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Hip Dislocation Increases Roughness of Oxidized Zirconium Femoral Heads in Total Hip Arthroplasty: An Analysis of 59 Retrievals

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Abstract

The aims of this study were to assess damage on the surface of retrieved oxidized zirconium metal (OxZr) femoral heads, to measure surface roughness of scratches, and to evaluate the extent of surface effacement using scanning electron microscopy (SEM). Ceramic zirconia-toughened alumina (ZTA) heads were analyzed for comparison. OxZr femoral heads explanted for recurrent dislocation had the most severe damage ($p < 0.001$). The median surface roughness of damaged OxZr femoral heads was $1.49\mu\text{m}$, compared to $0.084\mu\text{m}$ for damaged ZTA heads and $0.052\mu\text{m}$ for undamaged OxZr ($p < 0.001$). This may be of clinical concern because increased surface roughness has the potential to increase the wear of polyethylene liners articulating against these OxZr heads in THA.

Introduction

Since wear-related osteolysis continues to be a concern in the long-term outcome and survivorship of total hip arthroplasty (THA), especially in younger, active patients who put more demand on their prostheses, there continues to be an emphasis on bearing materials that exhibit improved wear resistance. Oxidized zirconium (OxZr) metal (Oxinium, Smith & Nephew, Memphis, TN) femoral heads were developed to reduce polyethylene wear relative to metallic cobalt-chrome (CoCr) alloy femoral heads, while eliminating the concerns of fracture seen with heads fabricated entirely from ceramics. OxZr is created by oxidation of a zirconium alloy at high temperature to form a stable ceramic oxide layer, approximately $4\mu\text{m}$ thick on the surface of the femoral head[1,2]. The combination of a metal head with an oxidized, ceramic surface provides two potential advantages: the improved wear resistance of a ceramic bearing surface and the fracture resistance of a metallic head.

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In a hip simulator study, OxZr generated 61% fewer polyethylene particles compared to CoCr heads when both types of heads were roughened and articulated against ultra-high molecular weight polyethylene (UHMWPE)[1]. However, recent case reports showed significant damage on the surface of retrieved OxZr femoral heads, leading to concerns regarding the integrity of the oxidized zirconium layer when exposed to unintended contact (e.g., dislocation followed by reduction of the femoral head back into the acetabular component)[3,4].

Despite concerns of damage to both normal and unintended articulation of OxZr femoral heads, no large scale retrieval studies have been published evaluating the *in vivo* performance of this bearing material in THA. Therefore, the aims of this study were to: 1) visually assess damage on the surface of 59 retrieved OxZr femoral heads, 2) characterize the roughness profiles of damage areas observed on the surface of OxZr femoral heads as compared to the profiles on damaged surfaces of fourth generation, zirconia-toughened alumina femoral heads (BIOLOX[®] delta, CeramTec, Plochingen, Germany), and 3) determine whether damage observed on the surface of OxZr heads is surface effacement of the oxidized zirconium layer or metal transfer from unintended impingement.

Materials and Methods

From 2006 to 2013, 59 retrieved OxZr femoral heads were collected during consecutive revision surgeries after a mean time of 20 months (range 1 day to 102.5 months). Patients (32 females, 27 males) were a mean age of 62 years (range 46 to 89 years) at the time of revision. Reasons for revision surgery were recurrent dislocation (24 cases), femoral component loosening or subsidence (13), infection (9), acetabular loosening (4), periprosthetic fracture (4), acetabular malposition (2), heterotopic ossification (2), and leg length discrepancy (1).

The diameters of the retrieved femoral heads were 28 mm (9 cases), 32 mm (22), 36mm (26), and 40mm (2). Seven BIOLOX[®] delta ceramic femoral heads were collected during the same time period from patients with ceramic-on-UHMWPE THAs revised for recurrent dislocation after an average time to revision surgery of 26.5 months (range 0.2 to 76.3 months). The ceramic femoral heads were used as a comparison group, since they had severe damage patterns similar to those seen in badly damaged OxZr heads. The ceramic heads were 28mm (2 cases), 32mm (4), and 36mm (1) in diameter.

Surface damage on all of the femoral heads were graded by two independent observers graded according to the following scoring system: a score of 1 meant a pristine surface, a score of 2 meant minimal damage or the presence of one to two scratches (>0.5cm in length), and a score of 3 meant severe damage with multiple scratches, surface effacement, or metal transfer (examples of grade 2 and grade 3 can be seen in Fig. 1).

