Comparison of Surgical Outcomes and Implant Wear between Ceramic-on-Ceramic and Ceramic-on-Polyethylene Bearing Surfaces in Total Hip Arthroplasty

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0.026, respectively). Lastly, there was no statistically significant difference in the dislocation or revision rate between the two groups at the time of last clinical follow-up.

Conclusions: The use of ceramic-on-polyethylene articulations led to significant reduction in the linear and volumetric wear rates when compared to ceramic-on-ceramic articulations. This increase in wear suggests that ceramic-on-polyethylene articulation will not afford protection from osteolysis in longer term follow-up. However, ceramic component fracture and audible component-related noise remain complications to be considered when using a ceramic-on-ceramic bearing surface.

Level of Evidence: Therapeutic Level I.

Abstract

Background: Coupling a ceramic femoral head with a highly crosslinked ultrahigh molecular weight polyethylene acetabular component liner has gained popularity, especially in the young, active patient population. We hypothesized that this bearing surface combination may decrease the rate of ceramic component fracture and audible component-related noise while maintaining the beneficial wear characteristics associated with ceramic-on-ceramic articulations.

Methods: A prospective randomized multicenter trial comparing ceramic-on-ceramic or ceramic-on-polyethylene couplings was conducted where 357 total hip arthroplasties were performed in 312 patients. Clinical data were collected preoperatively and postoperatively at 3, 6, 12, 24, and 48 months as well as beyond 60 months. Linear and volumetric wear were measured postoperatively at 5 years.

Results: There was no statistically significant difference in the Harris Hip, SF-12 mental, and SF-12 physical scores between the ceramic-on-ceramic and ceramic-on-polyethylene groups at any time interval. The mean linear and volumetric rates were statistically lower ($p < 0.001$) in the ceramic-on-ceramic group (30.5 μm/year and 21.5 mm^3/year, respectively) when compared with the ceramic-on-polyethylene group (218.2 μm/year and 136.2 mm^3/year, respectively). The rates of ceramic implant fracture (2.6%) as well as audible component-related noise (3.1%) were statistically higher in the ceramic-on-ceramic group when compared to the ceramic-on-polyethylene group ($p < 0.049$ and

Introduction

Component wear leading to osteolysis and implant loosening remains a significant problem in total hip arthroplasty (THA). Early revision THA due to this problem is not uncommon[1-3]. The majority of the data implicate metal-on-polyethylene component articulations (i.e., couples) that utilized uncrosslinked or low molecular weight polyethylene. Submicron polyethylene debris generated by abrasive wear stimulate the process of osteolysis[4]. It has been suggested that a linear wear rate of less than 50 μm/year would completely eliminate osteolysis[5].

Ceramic-on-ceramic component articulations were developed to reduce abrasive wear. Early generations of ceramics were associated with unacceptable failure rates due to loosening and ceramic implant fracture[3, 6-10]. Modern third generation ceramics are harder, more scratch-resistant, and more hydrophilic than older generation ceramics. A linear wear rate of approximately 5 μm/year has been established for modern ceramic-on-ceramic couplings[10-15]. A correspondingly lower rate of osteolysis has been confirmed in a clinical setting when ceramic-on-ceramic couplings are utilized[16]. Prospective randomized trials have reported good short-term outcomes with ceramic-on-ceramic components that are comparable to metal-on-polyethylene components[17, 18].

Modern ceramics components are routinely implanted into younger high-demand patients due to their low wear rates and good clinical results. Modern ceramics fared well in two large investigational device exemption trials[14, 19]. One such study of 194 hips at 2 to 9 years of follow-up reported an implant survivorship of 96%[19]. Another large prospective randomized trial comparing ceramic-on-ceramic and metal-on-polyethylene bearings demonstrated no component fractures and comparable clinical outcomes with fewer revisions in the ceramic-on-ceramic group when compared to the metal-on-polyethylene group[14]. These results have also been supported by other more recent studies[20]. Some studies also show that ceramic-on-polyethylene components have wear rates between that of traditional metal-on-polyethylene and ceramic-on-ceramic components[21-23]. Several studies have demonstrated good short and medium term clinical outcomes using these components[22, 24-27]. However, despite these results, substantial concerns remain regarding ceramic-on-ceramic articulations including stripe wear, audible component-related noise (i.e., squeaking), limited sizing options, and ceramic implant fracture[8].

The possibility of coupling a ceramic head with the more conventional crosslinked ultrahigh molecular weight polyethylene acetabular component liner has been offered as a possible alternative to reduce the rate of component fracture while maintaining the wear characteristics associated with ceramic-on-ceramic bearings. Ceramic-on-polyethylene articulations maintain relatively low wear rates while potentially avoiding some of the complications of ceramic-on-ceramic bearings, yet few clinical comparisons of ceramic-on-ceramic and ceramic-on-polyethylene exist[28]. Hence, the goal of this study was to compare the clinical performance and evaluate the wear rate of these two bearing surfaces utilizing a prospective randomized study design.

Materials and Methods

In 1998, Smith & Nephew (Memphis, TN) received an investigational device exemption from the Food and Drug Administration to conduct the clinical research necessary to approve the Reflection® Ceramic-Ceramic Hip System (IDE number:

G980027). A prospective randomized study was begun the same year comparing that implant system with a polyethylene acetabular shell and ceramic head coupling. Enrollment of 357 hips in 312 patients was completed between 1999 and 2001. All patients were followed for 5 years, therefore final clinical and radiographic follow-up was complete in 2006 (Figure 1). Nine orthopaedic surgeons participated in the study at nine sites (see Acknowledgments). Each site received institutional review board approval of the protocol and consent forms prior to patient enrollment. Patients were randomized to receive either a ceramic-on-ceramic or a ceramic-on-polyethylene bearing. Each ceramic-on-ceramic articulation was implanted with a 28 or 32 mm alumina ceramic femoral head and an alumina ceramic acetabular cup liner. Each ceramic-on-polyethylene articulation was implanted with a 28 mm alumina ceramic femoral head and a ultrahigh molecular weight polyethylene acetabular cup liner prepared using modern sterilization techniques and within their expiration date.

