Exploring the Wear of a PEEK All-Polymer Articulation for Spinal Applications

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Introduction: Cervical disc arthroplasty is a surgical procedure that allows the disc to be replaced with metal-polymer, ceramic-ceramic or metal-metal articulations thus preserving the natural kinematics [1]. Some explants (metal-polymer; metal-metal) have shown low wear with no wear particle-induced osteolysis [2] but the clinical experience is not yet extensive. Almost all of the implant designs use tough, relatively rigid metallic materials to ensure a stable fixation at the implant-bone interface. However, metals impair (to varying extents) the clarity of medical imaging [3]. Thus, a radiolucent all-polymer implant has some appeal provided structural strength, implant-bone interface stability and, in particular, wear resistance can be considered acceptable.

Medical grade polyetheretherketone (PEEK) has the structural strength and stiffness to provide a stable implant-bone interface [4]. Thus, it is a good candidate for an all-polymer cervical disc replacement. Initial pin-on-plate wear of PEEK-PEEK pairings has been surprisingly low [5, 6]. The purpose of the present study is to further explore the wear behavior of various PEEK-PEEK pairings, looking for governing principles and tribological limits in order to assess the risk of gross surface damage and/or wear particle-induced osteolysis.

Materials and Methods: Three sets, each having 4 or 5 specimen pairs all made from PEEK (supplied by Invibio Ltd, Thornton Cleveleys, UK) in Optima (OPT), Carbon Fiber Reinforced (CFR) or Carbon Nano-Fiber reinforced (CNF) versions. The specimen pairs consisted of a 9.5 mm diameter pin, with a 100 mm radius spherical tip, in contact with a flat plate. Wear testing was performed on each set of specimen pairs using a multi-station Ortho-POD™ (AMTI, Watertown, MA) pin-on-plate apparatus that had crossing-path motion. To establish a "baseline" wear rate, the load was held at 80 N for the first 2 million cycles (Mc) and then incrementally increased for the next 0.75 – 1.05 Mc to create "adverse" conditions. Wear testing of the CNF was only completed for the first 0.75 Mc. The Ortho-POD™ imposed a reciprocating rotation on the lower plate in a slight arc that gave a stroke length of 8.5 mm and it also imposed a reciprocal rotation on the pin through a 50˚ angle. The specimen pairs were run at 1 Hz in an alpha calf serum solution diluted with phosphate buffer solution to 12g/L. A general antibiotic was added to the serum and the lubricant was held at 37˚C for all tests.

PEEK wear was measured gravimetrically using an analytical balance (AX 205, Mettler-Toledo, Columbus, OH) with a precision of 0.01 mg and converted to volumetric wear in mm^3 using the density. Gravimetric wear measurement protocols involved partially drying all specimens before measuring the mass, first by placing them in a desiccator and then by applying a vacuum of 16 inches Hg for 1 hour. To allow a correction for fluid adsorption, two load-soak specimen pairs were also made for each version of PEEK and held in the serum solution at 37˚C in a custom-built apparatus under an 80 N load but, on average, they showed little change in mass.

Results and Discussion: For the baseline 2 Mc, the CFR had lower wear than the OPT (Fig. 1). The CNF was expected to be a better integrated composite than the CFR and thus have even lower wear but over 0.75 Mc, it had about the same wear as the OPT. Interestingly, when the density of OPT (1.265 mg/mm^3) was considered, the wear amounts at 2 Mc were very similar to those found by Schwenke et al [5] who tested an all-polymer bearing made from OPT in a spinal wear simulator.

Under the increasing loads, all of the OPT specimen pairs showed significantly higher wear (Fig. 1) along with new damaged regions consisting of depressions with torn and shredded surfaces (Fig 2a). This might have been caused by an adhesive/fatigue wear mechanism perhaps enhanced by elevated surface temperatures.

Under the increasing loads, 2 of the 4 CFR specimen pairs showed some higher wear (Fig. 1). In this case, the damaged regions were again depressions but they showed intact fibers at the surface thus suggesting a delamination (Fig. 2b). Overall, the CFR had much lower wear than the OPT or the CNF. The carbon fibers must have helped the PEEK matrix resist the surface adhesion/abrasion, only delaminating eventually due to sub-surface fatigue.

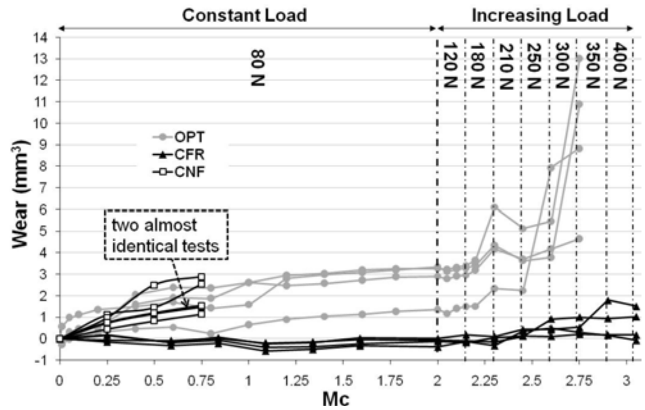
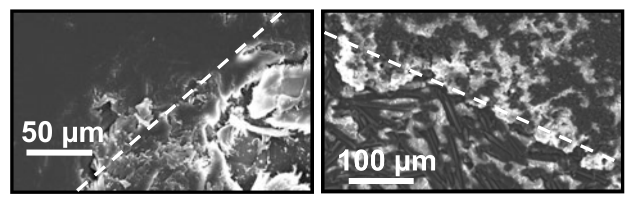


Fig. 1: Wear test of PEEK (OPT, CFR and CNF) material pairs.



(a) OPT (polished region: top left) (b) CFR (polished region: top right)

Fig. 2: Interface of polished and damaged regions in the wear tracks of plates at the end of the wear test (after the increasing loads).

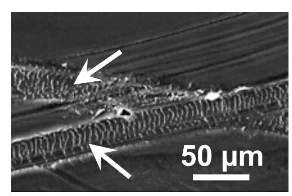


Fig. 3: Abrasive damage to CNF plates at 0.25 Mc.

The CNF showed early evidence of extensive third body abrasive wear damage (Fig. 3). The third bodies might have been wear particles that were rich in carbon nano-fibers. Thus, the CNF seemed to be a poorly formulated composite from a wear perspective.

Conclusions: The CFR all-polymer articulation had the lowest wear of the versions of PEEK that were tested and thus showed the most promise for application in cervical disc arthroplasty. As mentioned in the last section, the wear amounts of the OPT at 2 Mc under a load of 80 N were similar to those reported in a spine wear simulator study of an all-polymer OPT bearing [5]. This suggested that the present wear tests under the "baseline" load might be in a clinically realistic range. Severe surface damage occurred in the pin-on-plate wear tests by increasing the load. However, it was not known how these higher load tests would relate to an all-polymer implant under typical or extreme clinical conditions.

It is important to recognize that an all-polymer PEEK implant for cervical disc arthroplasty would be advantageous in terms of medical imaging but the present study suggests that it might also have some tribological risks that need to be addressed in future simulator studies.

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Acknowledgements: Funding was provided by Medtronic Spinal & Biologics, Memphis TN. Superb technical support was given at the University of Waterloo by Mr. T. Gawel.