No Difference in Conventional Polyethylene Wear Between Yttria-stabilized Zirconia and Cobalt-chromium-molybdenum Femoral Heads at 10 Years

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Abstract *Background:* Concerns have arisen regarding deterioration of wear properties of yttria-stabilized zirconia (YSZ) femoral head on conventional polyethylene (PE) bearings due to YSZ phase transformation. *Questions/Purposes:* The purpose of this study was to determine if there is a difference in long-term PE wear properties between YSZ and cobalt-chromium-molybdenum (Co-Cr-Mo) femoral heads. *Methods:* Ten-year radiographic wear assessment was performed on a cohort of patients enrolled in a prospective randomized clinical trial comparing total hip arthroplasty with YSZ or Co-Cr-Mo femoral heads on conventional, non-cross-linked PE. *Results:* PE linear wear, annualized wear, and steady-state wear rates remained low and similar between groups. No cases of osteolysis were observed. *Conclusions:* Measured conventional PE wear was similar between YSZ and Co-Cr-Mo femoral heads with the steady-state wear rates for both remaining below

the generally accepted threshold at which osteolysis typically occurs. Whether clinically relevant phase transformation with YSZ femoral heads occurs is uncertain; however, the use of YSZ femoral heads in this study was not associated with increased PE wear, osteolysis, or deterioration of wear properties.

Keywords hip · wear analysis · ceramic · polyethylene · zirconia

Introduction

The search for alternative bearing surfaces for total hip arthroplasty (THA) to combat osteolysis resulted in the adoption of several different ceramic bearing surfaces. Yttria-stabilized zirconia (YSZ) was thought to be the solution to the more brittle, first-generation alumina ceramics. However, YSZ femoral heads were shown to undergo tetragonal-to-monoclinic phase transformation [20] resulting in volumetric expansion and subsequent surface roughening, potentially compromising long-term wear properties when paired with polyethylene (PE) liners [8]. To further complicate matters, YSZ femoral heads manufactured by Saint Gobain Desmarquest (Evreux, France) were withdrawn from the market after an increased incidence of component fracture was observed [15]. Although this was likely the result of a manufacturing error, it ultimately led to the abandonment of YSZ as a bearing surface in favor of oxidized zirconium and an alumina-zirconia composite ceramic [14].

The tainted history of YSZ as a bearing surface makes its clinical track record difficult to interpret. Mid-term wear results were disappointing and failed to show any advantage compared with cobalt-chromium-molybdenum (Co-Cr-Mo) femoral heads [1, 8, 9, 12, 22]. It remains essential, however, that the long-term wear properties of YSZ be assessed, as countless total hip arthroplasties have been performed using

Level of Evidence: Level II: Randomized Control Trial

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this bearing surface, and any deterioration of wear properties would warrant closer clinical monitoring for evidence of excessive wear or osteolysis. The purpose of this study was to answer the following questions: (1) is there a difference in long-term wear properties of conventional PE with YSZ or Co-Cr-Mo femoral heads? (2) Is the rate of osteolysis with conventional PE different with YSZ or Co-Cr-Mo femoral heads? (3) Is there a deterioration of the wear properties of conventional PE with YSZ femoral heads with time?

Patients and Methods

We obtained additional long-term follow-up of a previously reported cohort of patients from a prospective randomized control clinical trial comparing YSZ and Co-Cr-Mo alloy femoral heads on conventional, non-cross-linked PE liners [13]. We hypothesized that, given the potential for monoclinic phase transformation, PE wear rate and incidence of osteolysis in THAs with YSZ femoral heads would be greater and that THAs with YSZ femoral heads would demonstrate deterioration of PE wear properties over time. Enrollment began in 1998 and ceased in 2002 following the US Food and Drug Administration (FDA) recall of YSZ femoral heads manufactured by St. Gobain Desmarquest (Evreux, France for Zimmer, Inc.). Original study methods are described elsewhere [13].

Patients were eligible for inclusion in the initial trial if they met the following criteria: primary THA surgery, diagnosis with primary or secondary osteoarthritis or osteonecrosis, age 50–75 years, and weight less than 225 lb.

