

## Performance of Tibial Bearings Manufactured from Highly-Crosslinked, Vitamin E Infused, UHMWPE

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**Statement of Purpose:** Vitamin E infused highly crosslinked ultra-high molecular weight polyethylene (UHMWPE) is currently utilized for acetabular components in total hip arthroplasty. The vitamin E infused polyethylene has demonstrated low in vitro wear, good mechanical properties, and excellent oxidation resistance<sup>1</sup>. This study evaluated the in vitro wear performance of CR bearings and the fatigue performance of the PS post to determine if highly-crosslinked, vitamin E infused UHMWPE is applicable for use in total knee arthroplasty.

**Methods:** Tibial bearings were manufactured from isostatically compression molded UHMWPE barstock (GUR1020 resin from Ticona, Germany). The material was irradiated to a dose of 100kGy  $\pm$ 10 kGy (Steris, Libertyville, IL), and infused with vitamin E in a two-step process. The specimens were soaked in vitamin E for 4.5 hours at 122 °C and the vitamin E was allowed to diffuse through the thickness of the parts in an inert gas oven for 360 hours at 130°C. The finished tibial bearings (59 mm CR, 87 mm CR, and 71 mm PS) were cleaned in isopropyl alcohol and gamma sterilized in barrier film packaging (25-40kGy, Steris, Libertyville, IL). The  $\alpha$ -tocopherol (vitamin E) index of the bearings was maintained between 0.02 and 0.15.

The control bearings were direct compression molded GUR 1050 UHMWPE with geometries identical to those of the vitamin E infused bearings. The bearings were cleaned in isopropyl alcohol, and gamma sterilized in barrier film packaging (25-40kGy, Steris, Libertyville, IL).

The 59 and 87 mm CR specimens were tested with 55mm and 80mm femoral components, respectively, on an AMTI 6-station knee simulator under force control per ISO 14243-2. Bovine calf serum diluted to a protein concentration around 20 g/L was used as the lubricant. The vitamin E infused and the conventional bearings were ran in series. Two load soaks and three motion stations were tested for each test group. Gravimetric measurements were taken at 500,000 cycle intervals and the testing continued for a minimum of 3.7 million cycles. SEM images were taken (Bodycote Polymer Laboratories, Skokie, IL) of the wear surfaces of the large contact area bearings for both materials after 5 million cycles.

The 71 mm PS bearings were coupled with the largest femoral component and cyclically loaded for 3 million cycles (130-1,300 lbs) with the bearing at a 30° angle from the table and the femoral at a 45° angle to the bearing. This setup placed the contact point at its highest point between the femoral and the post of the bearing.

**Results:** The 59mm and 87mm vitamin E infused bearings had average volumetric wear rates (Figure 1) that were 74% and 86% less than that of the direct molded control bearings respectively.

The SEM images of the large contact area specimens (Figure 2) showed no significant differences in the wear surfaces of the two material groups.

After 3 million cycles of cyclic loading, the impingement regions on the posts of the vitamin E infused bearings were not noticeably different from the impingement region of the conventional bearings.

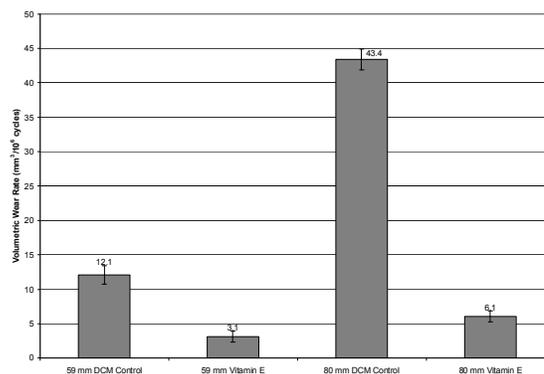


Figure 1. Volumetric Wear Rates

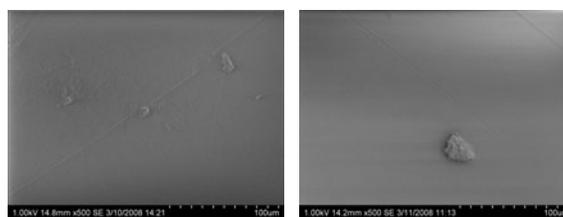


Figure 2. Representative SEM Images of the Wear Surface of the Large Contact Area Vitamin E Infused (Left) and Control (Right) Tibial Bearings After 5 Million Cycles at 500X



Figure 3. Representative Photos of the Impingement Regions of the Vitamin E Infused (Left) and Control (Right) Tibial Bearings After 3 Million Cycles of Cyclic Loading

**Conclusions:** The highly crosslinked, vitamin E infused tibial bearings showed significant improvements in wear resistance over the conventional material, and demonstrated resistance to post fatigue loading similar to that of the conventional bearing. The vitamin E infused material is well suited for use as a bearing surface in total knee arthroplasty. Additional research should be conducted to look at the wear behavior after accelerated aging and wear particle morphology.

### References:

- (1) Oral, E. J.Arth. 2006;vol 21, #4:580-591