The OxZr and ceramic femoral heads were cleaned with acetone, after which surface roughness profiles were made with a white light noncontact interferomic profiler (MicroXAM Optical Profiler; ADE PhaseShift, Tuscon, AZ, USA). Three roughness profiles were taken, one each at the apex, equator and rim of the head. Each profile scan

measured a 600 x 800µm region on the component's articular surface. If scratches or metal transfer was observed on the articular surface, then an additional profile was collected of the damaged region. Prior to calculating roughness parameters for each scan, a spherical plane correction algorithm was applied to correct for the curvature of the surface from the scan. The following parameters were calculated to describe the surface topography: average surface roughness (S_a), maximum peak height (linear elevation from original surface; S_p), maximum valley depth (linear indentation from original surface; S_v), and maximum peak-to-peak height (maximum height from peak to valley; S_y) using SPIP software (Image Metrology A/S, Hørsholm, Denmark)[5].

To understand whether damage on the femoral heads resulted from metal transfer or scratching, we chose two heads for scanning electron microscope (SEM) analysis from each group: (1) OxZr heads with one stripe, (2) OxZr heads with multiple stripes, (3) ceramic heads with one stripe and (4) ceramic heads with multiple stripes. Our region of interest was identified before loading the femoral head in the SEM chamber with copper tape. The SEM images were collected using a Zeiss Supra 55VP SEM (Carl Zeiss Microscopy GmbH, Jena, Germany) equipped with a backscatter detector. Once the stripes were visible in backscatter mode, energy dispersive x-ray analysis (EDAX) was used to determine the elemental composition of the metal transfer regions seen on both types of femoral heads.

Statistical Analysis

A chi-squared test was used to determine whether or not a difference existed in severe damage (score of 3) of the femoral heads between THAs revised for dislocation and those revised for other reasons. The distribution of roughness parameters was assessed using the Shapiro-Wilk test, and we compared the roughness parameters of unscratched Grade 1 heads, scratched Grade 2 heads and scratched Grade 3 heads using Kruskal-Wallis one-way analysis of variance on ranks tests. To isolate the groups that differed, we used multiple comparison procedures. We compared roughness parameters of dislocators to nondislocators using Mann-Whitney rank sum tests. Significance was set at $p < 0.05$. All statistical analyses were performed using Sigma Plot 12 (Systat Software, Inc., San Jose, CA, USA).

Results

Eighteen of 24 OxZr heads (75%) explanted for recurrent dislocation had severe surface damage (grade 3), compared to five of 35 heads (14%) revised for other causes ($p < 0.001$; Table 1). Multiple stripes on the surface of Oxinium were found to be aligned in a similar direction, usually with a positive or negative slope relative to the bottom of the head (Fig. 1). The direction of the stripes is dependent on hip side (left or right) and type of hip dislocation (anterior or posterior).

For all four surface roughness parameters, the retrieved OxZr bearing surfaces were rougher than the ceramic surfaces in areas with damage (S_a : $p < 0.001$, S_y : $p = 0.003$, S_p : $p = 0.002$, S_v : $p = 0.002$). The median S_a was 1.49 µm for Grade 3 scratched regions on retrieved OxZr heads (Table 2), compared to 0.09µm for the scratched regions on retrieved ceramic heads. The highest S_a and S_y values for damaged OxZr bearing surfaces were 8.6 µm and 144.29 µm on OxZr bearings revised for dislocation, compared to 0.25 µm and 7.41µm for ceramic

bearing surfaces revised for dislocation. The visually undamaged OxZr surfaces also had higher S_a values ($p<0.001$) and S_y values ($p=0.013$) than the undamaged regions on the ZTA surfaces. This was evident in the 3D profilometry maps, which demonstrated a smooth surface in the undamaged ceramic surfaces compared to the undamaged OxZr surfaces. In the damaged OxZr regions, these plots showed elongated cavernous depressions in the scratched regions, while subtle peaks were seen in the metal transfer regions of the damaged ceramic plots. Scratched OxZr bearings were significantly rougher than the undamaged surfaces of the OxZr bearings (all parameters $p<0.001$). We found no significant difference in the roughness of OxZr bearings with Grade 2 damage compared to Grade 3 damage, and no significant difference in roughness of heads revised for dislocation compared to those revised for other reasons (Table 2). However, the roughest scratches were on the surface of heads revised for dislocation.

