M6®-C artificial cervical disc

Mechanical Characterization

FUNCTIONAL KINEMATIC TESTING AND MECHANICAL CHARACTERIZATION OF THE M6-C ARTIFICIAL CERVICAL DISC

Introduction

The Spinal Kinetics M6®-C is an artificial cervical 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-C 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-C 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 F2423-05, and under physiologic creep per ASTM D2990-01. Additional testing of the M6-C to hyperphysiologic loads was conducted in static and dynamic compression, compression-shear, and torsion per ASTM F2346-05; and to extreme physiologic rotation in dynamic extension.

Functional Kinematic Testing:

- n=6 devices tested in water at 37°C
- 20 million cycles combined-motion modes (2Hz):
  - 10M cycles Lateral Bend (±6°) + Torsion (±6°)
  - 10M cycles Flexion/Extension (±7.5°)
- 100N 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 100N 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 100N axial load

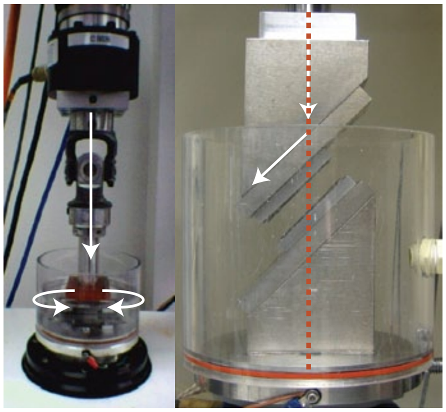

Figure 2: Static and Dynamic testing. Left: Compression and Torsion. Right: Compression Shear.

Creep Testing:

- n=6 devices tested in water at 37°C
- 100N axial compressive load
- 42 day test, results extrapolated to 100yrs

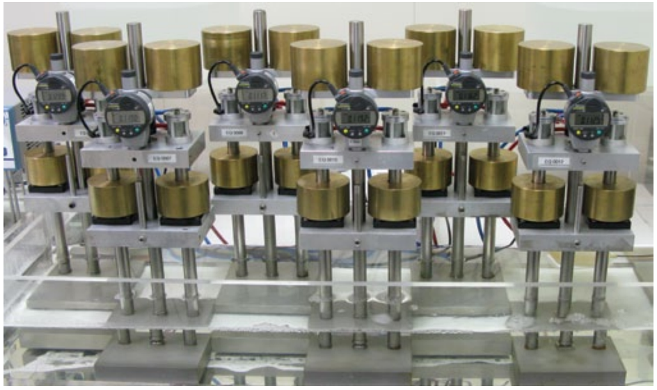

Figure 3: Creep testers.

Extreme Physiologic Sheath Retention Characterization:

- n=6 devices tested in water at 37°C
- Neutral to 18° of extension at 2Hz for 30,000 cycles
  - Worst case for extension[1]
  - 30,000 cycles = ~12 weeks[2]

Analysis:

- Samples were assessed at regular intervals (dynamic tests only) and at completion of testing:
  - Height loss under physiologic loading (100N)
  - Axial compressive stiffness at 100N
  - Assembly and component integrity

M6-C® artificial cervical disc

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 physiologic 100N axial compressive load was 0.47 ± 0.05 mm.
- Axial compressive stiffness was 873 ± 168 N/mm.

Dynamic mechanical characterization at physiologic loads:

- All assemblies and components were fully intact and functional, including physiologic height (<0.25mm height loss) and stiffness (761 ± 200 N/mm), at completion of 10M cycles.

Static non-physiologic mechanical characterization (Table 1):

- It was not possible to obtain static compressive failure within the limit of available equipment.
- Only *mechanical* rather than *functional* failures were achieved in static compression shear and torsion. Due to the redundancy built into the device design, all devices remained intact and were fully functional (including physiologic height and axial stiffness) subsequent to these mechanical failures.

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

Testing Mode	Cervical Physiologic Load or Torque to Failure	M6-C Average Load or Torque to Mech. Failure*	Safety Factor
Compression	3200[3]	> 24,694 ± 460 N	> 7.5x
Compression Shear	845[4]	6714 ± 113 N	8x
Torsion	6Nm[3]	10.4 ± 1.4 Nm**	1.7x

* All failures were mechanical, not functional, failures.
** Mechanical failure at 130° of axial rotation.

Creep Testing:

- All assemblies and components were fully intact and functional.
- Average height loss under a physiologic 100N axial compressive load, extrapolated to 100 years, was 0.42 ± 0.12 mm.
- Axial compressive stiffness was 764 ± 29 N/mm.

Hyper-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-C passed all acceptance criteria. The assembly and all the components remained fully intact and functional. The device lost only 0.02 mm/million cycles; this minimal height loss is acceptable, and is comparable to the height loss observed in other prostheses[5]. The axial compressive stiffness of the M6-C 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, Moroney et al[6] report an axial stiffness of 737 ± 885 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-C: despite being subjected to highly non-physiologic loads, only *mechanical* rather than *functional* failures were achieved. Due to the redundancy built into the device design, all devices remained intact and were fully functional, including physiologic height and axial stiffness, subsequent to these mechanical failures.

The results of the creep testing and the hyper-physiologic sheath retention testing provide further verification of the robustness of the M6-C. The sheath is retained even under extreme 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-C 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 100 years; and extreme physiologic extension over 30,000 cycles. When hyper-physiologic loads are applied, mechanical rather than functional failures are observed due to the redundancy built in to the device design.

The static and dynamic mechanical characterization of the M6-C cervical 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.

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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