Patients were included in this trial if clinically indicated for a THA as a result of osteoarthritis or rheumatoid arthritis and were 21 to 80 years of age with a Harris Hip Score (HHS) less than or equal to 60, availability for at least 2 years of clinical follow-up, ability to meet acceptable preoperative medical clearance, and without the presence or history of treatment for cardiac, pulmonary, hematological, or any other medical condition that would pose excessive operative risk. Exclusion criteria included active localized or systemic infection; skeletal immaturity; insufficiency of quality or quantity of bone support resulting from conditions such as cancer, femoral osteotomy, girdlestone resection, significant osteoporosis, or metabolic disorder of calcified tissue; morbid obesity; Charcot joints; muscle deficiencies; multiple joint deficiencies;

immunosuppressive disorder; pregnancy; unknown sensitivity to the device materials; and participation in any other pharmaceutical, biological, or medical device clinical investigation.

Radiographic and clinical data were collected preoperatively and postoperatively at 3, 6, 12, 24, and 48 months as well as after 60 months. At each visit a history was taken and physical examination performed, the HHS was calculated, patients completed an SF-12 mental and physical survey, and anteroposterior and frog-leg lateral radiographs of the hip were obtained. All intraoperative and postoperative events were recorded, and patients were asked about any perceived problems or complications related to their surgery. Radiographs were evaluated by the surgeon at each site and their interpretation was confirmed by an independent radiologist, who was blind to implant type and length of follow-up, for signs of loosening, migration, heterotopic ossification, and osteolysis[29-31]. Wear rates were measured by independent observers blinded to implant type and operating surgeon. Early postoperative (4- and 12-week) and final follow-up (5 year) radiographs were analyzed to determine uniplanar (i.e., linear) and volumetric wear using the Avenger Digital Caliper (Avenger Products, Boulder City, NV)[32]. At final follow-up, 39 hips had insufficient radiographs for evaluation using the Livermore technique and were excluded from linear and volumetric wear rate analysis.

Statistical Considerations

Since the randomization process used sealed envelopes, it did not yield the number of patients assigned to each group resulting in the variations in the number of cases per group. All errors are reported as standard error of the mean or standard deviation where applicable. For the comparison of changes in patient-reported outcomes within each group, a paired t-test was conducted. To compare the changes in self-reported outcomes after surgery, the difference from the preoperative baseline was computed and each case was compared using a t-test. All other comparisons between groups were performed using a 1-sided Fisher's exact test or a Chi Square analysis where applicable.

Source of Funding

Funding for data collection was provided by Smith and Nephew under the FDA guidelines for IDE. This secondary data analysis was conducted without contract or direct funding from any sponsor.

Results

A total of 357 hips (161 hips in the ceramic-polyethylene group; 196 hips in the ceramic-ceramic group) in 312 patients were eligible for this study. Patient characteristics are summarized in Table 1. There was a statistically significant difference in the mean age of the patients randomized to each group ($p = 0.003$). However, the mean age only differs by four years and there is no other difference between the patient characteristics of either study group suggesting that the populations were indeed random despite this observation. In the ceramic-ceramic group, 31% received a 28 mm femoral head and 69% received a 32 mm femoral head. Follow-up was completed for 87.7% (313 hips) at a minimum of 2 years postoperatively (85.1% for the ceramic-on-polyethylene group and 89.8% for the ceramic-on-ceramic group). By 5 years postoperatively, several patients were either deceased or withdrew from the study. A resultant 61.6% (220 hips) of the initial population completed the study protocol (Figure 1).

There was a statistically significant increase ($p < 0.01$) in mean postoperative HHS when compared to the mean preoperative HHS at all follow-up intervals. However, there was no significantly difference ($p > 0.05$) in HHS at any follow-up interval between the ceramic-on-ceramic and ceramic-on-polyethylene groups (Figure 2). There was a similar statistically significant increase ($p < 0.01$) in the postoperative SF-12 mental and physical scores, but again there was no statistically significant difference ($p > 0.05$) between the two groups at any follow-up interval.

Complete radiographic assessment at a mean follow-up after 5 years postoperatively was ultimately available for 125 hips (63.8%) in the ceramic-on-ceramic group and 95 hips (59.0%) in the ceramic-on-polyethylene group (Figure 1). Few patients demonstrated radiolucency in any of the femoral or acetabular zones (9 and 6 in the ceramic-on-ceramic and ceramic-on-polyethylene groups, respectively). There was no statistically significant difference ($p = 0.448$) in these radiographic findings between the two groups. In the ceramic-on-ceramic group, the radiographic determination of the mean linear wear rate was 30.5 ± 7.0 μm/year and the mean volumetric wear rate was 21.5 ± 4.5 mm^3/year. No measurable radiographic wear was present in 53 hips (44.9%) in the ceramic-on-ceramic group. In the ceramic-on-polyethylene group, the radiographic determination of the mean linear wear rate was 218.2 ± 13.7 μm/year and the mean volumetric wear rate was 136.2 ± 8.5 mm^3/year. No measurable radiographic wear was present in 6 hips (6.3%) in the ceramic-on-polyethylene group. The increase in mean linear and volumetric wear rates in the ceramic-on-polyethylene group was statistically significant ($p < 0.001$; Figure 3).

