

## FUNCTIONAL KINEMATIC TESTING AND MECHANICAL CHARACTERIZATION OF THE M6-L ARTIFICIAL LUMBAR DISC

### Introduction

The Spinal Kinetics M6<sup>®</sup>-L is an artificial lumbar intervertebral disc designed to replicate the anatomic structure and biomechanical performance of the natural disc. Its unique design allows for a controlled range of motion in all 6 degrees of freedom. The compressible viscoelastic polymer nucleus of the M6-L is designed to simulate the function of the native nucleus, while the surrounding multi-layer high tensile strength UHMWPE fiber annulus provides progressive resistance to motion and a physiologically restrained construct. The robustness of any motion-preserving implant must be addressed. The goal of this study was to characterize the robustness of the M6-L over the projected life of the implant.

### Methods

The robustness of the device was tested under physiologic flexion/extension (F/E) and under combined lateral bending and axial rotation per ASTM 2423-05, and under physiologic creep per ASTM D2990-01. Additional testing of the M6-L to hyper-physiologic loads was conducted in static and dynamic compression, compression-shear, and torsion per ASTM F2346-05; and to extreme rotation in dynamic flexion/extension.

#### Functional Kinematic Testing:

- n=6 devices tested in water at 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 throughout



Figure 1: Functional kinematic testing was conducted using custom-built machines designed by Spinal Kinetics.

#### Dynamic Physiologic Mechanical Characterization:

- 10 million cycles in 0.9% saline at 37°C (n=2 each):
  - Compression
  - Compression shear (CS = Axial load w/shear load at 45°)
  - Torsion with 500N axial load

#### Static Non-physiologic Mechanical Characterization:

- Static tests to failure in 0.9% saline at 37°C (n=5 each):
  - Compression
  - Compression shear
  - Torsion with 500N axial load

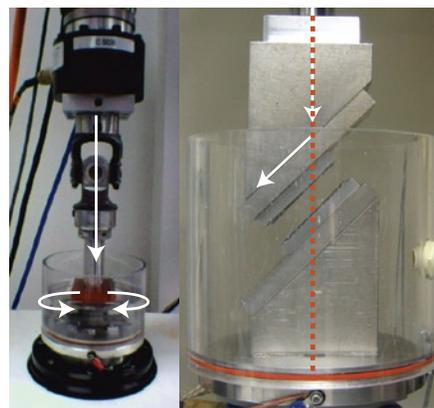


Figure 2: Static and Dynamic testing. Left: Compression and Torsion. Right: Compression Shear.

#### Creep Testing:

- n=6 devices tested in water at 37°C
- 1200N axial compressive load
- 42 day test, results extrapolated to 80yrs

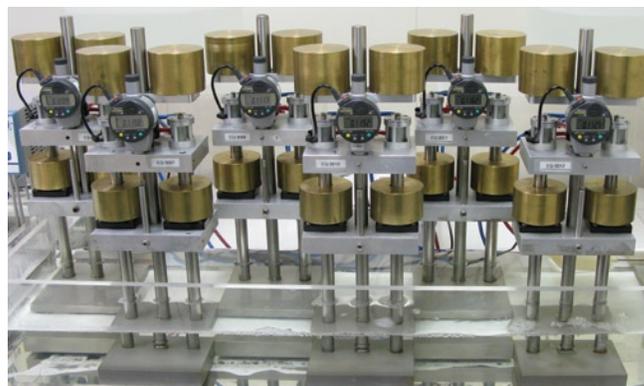


Figure 3: Creep testers.

#### Worst Case Physiologic Sheath Retention Characterization:

- n=6 devices tested in water at 37°C
- $\pm 10^\circ$  of flexion/extension at 2Hz for 30,000 cycles
  - Physiologic worst case for extension<sup>1</sup>
  - 30,000 cycles =  $\sim 12$  weeks<sup>2</sup>

#### Analysis:

- Samples were assessed at regular intervals (dynamic tests only) and at completion of testing:
  - Height loss under 1200N axial compressive load
  - Axial compressive stiffness
  - Assembly and component integrity

## Results

### After completion of 20 million cycles in functional kinematic testing:

- All assemblies and components were fully intact and functional.
- Average height loss under a 1200N axial compressive load was  $1.3 \pm 0.6$  mm.
- Axial compressive stiffness was  $808 \pm 305$  N/mm.

### Dynamic mechanical characterization at physiologic loads:

- All assemblies and components were fully intact and functional, including physiologic height ( $<0.35$ mm height loss) and stiffness ( $1595 \pm 237$  N/mm), at completion of 10M cycles.

### Static non-physiologic mechanical characterization (Table 1):

- It was not possible to elucidate either mechanical or functional failures in static testing to highly nonphysiologic loads within the limits of available equipment.

