

WEAR DEBRIS ANALYSIS OF THE M6-L ARTIFICIAL LUMBAR DISC

Introduction

The Spinal Kinetics M6[®]-L is an artificial lumbar intervertebral disc designed to replicate the anatomic structure and biomechanical performance of the natural disc. Its innovative design allows for a controlled range of motion in all 6 degrees of freedom. It incorporates a compressible nucleus within a woven fiber annulus, allowing for natural kinematics. The potential for production of wear debris must be addressed in the design of any motion-preserving implant. The goal of this study was to characterize the wear characteristics of the M6-L over the projected life of the implant.

Methods

Test Protocol:

Assessments were performed per ASTM F 2423, *Standard Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses*. Wear debris analysis was conducted per ASTM 1877, *Standard Practice for Characterization of Particles*.

Test Conditions:

- n=6 in bovine calf serum (BCS), 20 mg/mL, 37°C
- 20 million cycles combined-motion modes (2Hz):
 - 10M cycles Lateral Bend ($\pm 6^\circ$) + Torsion ($\pm 3^\circ$)
 - 10M cycles Flexion/Extension ($\pm 7.5^\circ$)
- 1200N axial compressive load
- n=2 "load soak" controls for each test to correct for test artifact; experienced compressive load only, in BCS
- All wear debris was collected at regular intervals

Analysis

- Samples were assessed at regular intervals and at completion of 20M cycles:
 - Overall functionality
 - Height loss under worst-case physiologic loading (1200N)
 - Axial compressive stiffness under physiologic loading
- Wear debris analysis was conducted by an independent test laboratory, using Computer Controlled Scanning Electron Microscope (CCSEM) techniques
- ASTM 2423-05 specifies that the weight of the device over time must be measured to determine the quantity of debris released into the body, however due to the unique nature of the M6-L it was not possible to perform this analysis. A technique was therefore developed and validated which quantified the mass loss through analysis of the collected wear debris
- As a worst case scenario, Spinal Kinetics also collected and analyzed additional wear debris that would normally be trapped underneath the outer endplates and behind the sheath
- Wear debris was analyzed to determine:
 - Mass loss
 - Particle size
 - Morphology



Figure 1: Kinematic wear testing was conducted using custom-built machines designed by Spinal Kinetics

Results

After completion of 20 million cycles in all modes of motion:

- All samples were functional and passed all acceptance criteria.
- Average height loss under a worst-case physiologic 1200N axial compressive load was $1.6 \pm 0.3\text{mm}$.
- Axial compressive stiffness was $1487 \pm 196 \text{ N/mm}$.

Wear debris analysis to 20 million cycles:

- Mass loss: $16.9 \pm 12.0\text{mg}$.
- An average of an additional 25.9 mg of debris were generated and trapped inside the device. Total device debris was therefore less than 43 mg.

Particle size and morphologic characteristics are described in Table 1 and Figure 2, below.

Table 1: Size and Morphologic Characteristics of the M6-L Debris

Measure	Mean \pm SD
Size:	
Feret Diameter, μm	3.5 ± 3.9
Equivalent Circle Diameter, μm	3.2 ± 3.0
Morphology:	
Aspect Ratio	2.3 ± 2.1
Elongation	2.4 ± 1.6
Form Factor	0.50 ± 0.18
Roundness	0.51 ± 0.28

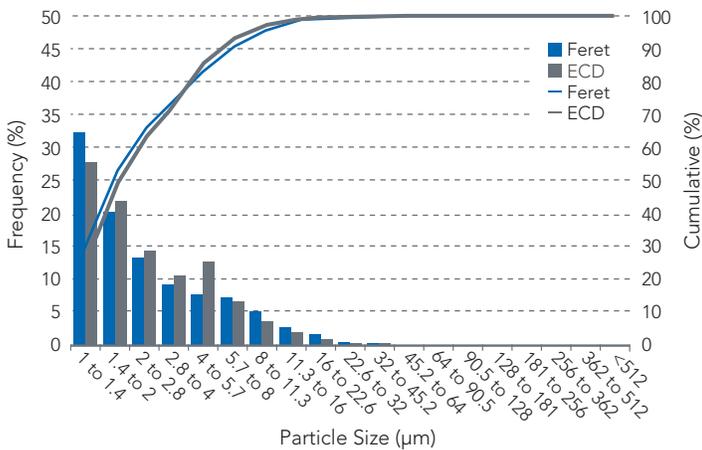


Figure 2: Size Distribution Data, 0-20 million Cycles

Discussion

The results of this rigorous kinematic wear test battery indicate that the M6-L will successfully last the projected life of the implant. From a functional perspective, the device passed all acceptance criteria. The device remained fully functional after 20 million cycles with a height loss of 1.6mm, or 0.08mm per million cycles, under a worst case physiologic load. This minimal height loss is acceptable, and is comparable to the 1.2-2.8mm height loss observed in the natural disc after creep loading to 1500N¹. The axial compressive stiffness of the M6-L remained in the physiologic range throughout and after all 20 million cycles of testing. While there are few data describing the axial stiffness of healthy anterior column units, Spenciner et al² report an axial stiffness of 1288 ± 271 N/mm. From an assembly and component integrity perspective, the assembly and all the components remained fully intact and functional.

With respect to wear debris, the amount of wear debris that was generated after testing for 20 million cycles in all modes of motion was minimal. This amount of debris corresponds to 0.85 mg/million cycles or, in the worst case including debris trapped behind the sheath, 2.13 mg/million cycles. This debris mass is in the range of that found in other lumbar devices tested under a variety of conditions, including the Charité (0.13 to 19.35 mg/million cycles)^{3,4}, the Maverick (9.96 to 11.62 mg/million cycles)⁵ and the ProDisc-L (4.64 to 16.59 mg/million cycles)^{4,6}. The debris mass is also well below the threshold tested in an *in vivo* model (see Pre-Clinical Biocompatibility Testing of the M6 Artificial Disc).

Wear Debris Per Million Cycles

M6-L	0.85 to 2.13 mg/million cycles
Charité	0.13 to 19.35 mg/million cycles
Maverick	9.96 to 11.62 mg/million cycles
ProDisc-L	4.64 to 16.59 mg/million cycles

Conclusion

The Spinal Kinetics M6-L is a robust device which exhibits minimal wear over the projected life of the implant.

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