Patients were randomly assigned to receive either a 28-mm YSZ femoral head (St. Gobain Desmarquest (Evreux, France for Zimmer, Inc.)) or 28-mm Co-Cr-Mo alloy femoral head (Zimmer, Inc.) (Fig. 1). Initial power analysis indicated that 60 patients were needed in each group to detect a 20% difference in wear. Due to the FDA recall of the YSZ heads used in this study, enrollment was prematurely terminated with only 60 hips enrolled (30 in each cohort). Three patients were lost to follow-up; thus, 27 THAs with YSZ femoral heads and 30 THAs with Co-Cr-Mo femoral heads comprised the original study cohorts. Two of the patients in this study received YSZ heads from the high-risk group for femoral head fracture identified by the FDA recall, although neither patient has experienced a fracture of the zirconia head to date. Eight patients received bilateral THA with a YSZ head on one side and a Co-Cr-Mo head on the contralateral side per randomization protocol.

All surgeries were performed by one of two fellowship-trained adult reconstructive surgeons at the authors' institution as previously described [13]. With the exception of the femoral head material, all implants used in both study groups were identical (Cementless Trilogy acetabular component and cemented Versys femoral components (Zimmer, Inc., Warsaw, IN)). Acetabular liners were all manufactured from GUR 1050 ultra-high molecular weight, non-cross-linked PE resin and were obtained from a limited number of batches to control for differences in polyethylene material quality that could have an effect on measured PE wear. All

Fig. 1. a, b: Examples of the 28-mm Co-Cr-Mo and YSZ femoral heads used in this study.

patients were treated under an identical, standardized post-operative care path following surgery. Follow-up clinical evaluations were performed by the senior author. Standardized digital hip radiographs (anteroposterior (AP) pelvis, and AP and cross-table lateral of hip) were obtained at follow-up visits.

Primary outcomes were total linear wear (mm) and annualized wear rate (mm/yr). Secondary outcomes were the presence of osteolysis or interface lucencies. Patient gender, age, time from index surgery, and body mass index (BMI) were determined by review of the medical record. Postoperative radiographs obtained at follow-up evaluations were assessed by two separate observers (TAM, JM) in a blinded fashion using a widely utilized two-dimensional computerized wear analysis program (Hip Analysis Suite (HAS) Version 8.0.4.3, UChicagoTech, Chicago, IL) (Fig. 2). Cup inclination angle, linear wear as measured by the femoral head penetration were determined using HAS, and annualized wear rates were calculated from this data. Radiographic analysis was blinded as the radiographic densities of ceramic and metal are indistinguishable (Fig. 3). Radiographs were evaluated for osteolysis using the method of Weber et al. [21] and for interface radiolucencies using the method of Gruen et al. [7] and DeLee and Charnley [3].

Interclass correlation coefficient was used to assess the agreement between wear measurements determined by the two observers. The average interclass correlation coefficient was 0.963, indicating excellent agreement between the two observers who performed the radiographic wear analysis. In our earlier report, a paired analysis was used, which compared follow-up radiographs to initial 6-week postoperative radiographs. Subsequent to this, single-image analysis has

Fig. 2. Radiographic parameters for calculation of wear using the Martell method. User-defined parameters included the horizontal line bisecting the ellipse of the outer diameter of the acetabular component and the circular diameter of the femoral head. Linear and volumetric wear was then calculated using Martell analysis based on the distance between the center of the acetabular component and femoral head, using the known femoral head size as a reference.

been shown to be more accurate and has several other advantages over the paired analysis method [6]. Therefore, single-image analysis was used in the current study. Steady-

Fig. 3 . a, b: Radiographs at >10 years following THA with Co-Cr-Mo femoral head (A) and YSZ femoral head (B) demonstrating no evidence of osteolysis. Note that the femoral head materials have indistinguishable radiographic appearances.

state wear was determined using the method previously described by Sychterz et al. [19]. Comparison of cohort characteristics including age, gender, BMI, time from surgery, and cup angle at most recent follow-up and their relationship to wear properties was performed using independent *T* test and chi-square analyses. Pearson's correlation coefficient was calculated for bivariate correlation. Comparison of wear properties between study groups was accomplished using a Mann-Whitney *U* test. A Hodges-Lehmann estimate and 95% confidence interval were calculated to compare the median difference between ranked cohort values for wear performance. Moses's test of extreme reactions was used to determine if wear performance outliers were more likely to occur in either group, plausibly representing instances of degradation of wear properties. All statistical analysis was performed using SPSS Statistics 23.0 (IBM, Armonk, NY).

