Wear Analysis in THA Utilizing Oxidized Zirconium and Crosslinked Polyethylene

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Abstract Oxidized zirconium, a material with a ceramic surface on a metal substrate, and highly cross-linked polyethylene are two materials developed to reduce wear. We measured in vivo femoral head penetration in patients with these advanced bearings. We hypothesized the linear wear rates would be lower than those published for cobalt-chrome and standard polyethylene. We retrospectively reviewed a select series of 56 THAs in a relatively young, active patient population utilizing oxidized zirconium femoral heads and highly cross-linked polyethylene acetabular liners. Femoral head penetration was determined using the Martell computerized edge-detection method. All patients were available for 2-year clinical and radiographic followup. True linear wear was 4 $\mu\text{m}/\text{year}$ (95% confidence intervals, $\pm 59 \mu\text{m}/\text{year}$). The early wear rates in this cohort of relatively young, active patients were low and we believe justify the continued study of these alternative bearing surfaces.

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

Introduction

The bearing surface of THA is one of the most critical factors for long-term survival of hip implants. The traditional bearing of metal-on-polyethylene has been challenged by metal-on-metal, ceramic-on-ceramic, ceramic-on-polyethylene, metal-on-cross-linked polyethylene, and other combinations with the purpose of minimizing wear debris and extending the life of the implant [3, 10, 16–22].

A ceramic femoral head on a polyethylene acetabular liner is among the most common alternative bearing couples currently used in THA [10]. Ceramic bearings offer the advantage of improved lubrication, smoother surface finish, and improved resistance to scratching and are biologically inert compounds. Ceramic femoral heads therefore have substantial tribologic advantages over metal femoral heads and result in much lower wear rates [10]. Clinical studies have demonstrated mean linear wear rates with ceramic on polyethylene are between 0.03 and 0.1 mm/year in patients followed for up to 18 years [16–20]. The risk of fracture with monolithic ceramic heads has been one drawback to the use of this material, particularly in young, active patients, and has led to the development of alternative bearing materials including oxidized zirconium [1, 7].

Zirconium alloy is composed of zirconium (97.5%) and niobium (2.5%). Oxidized zirconium is produced by heating the zirconium alloy in air to greater than 500°C. Thermal oxidation occurs, transforming the metal alloy at

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the surface to a 5- μ m-thick ceramic (zirconia) [6]. Oxidized zirconium femoral heads articulating with highly cross-linked polyethylene have undetectable wear rates in hip simulators [6].

The primary purpose of our study was to evaluate the *in vivo* wear rates (femoral head penetration) of THAs using oxidized zirconium femoral heads and highly cross-linked polyethylene and compare these to published wear rates of cobalt-chrome on standard or cross-linked polyethylene. The secondary purpose was to describe short-term outcomes and complications associated with the use of these alternative bearings.

Materials and Methods

Following approval by the institutional review board, we retrospectively reviewed a select series of 54 patients (56 hips) who underwent THA between March 2003 and March 2005 using an oxidized zirconium femoral head and a highly crosslinked polyethylene acetabular liner. Patients were considered candidates for oxidized zirconium based primarily on age (< 68 years) and relative activity levels and overall health status as judged by the surgeon. They had no major comorbid conditions that would alter life expectancy and led an active lifestyle. During this same time we performed 91 THAs using cobalt-chrome femoral heads. To be included, we required anteroposterior pelvis radiographs taken at least 4 weeks after surgery with a minimum followup radiograph at 2 years for all patients. The cohort included 28 men and 26 women with a mean age of 53 years (range, 31–68 years). The patients in the cohort had a mean body mass index of 29.6 kg/m² (range, 17–49 kg/m²). The index diagnoses were osteoarthritis (36), childhood hip disease (12), avascular necrosis (four), and inflammatory arthritis (three). All patients had a minimum 2-year clinical and radiographic followup with a mean followup of 30 months (range, 24–48 months). Thirty-seven hips in 35 patients were not included in the analysis because 2-year followup radiographs were not available at the time of preparation of the manuscript.

All operations were performed with a posterior approach. The components used in all patients included a SynergyTM femoral stem and OxiniumTM modular femoral head (Smith and Nephew, Inc, Memphis, TN) with a Trilogy[®] acetabular shell and Longevity[®] acetabular liner (Zimmer, Inc, Warsaw, IN). Acetabular components ranged in size from 50 to 62 mm. A 28-mm femoral head was implanted in 40 patients, a 32-mm head in 15 patients, and a 36-mm head in one patient. The minimum polyethylene thickness was 6.3 mm with a mean thickness of 7.8 ± 1.2 mm (standard deviation).