High magnification SEM imaging showed severe damage and effacement of the oxidized zirconium layer, exposing the underlying zirconium alloy (Fig. 2). This was confirmed using EDAX, which also highlighted areas of titanium transfer outlining the scratches (Fig. 3). In contrast to oxidized zirconium heads, there was no visible evidence of cracking on the surface of the ceramic heads. Stripes on ceramic surfaces were primarily titanium in composition.

Discussion

We conducted retrieval analysis of a large number of OxZr femoral heads from revised THAs. Our results indicate that reason for revision is predictive of degree of damage sustained by this type of head, with 75% of patients revised for recurrent dislocation exhibiting severe damage on the OxZr surfaces. High-energy contact, such as when the metallic acetabular shell impacts the femoral head during a dislocation or during a reduction maneuver, increases the surface roughness and causes substantial effacement of the oxidized zirconium layer. Although hip simulator wear testing showed an advantage of OxZr heads when artificially damaged heads were compared to similarly damaged heads made from CoCr[1], such an in vitro study does not necessarily mimic abnormal kinematic events such as an in vivo hip dislocation.

Damage to OxZr femoral heads and increased roughness has been substantiated in case reports and retrieval studies with small numbers of femoral heads[3,4,6–8]. For example, in an early retrieval of an OxZr femoral head that had been in situ for less than 48 hours, McCalden et al[9] reported significant damage and metal transfer to the head and visual damage to the corresponding liner. Micro-CT analysis showed the scratches to be as deep as $38\mu\text{m}$. In our cohort, the median maximum valley depth (S_v) for scratched regions on OxZr heads was greater than the thickness of the oxidized surface layer, with the most severe scratch having a maximum depth of $113.6\mu\text{m}$ in a patient revised for dislocation after 11 months. This supports the conclusion that the ceramic oxide layer was removed, exposing the underlying alloy underneath.

The damage that we observed in OxZr heads was not only more severe as measured with subjective grading, but also had a much rougher surface in the damaged regions (as

measured by high magnification profilometry) compared with heads fabricated from a ZTA ceramic. The surface roughness of grade 3 damaged OxZr femoral heads ($1.49\mu\text{m}$) was 30 times rougher than undamaged OxZr ($0.05\mu\text{m}$), and 19 times rougher than grade 3 damaged ZTA heads ($0.08\mu\text{m}$). This is of clinical concern, since increased surface roughness has been shown to increase polyethylene wear[10–12]. Jaffe et al[10] showed that when retrieved, damaged OxZr femoral heads were articulated against highly cross-linked UHMWPE liners in a hip simulator to one million cycles, a 50-fold increase in wear particle generation occurred as compared to when pristine OxZr heads were tested. Kim et al[11] also described increased wear of conventional UHMWPE in the setting of retrieved ceramic femoral heads when metal transfer was present. They found that linear wear increased with the roughness of the metal transfer regions present on the heads. Interestingly we also found scratches on the surface of OxZr femoral heads had similar median roughness profiles whether or not the head was retrieved from a patient that experience dislocation (Table 2). This study suggests that any event that may scratch the OxZr surface can predispose the OxZr bearing to a similar rate of accelerated wear.

The use of SEM and EDAX allowed us to evaluate the integrity of the surface oxide layer in damaged areas and quantify the extent of metal transfer. Although metal transfer was visible on the surface of both OxZr and ZTA ceramic heads, the OxZr heads demonstrated physical gouging of the head with exposure of the zirconium alloy underneath. Titanium metal transfer present from the acetabular shell in the areas surrounding the scratches was also present. Particulate-like debris was likely removed from the surfaces of the OxZr heads during dislocation, and the introduction of third-body zirconia debris into the joint may also increase the wear rate of the accompanying polyethylene[13]. Heads composed completely of ceramic may be advantageous because there is no discrepancy in material hardness between the surface and the underlying material. The base material for OxZr femoral heads is ZrNb2.5, which has a lower micro hardness than CoCrMo and a similar micro hardness to Ti-6Al-4V[14]. Small local loads can result in large imprints in ZrNb2.5 and Ti-6Al-4V alloys [14]. This projects ZrNb2.5 would be vulnerable to scratching and wear if the OxZr coating fails and the bare material is exposed.

