Carbon-Fiber Reinforced PEEK for Cervical Disc Arthroplasty

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Statement of Purpose: Metallic materials, when implanted near the spinal cord, reduce the clarity of medical imaging [1]. Thus, all-polymer implants have been suggested. Medical grade polyetheretherketone or PEEK (Invibio Ltd, UK) is already used as a structural implant material in the spine, has the stiffness to provide a stable implant-bone interface [2] and is suitably radiolucent. *In vitro* pin-on-plate testing showed that carbon fiber reinforced (CFR) PEEK all-polymer contacts had much lower wear rates than unfilled PEEK when tested in lubricants with ~12 g/L protein levels under both constant [3-5] and progressively increasing load regimes [4,5]. This lower CFR wear was also found in 10 million cycles (Mc) of simulator testing in lubricants with 30 g/L protein levels [6].

To further explore the wear of CFR PEEK, the present study examines the influence of testing in lubricants with protein levels of 6 g/L.

Methods: Wear testing of self-mating CFR PEEK (n=6) provided by Invibio Ltd. was performed using a six station OrthoPOD™ pin-on-plate apparatus (AMTI, Watertown, MA). Specimens consisted of 9.5 mm diameter pins with a 60 mm radius spherical contact surface articulating on a flat plate. The PAN-based carbon fibers were oriented parallel to the contact surface in both the pins and plates. A crossing path motion was achieved with a pin rotation of 87° and oscillation of the plate resulting in a stroke length of 17 mm applied at a frequency of 1 Hz. The lubricant was alpha calf fraction serum (+ antibiotics), held at 37°C, and diluted with phosphate buffer solution to 12 g/L from 0-1.0 Mc, and then 6 g/L from 1.0-3.0 Mc. A load of 80 N was applied to the material pairs providing an average contact stress of about 3.1 ± 0.5 MPa over a total of 3 Mc. The wear was assessed gravimetrically and converted to volumetric wear using material density. Contact area was obtained by measuring the wear scar on the pin. Load soak controls were used to compensate for fluid uptake.

Results: Volumetric wear was plotted as a function of the number of cycles (Fig. 1) alongside previous wear results [4,5]. Polished contact areas were observed immediately, with light scratching appearing after 1.25 Mc. SEM microscopy showed exposed carbon fibers at the surface (Fig. 2), with some evidence of fiber pullout.

After the initial run-in wear (0-0.25 Mc), four specimen pairs showed low and then negative wear in general agreement with previous studies [4,5] whereas the other two showed an increasing positive wear yet microscopy failed to indicate any increase in surface damage. Thus, the differences in wear were tentatively attributed to differences in fluid uptake of the wear and load-soak specimens. However, despite these precision issues, no statistically significant difference in wear rate was detected (p=0.9) when the protein concentration was reduced from 12 to 6 g/L. Furthermore, the parallel fiber orientation in the pins of the present study seemed to give similar wear compared with the perpendicular fiber orientation in the pins of the previous studies [4,5]. However, pitting surface damage at the pin center [4] was not found.

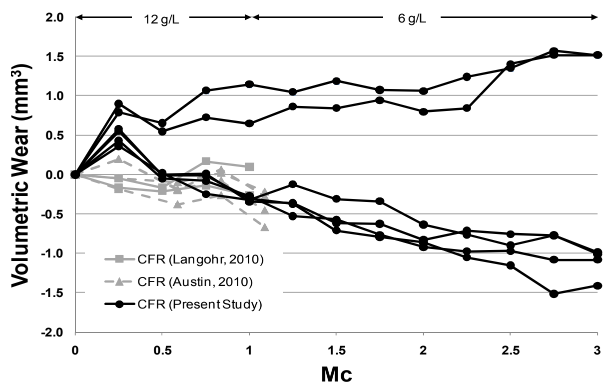

Fig. 1: Wear of all-polymer CFR PEEK contacts

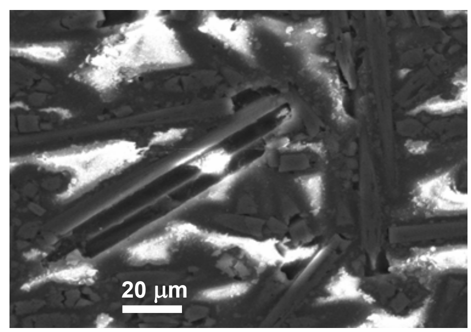

Fig. 2:Ex posed carbon fibers at the worn surface

Conclusions: Reducing the lubricant protein level did not cause a statistically significant change in the wear rate. Fiber orientation does not seems to have a strong effect on wear. However, the possibility (Fig. 2) of eventual surface fatigue wear with fiber pullout and third-body abrasive wear is a concern, particularly at higher loads and will be the subject of future studies.

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