Triggering the Phase Transformation of Zirconia Balls *In Vivo* and *In Vitro*

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Statement of Purpose: Clinical studies of metastable zirconia (Zr) on polyethylene (PE) have yielded ambivalent results. Osteolysis has ranged from 0%[1] to 35%[2]. PE wear with Zr balls has ranged from no discernable wear[3] to 0.4mm/yr[4]. It has been suggested that transformation of the zirconia from the tetragonal phase to the monoclinic phase (with an accompanying volume increase) was responsible for the increased surface roughness with higher PE wear and osteolysis seen in some studies[3]. Possible causes of zirconia phase transformation were:

1. Damage suffered under severe mechanical stress such as micro-separation, rim impingement or 3-body abrasive wear[4,5].
2. An aging effect in the moist body environment.
3. The pressure-temperature shear effects of sliding on the surface of a PE cup.
4. Sensitivity created by manufacturing variations.

Zr phase transformation is very sensitive to a number of micro-structural features. By modifying parameters such as purity, density, porosity, particle size and crystalline structure, the kinetics can be shifted by several orders of magnitude. In addition, HIPing and doping are reputed to have greatly improved the performance of zirconia implants. We have attempted to reproduce such phase transformation *in vitro* to determine the most likely cause of inconsistent Zr transformation.

Methods:

a. 32 mm Prozyr™ ball (St. Gobain Desmarquest, France)
b. 22 mm Zyranox™ ball (Morgan Matroc, UK)
c. 22 mm Bioceram™ ball (Kyocera, Japan)
d. 28 mm Cerasive™ ball (Plochingen, Germany)

These experimental balls were subjected to:

1. Physical damage by loading Ti cup rim against Zr ball with static loads, running an autoclaved Zr ball against a diamond rasp on a hip simulator and simulating 3-body abrasion with alumina powder slurry in hip simulator.
2. Aging in autoclave (134^{o}C, 2 bars pressure, 5-20 hrs).
3. Simulator wear up to 5 million cycles duration.

We also studies retrieval Zr balls as follows:
Prozyr™ from W. Walters MD. Sydney, Australia (N=52)
Prozyr™ from T. Stewart, PhD. Leeds (UK, N=7)
(4 vendors) UCSF, USA (N=23)
Prozyr™ from T. Donaldson, MD. LLUMC, USA (N=2)

We analyzed the experimental and retrieval balls by:

1. Scanning electron microscope (SEM).
2. X-ray diffraction (XRD) and Raman Spectroscopy for tetragonal to monoclinic transformations.
3. Laser interferometry to determine roughness (Newscan, Zygo).

Results / Discussion:

1. Physical damage: Mechanical challenge caused only minor Zr phase transformation of 4% to 13%, although SEM imaging showed considerable surface damage.

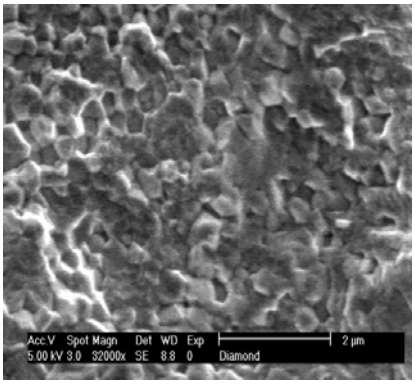

Fig. 1. SEM of an autoclaved Zr ball run against a diamond rasp on a hip simulator with 13% t-m transformation.

2. Aging: 5 hours autoclaving resulted in < 4% monoclinic transformation. A mechanically damaged ball that was aged 5 hours had 13% transformation and twenty hours in autoclave gave 53% to 77% transformation.
3. Retrievals: There was great variety in the condition of our retrieved zirconia balls. Transformation ranged from < 2 % at 10 years to > 80% at 8 years, while roughness varied from 10 to 250 nm. Transformation was found on retrieval balls in the area under the PE cup, not around the lower hemisphere. Transformation began as early as 3 years. One retrieval had 20% transformation in an area contaminated by titanium, suggesting rim impingement.

Conclusions: Severe mechanical stress alone did not produce the catastrophic transformation seen in some of the retrievals. Extended autoclaving was necessary to create the higher levels of transformation. Physically damaged balls transformed faster after autoclaving than undamaged balls. The fact that transformation was found on retrieval balls in the area under the cup suggests that pressure-temperature shear effects of sliding on UHMWPE facilitated transformation.

There may be more than one cause for *in vivo* transformation. Slight manufacturing differences may cause a sensitivity to transformation. Mechanical damage may act as one trigger. The friction and wear mechanism operating under the PE cup *in vivo* may be capable of transforming the zirconia balls. Patient variability may also influence transformation.

References:

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