Evaluation of the intraoperative and postoperative complications reveals little significant difference except with respect to audible component-related noise and implant fracture (Table 2). Audible component-related noise was detected in 6 hips (3.1%) in the ceramic-on-ceramic group, while no patient in the ceramic-on-polyethylene group reported or experienced an audible component-related noise ($p = 0.026$; Table 2). Only one patient with an audible component-related noise has undergone a revision due to recurrent anterior dislocation and pain (Table 2). The ceramic-on-ceramic group had 2 hips (1.0%) with intraoperative liner fracture and 3 hips (1.5%) with postoperative implant fractures (2 liner fractures and 1 head fracture). All ceramic implant fractures underwent intraoperative exchange or revision (Table 3). The total incidence of intraoperative and postoperative implant fracture in the ceramic-on-ceramic group was statistically significant ($p = 0.049$) when compared to the ceramic-on-polyethylene group.

The revision and dislocation rates were not statistically different in the ceramic-on-ceramic and ceramic-on-polyethylene groups ($p = 0.059$ and 0.672, respectively). There were 11 (5.6%) revisions in the ceramic-on-ceramic group and 3 (1.9%) revisions in the ceramic-on-polyethylene group at latest follow-up (Table 3). There were 10 (5.1%) dislocations in the ceramic-on-ceramic group and 9 (5.6%) dislocations in the ceramic-on-polyethylene group at latest follow-up. Four hips underwent revision due to recurrent or early dislocation, three hips in the ceramic-on-ceramic group and one hip in the ceramic-on-polyethylene group (Table 4). Additionally, there was no statistically significant relationship between dislocation rate and operative side, surgeon, gender, surgical approach, history of cerebral dysfunction or alcohol abuse, or previous ipsilateral hip surgery.

Discussion

Overall clinical results were similarly excellent in both the ceramic-on-ceramic and ceramic-on-polyethylene groups. In both groups, the mean HHS, SF-12 mental scores, and SF-12 physical scores were higher postoperatively and there was no statistical difference between either group at any follow-up interval.

Plain radiographs were used to determine in vivo wear using a digital caliper according to the method of Livermore[32]. It can be challenging to determine in vivo wear in ceramic-on-ceramic hips due to the difficulty of differentiating the femoral head from the cup on plain radiographs or by using edge detection software as well as the extremely low rate of wear seen in these components[10]. Thus, wear rates measured using this technique have been variable[19, 33, 34]. Some investigators, however, have been able to use plain radiographs to measure linear wear in all patients[35, 36]. Computerized software programs introduced in more recent years to measure wear rates on plain radiographs have poor accuracy, especially if used on bearings or the same material[37, 38]. Ultimately, while the technique of Livermore used in this paper is imperfect; we chose this method because we felt that was the best method available.

The mean linear wear rate in the ceramic-on-ceramic group was statistically lower ($p < 0.001$) than the ceramic-on-polyethylene group. Reported linear wear rates for ceramic-on-ceramic bearings has been variable, but are generally found to be less than 20 μm/year (Table 4). The mean linear wear rate in our study for this bearing surface was 30.5 μm/year. This is statistically similar to the reported values of mean linear wear rate that may dramatically reduce osteolysis[5]. Hence, our data is consistent with observations that ceramic-on-ceramic bearings may minimize osteolysis in long term follow-up. The mean linear wear rate for the ceramic-on-polyethylene group was 218.2 μm/year. This is higher than the rates reported in many studies (Table 4). However, the reported wear rates for ceramic-on-polyethylene bearings have also been variable[39, 40]. Ceramic-on-polyethylene couples wear at about 1.7 to 4.0 times the rate of traditional metal-on-polyethylene couples[24, 39, 41]. Catastrophic wear has been rarely reported; this complication has apparently been eliminated with newer ceramics and was not encountered in this study[42]. It should be noted that 69% of the patients in the ceramic-on-ceramic group received a larger femoral head than the patients in the ceramic-on-polyethylene group. This may account for some of the increased wear seen in the ceramic-on-polyethylene group, but does not change the observation that ceramic-on-polyethylene bearings have a high mean linear wear rate that is inconsistent with protection from osteolysis in long-term follow-up[5]. It also must be noted that while clinical follow-up was over 80%, we were only able to obtain approximately 60% follow-up for our mean linear wear rates analysis, because this was not initially included in the FDA approved data collection. Hence, definitive conclusions about exact wear rates should be avoided. However, the statistically relevant ($p < 0.001$) increase in the mean linear wear rate in the ceramic-on-polyethylene group is relevant despite this lack of follow-up.

Painless audible component-related noise was originally thought to be rare; it can occasionally be bothersome enough to require revision and may be an early sign of component malpositioning or impending failure. The rate to audible component-related noise has been reported as 0.66% to 1.8% in patients with ceramic-on-ceramic couplings[43, 44]. Patients with squeaking implants tended to be younger, heavier, and taller. In our study, the incidence of audible component-related noise was 3.1% and statistically increased in the ceramic-on-ceramic group ($p = 0.026$). There were no cases of audible component-related noise in the ceramic-on-polyethylene group, this phenomenon has previously been reported in hips without any ceramic components, although in all cases it has been related to two hard surfaces rubbing together[45, 46]. Although, all patients were asked about any perceived problems or complications related to the surgery, it is possible that some cases of audible component-related noise may have been missed if it was not bothersome to the patient or not noted on physical examination.

