Wear characterization of a metal-on-metal cervical disc under ISO and ASTM test conditions

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Introduction: Cervical disc arthroplasty has been developed as an alternative to the cervical discectomy and fusion. The biological response of the *in-vivo* wear debris has encouraged the wear evaluation of artificial discs [1]. The two available wear testing standards (ASTM and ISO) propose different loading and kinematic conditions. In-vitro studies have shown wear dependence on the articulating material and test parameters [2]. The objective of this study was to examine and compare the *in vitro* wear of a metal-on-metal cervical disc under both ASTM and ISO testing conditions.

Methods: In this study, twelve PRESTIGE® LP (Medtronic, Memphis, TN) cervical discs were tested in either a MTS Bionix Spine Wear Simulator (MTS, Eden Prairie, MN) or a multi-station spine wear simulator (Laveen, Burnsville, MN). The device contains a ball-in-trough metal-on-metal (MOM) articulation manufactured from a titanium ceramic composite which consists of a base matrix of titanium alloy (Ti-6Al-4V) mixed with titanium carbide. Six specimens were tested per ISO 18192-1 with a cyclic load of 50-150 N. Combined motion of ±7.5° flexion-extension (FE), ±6.0° lateral bending (LB) and ±4.0° axial rotation (AR) was applied for 10 million cycles (MC) at a frequency of 2 Hz. The remaining six specimens were tested under ASTM 2423-05 with a constant load of 100 N along with coupled motion of ±6.0° LB combined with ±6.0° AR for 10 MC at 2 Hz. The ASTM test continued for an additional 10 MC under a constant load (100 N) in ±7.5° of FE at 2 Hz. All tests were conducted with a lubricant consisting of 25% Alpha Calf Fraction (HyClone, Logan, UT) at 37°C. Wear was measured gravimetrically every 0.5 MC. The surface roughness of the articulating surfaces was measured throughout the test using a white light interferometer (NewView 5000™, Zygo, Middlefield, CT).

Results: For both wear tests, an initial run-in wear period was observed for the first 1.0 MC and was followed by a steady-state wear rate (Fig 1). Both ASTM and ISO wear tests generated an elliptic wear track in the medial-lateral direction. However, for ASTM LB+AR the articular surfaces were characterized by curvilinear abrasive wear marks oriented along the wear track, followed by polishing of the surfaces with ASTM FE (Fig 2). The average surface roughness for the ASTM test increased from 0.14 ± 0.03 µm to 0.45 ± 0.21 µm when the specimens were tested under the combined motion and decreased to 0.30 ± 0.14 µm after FE. In the ISO test, the wear tracks were characterized by polishing of the surfaces with "S" shaped wear path in the anterior-posterior direction across the width of the elliptical wear track (Fig 2). The average surface roughness of the specimens tested in ISO reduced from 0.137 ± 0.038 µm to 0.036 ± 0.012 µm in 10 MC.

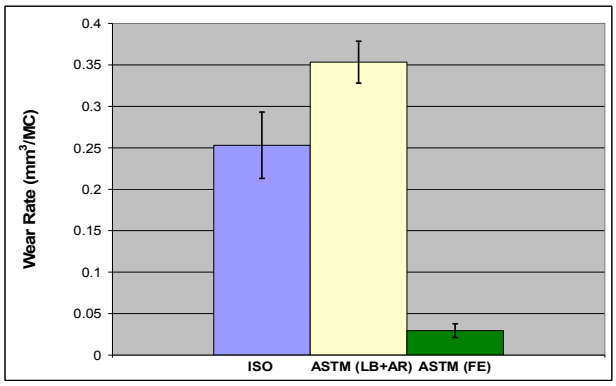
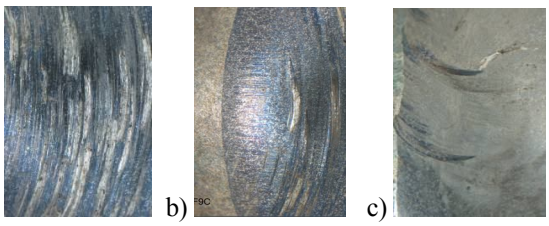


Figure 1: Steady-state wear rates



a) b) c)

Figure 2: Wear pattern a) ASTM LB+AR, b) ASTM FE, c) ISO

Discussion: The *in vitro* wear performance of a self-mating metal-on-metal cervical disc replacement has been simulated under two test standards with both multidirectional and unidirectional testing. Both the ISO and ASTM combined motion conditions resulted in similar wear pattern in medial-lateral direction but with different orientations of the wear paths. The wear marks and mechanisms observed under the ASTM conditions of this study are consistent with the retrieved PRESTIGE® stainless steel cervical discs [3]. Unidirectional motion (ASTM FE) demonstrated lower wear rates than coupled motion which was in contrast to previous published results for MOM articulation [4]. The lower wear rate could be a result of the ball-in-trough design, material properties for the device, or even due to the motion sequence selected for the ASTM test conditions. The observed wear rates of the tested samples are within the range of previously reported studies of articulating MOM lumbar disc replacements and total hip replacements [4,5]. In conclusion, this study demonstrate that the wear rate is influenced by the load and motion inputs parameters and that the different test conditions may be appropriate for different articulating materials and designs. Continued efforts should be made to analyze the retrieved discs to better understand the *in-vivo* wear mechanisms which are necessary to develop clinically relevant test conditions.

References: [1] Hallab et al, Spine 28(20S):S125-S138, 2003 [2] Dooris et al, SAS 2007 [3] Kurtz et al, SAS 2007 [4] Firkins et al, Proc Instn Mech Engrs [H]. 215: 119-121, 2001 [5] Paré et al, Wear, 263: 1055-1059, 2007