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Short communication

Wear characterization of the A-MAV^{TM} anterior motion replacement using a spine wear simulator

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Abstract

Total disc replacement emerged as an alternative to fusion for the treatment of degenerative disc disease. Optimization of the bearing surfaces is critical to mitigate wear-related biological reaction. The purpose of this study was to characterize the wear of the A-MAV^{TM} metal-on-metal total disc replacement using a spine wear simulator, per the ASTM F2423-05 standard guide. Six specimens were tested under flexion-extension (FE) conditions for ten million cycles (MC), followed by lateral bending (LB) combined with axial rotation (AR) for an additional ten MC. A run-in wear period was observed during the first 0.5 MC for both testing conditions, followed by a steady-state wear rate of $0.33 \pm 0.12\,mm^3$/MC in FE and $0.43 \pm 0.06\,mm^3$/MC in combined motion. Phasing between LB and AR led to a crossing-path motion as observed on explanted devices. This study suggests that clinically-realistic surface morphology may be achieved by carefully selecting the wear test parameters specified in the ASTM standard guide. Furthermore, the use of metal-on-metal bearings in spinal arthroplasty may be viable in view of the low wear exhibited by this material combination.

Keywords: Artificial disc; Total disc replacement; Spine arthroplasty; Tribology; Wear testing; Metal-on-metal

1. Introduction

Total disc arthroplasty is an alternative to fusion for the treatment of degenerative disc disease. While both surgical interventions are intended to restore disc height and provide stability, fusion may result in abnormal biomechanics leading to degeneration at the adjacent functional spinal units [1–3]. Artificial discs are designed to preserve motion at the index level and minimize overall biomechanical changes in the spine.

Similar to devices used for large joint arthroplasty, artificial discs must be designed for optimum wear performance in order to mitigate wear-related problems [4,5]. Within the realm of possible biomaterials for use in bearing applications, conventional ultra-high-molecular-weight-polyethylene (UHMWPE) and other polymers such as polyolefin have been associated with wear particle-induced inflammatory reactions leading to osteolysis in the spine [6–9]. Other material combinations such as the use of metal-on-metal (M-M) bearings have been used in large joint arthroplasty in attempts to minimize joint wear. Cobalt–chromium–molybdenum (CoCrMo) alloys are well known for their excellent wear properties and have experienced increased recognition in the orthopaedic community as viable material combinations for hip arthroplasty applications [10–12]. A similar philosophy can be applied for spinal applications in view of the potential benefits of a low wearing material combination in a younger and more active patient population.

Until recently, there has been no consensus on the appropriate conditions with which to evaluate the wear performance of total disc prostheses. Early in 2006, the American Society for Testing and Materials (ASTM) published a standard guide (ASTM F2423-05) for wear testing artificial discs and the International Standards Organization (ISO) is expected to publish a standard on the same matter in 2007. The purpose of this study was to characterize the wear performance of a metal-on-metal artificial disc tested according to the ASTM F2423-05 standard guide and compare the wear performance of this device to published results for metal-on-UHMWPE (M-PE) artificial discs.

2. Material and methods

The A-MAV^{TM} anterior motion replacement (Medtronic, Memphis, TN) is a M-M lumbar artificial disc. It consists of a

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Fig. 1. Laveen spine wear simulator.

CoCrMo (ASTM F1537-00) ball-in-socket design with a nominal diameter of 20 mm. The average surface roughness (S_a) of the articular surfaces varied between 5 and 20 nm for all implants, with an average of 9.6 ± 2.2 nm.

The wear performance of six implants was evaluated using a multi-station spine wear simulator (Laveen, Burnsville, MN) (Fig. 1), capable of combining two degrees of freedom of motion. The specimens were mounted on custom fixtures designed to align both the simulator and implant centers of rotation. The testing conditions were based on the ASTM F2423-05 standard guide for wear assessment of total disc prostheses. Since the current work began prior to the ratification of the standard guide, the range of motion parameters were based on the draft document available at the time. Each specimen was tested under a constant load of 1200 N for 10 million cycles (MC) in flexion-extension (FE) (±10°) followed by an additional 10 MC of combined lateral bending (LB) (±7.5°) phased by 90° with axial rotation (AR) (±3°). The testing frequency was 2 Hz. The load of 1200 N corresponds to the maximum force transmitted through the disc during normal walking [13]. While the ASTM standard guide does not require phasing for combined motion, phasing was selected in order to produce crossing-path motion that has been shown by explant analyses to occur *in vivo* [14]. Furthermore, the ranges of motion in FE and LB were higher than the ±7.5° and ±6°, respectively, recommended in the standard guide.