In vivo penetration of the femoral head into the polyethylene was determined as two-dimensional (2-D) linear femoral head penetration using the semiautomated computerized measuring method HAS version 8.0.4.0 (Hip Analysis Suite, The University of Chicago, Chicago, IL) [13]. This method is a validated edge-detection method that calculates femoral penetration by tracking head center movement relative to the fixed acetabular cup center over time. We have shown 2-D wear analysis is highly correlated and in good agreement with 3-D analysis, making 3-D analysis unnecessary [14]. Additionally, load-bearing radiographs do not substantially improve the performance of wear measurements using this system [15]. Accordingly, wear was evaluated using supine anteroposterior pelvis radiographs. We (KLG, CWH, JM, JMM; KLG is the treating surgeon) evaluated osteolysis with anteroposterior and lateral radiographs of the hip. Acetabular inclination angle and radiographic anteversion were also measured. Radiographic anteversion is determined digitally by HAS using the major and minor axes of an ellipse fitting the face of the cup. All radiographs were obtained using a Siemens digital CR system (Siemens Medical Solutions USA, Inc, Malvern, PA) and were analyzed using HAS in their original DICOM format. Femoral head penetration measurements were performed on all intermediate or later available radiographs with a minimum radiographic interval of 6 months. Radiographs demonstrating asymmetry of the obturator foramen (rotation about the y axis) or in which the iliac crests or lesser trochanters were not visible were excluded from wear analysis. Rotation about the x axis is accounted for by the software, which reports the rotational difference of each radiographic pair. Image pairs with more than 25° of rotation are excluded from the analysis. The rotation about the z axis is controlled using the ischial tuberosities as a reference line in each radiograph. Magnification is controlled in every image by measuring the known head diameter.

The femoral head penetration rate was calculated using methods recently described by Geller et al. [5] and Bragdon et al. [2]. The mean femoral head penetration was calculated by determining the magnitude of femoral head penetration between the first postoperative radiograph and the longest followup film and dividing by the radiographic followup interval in years. This measurement of the total penetration rate of the femoral head into the acetabular polyethylene is the result of a combination of both creep of the plastic and wear of the material. To separate the early bedding-in process and the true steady-state wear, we calculated mean total femoral head penetration between the postoperative and 1-year radiographs and the mean femoral head penetration between the 1-year radiograph and the longest followup radiograph. True wear rates (without bedding-in) were determined by the slope of the best-fit

Fig. 1 Steady state (true) wear rates for oxidized zirconium on crosslinked polyethylene are shown. 95% CI = 95% confidence interval.

regression line through a plot of all total penetration values versus years from surgery using the 1-year film as baseline (Fig. 1). A total of 457 of all 586 available radiograph pairs (78%) were accepted for the computerized radiographic determination of wear. We excluded radiograph pairs separated by less than 6 months of time and with rotation of 25° on the x axis. All analyses were performed at the Orthopaedic Biomedical Imaging Institute at the University of Chicago where this (HAS) technique was developed and which specializes in wear analysis of hip implants.

Results

The in vivo femoral head penetration rate after 12 months was $4 \mu\text{m}/\text{year}$ (95% confidence intervals, $\pm 59 \mu\text{m}/\text{year}$) (Fig. 1). The true wear data were distributed around zero during all time periods (Fig. 1). We made wear determination based on the two points and the regression method using the 4-week and 1-year postoperative films as a baseline (Table 1). After 24 months, we observed no effect ($p = 0.10$) of time on the measured amount of wear. Wear was also calculated for 28-mm heads and 32-mm heads separately. The slopes of the regression plots were similar ($p = 0.2657$). Based on this, we concluded there was no difference in wear between the 28-mm and 32-mm heads. Average inclination angle was $45.4^\circ \pm 5.7^\circ$ (range, 35° – 56°). Average radiographic anteversion

was $16.6^\circ \pm 5.6^\circ$ (range, 3° – 28.6°). No patient had radiographic evidence of osteolysis and no patient has been revised for mechanical loosening or wear.

Our relevant complications included one dislocation. The dislocation was discovered in the recovery room and it was believed the cup position was a contributing factor. The patient was returned to the operating room for open reduction and cup repositioning. The femoral head was inspected and free of damage. The patient experienced no further instability.

Discussion

We evaluated the in vivo wear rates of THAs using oxidized zirconium femoral heads and highly crosslinked polyethylene and compared these to published wear rates of cobalt-chrome on standard or crosslinked polyethylene. We also evaluated short-term outcomes and complications associated with the use of these alternative bearings.

The limitations of our study include the selection criteria, the small cohort, short followup, inconsistent head size, and mixed components. While we did use age as an objective criterion, the other selection criteria are relatively subjective and could be difficult to apply in clinical practice. The size of our cohort is small and wear may have been more substantial in a larger cohort. Our followup is only 2 years, which is certainly short-term for arthroplasty research. This cohort will need to be followed for many more years to determine if the wear remains low. Additionally, the head size used in this cohort was not consistent. All but one patient had either a 28-mm or 32-mm head. This may make data interpretation difficult, as linear wear is also a function of head size. Lastly, we used acetabular and femoral components from different manufacturers. While one would expect elevated wear rates if the component mismatch were remarkable, we cannot

Table 1. Results of wear determination with and without bedding-in

Bedding-in	Count	First to last		Regression method	
		Linear rate*	Volumetric rate*	Linear rate	Volumetric rate
Included	56	0.041 ± 0.11	34.0 ± 27	0.005	8.916
Excluded	46	0.067 ± 0.27	70.2 ± 99	0.004	9.867

* Values are expressed as mean $\pm$ standard deviation.

