M6-L artificial lumbar disc

TOTAL DISC ARTHROPLASTY USING A COMPRESSIBLE DISC PROSTHESIS: EFFECT OF COMPRESSIVE PRELOAD MAGNITUDE ON THE KINEMATICS OF LUMBAR SPINE

As presented at the Ninth Annual Global Symposium on Motion Preservation Technology • 28 April - 1 May, 2009 London/England

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Summary

- Eight human cadaveric human lumbar spines (L1-S1, 44±6.5 yr) were tested in flexion (8Nm) and extension (6Nm) under 0N, 400N and 800N compressive follower preloads.
- The Load-Displacement Curves of the M6-L closely approximate intact controls.
- M6-L disc maintained physiologic ROM in flexion-extension under preloads up to 800 N
- M6-L disc maintained physiologic quality of motion under preloads up to 800 N

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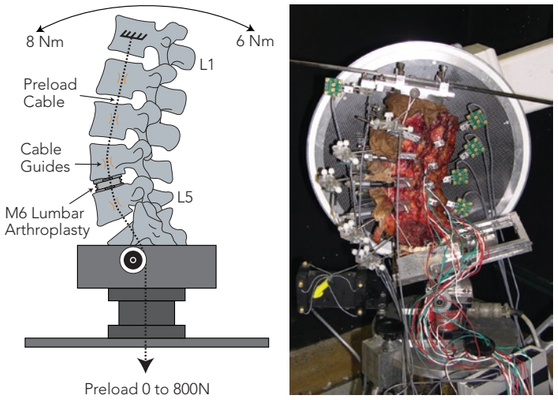
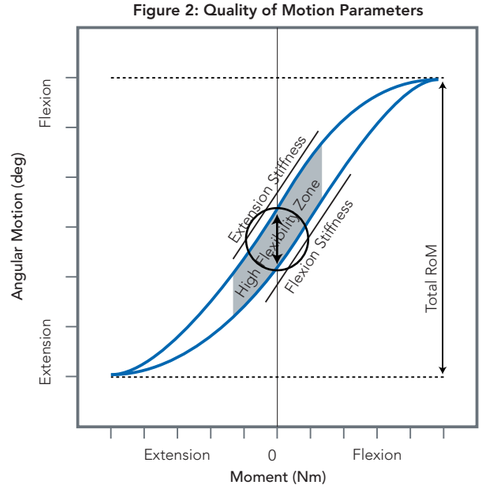


Figure 1: Schematic of a lumbar spine mounted in the biomechanical test set-up (left). A follower load is applied through the center of rotation of each segment via the Preload Cable. A moment is applied and the resulting ROM is measured with the attached sensors (right).

Figure 2: Quality of Motion Parameters



Ability to replicate the "Kinematic Signature" of a healthy motion segment
- Bending Stiffness (Nm/deg) in the High Flexibility Zone
- Neutral Zone ⟷ (Deg)

Introduction

The lumbar spine experiences compressive preloads up to 800N during activities of daily living (ADL). However, kinematics of lumbar disc prostheses under large preloads have not been reported. In our experience, disc prostheses with articulating bearings tend to "bind" under large preloads, resulting in degradation of motion quantity and quality.

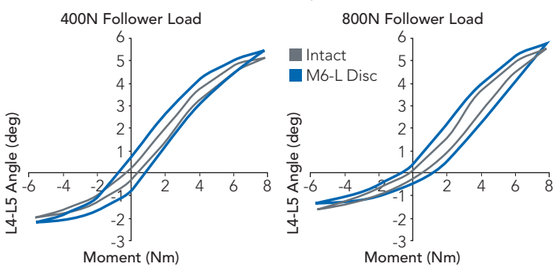
Purpose

To test the hypothesis that quantity and quality of motion of lumbar segments implanted with compressible non-articulating disc prostheses will not be significantly affected by compressive preload magnitude.

Methods

Eight human cadaveric human lumbar spines (L1-S1, 44±6.5 yr) were tested in flexion (8Nm) and extension (6Nm) under 0N, 400N and 800N compressive follower preloads (Fig. 1). Following intact tests, the PLL was resected and a disc prosthesis, composed of a compressible polymer core and fiber matrix between two metal endplates (Spinal Kinetics, Sunnyvale, CA), was implanted in the L3-L4 (n=2) or L4-L5 (n=6) disc space, centered in the frontal plane and centered on or slightly posterior to the sagittal midline. Range of motion (ROM) was calculated in all conditions. Quality of motion was assessed by calculating stiffness in flexion and extension (FE, Fig. 2), and center of rotation (COR).