The implants were tested in a solution of alpha calf fraction (HyClone, Logan, UT) diluted with deionized water to a protein concentration of 11.5 g/L. This concentration is substantially lower than the standard guide's recommendation of 20 g/L. A lower protein concentration was selected in view of the unknown nature of the periprosthetic fluid in the spine. Moreover, as elevated protein concentrations can provide for additional protection of the articulating surfaces through boundary lubrication [15,16], it was believed that this lower concentration represented a conservative scenario (may provide for harsher than realistic conditions) for a M-M bearing. Penicillin–streptomycin (0.15% per volume) and amphotericin B (0.25% per volume) (Invitrogen, Carlsbad, CA) were added to the solution to prevent bacterial and fungal growth, respectively. The test chambers were placed inside temperature-controlled baths maintained at a temperature of 37 °C. Temperature and pH of the test fluid solution were recorded throughout the testing period. The fluid solution was saved after wear test intervals for particle analysis.

Wear was measured gravimetrically every 0.5 MC using a precision balance (AX205, Mettler-Toledo, Columbus, OH). Specimens were cleaned and weighed according to the ASTM F1714-02 standard. Volumetric wear rate, defined as the increase in volumetric wear for a given testing period, was calculated using a density of 8.29 mg/mm^3 for CoCrMo. Before the test begun and at various intervals throughout the test period, surface texture was characterized using a white light interferometer (NewView 5000^{TM}, Zygo Corp, Middlefield, CT).

The steady-state volumetric wear rate of the A-MAV anterior motion replacement device obtained under crossing-path motion conditions was compared with published volumetric wear data for two M-PE lumbar artificial discs: the Charité® Artificial Disc (DePuy Spine, Raynham, MA) and the ProDisc®-L Total Disc Replacement (Synthes, West Chester, PA) [17]. The Charité consists of a UHMWPE core sandwiched between two metallic endplates. The device is symmetric about the transverse plane and both articular surfaces consist of a ball-in-socket articulation. The ProDisc-L is a ball-in-socket joint with a UHMWPE ball and metallic socket. The Charité and Prodisc-L have been tested in combined motion (FE: −3/+6°; LB: ±2°; AR: ±1.5°) under cyclic loading (200–1750 N) for 8.0 MC [18]. Different frequencies were used for every degree of freedom (FE: 1.10 Hz; LB: 1.04 Hz; AR: 1.16 Hz; load: 1.56 Hz), leading to variable phasing angles and crossing-path motion. The implants were submerged in a solution of bovine serum with a protein concentration of 30 g/L.

3. Results

The M-M A-MAV lumbar disc exhibited an initial run-in wear period for the first 0.5 MC of FE testing followed by a steady-state wear rate of 0.33 ± 0.12 mm^3/MC (Fig. 2) for the remainder of the FE motion conditions. The contact areas of the

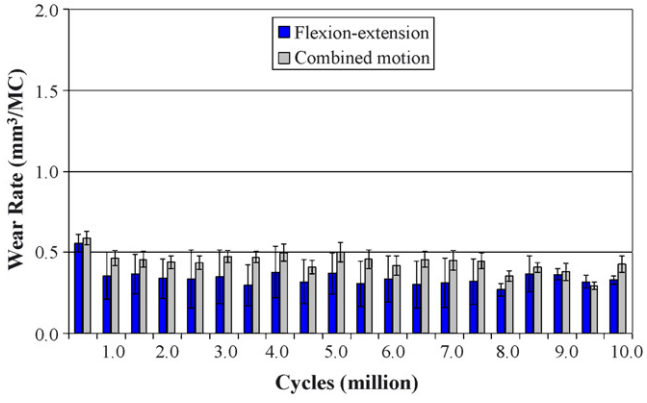

Fig. 2. Volumetric wear rate of the A-MAV artificial disc.