M6-C®
artificial cervical disc

QUALITY AND QUANTITY OF MOTION OF CERVICAL SPINE AFTER TOTAL DISC REPLACEMENT (TDR) USING A NOVEL COMPRESSIBLE SIX-DEGREE-OF-FREEDOM PROSTHESIS

PUBLICATIONS

As presented at the Global Symposium on Motion Preservation Technology • 7th Annual Meeting • 1– 4 May, 2007 Berlin/Germany

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Summary

- This study compares the load-displacement response of segments implanted with this prosthesis to that of intact controls.
- The prosthesis restored quantity of motion (ROM) in flexion-extension and axial rotation to previously reported physiologic norms.
- The location of the composite COR calculated in the intact controls agreed well with the in vivo data reported in healthy subjects, validating the in vitro method used for TDR kinematics assessment.
- The pattern of load-displacement curves of implanted segments approximated intact controls.
- Overall, the data suggest that this TDR provides similar kinematics to the lower cervical spine as compared to the in-tact spine.

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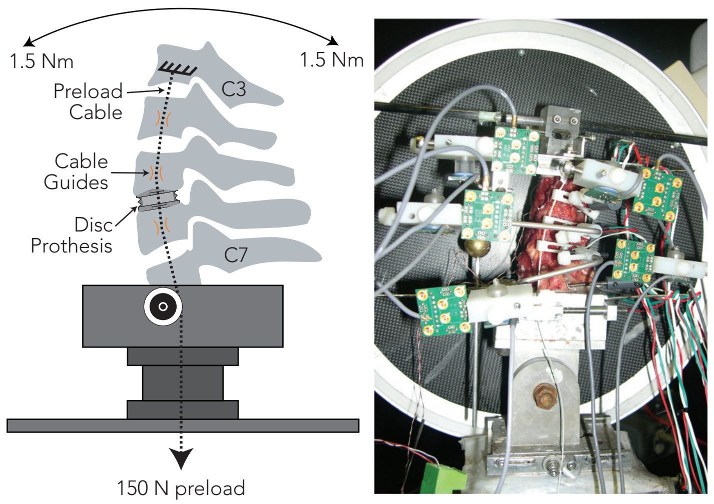
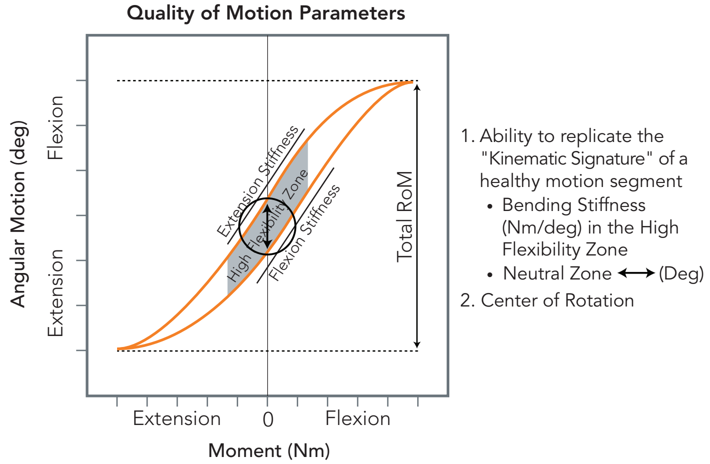
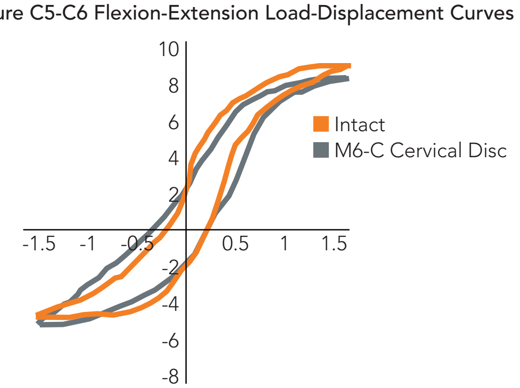


Schematic of a cervical spine mounted in the biomechanical test set-up (left). A 150N follower load is applied through the center of rotation of each segment via the Preload Cable. A moment of ± 1.5 Nm is applied and the resulting ROM is measured with the attached sensors (right).

Quality of Motion Parameters



Kinematic Signature C5-C6 Flexion-Extension Load-Displacement Curves



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

Purpose

A novel compressible six-degree-of-freedom cervical disc prothesis (Spinal Kinetics, Sunnyvale, CA) composed of fiber matrix and polymer core between two metal endplates, is designed to replicate the response of the native annulus and nucleus. We compared the load-displacement response of segments implanted with this prosthesis to that of intact controls.

Methods

Six human cervical spines (C3-C7, 51.5±5.5 years) were tested in flexion-extension, lateral bending and axial rotation (±1.5 Nm). Flexion-extension was tested under 150N follower preload. Disc prostheses were implanted at C5-C6 with the prosthesis midline 0.9±0.6 mm posterior to the segment midline. Range of motion (ROM) was calculated in all tested directions. The quality of motion was assessed in flexion-extension by calculating: (1) stiffness (slope of load-displacement curve) in the high flexibility zone in flexion and extension; and (2) center of rotation (COR) assessed using digital fluoroscopic images. Data after TDR were compared to (i) intact controls of the specimens, and (ii) "population" intact controls from our database of 36 cervical spines tested using an identical flexibility protocol.