Table 1: Results of the Static Characterization of the M6-L

Testing Mode	Lumbar Physiologic Load or Torque to Failure	M6-L Average Load or Torque to Equipment limit	Safety Factor
Compression	15350 N <sup>3</sup>	$> 24,910 \pm 60$ N	$> 1.5x$
Compression Shear	3600 <sup>4</sup>	$> 12054 \pm 24$ N	$> 3x$
Torsion	10Nm <sup>5</sup>	$> 28.1 \pm 0.1$ Nm	$> 2.5x$

### Creep Testing:

- All assemblies and components were fully intact and functional.
- Average height loss under a 1200N axial compressive load, extrapolated to 80 years, was  $0.37 \pm 0.04$  mm.
- Axial compressive stiffness was  $1304 \pm 77$  N/mm.

### Worst Case Physiologic Sheath Retention Characterization:

- Sheaths retained throughout testing.
- All devices were fully functional, including physiologic height and axial stiffness.

## Discussion

All testing indicated an extremely robust device that successfully lasts the projected life of the implant. The functional kinematic testing and physiologic dynamic testing demonstrated that the M6-L passed all acceptance criteria. The assembly and all the components remained fully intact and functional. The device remained fully functional after 20 million cycles with a height loss of 1.3mm over 20 million cycles, or 0.07mm/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 1500N<sup>6</sup>. The axial compressive stiffness of the M6-L remained in the physiologic range throughout

and at completion of all cycles of testing. While there are few data describing the axial stiffness of healthy anterior column units, Spenciner et al<sup>4</sup> report an axial stiffness of  $1288 \pm 271$  N/mm.

The static to failure non-physiologic testing is not intended to mimic physiological conditions or address all clinically-relevant failure modes, but rather to characterize the mechanical performance of the load bearing components of the disc—i.e., the endplates, core, and fibers—at highly non-physiologic loads. The results demonstrate the durability of the M6-L: despite being subjected to highly non-physiologic loading up to the limits of the test equipment, no mechanical or functional failures were achieved.

The results of the creep testing and the worst case physiologic sheath retention testing provide further verification of the robustness of the M6-L. The sheath is retained even worst case physiologic extensions during the first 12 weeks, after which device encapsulation may serve as an additional constraint to keep the sheath in place.

## Conclusion

The M6-L was subjected to rigorous testing which confirms the inherent robustness of the device. The disc remains fully intact and functional after functional kinematic testing to 20M cycles of combined motion; physiologic dynamic compression, compression shear, and torsion; creep to the equivalent of 80 years; and worst case physiologic extension over 30,000 cycles. Even when highly nonphysiologic static loads are applied, the device does not exhibit any mechanical or functional failures.

The static and dynamic mechanical characterization of the M6-L lumbar disc demonstrated that the device has the structural integrity to last the life of the implant and that it exceeds the necessary criteria for device safety over the life of the device.

1. Huang, R. C., F. P. Girardi, et al. (2005). "Correlation between range of motion and outcome after lumbar total disc replacement: 8.6-year follow-up." *Spine* 30(12): 1407-11.
2. Hedman, T. P., J. P. Kostuik, et al. (1991). "Design of an intervertebral disc prosthesis." *Spine* 16(6 Suppl): S256-60.
3. Hutton, W. C. and M. A. Adams (1982). "Can the lumbar spine be crushed in heavy lifting?" *Spine* 7(6): 586-90.
4. Spenciner D.B. et al. (2003). Testing of Human Cadaveric Functional Spinal Units to the ASTM Draft Standard'. In: *Spinal Implants: Are We Evaluating Them Appropriately* 114:126, ASTM STP 1431, ASTM International, West Conshohocken, PA.
5. ASTM F2423-05, Standard Guide for Functional, Kinematic, and Wear Assessment of Total DiscProstheses
6. McMillan, D. W., G. Garbutt, et al. (1996). "Effect of sustained loading on the water content of intervertebral discs: implications for disc metabolism." *Ann Rheum Dis* 55(12): 880-7.



Spinal Kinetics, Inc. 595 N. Pastoria Avenue Sunnyvale, CA 94085 USA

Telephone: +1-408-636-2500 Fax: +1-408-273-6018 www.spinalkinetics.com info@spinalkinetics.com

© 2009 Spinal Kinetics, Inc. SPINAL KINETICS, MOTION FOR LIFE, M6, and the Spinal Kinetics Spine Logo are trademarks or registered trademarks of Spinal Kinetics, Inc. in the U.S. and in other countries. U.S. Patent No. 7,153,325; Pending U.S. and foreign patent applications.