While some large studies have reported few or no postoperative ceramic component fractures[14-16], the reported rate of component fracture is 1.7%[47]. This is similar to our postoperative ceramic component fracture rate of 1.5%. Our postoperative ceramic component fractures consisted of 1 femoral head fracture in each group and 2 acetabular liner fractures in the ceramic-on-ceramic group. Both head fractures occurred in 28-mm heads, which are more likely to fracture than 32-mm heads[48]. Although fracture rates as high as 13.4% were reported in some ceramic heads manufactured before 1990, reported rates of modern ceramic head fractures have typically been less than 0.5%[15, 16, 49, 50]. The rate of acetabular liner fracture in the present study was 2.0%, which is similar to published reports[47]. The ceramic-on-polyethylene couple led to one ceramic femoral head fracture. This is rare but has been reported in the literature[47]. The rate of ceramic component fracture has been shown to be manufacturer dependent and based on material defect[48]. However, the reasons for ceramic implant fracture include impingement during extremes of range of motion or sudden high-impact loading[51]. Hence, technical errors such as improperly seated acetabular liners or tapping the edge of the acetabular cup intraoperatively to adjust its position must be considered in the case of any liner fracture[48]. Additionally, vertical acetabular cup position and careless handling may also increase the risk of ceramic component fracture[49, 52]. Excessive anteversion has been established as a risk factor for liner fracture occurring during high flexion and wide abduction activities such as squatting, as was demonstrated in a study of Korean patients who squat commonly and had a higher (3.5%) rate of liner fracture[51]. All postoperative femoral head and acetabular liner fractures occurred between 2 and 5 years, hence longer follow-up may yield an even higher ceramic component fracture rate.

In conclusion, both ceramic-on-ceramic and ceramic-on-polyethylene couples had excellent short-term clinical results. However, it should be noted that ceramic-on-polyethylene couples did not offer sufficiently low linear wear rates to theoretically prevent osteolysis in longer-term follow-up and likely have an inferior wear profile when compared to traditional metal-on-polyethylene articulations. Long-term follow-up or registry data will help determine if this prediction is valid. For now, the potential for minimization or wear and subsequent osteolysis in ceramic-on-ceramic articulations must be considered with the increased risk of ceramic fracture and audible component-related noise.

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References

1. 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.* Jun 1969;51(4):737-755.
2. Hellman EJ, Capello WN, Feinberg JR. Omnifit cementless total hip arthroplasty. A 10-year average followup. *Clin Orthop Relat Res.* Jul 1999(364):164-174.
3. Mahoney OM, Dimon JH, 3rd. Unsatisfactory results with a ceramic total hip prosthesis. *J Bone Joint Surg Am.* Jun 1990;72(5):663-671.
4. Harris WH. Osteolysis and particle disease in hip replacement. A review. *Acta Orthop Scand.* Feb 1994;65(1):113-123.
5. Dumbleton JH, Manley MT, Edidin AA. A literature review of the association between wear rate and osteolysis in total hip arthroplasty. *J Arthroplasty.* Aug 2002;17(5):649-661.
6. Holmer P, Nielsen PT. Fracture of ceramic femoral heads in total hip arthroplasty. *J Arthroplasty.* Dec 1993;8(6):567-571.
7. Moreschini O, Braidotti P. Traumatic breakage of the ceramic head of prosthesis in total hip replacement. *Ital J Orthop Traumatol.* Sep 1991;17(3):339-343.
8. Winter M, Griss P, Scheller G, Moser T. Ten- to 14-year results of a ceramic hip prosthesis. *Clin Orthop Relat Res.* Sep 1992(282):73-80.
9. Yoon TR, Rowe SM, Jung ST, Seon KJ, Maloney WJ. Osteolysis in association with a total hip arthroplasty with ceramic bearing surfaces. *J Bone Joint Surg Am.* Oct 1998;80(10):1459-1468.
10. Yoo JJ, Kim YM, Yoon KS, Koo KH, Song WS, Kim HJ. Alumina-on-alumina total hip arthroplasty. A five-year minimum follow-up study. *J Bone Joint Surg Am.* Mar 2005;87(3):530-535.
11. Kawanabe K, Tanaka K, Tamura J, et al. Effect of alumina femoral head on clinical results in cemented total hip arthroplasty: old versus current alumina. *J Orthop Sci.* Jul 2005;10(4):378-384.
12. Sedel L. Evolution of alumina-on-alumina implants: a review. *Clin Orthop Relat Res.* Oct 2000(379):48-54.
13. Nau T, Raschid J, Kirnbauer W, Schwischei H, Ehall R. [Modern ceramic-on-ceramic bearings in total hip arthroplasty]. *Wien Med Wochenschr.* Feb 2005;155(3-4):70-74.
14. D'Antonio J, Capello W, Manley M, Naughton M, Sutton K. Alumina ceramic bearings for total hip arthroplasty: five-year results of a prospective randomized study. *Clin Orthop Relat Res.* Jul 2005(436):164-171.
15. Capello WN, Dantonio JA, Feinberg JR, Manley MT. Alternative bearing surfaces: alumina ceramic bearings for total hip arthroplasty. *Instr Course Lect.* 2005;54:171-176.
16. D'Antonio J, Capello W, Manley M. Alumina ceramic bearings for total hip arthroplasty. *Orthopedics.* Jan 2003;26(1):39-46.
17. Bierbaum BE, Nairus J, Kuesis D, Morrison JC, Ward D. Ceramic-on-ceramic bearings in total hip arthroplasty. *Clin Orthop Relat Res.* Dec 2002(405):158-163.

