CI, 87%–99%). The second group (cup inclination of 40° – 50° , $n = 277$) had nine revisions, and an estimated 5-year survival rate of 98% (95% CI,

Table 3. Effect of cup inclination angle on revision rates

Cup inclination group	Revision		Total
	No	Yes	
$< 40^\circ$	64 (94.1%)	4 (5.9%)	68
40° – 50°	268 (96.8%)	9 (3.3%)	277
$> 50^\circ$	171 (95.0%)	9 (5.0%)	180
Total	503 (95.8%)	22 (4.2%)	525

Table 4. Effect of cup inclination angle on HHS

HHS	Cup inclination group		
	$< 40^\circ$	40° – 50°	$> 50^\circ$
Preoperative HHS			
Mean	50.4	49.8	46.5
SD	13.5	12.1	10.5
Range	22–75	19–87	16–90
Postoperative HHS			
Mean	96.5	96.4	96.7
SD	7.3	7.3	8.5
Range	60–100	56–100	30–100
< 70	2	4	3

HHS = Harris hip score.

95%–99%). There were nine revisions performed in the third group (cup inclination $> 50^\circ$, $n = 180$) for an estimated 5-year survival of 95% (95% CI, 91%–98%). The postoperative HHS was also similar for all three groups. The mean HHS for all patients improved from 49 to 97 points (Table 4). The mean postoperative HHS of the group of patients with inclination angles of less than 40° and the group with angles of greater than 50° were similar ($p = 0.10$ and 0.30 , respectively) to those of the ideal component position group. The patient satisfaction index (HSQ-12) showed 98% of patients to be satisfied with their results.

We observed no difference in radiographic radiolucencies, osteolysis, or incidence of subsidence based on acetabular inclination angles. At latest followup, two acetabular components were radiographically unstable and two femoral components had subsided (Table 2). Of the two cases of acetabular loosening, one was revised for periprosthetic infection and was subsequently excluded from consideration. The other patient had acceptable acetabular inclination and underwent acetabular revision only for radiographic loosening. For the femoral component, although there were multiple patients who had minor nonprogressive radiographic radiolucencies, there were only two patients who had femoral component subsidence. Both instances were posttrauma (one patient sustained a fall from standing and the other patient fell while skiing)

Fig. 2 Kaplan-Meier survivorship curves demonstrate improved survivorship (log rank score = 0.01), with nonoverlapping 95% CIs, for all alumina-on-alumina articulations (96.2%–99.0%) compared to that for the cobalt-chromium-on-PE articulations (85.1%–96.1%).

and were subsequently not related to acetabular component positioning. The patient who fell from standing had the femoral component revised and the other patient did not receive revision. All patients who underwent revision for radiographic loosening were doing well clinically (HHS > 80 points) at their most recent followup visit (range, 2–4 years).

When the absence of revision for any reason was used as an end point, the estimated Kaplan-Meier 5-year survival rate was higher for ceramic-on-ceramic articulations (98%; 95% CI, 96.2%–99.0%) than for the standard metal-on-PE cohort (92%; 95% CI, 85.1%–96.1%) (Fig. 2). Two acetabular inserts fractured during this series. At 6.5 years postoperatively, a ceramic liner fractured, and 9 years postoperatively, a PE liner fractured. These components were revised, and at most recent followup (2 and 3 years), these two patients were doing well clinically (HHS, 90 and 95 points).

Discussion

This study was part of a prospective randomized US Investigational Device Exemption study analyzing ceramic-on-ceramic articulations in relation to metal-on-PE devices. Despite investigators having linked nonideal acetabular inclination angles to increased component wear [4, 11, 19, 23], there is little reported data evaluating the association between acetabular component inclination angles with overall survivorship. We therefore determined: (1) whether the cup inclination angle influence survival or function in patients with ceramic-on-ceramic implants; (2) the incidence of radiolucencies, osteolysis, and subsidence of ceramic-on-ceramic implants; and (3) whether the

survival rate higher for ceramic-on-ceramic THAs than for conventional metal-on-polyethylene THAs.

