A Comparison of Wear and Wear Particles Generated by Injection Molded PEEK-based Materials with Cross Linked Polyethylene Sliding Against Metal and Ceramic Counterface in a Simple Configuration Wear Simulation.

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Introduction: Polyethylene (PE) on metal is the most frequently used bearing combination in total hip replacements (THR) in the US. PE THRs can fail due to late aseptic loosening; this is due to the macrophages’ response to generated PE wear particles and the subsequent cytokine cascade. The degree of the response is determined by the wear volume and the chemical nature of wear particles, as well as their size and morphology (1, 2). The volumetric wear of a THR is dependent on the nature of the articulating surfaces and the mechanical environment. In terms of size and morphology, wear particles in the sub-micron size range are more likely to stimulate a cytokine response (3). Therefore, a material that demonstrates low wear regardless of the mechanical environment, with fewer particles in the sub-micron size range and low bioactivity would be advantageous.

There have been some preliminary investigations of PEEK (poly-ether-ether-ketone) in medical applications (4). However, there has been very limited assessment of the wear behavior of injection molded PEEK-based resins and no full assessment of wear particle size and area distributions. Therefore, this study has compared the wear factors of injection molded unfilled and carbon fiber reinforced (CFR) PEEK against metallic counterfaces to that of cross-linked (XL) PE; and assessed the effect of changing the counterface to Biolox Delta and of increasing the contact stress on the wear factor of CFR-PEEK. Frequency and area distributions of wear particle size ranges of unfilled PEEK and XL PE were compared.

Methods: The following materials were studied: unfilled PEEK (OPTIMA, Invibio) and CFR-PEEK (MOTIS, Invibio) against high carbon (HC) CoCr or Biolox Delta ceramic plates. The comparative control material was a moderately XL PE (Marathon, DePuy Synthes).

A simple geometry wear study was undertaken. A rotational motion of ±30° across a sliding distance of ±28 mm (cross shear of 0.087), and contact pressures of 1.6 or 4 MPa were applied. The lubricant was 25% (v/v) bovine serum and the wear test was conducted for 1 million cycles at 1 Hz. Wear was assessed gravimetrically. A validated soak control method was used to adjust for serum absorption-induced mass changes during the wear test. Surface profilometry was assessed pre and post wear test. The lubricant was removed at 600,000 cycles and stored at -18º C until required for wear particle isolation. Wear particles were isolated using the protocol described in ISO 17853 (5). Briefly, samples of serum lubricant were defrosted; 10 ml of the lubricant was added to 40 ml of hydrochloric acid (37%, v/v). This solution was stirred at 50º C until it turned light purple; indicating complete serum digestion. A
volume of 0.5 ml of the digest was added to 100 ml of methanol (100%). The resultant solution was filtered through 10 µm, 1 µm and 0.015µm filters consecutively. A section of each filter was coated with 10 nm of carbon, viewed and analyzed using a high performance cold field emission scanning electron microscopy (Hitachi SU8230) at a range of magnifications. Image Pro Plus® V 6 imaging software (Media Cybernetics Inc., USA) was used to measure the area and size of the particles. Measurements were combined to generate size and area distributions. Percentage data were arcsine transformed and then analyzed by one-way ANOVA.

Results: Unfilled PEEK produced a six-fold higher wear factor than XL PE against HC CoCr (p value <0.0001). CFR-PEEK articulating against Biolox Delta produced a two-fold lower wear factor than XL PE against HC CoCr (p value = 0.003). CFR-PEEK against Biolox Delta had the lowest wear factor among all studied combinations (Figure 1). Higher contact pressures led to a 30 % reduction in the wear factor of CFR-PEEK against Biolox Delta combination (p value = 0.048) (Figure 2). The wear of CFR-PEEK against HC CoCr was higher than XL PE against HC CoCr. The counterface surfaces were scratched following articulation against CFR-PEEK. This was more evident on CoCr plates, with the average surface roughness increasing from 0.005 µm to 0.32 µm (p value = 0.0048) and may provide a reason for the increased wear factor in the CFR-PEEK against HC CoCr combinations.

To maximize the number of particles available for analysis, the highest wear-producing PEEK-based material combination was analyzed (i.e. unfilled PEEK articulating against HC CoCr) and compared with XL PE wear particles articulating against HC CoCr plates. The number of wear particles isolated per material combination exceeded 1500 particles; with flake, fibril and granule-like morphology particles being observed. The XL PE wear particles were predominantly less than 100 nm in size (91%) compared with only 48% in the unfilled-PEEK (p value < 0.001). When unfilled PEEK articulated against HC CoCr, it generated greater percentages of wear particles in the 0.1-1 micron range (51% compared with 8.5% in the case of XL PE; p value < 0.001; Figure 3 a).

As a function of volumetric concentration, XL PE articulating against HC CoCr significantly generated greater volumes of wear particles in the <0.1 µm range compared with the unfilled PEEK particles generated (p value <0.01). No statistically significant differences were observed in the volumetric concentration in the rest of the size ranges (Figure 3 b).

Discussion: Injection molded carbon fiber reinforced PEEK against Biolox Delta ceramic generated significantly lower wear compared with XL PE (even under higher contact pressures). Frequency distributions of wear particle size ranges showed that while unfilled PEEK wear particles were more evenly distributed over the (<100 nm) and (1-0.1µm) size ranges, XL PE wear particles were predominantly in the sub-micron (< 100 nm) size range. Purportedly, wear particles in the submicron size range are more bioactive (3, 6). We therefore hypothesize that, based on this size difference, unfilled-PEEK wear particles may be less bioactive than XL PE and less likely to induce aseptic loosening. The effect of chemical nature-specific antigenicity, besides the effect of carbon fiber reinforcement should be accounted for; this will be the subject of further investigations. With low wear rates and possibly favorable wear particles size range (similar to unfilled PEEK wear particles), CFR-PEEK vs. Biolox Delta combination may lead to longer lasting hip replacements.

Significance: This is the most comprehensive wear and wear particle analysis study to date of injection molded PEEK-based resins. It has shown that injection molded CFR-PEEK against Biolox Delta
combination has low wear rates and unfilled PEEK has a favorable wear particles size range; such materials should be further assessed in THR applications.

**Figure (1):** Mean pin wear factors of studied material combinations at 1.6 MPa. Error bars represent 95% confidence intervals.

**Figure (2):** Mean pin wear factors of CFR-PEEK vs. Biolox Delta combinations at 1.6 MPa and 4 MPa. Error bars represent 95% confidence intervals.
Figure (3 a): Frequency distributions (± standard error) as a function of particle size for wear particles from unfilled PEEK against HC CoCr and XL PE against HC CoCr wear stations. (Figure 3 b): Volumetric concentration distributions (± 95% standard error) as a function of particle size for wear particles from unfilled PEEK vs. HC CoCr and XL PE vs. HC CoCr wear stations.

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