18. D'Antonio J, Capello W, Manley M, Bierbaum B. New experience with alumina-on-alumina ceramic bearings for total hip arthroplasty. *J Arthroplasty.* Jun 2002;17(4):390-397.
19. Murphy SB, Ecker TM, Tannast M. Two- to 9-Year Clinical Results of Alumina Ceramic-on-Ceramic THA. *Clin Orthop Relat Res.* Oct 5 2006.
20. Yoo JJ, Kim YM, Yoon KS, et al. Contemporary alumina-on-alumina total hip arthroplasty performed in patients younger than forty years: a 5-year minimum follow-up study. *J Biomed Mater Res B Appl Biomater.* Jul 2006;78(1):70-75.
21. Simon JA, Dayan AJ, Ergas E, Stuchin SA, Di Cesare PE. Catastrophic failure of the acetabular component in a ceramic-polyethylene bearing total hip arthroplasty. *J Arthroplasty.* Jan 1998;13(1):108-113.
22. Zichner LP, Willert HG. Comparison of alumina-polyethylene and metal-polyethylene in clinical trials. *Clin Orthop Relat Res.* Sep 1992(282):86-94.
23. Tanaka K, Tamura J, Kawanabe K, Shimizu M, Nakamura T. Effect of alumina femoral heads on polyethylene wear in cemented total hip arthroplasty. Old versus current alumina. *J Bone Joint Surg Br.* Jul 2003;85(5):655-660.
24. Hannouche D, Hamadouche M, Nizard R, Bizot P, Meunier A, Sedel L. Ceramics in total hip replacement. *Clin Orthop Relat Res.* Jan 2005(430):62-71.
25. Sugano N, Nishii T, Nakata K, Masuhara K, Takaoka K. Polyethylene sockets and alumina ceramic heads in cemented total hip arthroplasty. A ten-year study. *J Bone Joint Surg Br.* Jul 1995;77(4):548-556.
26. Zichner L, Lindenfeld T. [In-vivo wear of the slide combinations ceramics-polyethylene as opposed to metal-polyethylene]. *Orthopade.* Feb 1997;26(2):129-134.
27. Singh S, Trikha SP, Edge AJ. Hydroxyapatite ceramic-coated femoral stems in young patients. A prospective ten-year study. *J Bone Joint Surg Br.* Nov 2004;86(8):1118-1123.
28. Mochida Y, Boehler M, Salzer M, Bauer TW. Debris from failed ceramic-on-ceramic and ceramic-on-polyethylene hip prostheses. *Clin Orthop Relat Res.* Aug 2001(389):113-125.
29. Brooker AF, Bowerman JW, Robinson RA, Riley LH, Jr. Ectopic ossification following total hip replacement. Incidence and a method of classification. *J Bone Joint Surg Am.* Dec 1973;55(8):1629-1632.
30. DeLee JG, Charnley J. Radiological demarcation of cemented sockets in total hip replacement. *Clin Orthop Relat Res.* Nov-Dec 1976(121):20-32.
31. Gruen TA, McNeice GM, Amstutz HC. "Modes of failure" of cemented stem-type femoral components: a radiographic analysis of loosening. *Clin Orthop Relat Res.* Jun 1979(141):17-27.
32. Livermore J, Ilstrup D, Morrey B. Effect of femoral head size on wear of the polyethylene acetabular component. *J Bone Joint Surg Am.* Apr 1990;72(4):518-528.
33. Hamadouche M, Boutin P, Daussange J, Bolander ME, Sedel L. Alumina-on-alumina total hip arthroplasty: a minimum 18.5-year follow-up study. *J Bone Joint Surg Am.* Jan 2002;84-A(1):69-77.

34. Bizot P, Larrouy M, Witvoet J, Sedel L, Nizard R. Press-fit metal-backed alumina sockets: a minimum 5-year followup study. *Clin Orthop Relat Res.* Oct 2000(379):134-142.

35. Hernigou P, Bahrami T. Zirconia and alumina ceramics in comparison with stainless-steel heads. Polyethylene wear after a minimum ten-year follow-up. *J Bone Joint Surg Br.* May 2003;85(4):504-509.

36. Urban JA, Garvin KL, Boese CK, et al. Ceramic-on-polyethylene bearing surfaces in total hip arthroplasty. Seventeen to twenty-one-year results. *J Bone Joint Surg Am.* Nov 2001;83-A(11):1688-1694.

37. Collier MB, Kraay MJ, Rimnac CM, Goldberg VM. Evaluation of contemporary software methods used to quantify polyethylene wear after total hip arthroplasty. *J Bone Joint Surg Am.* Dec 2003;85-A(12):2410-2418.

38. Wan Z, Boutary M, Dorr LD. Precision and limitation of measuring two-dimensional wear on clinical radiographs. *Clin Orthop Relat Res.* Aug 2006;449:267-274.

39. Clarke IC, Gustafson A. Clinical and hip simulator comparisons of ceramic-on-polyethylene and metal-on-polyethylene wear. *Clin Orthop Relat Res.* Oct 2000(379):34-40.

40. Kumar P, Oka M, Ikeuchi K, et al. Low wear rate of UHMWPE against zirconia ceramic (Y-PSZ) in comparison to alumina ceramic and SUS 316L alloy. *J Biomed Mater Res.* Jul 1991;25(7):813-828.

41. Clarke IC, Good V, Williams P, et al. Ultra-low wear rates for rigid-on-rigid bearings in total hip replacements. *Proc Inst Mech Eng [H].* 2000;214(4):331-347.

42. Prudhommeaux F, Hamadouche M, Nevelos J, Doyle C, Meunier A, Sedel L. Wear of alumina-on-alumina total hip arthroplasties at a mean 11-year followup. *Clin Orthop Relat Res.* Oct 2000(379):113-122.

43. O'Toole GC, Walter WL, Zicat BA, Walter WK. Squeaking in Ceramic-on-Ceramic Hips; incidence, causes and solutions. Paper presented at: American Association of Orthopaedic Surgeons2006; San Diego, CA.

44. Toni A, Traina F, Stea S, et al. Early diagnosis of ceramic liner fracture. Guidelines based on a twelve-year clinical experience. *J Bone Joint Surg Am.* Dec 2006;88 Suppl 4:55-63.

45. Stea S, Visentin M, Granchi D, et al. Wear debris and cytokine production in the interface membrane of loosened prostheses. *J Biomater Sci Polym Ed.* 1999;10(2):247-257.

46. Bono JV, Sanford L, Toussaint JT. Severe polyethylene wear in total hip arthroplasty. Observations from retrieved AML PLUS hip implants with an ACS polyethylene liner. *J Arthroplasty.* Apr 1994;9(2):119-125.

47. Park YS, Hwang SK, Choy WS, Kim YS, Moon YW, Lim SJ. Ceramic failure after total hip arthroplasty with an alumina-on-alumina bearing. *J Bone Joint Surg Am.* Apr 2006;88(4):780-787.