We were able to obtain long-term follow-up on 38 hips (20 hips with YSZ femoral heads and 18 hips with Co-Cr-Mo femoral heads) in 33 patients, or approximately 67% of our original study cohort. Of the remaining 19 hips that were not included in this analysis, nine patients (ten hips) had died, six patients (six hips) were lost to follow-up, and two patients (three hips) had postoperative radiographs of insufficient quality for wear analysis (Fig. 4). There were two periprosthetic femur fractures in the YSZ group, neither of which required component revision. There were no cases of femoral head fracture.

Average age of the YSZ and Co-Cr-Mo study cohorts was 81.7 and 80.6, respectively. The YSZ cohort was comprised of 6/14 males and the Co-Cr-Mo group was 5/13 males. Average follow-up time was 139 ± 45 months (range 70 to 196 months, Table 1). Of the 20 patients in the YSZ cohort, 15 had greater than 10 years of follow-up. Of the 18 patients in the Co-Cr-Mo cohort, 12 had greater than 10 years of follow-up. There was no difference in age, gender, weight, or preoperative Harris Hip Score preoperatively and no difference in duration of follow-up postoperatively,

Fig. 4. Study flowchart of subjects included in prior early follow-up report and current 10-year average report. The current study cohort represents 67% of the original study cohort.

Table 1 Descriptive statistics of follow-up cohort. Characteristics of groups at study follow-up were similar

	Yttria-stabilized zirconia	Co-Cr-Mo	Total	Sig
Number of THAs (%)	20/27 (70.0%)	18/30 (64.3%)	38/57 (66.7%)	$\chi = 1.27$ $p = 0.260$
Mean follow-up (months $\pm$ SD)	139 $\pm$ 41.4	140 $\pm$ 49.0	139 $\pm$ 44.5	$p = 0.806$
Age at follow-up (years $\pm$ SD)	81.7 $\pm$ 5.0	80.6 $\pm$ 6.1	81.2 $\pm$ 5.5	$p = 0.718$
Gender (M:F)	6:14	5:13	11:27	$\chi = 0.023$ $p = 0.880$
Mean follow-up BMI	26.2 $\pm$ 4.1	32.6 $\pm$ 10.3	29.0 $\pm$ 8.3	$p = 0.034$

(“Number of THA” variable is listed as proportion relative to the original study group)

SD standard deviation, M male, F female, BMI body mass index

age at last follow-up, or gender at last follow-up. The Co-Cr-Mo group had a higher mean BMI at follow-up however (26.2 $\pm$ 4.1 vs 32.6 $\pm$ 10.3, $p = 0.034$).

Results

Median total linear wear for the YSZ and Co-Cr-Mo groups was 0.63 mm (range 0.16 to 2.00 mm) and 0.74 mm (range 0.23 to 1.33 mm), respectively, and the distributions of the two groups did not differ (Mann-Whitney $U = 157.5$, $n_1 = 20$, $n_2 = 18$, $p = 0.515$). Median annualized linear wear rate for the YSZ and Co-Cr-Mo groups was 0.06 mm/year (range 0.02 to 0.13 mm/year) and 0.07 mm/year (range 0.01 to 0.17 mm/year), respectively, and the distributions of the two groups did not differ (Mann-Whitney $U = 132$, $n_1 = 20$, $n_2 = 18$, $p = 0.167$) (Table 2). Increased age at follow-up and longer implantation time correlated with lower annualized wear ($R = -0.55$, $p = 0.00$, and $R = -0.43$, $p = 0.007$). Longer implantation time also correlated with greater total linear wear ($R = 0.362$, $p = 0.25$). Median total linear wear for THAs (regardless of bearing couple) in males compared with females was 0.82 and 0.62 mm, respectively. The distributions differed between males and females (Mann-Whitney $U = 45$, $n_1 = 11$, $n_2 = 27$, $p = 0.001$). Median annualized linear wear rate for THAs (regardless of bearing couple) in males compared with females was 0.09 and 0.06 mm/year, respectively. Similarly, the distributions differed between males and females (Mann-Whitney $U = 82$, $n_1 = 11$, $n_2 = 27$, $p = 0.032$). Steady-state wear analysis using the method previously described by Sychterz et al. [19] demonstrated that femoral head penetration in the YSZ and

Co-Cr-Mo groups secondary to initial “bedding in” was 0.22 and 0.41 mm, respectively, and the steady-state wear rate after the “bedding in” period was 0.042 and 0.034 mm/year, respectively (Fig. 5).