There were several limitations of this study. First, we had short-term followup with a minimum of 2 years, although the mean followup was 5 years. We therefore believe the data important as an initial investigation to determine the *in vivo* effects of cup inclination and its effect on prosthetic survivorship. This cohort will continue to be followed to determine whether these results are maintained at longer-term followup. Second, we used only one type of ceramic-on-ceramic component. Although this type of implant demonstrated no dependence of wear rates on cup inclination angle, other ceramic designs and materials may not exhibit the same characteristics. Third, we examined only acetabular inclination; anteversion may also play a role. We chose to focus on inclination values in this study because there are more *in vitro* studies published relating inclination to wear rates. Fourth, the purposes of the original studies were not specifically designed to compare survivorship based on acetabular inclination angles. Rather, this variable was not specifically controlled and was merely a consequence of how the cup was implanted. A retrospective power analysis was performed on for the third research directive, comparing survivorship between the ceramic-on-ceramic and the metal-on-PE articulations. Given the results obtained, the power was 73%. A study is typically considered “powered” if the power is at least 80%. However, given the 95% CIs do not overlap, we are confident in our conclusion that the overall survivorship of the alumina articulations was higher than that of the conventional metal-on-PE articulations. Finally, with the small numbers of patients there is a possibility of a Type II error with respect to survival. Despite similar survivorship, the revision rate was higher in the cohorts with inclination angles higher than 50° and lower than 40°.

At a mean followup of 5 years, there were no differences in implant survivorship, evidence of radiographic loosening or subsidence, or clinical ratings (eg, HHS and HSQ-12 scores) of the three acetabular cup inclination groups. When absence of revision for any reason was used as an end point, the ceramic-on-ceramic articulations had a higher survival rate at 120 months when compared to metal-on-PE articulations. Studies reporting the survival rates of alumina-on-alumina bearing surfaces report survival rates ranging from 94% to 100% at variable followups [6–8, 15, 20, 27, 37, 38] (Table 5). The survival rate for the ceramic cohort (98% 5-year survival) is comparable to those reported in the literature.

Several studies have demonstrated survivorship of up to 97% in studies of ceramic-on-ceramic bearing surfaces with followup close to 10 years [2, 8, 9]. Survival rates in the reported literature of medium-term followup for ceramic-on-ceramic THA range from 94% to 97% [2, 6, 8, 20, 27].

Table 5. Survivorship rates of alumina-on-alumina bearing surfaces reported in the literature

Study	Number of hips (patients)	Mean followup (months)	Survival (%)
Capello et al. [7] (2008)	380 (275)	96 (60–NR)	96*
Murphy et al. [27] (2006)	194 (173)	50 (24–108)	96
Yoo et al. [38] (2006)	72 (61)	69 (60–83)	100
D'Antonio et al. [8] (2005)	222 (201)	62 (2–86)	97
Kawanabe et al. [20] (2005)	138 (113)	130 (78–169)	98
Yoo et al. [37] (2005)	93 (79)	68 (60–73)	100
Bizot et al. [6] (2004)	71 (62)	108	94*
Garino [15] (2000)	333 (NR)	22 (18–36)	99

NR = not reported.

Aldrian et al. [2], reporting on a series of 107 ceramic-on-ceramic THAs, found at a mean followup of 7.6 years (range, 7.1–8.3 years) three failures, resulting in a 97% survival rate. This is consistent with the Kaplan-Meier survival rate reported in our study of 98%. Additionally, there were no catastrophic failures in this reported study cohort, which had been a problem with prior generations of ceramic-on-ceramic bearing surfaces. Longer followup may prove the current generation of ceramic-on-ceramic THAs may offer a viable alternative to metal-on-PE articulations, with the added benefit of improved component wear.

Although the effect of cup inclination angle during THA with metal-on-PE articulations has been well studied, few studies have addressed this variable in ceramic-on-ceramic bearings [3–5, 13, 19, 21–23, 25, 29, 30, 33, 39]. A hip simulator study demonstrated no adverse effects of steep inclination angles on wear rates in contrast to metal-on-PE bearings [29]. However, that study was conducted under ideal conditions and the different results of in vitro and in vivo studies on metal-on-PE bearings suggest this may not hold true for clinical application [29]. These preliminary findings appear to be supported by our data, with no increased rate of clinical failures when the inclination angle was greater than 50°. Longer followup is required before it is certain long-term wear rates or survival rate are similar regardless of inclination angle. It was not possible to determine from our study whether there was increased wear in the group of patients who had a higher acetabular inclination angle. Fortunately, there was no effect on the clinical outcomes for patients.

Our results demonstrate the safety of modern ceramic-on-ceramic articulations in THA. Different acetabular cup inclination angles did not lead to any differences in clinical or radiographic outcome, and the comparison between the two articulation types (ceramic-on-ceramic and metal-on-PE) revealed similar survival rates.

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