48. Garino JP. Ceramic component fracture: trends and recommendations with modern components based on improving reported methods. Paper presented at: 10th International BIOLOX® Symposium 2005June 10-11, 2005; Washington, D.C.

49. Willmann G. Ceramic femoral head retrieval data. *Clin Orthop Relat Res.* Oct 2000(379):22-28.

50. Pignatti G, Stagni C, Fravisini M, Giunti A. Ceramic-ceramic coupling. Total hip arthroplasty in young patients. *Chir Organi Mov.* Oct-Dec 2003;88(4):369-375.

51. Ha YC, Kim SY, Kim HJ, Yoo JJ, Koo KH. Ceramic Liner Fracture after Cementless Alumina-on-Alumina Total Hip Arthroplasty. *Clin Orthop Relat Res.* Dec 14 2006.

52. Barrack RL, Burak C, Skinner HB. Concerns about ceramics in THA. *Clin Orthop Relat Res.* Dec 2004(429):73-79.

53. Wroblewski BM, Siney PD, Dowson D, Collins SN. Prospective clinical and joint simulator studies of a new total hip arthroplasty using alumina ceramic heads and cross-linked polyethylene cups. *J Bone Joint Surg Br.* Mar 1996;78(2):280-285.

54. Walter A. On the material and the tribology of alumina-alumina couplings for hip joint prostheses. *Clin Orthop Relat Res.* Sep 1992(282):31-46.

55. Boutin P, Blanquaert D. [A study of the mechanical properties of alumina-on-alumina total hip prosthesis (author's transl)]. *Rev Chir Orthop Reparatrice Appar Mot.* 1981;67(3):279-287.

56. Jazrawi LM, Bogner E, Della Valle CJ, et al. Wear rates of ceramic-on-ceramic bearing surfaces in total hip implants: a 12-year follow-up study. *J Arthroplasty.* Oct 1999;14(7):781-787.

Table 1
Patient Characteristics

	Ceramic-on-Ceramic	Ceramic-on-Polyethylene	*p*-value
Patients	166	146	-
Total Hip Arthroplasties	196	161	-
Bilateral THA (%)	30 (15.3%)	15 (9.3%)	0.061[*]
Men (%)	106 (63.9%)	84 (57.5%)	0.152[*]
Mean Age (years) ± SD	50.4 ± 12.8	54.7 ± 12.9	0.004[‡]
Mean Height (cm) ± SD	173.2 ± 10.1	172.3 ± 9.7	0.355[†]
Mean Weight (kg) ± SD	86.9 ± 20.0	83.7 ± 18.5	0.114[†]
Mean BMI (kg/m^2) ± SD	29.6 ± 12.4	28.0 ± 5.1	0.108[†]
Contralateral Hip Involvement (%)	64 (38.6%)	57 (39.0%)	1.000[*]
Joint Involvement Other than Hip (%)	47 (28.3%)	46 (31.5%)	0.621[*]
Physical Activity Prior to Surgery			[‡]
None (%)	14 (7.1%)	5 (3.1%)	-
Light (%)	123 (62.8%)	111 (68.9%)	-
Moderate (%)	54 (27.6%)	38 (23.6%)	-
Intense (%)	5 (2.6%)	6 (3.7%)	-
Operative Blood Loss (ml) ± SD	527 ± 371	510 ± 396	0.819[†]
Operative Time (minutes) ± SD	110 ± 52	114 ± 64	0.542[†]
Hospital Stay (days) ± SD	4.4 ± 2.0	4.4 ± 1.7	0.677[†]

Standard Deviation (SD), Body Mass Index (BMI), [*]One-sided Fischer exact test, [†]Two-tailed T-test of Unequal Variance, [‡]Chi-square analysis

Comment [DA1]: Not sure this was the right T test

Comment [DA2]: Need chi square

Table 2

Intraoperative and Postoperative Complication Rates

Complication	Ceramic-on-Ceramic (%) (n = 196)	Ceramic-on-Polyethylene (%) (n = 161)	p-value
		Intraoperative	
Liner Fracture	2 (1.0%)	0 (0.0%)	0.301
Sciatic Nerve Injury	1 (0.5%)	0 (0.0%)	0.549
Greater Trochanter Fracture	1 (0.5%)	1 (0.6%)	0.797
Difficulty Implanting Cup or Liner	2 (1.0%)	2 (1.2%)	0.758
		Postoperative	
Heterotopic Ossification (HO)	59 (30.1%)	41 (25.5%)	0.197
Dislocation	10 (5.1%)	9 (5.6%)	0.672
Trochanteric Bursitis	8 (4.1%)	5 (3.1%)	0.422
Audible Component Related Noise	6 (3.1%)	0 (0.0%)	0.026
Deep Venous Thrombosis	3 (1.5%)	2 (1.2%)	0.592
Pulmonary Embolus	2 (1.0%)	1 (0.6%)	0.573
Infection, superficial	6 (3.1%)	3 (1.9%)	0.357
Infection, deep	1 (0.5%)	2 (1.2%)	0.909
Implant Fracture: liner	2 (1.0%)	0 (0.0%)	0.301
Implant Fracture: head	1 (0.5%)	0 (0.0%)	0.549
Leg Length Discrepancy	2 (1.0%)	1 (0.6%)	0.573
Subluxation or Subsidence	3 (1.5%)	2 (1.2%)	0.592
Component Migration	4 (2.0%)	2 (1.2%)	0.439
Wear Debris or Osteolysis	1 (0.5%)	1 (0.6%)	0.797
Revision Surgery	11 (5.6%)	3 (1.9%)	0.059

