Wear Testing of Diffusion Hardened Oxidized Zirconium Hard-on-Hard Bearings after Inducing Liner Deformation

INTRODUCTION:
A new composition of oxidized zirconium (DHOxZr) with a thick diffusion hardened (DH) zone beneath the oxide has been developed as a potential bearing material for hard-on-hard hip arthroplasty [1]. The zirconium oxide ceramic surface and the underlying DH zone are expected to produce low wear and minimal metal ions, while the metallic substrate allows the implant to be manufactured in large sizes without risk of fracture. The goal of this study was to evaluate the effect of cup-deformation on the wear performance of DHOxZr couples.

METHODS:
Heads and liners were machined from Zr-2.5Nb alloy, oxidized, diffusion hardened, and polished to produce 38 mm articulating diameter DHOxZr prototype couples; liners were manufactured to mate with R3™ acetabular shells (Smith & Nephew). The diameter of each component was measured prior to testing using a coordinate measuring machine and used to calculate clearances. Liners were cleaned, weighed, and locked into R3 shells. A stainless steel ring with a set-screw was placed over each acetabular assembly. Deformation was induced by tightening the set-screw (Figure 1). Resulting out-of-roundness, defined as the maximum departure of the profile from the least-squares circle, was measured near the face of the liner using a Talyrond 385 roundness machine (Taylor Hobson Ltd, United Kingdom). The set-screw was then adjusted iteratively until the desired out-of-roundness was achieved; target out-of-roundness values were based on measured deformation of 42 mm ID liners and corresponding R3 shells upon insertion into reamed foam block [2]. Acetabular assemblies (with attached rings) were cemented into simulator fixtures using PMMA and positioned such that the applied deformation resulted in reduction of the anterior/posterior dimension of liners. After the cement cured, ten out-of-roundness measurements were taken moving from the edge of the liner inward (towards the pole). Each measurement was made 1 mm apart and was centered on the axis of the liner. A single roundness measurement was made near the face of each liner multiple times over the duration of testing in order to verify liners remained deformed.

Couples were tested on an AMTI hip simulator (Watertown MA) for approximately 10 million cycles (Mcycle) at 1 Hz (n=3). Load/motion inputs were alternated every 10,000 cycles [3]. Lubricant was 20mM EDTA, 0.2% NaN3, solution of calf serum (Alpha Calf Fraction, Hyclone Labs). Approximate protein concentration was 40 g/L. Heads were cleaned and weighed at least once every 1 Mcycle. In order to keep the deformed surface from being altered, liners were not removed from the shells or weighed during testing; liners were cleaned and weighed at the conclusion of testing.

Cumulative volume changes of each head were calculated using estimated densities of the oxide of DHOxZr components (8.28 g/cm3 and 5.6 g/cm3, respectively). The density of the DH zone is greater than that of the oxide, but less than that of the Zr-2.5Nb substrate (6.44 g/cm3). Therefore, use of oxide density in all calculations slightly overestimated volumetric wear of DHOxZr components when the bearing surface contained exposed DH zone. Wear rate, the slope of the least squares best-fit line of cumulative volume loss vs. cycles, was calculated during the run-in and steady-state periods.

RESULTS:
Mean diametric clearance (± standard deviation) of couples was 212 ± 9 µm. After deformation, mean out-of-roundness near the rim liners was 92 ± 10 µm. The difference in contact mechanics between the ring and liner and between the set-screw and liner caused the deformation to be asymmetric. However, as the distance from the face of the liner increased, deformation became more symmetric. As expected based on component orientation, burnishing was observed at the apex/pole of femoral heads and liners. However, due to the original form of implants and the applied deformation, additional areas of burnishing were observed early in testing (Figure 2). By the end of testing, wear through of the oxide was observed at the apex of heads.

Run-in appeared to be complete by 0.8 Mcycle. At that point, mean volume loss of was 0.14 ± 0.03 mm3. Mean steady-state wear rate of heads was 0.05 ± 0.00 mm2/Mcycle. Cumulative volume loss of each head is displayed in Figure 3. For comparative purposes, mean cumulative wear of DHOxZr heads tested against non-deformed liners was included [4]. Run-in wear of heads tested against deformed and non-deformed liners was similar. While heads tested against deformed liners had a higher steady-state wear rate, wear remained relatively low. At the conclusion of testing, mean volume loss of liners was 0.07 ± 0.19 mm3. This variation is believed to be a result of material transfer between the liner and shell.

DISCUSSION:
During hip arthroplasty, acetabular implants can deform upon impaction into the reamed acetabulum. While complete relaxation has been predicted to take 25 days in cadaveric specimen, the precise time required for surrounding bone to relax/remodel in-vivo is unknown [5]. The current study, in which deformation of the liner is maintained for 10 Mcycle, is believed to be more aggressive than the clinical reality. Despite having exposed DH zone in the bearing surface, wear of DHOxZr implants remained relatively low under this aggressive test condition.

SIGNIFICANCE:
Cup deformation has been postulated to affect the wear of hard bearing couples. In this pre-clinical study, wear of DHOxZr prototypes appeared to be relatively insensitive to cup deformation.

REFERENCES: