Self-Reinforced Composites for Prevention of Fretting Corrosion of Biomedical Alloys: Electrochemistry and Surface Characterization

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Statement of Purpose: Recently, fretting corrosion due to modularity in total hip replacements has been a subject of increasing concern in the orthopedic community. Studies *in vitro* have shown that fretting corrosion can be initiated in both total hip replacement cyclic loading tests and more fundamental pin on disk fretting corrosion tests of various alloy counterfaces[1,2]. Meanwhile, modular designs also offer a number of benefits in that they allow for more effective restoration of anatomy, and reduce the effect of varying surgical technique. A desirable solution to the problem of fretting crevice corrosion of total hip replacements would prevent the onset of fretting corrosion over the life of the implant or revision, and allow the continued implementation of modular designs. This work details the concept of thin films of self-reinforced composite Poly(Ether Ether Ketone) (PEEK) as a novel material for use in the prevention of fretting corrosion of biomedical alloys.

Methods: Melt-spun fibers of PEEK (diameter ~47 μm), produced in-house, were arranged uniaxially about two separated stainless steel rods, resulting in a wrapping of fibers nominally two fibers thick. Fibers were subjected to a hot compaction process at 342 °C for 12 minutes, at a constant pressure of 22 MPa. Self-Reinforced Composites (SRCs) were mounted about the hip trunnion with fiber orientation running proximal to distal along the trunnion. The femoral head was then seated over the SRC gasket. A control construct of CoCrMo/CoCrMo was employed for comparison. Currents were measured in a potentiostatic test (held at -50 mV) over the course of cyclic loading on an Instron servo-hydraulic load frame (Instron, Norwood, MA) from 100-1000 N in 100 N increments and 1200-3200 N in 200 N increments at 3 Hz, with R=0.1. SRC surfaces were evaluated with SEM and digital optical microscopy following testing.

Pin on disk tests were carried out with SRC mounted between a CoCrMo disk and Ti6Al4V pin. Mechanical (moment, load, coefficient of friction) data and electrochemical (current) data were collected for a constant nominal contact stress of 100 MPa for a test of 10,500 cycles, to compare with hip construct testing. Surfaces were analyzed with SEM (Jeol, Japan), digital optical microscopy (Hirox, Pennsylvania) to quantify surface morphology, EDS, and FTIR (Perkin-Elmer, CT) to evaluate post-test surface morphology and assess the surface chemistry for any possible material transfer.

Results: Electrochemical data from *In vitro* THR testing showed that SRC-lined tapers develop significantly lower currents than control CoCrMo/CoCrMo tapers. Average currents ranged from ~0-0.150 μA, which can considered to be within the range of noise as measured by the potentiostat as compared to the control which peaked at ~3.5 μA (see Figure 1). Analysis of the SRC after testing showed minimal damage to the SRC. Backscattered SEM images suggested no presence of oxide on surfaces, and optical digital microscopy revealed that the damage to the SRC surface was largely plastic deformation. 3D imaging and digital line profiling confirmed that machine striations from the femoral head counterface indented about 2 μm into the surface of the SRC. This created an undulating surface with a periodicity of approximately 80 μm. This is a similar topography to the femoral head component, suggesting little relative displacement between the two.

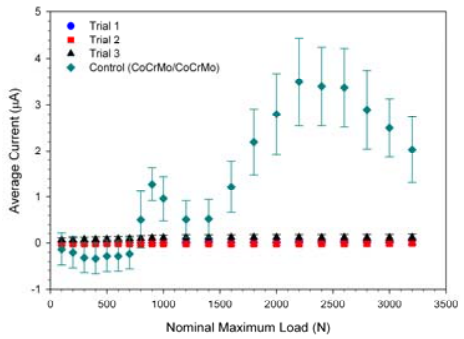

Figure 1. Current vs. load for *in vitro* THR corrosion test, showing difference between SRC-lined and control construct.

Pin on disk testing showed little current evolution over time similar to THR testing. Additionally, COF started at a value of ~0.125, and rose to a plateau of ~0.26 within 4,000 cycles. Digital microscopy showed similar deformation behavior to THR testing; plastic deformation of the surface dominates, with indentation of the pin into the SRC surface a maximum of 8 μm. EDS indicated no material transfer between surfaces. FTIR of CoCrMo disk indicated that PEEK was not detected on the disk surface when compared with SRC-PEEK control. This indicates that there is minimal damage and no detectable material transfer to either alloy or SRC surfaces.

Conclusions: A method of producing SRC gaskets to electrically insulate femoral heads from neck trunnions, and minimize corrosion via hot compaction was demonstrated. *In vitro* cyclic loading of a THR construct over three trials showed no detectable current rise above baseline levels. SEM and 3D digital optical imaging showed that damage to SRC surfaces was minimal and that there was little to no relative displacement of SRC and alloy counterfaces during testing. Pin on disk testing resulted in consistent electrochemical behavior to THR constructs. COF saw a rise and plateau over the course of testing, and surface analysis via EDS and FTIR revealed no detectable transfer of alloy, oxide, or polymer.

References:

1.) Swaminathan V, Gilbert JL, Biomaterials, 2012; 33; 5487-5503.
2.) Goldberg JR, Gilbert JL, J Biomed Mat Res Part B; 2002; 64B; 78-93.