Table 3
Revisions Undertaken in Each Trial Group

Initial Treatment	Interval	Component(s) Revised	Reason for Revision
Ceramic-on-Ceramic (n = 11)	3 Months	Liner, Head	Recurrent Dislocations
	3 Months	All Components	Infection
	6 Months	Cup, Liner, Head	Recurrent Anterior Dislocations
	1 Year	Head, Stem	Stem Subsidence
	1 Year	Cup, Liner, Head	Recurrent Anterior Dislocations*
	2 Years	Liner, Head	Ceramic Head Fracture
	3 Years	Cup, Liner, Head	Ceramic Liner Fracture
	3 Years	Head, Stem	Loose Femoral Component
	4 Years	Cup, Liner, Head	Recurrent Dislocations
	5 Years	Cup, Liner, Head	Ceramic Liner Fracture
	6 Years	Head, Stem	Loose Femoral Component
Ceramic-on-Polyethylene (n=3)	Before Discharge	Liner, Head	Instability of the Hip
	3 Months	All Components	Infection
	5 Years	Liner, Head	Recurrent Dislocations

*Patient with audible component-related noise

Table 4
Comparison of wear rates of alumina ceramic-on-polyethylene and alumina ceramic-on-ceramic bearing surfaces

Bearing Surface	Wear rate	Head Size	Study Design	Reference
Ceramic-on-Polyethylene	22 µm/year	22.225 mm	Radiographic evaluation of clinical follow-up	53
	70 µm/year	32 mm	Radiographic evaluation of clinical follow-up	35
	100 µm/year	Variable	Radiographic evaluation of clinical follow-up	22
	156 µm/year	28 mm	Radiographic evaluation of clinical follow-up	23
Ceramic-on-Ceramic	2.1 µm/year	Variable	Implant Retrieval	54
	4 µm/year	28 mm	*In vitro* analysis	41
	6 µm/year	Variable	Radiographic evaluation of clinical follow-up	55
	16 µm/year	Variable	Radiographic evaluation of clinical follow-up	56

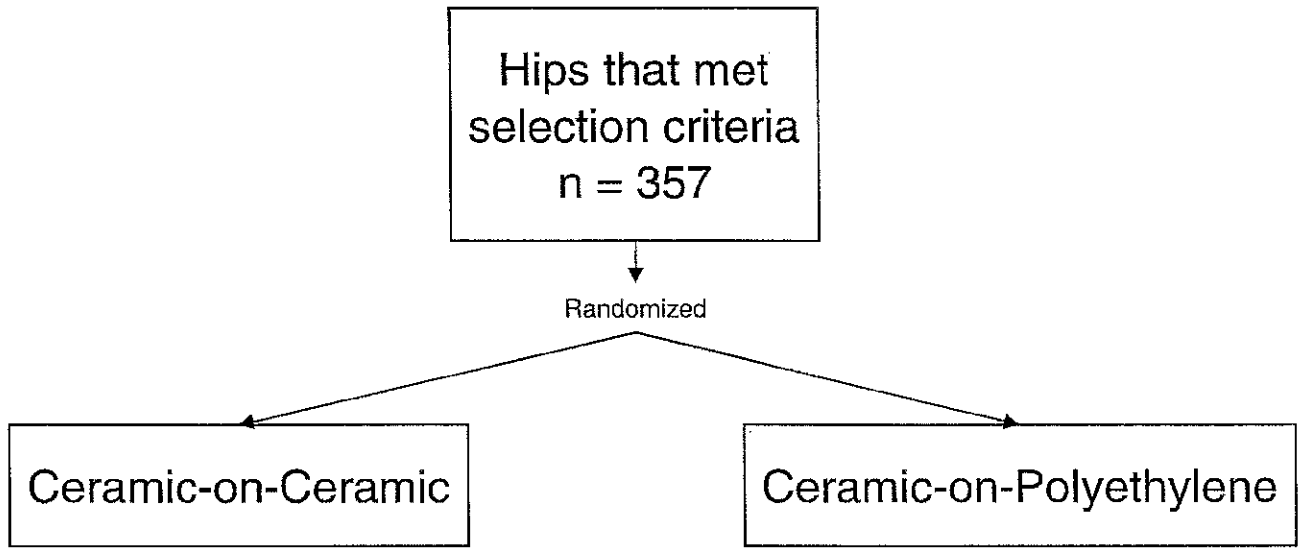
Figure Ledged

Figure 1: Hips enrolled and randomized in this trial as well as attrition from each arm of the study over time.

Figure 2: Harris Hip Score at each follow-up interval. $^*p < 0.01$

Figure 3: A) Linear and B) volumetric wear rates in each arm of the study. $^*p < 0.001$

Figure 1



Months	Ceramic-on-Ceramic n	Ceramic-on-Polyethylene n
0	196	161
3	187	154
6	183	147
12	182	144
24	176	137
48	131	99
>60	125	95

Patients were lost to follow-up as a result of missed appointments, death, and withdrawal from the study