There are limitations to this retrieval study. Inherent in the design is a bias towards the evaluation of failed components, and as such our results may not reflect other well-functioning THAs with OxZr femoral heads. In addition, although a comparison group of ZTA femoral heads retrieved for dislocation was used to compare to OxZr, a full comparison with retrieved components for other causes would have provided a more complete analysis. Finally, we used SEM to examine metal transfer in a limited number of components, and this may represent investigator bias. However, we did not intentionally choose the most damaged component since macroscopically femoral heads in each group looked similar.

Although improvements in UHMWPE have mitigated wear concerns substantially, increased longevity in THA will continue to be a major goal. Whether OxZr ultimately finds widespread acceptance as an alternative bearing surface awaits longer follow-up. To date, little evidence exists to suggest that a well-functioning OxZr head currently in situ is at risk in the absence of dislocation or other modes of THA failure. A radiographic analysis of wear

in OxZr on UHMWPE THAs showed a low wear rate (4µm/year) at two-year follow-up[15], and a comparison of THAs with OxZr or CoCr femoral heads showed equivalent outcomes at minimum two-year follow up[16]. Conversely, a recent, randomized, controlled trial using radioisometric analysis, also with two-year follow-up, found no difference in femoral head penetration and wear between OxZr and CoCr heads articulating with cemented all-UHMWPE liners[17]. Despite these early clinical results, longer-term follow studies are needed.

Nonetheless, our results demonstrate that OxZr femoral heads exhibit a substantial increase in surface roughness compared to BioloX *delta* when subjected to dislocation in vivo. Patients who have sustained a dislocation with this bearing material in place should be monitored closely for wear-related complications.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.

Surface damage on all femoral heads was scored according to the number of scratches on the surface. A) OxZr femoral head *in vivo* for 3 months revised for infection with 1 scratch (Grade 2). The single scratch has a positive slope relative to the horizontal. B) ZTA femoral head *in vivo* for 5 month revised for recurrent dislocation. Scratches have negative slopes relative to the horizontal. C) OxZr femoral head *in vivo* for 24 months revised for recurrent dislocation with scratches with negative slopes. D) A magnified image taken within the red box in Figure 3C. There were visible cracks in the surface coating.

Figure 2.

A) SEM photo (400x magnification) of OxZr femoral head *in vivo* for 8 months revised for recurrent dislocation. Cracking and small particle-like aggregates were evident on the surface. B) Roughness map of the same surface showing the scratches with maximum valley depths up to 20 μm . Red highlights peaks around the scratches and blue highlights valleys where material was removed.

Figure 3. SEM and EDAX maps of a OxZr femoral head (same as figure 5) showing concentrations of major elements. Zr, zirconium; O, oxygen; Al, aluminium; Ti, titanium; V, vanadium. Zirconium and oxygen were found on the surface, as expected. Titanium, aluminum and vanadium were found at the periphery of the scratch, suggesting a titanium (Ti-6Al-4V) component contacted and deposited material on the surface.

Table 1

Reason for Revision (total cases)	Damage Grade 1	Damage Grade 2	Damage Grade 3
Recurrent Dislocation (24)	3	3	18
Femoral Component Loosening or Subsidence (13)	8	4	1
Infection (9)	1	5	3
Acetabular Loosening (4)	2	2	0
Periprosthetic Fracture (4)	2	2	0
Acetabular malposition (2)	2	0	0
Heterotopic Ossification (2)	0	2	0
Leg Length Discrepancy (1)	1	0	0

Table 2

Parameters	OxZr Grade 1 unscratched surface (µm)	OxZr Grade 2 scratched (µm)	OxZr Grade 3 scratched (µm)	OxZr scratched non-dislocation cases (µm)	OxZr scratched dislocation cases (µm)
Median average Surface Roughness (Sa)	0.05*	0.38	1.49	0.56	1.41
Median maximum peak-to-peak (Sy)	1.55*	13.37	17.85	14.06	17.71
Median maximum peak height (Sp)	0.90*	5.85	8.75	6.38	8.16
Median maximum valley depth (Sv)	0.67*	5.44	8.94	8.32	9.23

* significantly different ($p < 0.05$) from other groups in each row