Wear Characterization of a Total Spinal Arthroplasty Device Under Different Shear Loads

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Introduction: Wear testing of lumbar spine arthroplasty devices is often performed to evaluate the potential for particle-induced osteolysis. Testing is typically performed using international standards developed for total disc replacements (TDR). Total Spine Arthroplasty (TSA) devices, however, are unique since both the disc and facets are removed to treat the degenerative segment, which may require them to carry different shear loads than other devices. The Flexuspine FSU is a TSA device consisting of a metal-on-metal disc component and a metal-silicone posterior component. The disc has a bearing surface for flexion-extension (F/E) and a coupled lateral bending and axial rotation (LB-AR) bearing surface. The LB-AR surface, which will be evaluated in this study, has a shear face that couples the two motions while also providing shear resistance. The objective of this study was to evaluate the durability and wear generation potential of the Flexuspine FSU under a range of shear loads.

Methods: Wear testing of six FSU disc components was performed for 10 million cycles (Mc) using an MTS Bionix Spine Wear Simulator. The implants were declined by 45°, which applies equal shear and axial loads to the implant and increases shear loading relative to testing with the implants declined by 10°. LB-AR motion (±2°) was applied under two shear load levels: Case 1) 424-1414N from 0-5Mc and Case 2) 200-600N from 5-10Mc. These loads were based on the axial loads in ISO/DIS 18192-1 and facet shear loads in ASTM F2694. Testing was carried out in 30g/L bovine calf serum. Wear results from a previous study (Case 3) with the disc declined by 10° and tested with ±2° LB-AR under 600-2000N loading (104-347N implant shear; 591-1970N implant axial loading) are also included for comparison (Gimbel, 2010).

Results: Linear wear marks were observed on the shear face and axial loading surface. For Cases 1 and 2, the specimens completed each segment without failure and the wear rates were 3.4 ± 0.2 mm³/Mc and 1.2 ± 0.0 mm³/Mc, respectively. The wear rate from the previous study (Case 3) was 2.6 ± 0.1 mm³/Mc. The LB-AR wear rates for the 3 cases were linearly correlated to the sum of the shear and axial load (r²=0.997).

Conclusions: This study demonstrated that the Flexuspine FSU disc component is durable under a range of shear loads while maintaining comparable wear rates to the previous study. In vivo spinal shear loading is not well characterized but based on various estimates (Lu, 2005; Potvin, 1991; Frei, 2001), the load scenarios evaluated were comparable to both physiological (Cases 2 and 3) and supra-physiological shear loads (Case 1). The implants’ wear rates were affected by both the axial and shear loads in an additive manner, indicating that both loading modes contribute to the overall wear and should be considered in wear testing of TSA devices.