Tribological Evaluation of a Drug Enriched Ultra-High Molecular Weight Polyethylene for Enhanced Total Joint Replacement Bearing Surface Functionality

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Statement of Purpose: The use of ultra high molecular weight polyethylene (UHMWPE) inserts in total joint replacements (TJR) results in wear particle-caused osteolysis, which is the predominant cause for prosthesis failure and revision surgery[1]. Sub-micron size particle generation is inevitable despite the numerous efforts in improving this bearing material. Work by others has shown that the use of oral systemic bisphosphonates (BP) can significantly contribute to minimize periprosthetic osteolysis. However, the systemic delivery and the high solubility of BPs results in a predominant portion of the drug being excreted via the kidney without reaching its target, bone. The goal of this research is to develop a novel method to administer BPs locally using the inherent wear of UHMWPE. It was hypothesized that optimum concentration of BP would not significantly affect the material properties and tribological performance of UHMWPE, and that BP would be released from the surface and particulate of the doped UHMWPE.

Methods: Blocks of drug enriched UHMWPE were prepared using 2% (by weight) 8-Anilino-1-naphthalenesulfonic acid hemimagnesium salt hydrate (Sigma) or 2% (by weight) alendronate (Tecoland, Edison, NJ) (PE-ALN) blended with GUR 4150 UHMWPE powder (Ticona, Houston, TX). The tag was used to approximate bisphosphonate for initial feasibility studies. All PE specimens (PE, PE-tag, and PE-ALN) were compression molded using a Carver press and methods previously published by Parasnis & Ramani[2]. Dogbone-shaped specimens of PE and PE-tag (20mm length & 4.9mm width) were cut from 2mm thick blocks and used for uni-axial tensile testing (ASTM 5937). PE and PE-tag pins of 3/8" shaft and 3mm pin tip diameters were machined for pin-on-disk (POD) (OrthoPOD - AMTI, Watertown, MA) wear tests. Test parameters included: 40km distance, 60mm diameter circular pattern, 6MPa contact tip pressure, CoCrMo counterpart. Tests were performed in 50% calf bovine serum with 0.2% sodium azide. Drug elution tests were performed using thin slices (15µm x 1.0cm x 1.0cm) of PE and PE-ALN cut from $1cm^3$ blocks. Particulate were maintained in 10 mL of HPLC-grade water in a shaker at 37°C. Aliquots of 1mL were taken at 1,2,3,5, and 7 days with equal fluid amounts being re-added. Samples (n=4; triplicate) were analyzed using high pressure liquid chromatography (HPLC, Waters, Milford, MA) anion exchange using in-line complexation[3]. A 6mM nitric acid + 1.5mM copper II nitrate mobile phase were used at a flow rate of 0.85mL/min using a Waters IC-Pak Anion HR column.

Results: Tensile test results showed that the yield stress of the PE-tag was not significantly different from that of PE. A significantly lower elastic modulus (p=.004) and lower ultimate stress (p=.002) were measured. POD wear tests show no significant difference in the gravimetric weight loss between the two material types (PE and PE-tag) at 40km (p=0.78, Fig 1). Drug elution tests showed ALN being eluted from the PE-ALN particulate over the course of 7 days with an expected bolus elution from the particles between day 0 and 1 (Fig 2). Control (PE) particulate showed no measurable peak at the ALN peak time (data not shown).

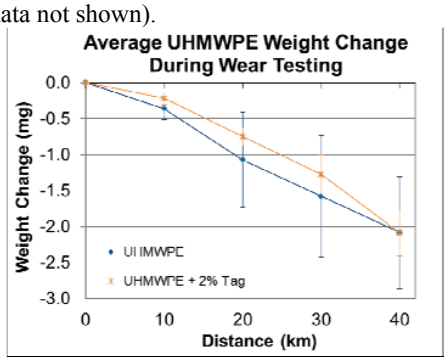

Figure 1. Average change in gravimetric weights over 40km OrthoPOD trial (6MPa contact pressure)

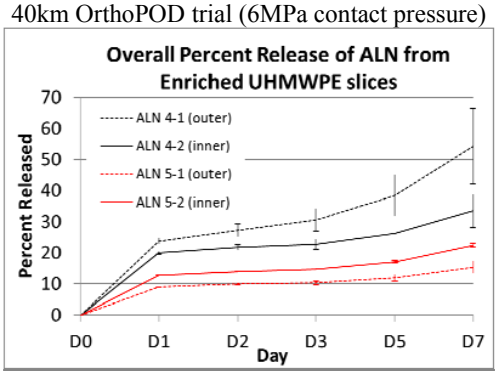

Figure 2. Percent of Alendronate release from enriched UHMWPE over 7-day trial

Conclusions: While there are differences in material properties of PE and PE-tag, the lower elastic modulus of PE-tag may be advantageous, and yield better lubrication when used *in vivo*[4]. The lower ultimate stress is not as problematic as if the yield stress had been different as the material will be frequently challenged at its yield stress but will likely never experience stresses comparable to its ultimate stress. The encouraging POD wear testing results will be further explored with PE-ALN POD testing including measurement of ALN release over time during a wear situation (dynamic drug elution testing) as well as functional total knee wear testing simulation. Overall, preliminary studies indicate that this material shows significant potential for an alternative bearing material to indirectly increase TJR longevity by addressing osteolysis related issues.

References: [1] Shanbhag AS et al. Clin Orth Rel Res. 1997; 33-43. [2] Parasnis NC, Ramani K. J Mater Sci - Mater Med. 1998; 9:165-172. [3] Cornelio RB et al. J Liq Chromatogr Related Technol. 2009; 32: 2857–2865. [4] Jalali-Vahid D et al. Proc IME JJ Eng Tribol. 2001; 215: 363-372.