Contemporary Alternatives to Zirconia: Retrieval Analysis of Oxinium® and Biolox® Delta Femoral Heads

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Statement of Purpose: Ceramics are attractive femoral head bearing materials due to their low wear rates when coupled with ultra-high molecular weight polyethylene. Zirconia was introduced as a femoral head material in the 1980's due to its improved fracture toughness over alumina. However, tetragonal to monoclinic phase transformations of zirconia may occur *in vivo* leading to surface roughening or decreased fracture toughness [1]. Phase transformations triggered by changes in the manufacturing process of zirconia heads by one vendor led to high fracture rates and a recall in 2001. Though the use of bulk zirconia has since fallen out of favor, alternative bearing materials have been developed. Oxinium® (Smith&Nephew Inc., Memphis, TN) is a metallic Zr-2.5Nb alloy oxidized at high temperatures to create a thin (5µm) monoclinic surface layer of zirconia. Biolox® Delta (CeramTec AG, Plochingen, Germany) consists of a 17% volume of zirconia nanoparticles homogeneously dispersed in an alumina matrix [2].

Our objective was to document the clinical outcomes, wear performance and microstructure of retrieved historical zirconia, Oxinium®, and Biolox® Delta femoral heads. Our hypothesis was that surface roughness and monoclinic content would change during time *in vivo*.

Methods: Thirty femoral heads were collected after revision surgery and classified as historical zirconia (n=9), Oxinium® (n=6), or Biolox® Delta (n=15). Patient information was collected from medical records. The superior (worn) and inferior (partially worn) faces were identified based upon the presence of scratching, metal transfer, or pitting. Surface topography was characterized with white light interferometry using a NewView 5000 Model 5032 with advanced texture analysis software (MetroPro 7.7.0; Zygo, Middlefield, CT). At least three average roughness (R_a) measurements were taken in the dome, worn, partially worn, and near equator regions. Measurements were also taken on the interior bore of fractured heads. Raman spectroscopy was used to evaluate phase transformations. Spectra were recorded at room temperature using a Microspectrometer (RM1000 VIS, Renishaw Inc., Chicago, IL) with a 50x objective, green excitation line (514 nm) and laser power of 18 mW. At least two spectra were obtained in each region, in the same location as R_a measurements. Monoclinic content was calculated using the following relation [3]:

$$c_m = \frac{I_m^{181} + I_m^{192}}{0.97(I_m^{148} + I_m^{264}) + I_m^{181} + I_m^{192}}$$

Where I_m^{181} and I_m^{192} represent the intensity of peaks associated with monoclinic phases, and I_m^{148} and I_m^{264} refer to the intensity of peaks associated with tetragonal phases.

Results: Patient groups were statistically comparable with respect to gender, BMI, and age at implantation (p≥0.8). Zirconia heads were revised for femoral head fracture (n=5), loosening (n=3), and instability (n=1). Oxinium® heads were revised for instability (n=4), loosening, and iliopsoas impingement (n=1 for each). Biolox® Delta heads were revised due to loosening (n=8), infection (n=4), instability, hematoma, and pain (n=1 for each). Zirconia heads were revised after an average of 7.9 years (range: 3.7-9.3y). Oxinium® and Biolox® Delta heads were implanted for 1.0 (range: 0.2- 2.8) and 1.1 years (range: 0.04-3.5y), respectively. Zirconia and Oxinium® heads were significantly rougher than Biolox® Delta heads for all regions (p<0.002, Student's t, Figure 1A). Typically, average R_a values for worn regions of zirconia and Oxinium® heads were higher than other regions, but this difference was not significant (p>0.05). Regional R_a variations were not significant for the Biolox® Delta group. Monoclinic content of Biolox® Delta heads correlated with implantation time for worn and dome areas (R^2= 0.30 and 0.38, respectively, Figure 1B). Oxinium® heads were >97% monoclinic phase for all regions. Monoclinic content and surface roughness were substantially elevated on the interior bore of the fractured zirconia heads (71±14% and 746±128 nm, respectively).

Conclusions: Increased roughness and monoclinic content have been previously reported for retrieved zirconia components [1,4]. In this study, we found these values to be significantly higher in the bore of fractured heads. This is partially attributable to differences in surface finishing (ground versus polished), but appropriate controls are necessary to determine if the values we observed relate to fracture as a reason for revision. Few data are available regarding the *in vivo* performance of Oxinium® and Biolox® Delta because they have been widely used for less than a decade. We found changes in the roughness but not microstructure of Oxinium® heads. Conversely, we observed changes in the zirconia microstructure but not roughness of Biolox® Delta heads. It is unclear whether this change will eventually cause changes in roughness since Biolox® Delta is primarily composed of alumina, which has been shown to be stable for decades *in vivo*. These findings of this study provide motivation for future investigations with longer-term implants.

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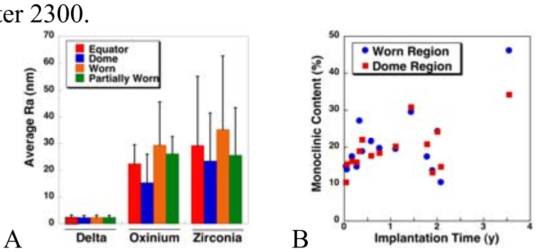
References: [1] Fernandez-Fairen et al. *COOR,* 2007. 462:122-9 [2] Kurtz et al. *The UHMWPE Biomaterials Handbook* (2nd Ed.), 2009 [3] Clarke et al. *Key Engineering Materials,* 2003 [4] Medel et al. ORS 2009, Poster 2300.



A B

Figure 1: (A) Average roughness values for each material group. (B) Monoclinic content of Biolox® Delta retrievals plotted with respect to implantation time.