Development of a Diamond Composite Material for Total Disc Replacement Bearings Enables Non-Congruent Articulations Emulating Physiologic Kinematics

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Purpose: The design of articulating TDR devices is constrained by the properties of materials available for fabrication. Problems related to wear and failure of current conventional materials have required congruent articulations and limit the designer’s ability to craft devices which emulate natural kinematics. The purpose of this study was to develop a material sufficiently robust to permit incongruent bearings without sustaining excessive wear or material failure. Such a material would enable a host of new design options incorporating translations and rotations which approximate normal kinematics. Polycrystalline diamond compact (PDC) is one of the toughest known abrasion resistant materials. Developed for the most demanding earth-boring and machine tool applications, when polished, it also has one of the lowest coefficients-of-friction. Adapting this industrial material to medical applications required that it be reformulated for biocompatibility, and that fabrication technologies be developed for precision non-planar polished articulations. First generation medical formulations of this diamond composite have been developed and qualified for 28 mm total hip diamond-on-diamond (DoD) bearing applications.

Methods: Wear studies were conducted in 25% bovine serum. Six sets of 28 mm bearings (Dimicron, Utah) were tested to 5 MC war simulator (AMTI, Boston) with a standard Paul 3kN walking cycle (ISO14242-1), followed by 2 MC aggressive micro-separation regimen in which swing-phase load was reduced to 120N, a side force of 129N applied, and abduction motion disabled. This resulted in separation of the spherical 28 mm bearings, and 0.5-0.7mm of horizontal displacement of the center of the head. Wear fluid was sampled for metal ions (inductively coupled plasma) and wear debris. The next phase of testing involved spherical pin-on-flat figure-of-eight wear studies (ASTM F2423/ISO Draft 18192-1) to define the Hertzian limits of the diamond composite. Four diamond wear couples were tested with a custom built 12 station simulator (Dimicron). A static load of 27 N (equivalent to projected cervical loads) was applied for 10,000,000 cycles in 25% Bovine Serum. Wear rates were calculated via optical geometric analysis, as rates were undetectable gravimetrically.

Findings: For hip simulator studies, both gravimetric and microscopic analysis of specimens could not detect any wear. Wear fluid Co ion levels were either near or below detection thresholds of 50 ppb. For pin-on-plate studies, no wear could be detected on plates. Microscopic analysis of pins showed wear rates of 0.00090 mm$^3$/million cycles.

Conclusions: These aggressive incongruent wear studies simulate the type of severe Hertzian stresses that would be sustained with incongruent TDR bearings, and have resulted in marked wear acceleration in metal-on-metal (MOM) and ceramic-on-ceramic (COC) bearings including grain failure and pluck-out for COC (characterized as “wear stripe” formation). The absence of detectable wear in the hip microseparation studies and the extremely low wear in the pin-on-plate studies is unprecedented, and demonstrates a material with the potential to sustain incongruent bearing design in TDR. This material robustness enables new TDR design characteristics in the quest to reproduce natural kinematics. Work is underway to further optimize this material for TDR design applications.