Figure 2

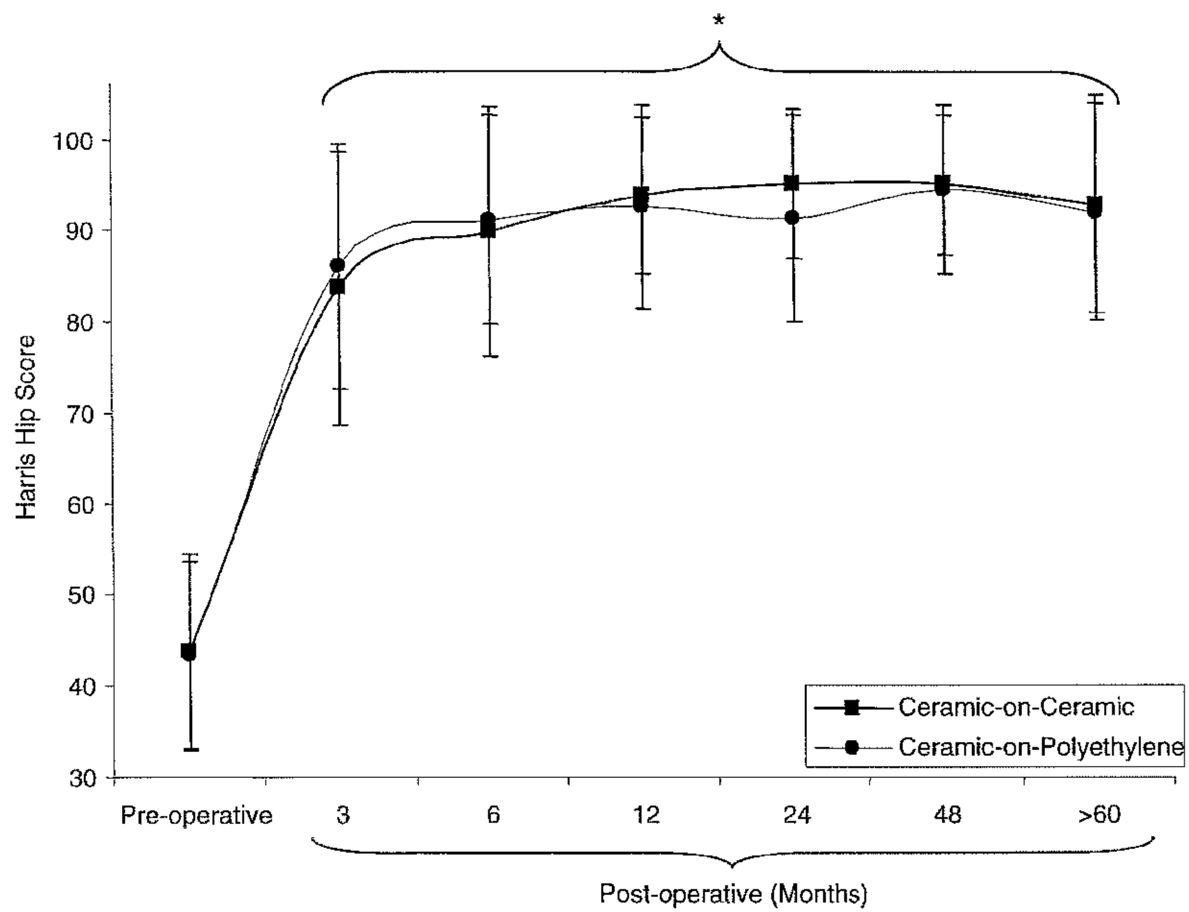
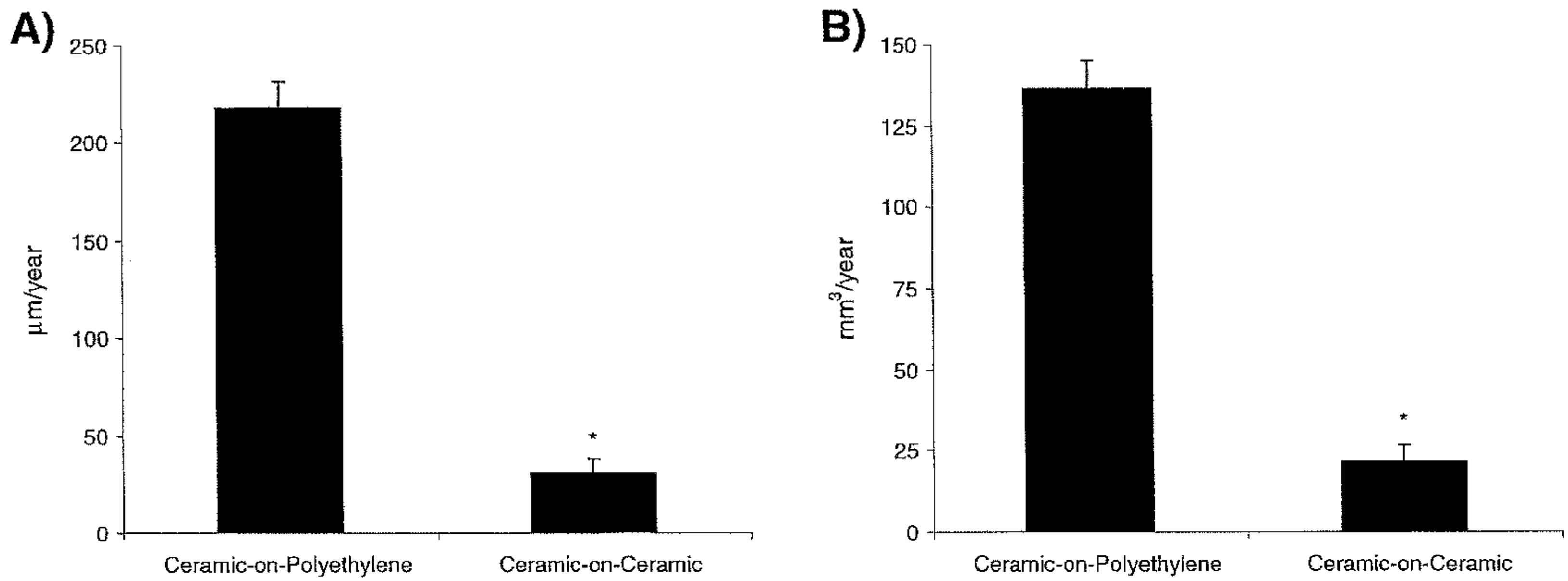

*
100
90
80
70
60
50
40
30
Harris Hip Score
Ceramic-on-Ceramic
Ceramic-on-Polyethylene
Pre-operative
3
6
12
24
48
>60
Post-operative (Months)

Figure 3



A)
250
200
150
100
50
0
µm/year
Ceramic-on-Polyethylene
Ceramic-on-Ceramic
*
B)
150
125
100
75
50
25
0
mm³/year
Ceramic-on-Polyethylene
Ceramic-on-Ceramic
*