There were no observed cases of osteolysis or implant loosening in either cohort. Radiographic evaluation for osteolysis at last follow-up demonstrated stress shielding of the proximal femur (Delee and Charnley zones I, VII) without interface radiolucency in three hips in the YSZ cohort and two hips in the Co-Cr-Mo cohort. Similarly, stress shielding of the acetabulum (Gruen zones 1, 2) without interface radiolucency was observed in one hip in the YSZ cohort and one hip from the Co-Cr-Mo cohort.

The Moses test for extreme reactions did not identify a difference in the occurrence of outlier total linear wear or outlier annualized linear wear rate between study cohorts. Median total linear wear for YSZ THAs with an implantation time of less than and greater than 10 years did not differ (0.62 and 0.63 mm, respectively, Mann-Whitney $U = 33$, $n_1 = 5$, $n_2 = 15$, $p = 0.735$). Median annualized wear rates for YSZ THAs with implantation time of less than and greater than 10 years did differ with 0.09 and 0.05 mm/year, respectively (Mann-Whitney $U = 12$, $n_1 = 5$, $n_2 = 15$, $p = 0.025$), indicating that YSZ annualized wear rates were lower after 10 years of implantation.

Discussion

This study asked whether the long-term wear properties of conventional, non-cross-linked PE were affected by choice of YSZ or Co-Cr-Mo femoral heads, whether

Table 2 Wear analysis results. There were no differences between groups for conventional PE wear or cup position based on Martell two-dimension vector analysis of follow-up radiographs. Total linear wear and annualized wear reported as median (range), cup inclination reported as mean ($\pm$ SD)

	Yttria-stabilized zirconia	Co-Cr-Mo	Mann-Whitney U	Hodges-Lehmann's estimate and 95% CI	Moses extreme reaction
Total linear wear (mm)	0.63 (0.16–2.00)	0.74 (0.23–1.33)	$U = 157.5$ $p = 0.515$	−0.080 (−0.324 to 0.140)	$p = 0.286$
Annualized wear (mm/yr)	0.06 (0.02–0.13)	0.07 (0.01–0.17)	$U = 132$ $p = 0.167$	−0.018 (−0.039 to 0.009)	$p = 0.437$
Cup inclination (°)	45.4 $\pm$ 3.9	46.6 $\pm$ 4.0	$U = -0.517$ $p = 0.620$	−0.786 (−3.458 to 1.812)	$p = 0.813$

Fig. 5. Steady-state wear of YSZ and Co-Cr-Mo femoral heads on conventional PE acetabular liners. Conventional PE wear in YSZ and Co-Cr-Mo groups secondary to creep was 0.22 and 0.41 mm, respectively. Steady-state wear rate was 0.042 mm/year in the YSZ group and 0.034 mm/year in the Co-Cr-Mo group.

there was a difference in the rate of osteolysis of these two femoral head materials, and whether there was a deterioration in PE wear rates in THAs with YSZ femoral heads over time. Long-term follow-up results of this prospective randomized clinical trial demonstrate that total linear wear, annualized linear wear rate, steady-state wear rate, and incidence of osteolysis of conventional, non-cross-linked PE were similar for THAs with both YSZ and Co-Cr-Mo femoral heads. Despite concerns about the possible degradation of wear properties of YSZ femoral heads, we did not observe an increase in annual wear rates in THAs with this bearing material.

This study has several limitations. Measuring small amounts of wear radiographically is difficult; however, the current versions of the software used in this study have been shown to be extremely sensitive in measuring small amounts of femoral head penetration [12]. Furthermore, interobserver correlation coefficient was high (0.963) indicating that wear measurements were reproducible. Another limitation of this study is that enrollment was prematurely halted due to the FDA recall of the YSZ femoral heads before recruitment goals could be met. We were only able to obtain additional follow-up on 67% of this initial study cohort. As a result, this study may be insufficiently powered to detect a difference in wear rates between the two femoral head materials. Despite the above shortcomings, we feel this is a high-quality prospective randomized trial with patients closely matched for important parameters such as age, gender, and weight.