Table 2. Comparison of studies evaluating wear on highly cross-linked polyethylene

Study	Patient age (years)*	Body mass index (kg/m ²)*	Male (%)	Femoral head material	Femoral head size (number of hips)
Garvin et al. (current study)	52.6 ± 9.6	29.6 ± 5.8	54	Oxidized zirconium	28 mm (40) 32 mm (15) 36 mm (1)
Manning et al. [12]	60.9 ± 11.1	25.9 ± 3.5	50	Cobalt-chrome	28 mm (70)
Heisel et al. [8]	60 ± 14	30.9 ± 5.2	32	Cobalt-chrome	28 mm (27) 32 mm (7)

* Values are expressed as mean ± standard deviation.

support this practice with scientific data and therefore must report it as a potential weakness of the study.

Our findings of a true linear wear rate of 4 µm/year are among the lowest reports of in vivo wear in the literature and have encouraged us to continue studying this bearing couple. Two similar studies have been published addressing in vivo wear of highly cross-linked polyethylene [8, 12]. Both studies compared a cohort of hips with standard polyethylene to one with cross-linked polyethylene. Both studies reported remarkably low wear rates for cobalt-chrome heads articulating with cross-linked polyethylene at a similar length of followup. Several similarities were evident when comparing these studies (Table 2). First, the technique for measuring wear was identical between the current report and those of Manning et al. [12] and Heisel et al. [8]. Orthopaedic surgeons trained in the Martell technique were responsible for wear measurement in both studies. The radiographs were also screened for their quality before measurements were performed. Length of followup was also comparable between the three. All studies reported early (2- to 4-year) results. The main difference in the studies was the femoral bearing. In the current study, the femoral heads were oxidized zirconium while Manning et al. [12] used cobalt-chrome and Heisel et al. [8] used cobalt-chrome and ceramic. Activity levels could not be compared between these cohorts and as such represents a limitation in comparison with the present study. In addition the head sizes between the three groups were not consistent, further complicating comparisons. It will be important to follow these cohorts to assess if the polyethylene wear rates remain low. In vitro studies have found oxidized zirconium to have undetectable wear rates when articulating against highly cross-linked polyethylene [6]. More importantly, when using roughened femoral heads oxidized zirconium produced 61% less polyethylene wear compared to CoCr [6]. We did not find a substantially reduced wear rate with our bearing couple compared to reports of CoCr and highly cross-linked polyethylene, which may be a consequence of the short followup.

In addition to a very low wear rate, there was no evidence of catastrophic wear or failure of the oxidized zirconium in

our study. The introduction of a new material brings a risk of unknown adverse effects. In vitro and in vivo data have helped address these concerns. Oxidized zirconium and cobalt-chrome articulating with standard and cross-linked polyethylene were evaluated in smooth and roughened conditions in vitro [6]. The roughened conditions were artificially created via a technique previously described to create clinically relevant abrasions [9]. The authors reported oxidized zirconium was more abrasion-resistant when compared to cobalt-chrome. In addition, oxidized zirconium had lower wear rates compared to cobalt-chrome under all conditions, but particularly in the clinically relevant abraded condition.

Two studies have been published dealing with damage to oxidized zirconium. Kop et al. [11] compared indentation damage of oxidized zirconium and cobalt-chrome femoral heads in vitro by pivoting on the edge of an acetabular shell rim. The oxidized zirconium head indentations were 54% deeper than the cobalt-chrome heads. These values were consistent with known bulk hardness values for oxidized zirconium and cobalt-chrome. In vivo studies of femoral head damage are case reports describing a total of four head retrievals secondary to dislocation. The authors reported substantial damage to the heads thought to have occurred at the time of dislocation or attempted closed reduction [4, 11]. The case reports of retrieval specimens give cause for concern. The recommendations of the authors of the reports are for careful monitoring after closed reduction to detect advanced polyethylene wear or open reduction and inspection of the femoral head to determine if it should be replaced. We believe the difficulty of the reduction should be a factor used to consider revising the head. In two of the reported patients, the hip was irreducible by closed manipulation. In the remaining two patients, the dislocations were recurrent. Both situations provide considerable opportunity for the femoral head to be damaged.

Oxidized zirconium articulating with highly cross-linked polyethylene in THA appears to have the potential to dramatically reduce wear. Our study found short-term wear rates were comparable to CoCr heads articulating with highly cross-linked polyethylene. This raises the question as

to whether the potential risks of an unknown bearing couple are mitigated by the potential benefits of wear reduction. We have found no major risks beyond what would be expected with the use of a CoCr femoral head. With in vitro data reporting such dramatic reductions in wear [6], we believe continued study, including careful monitoring of these alternative bearings, is necessary to determine if wear is reduced in the younger, active patient population.

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