Figure 3: Kinematic Signature: M6-L Lumbar Disc Flexion-Extension Load-Displacement Curves



The Load-Displacement Curves of the M6-L closely approximate intact controls.

Results

The kinematic signature of implanted segments approximated intact controls (Fig. 3). The compressible disc maintained physiologic quality of motion similar to that of the intact control at preloads up to 800N. The compressible disc was much better at maintaining the quality of motion regardless of preload as compared to an incompressible mobile core device (Fig. 4).

More than 90% of total intervertebral motion occurred within the implant under physiologic preloads; prosthesis-bone interface motion was less than 0.5 deg. The prosthesis maintained segmental FE ROM to intact levels at all preloads (p>0.05, Fig. 5). The compressible disc was much better at maintaining the quantity of motion regardless of preload as compared to an incompressible mobile core device (Fig. 6).

The flexion and extension stiffness values were not different between implanted and intact conditions at all preloads (p>0.05). The FE COR of implanted segments was 1.6±1.3mm posterior to midline and was similar to intact at each preload (p>0.05, Fig. 7).

Conclusions

The compressible disc prosthesis maintained physiologic quantity and quality of motion in FE under compressive preloads up to 800N. Maintenance of physiologic motion under preloads experienced during ADL may be one of the main benefits of compressible non-articulating disc prostheses.

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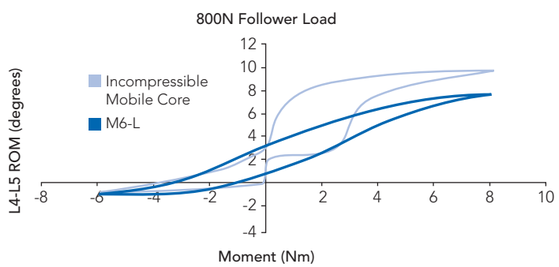
Figure 4: Effect of Preload on Motion Quality



M6-L disc maintained physiologic quality of motion under preloads up to 800N.

Figure 5: Segmental Lumbar ROM

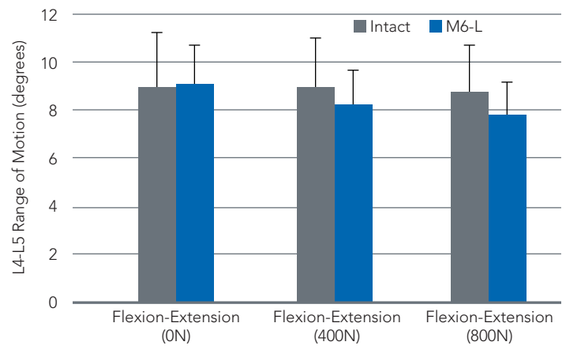
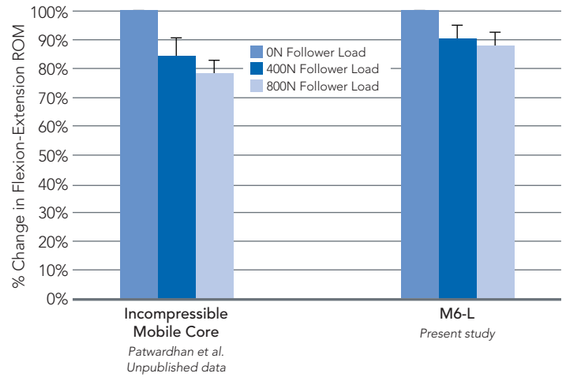


Figure 6: Effect of Preload on ROM



M6-L disc maintained physiologic ROM in flexion-extension under preloads up to 800N.

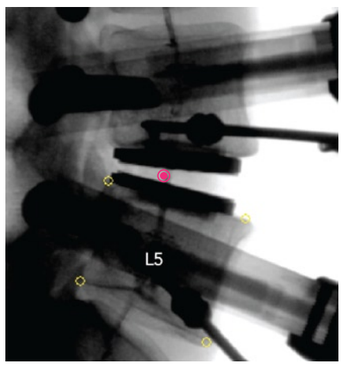


Figure 7: The FE COR of implanted segments was 1.6±1.3mm posterior to midline and was similar to intact at each preload (p>0.05).