At a mean follow-up of 10 years, annualized linear wear rate for the YSZ femoral head cohort was 0.06 mm/year compared to 0.07 mm/year for the Co-Cr-Mo, and steady-state wear rate for the YSZ femoral head cohort

was 0.04 mm/year compared to 0.03 mm/year for the Co-Cr-Mo. These wear rates are similar to previously reported wear rates with YSZ femoral heads [1, 2, 10, 11]. Our initial report of early wear of YSZ versus Co-Cr-Mo femoral heads with this same cohort of patients showed no differences in wear at a mean follow-up of 51 months. Cohn et al. [2] and Stilling et al. [18] demonstrated similar results in prospective cohort studies of YSZ and Co-Cr-Mo femoral heads on conventional, non-cross-linked PE at comparable follow-up.

There were no cases of osteolysis in either the YSZ or Co-Cr-Mo cohorts at a mean follow-up of 10 years. Annualized wear rate in both groups was below the generally accepted osteolysis threshold of 0.1 mm/year which should minimize the load of particulate debris generated due to articular surface wear. Additionally, design features of the acetabular component used in this study (polished backside, limited screw holes, effective capture mechanism), improvements in PE quality, and manufacturing and sterilization of PE in an inert environment may have minimized risk of osteolysis in both study groups.

We found no evidence of deterioration in the wear properties of conventional PE in the YSZ femoral head group in this study. On the contrary, annualized linear wear rate in the YSZ femoral head group decreased after 10 years. One likely and widely accepted explanation for this is the decrease in activity level in our patients as they aged over the course of this study [17]. The findings of our study do not support those of previous reports that raised concerns about progressive deterioration of PE wear properties that may be associated with phase transformation of YSZ femoral heads. It is impossible to determine the occurrence and potential effects of tetragonal-to-monoclinic phase transformation on the

wear properties of the femoral heads used in this study since we did not retrieve any YSZ femoral heads and thus could not correlate wear with the monoclinic phase content.

The degree to which phase transformation occurs and the impact it has on PE wear is uncertain, especially considering the potential variability in YSZ quality between implant manufacturers [4, 16, 22]. Fukui et al. were able to demonstrate increased monoclinic phase content in YSZ heads retrieved at a mean of 8.6 years; however, they did not demonstrate increased surface roughness on scanning electron microscopy analysis [5]. Kim et al. similarly noted monoclinic phase transformation without resultant surface roughness in two retrieved zirconia femoral heads from a cohort of young THA patients [10]. Based on the majority of published information and the results of this study, although monoclinic transformation of YSZ femoral heads may occur in vivo, the extent of these changes does not appear to have an adverse effect on PE wear at a mean of 10 years of follow-up.

Zirconia femoral heads were introduced to reduce PE wear in THA and address concerns regarding femoral head fracture that was seen with early alumina ceramic femoral heads. Shortly after their clinical introduction, zirconia femoral heads were noted to undergo phase transformation that was thought to potentially compromise the wear properties of these bearing materials. Results of this study and consensus of the available scientific literature regarding YSZ femoral heads in THA suggests conventional, non-cross-linked PE wear is comparable with either YSZ or traditional Co-Cr-Mo femoral heads. Whether clinically relevant phase transformation with YSZ femoral heads occurs is uncertain; however, the use of these femoral heads in the present study was not associated with increased wear or deterioration of wear properties at 10 years' follow-up. We observed annualized linear wear rates below the accepted threshold for osteolysis and no cases of osteolysis, regardless of femoral head composition. Based on the above, YSZ femoral heads did not meet the expectations of many as an improved alternative bearing for THA because of increased risk of fracture and lack of advantage with regard to PE wear compared to Co-Cr-Mo femoral heads; however, this bearing has not demonstrated a deterioration of wear properties at late follow-up. Additional monitoring of patients with YSZ femoral heads beyond routine follow-up is not warranted based on our study findings.

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Compliance with Ethical Standards

Conflict of Interest: Todd A. Morrison, MD; Clare M. Rimnac, PhD; Jia Meng, BS; Rebecca D. Moore, MS have declared that they have no conflict of interest. Matthew J. Kraay, MD, MS, reports a grant from Orthopaedic Research Education Foundation (OREF), during the conduct of the study.

Human/Animal Rights: All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008 (5).

Informed Consent: Informed consent was obtained from all patients for being included in the study.

Required Author Forms Disclosure forms provided by the authors are available with the online version of this article.

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