Results

After prothesis implantation, C5-C6 flexion-extension ROM increased from 13.2±3.1 degrees to 15.1±2.5 degrees (p=0.11). Total axial rotation decreased from 9.9±2.2 degrees to 8.0±1.9 degrees (p=0.01), and total lateral bending decreased substantially from 9.0±1.6 degrees to 4.4±1.0 degrees (p<0.01).

The load-displacement curve pattern in flexion-extension after TDR was sigmoidal, and closely approximated intact controls. The flexion-extension stiffness in the high flexibility zone was not different between implanted and specimens' intact segments or population controls (p>0.30). The COR for total motion from extension to flexion was 2.7±0.7 mm posterior to the midpoint of C5 superior endplate in the implanted segment, similar to intact controls (p=0.74); but was 3.4±0.8 mm more cephalad than the intact location which was just below the endplate within C6 vertebral body (p<0.01).

Conclusions

The prosthesis restored quantity of motion (ROM) in flexion-extension and axial rotation to previously reported physiologic norms. The decrease in lateral bending motion after implantation may be a multi-factorial phenomenon. The antero-lateral annulus was preserved during implantation to minimize the loss of anterior tension band. Increased pre-tensioning of annulus fibers after prothesis insertion might have increased stiffness in lateral bending and axial rotation. Further, the uncinate processes were untouched. Previous studies suggest that uncinate process resection, apart from allowing neural decompression, may also restore lateral bending to normal values.

The location of the composite COR calculated in the intact controls agreed well with the in vivo data reported in healthy subjects, validating the in vitro method used for TDR kinematics assessment. The pattern of load-displacement curves of implanted segments approximated intact controls. COR for total extension-to-flexion motion of implanted segments was posterior to the midpoint of C5 vertebra, similar to intact controls; but was about 3 mm more cephalad. Further studies are needed to assess the long-term clinical implication of COR location on the fate of facets joints. Overall, the data suggest that this TDR provides similar kinematics to the lower cervical spine as compared to the intact spine.

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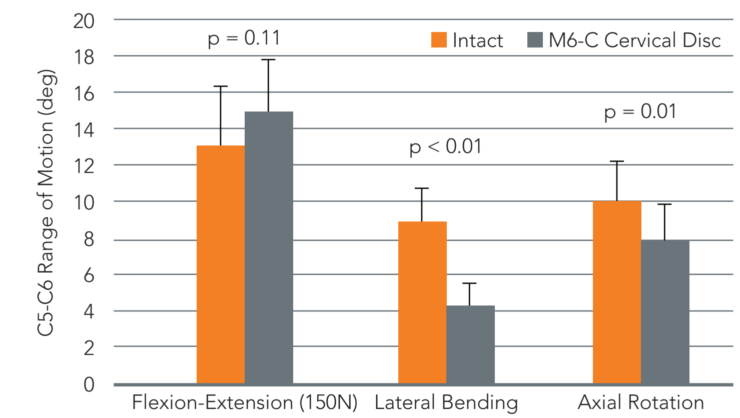
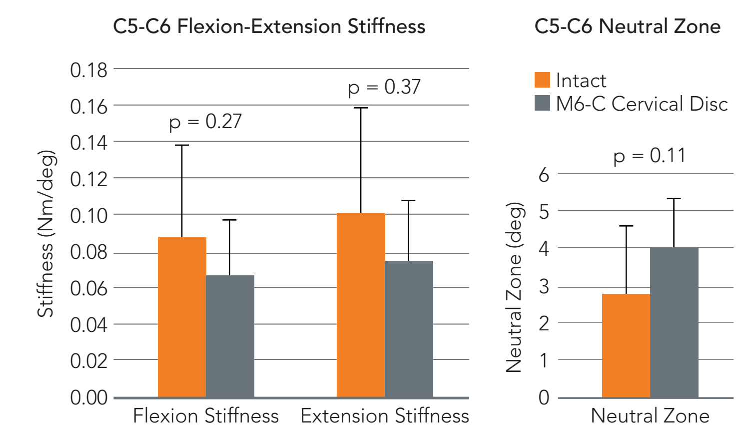
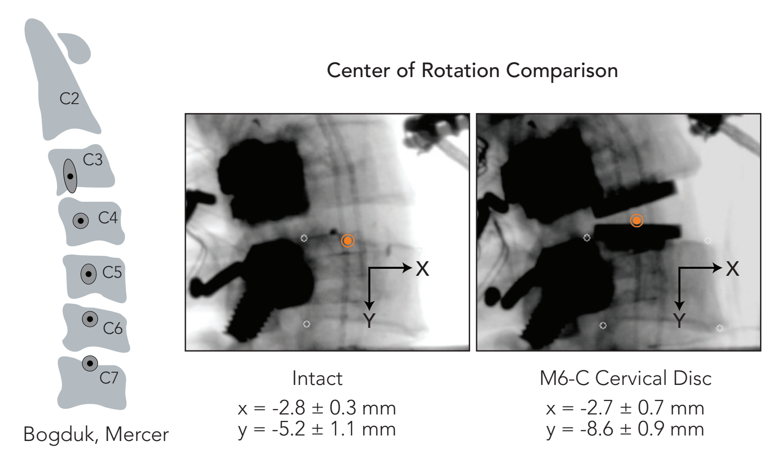
Segmental ROM at C5-C6





No difference in flexion/extension stiffness in the high flexibility zone or in the magnitude of the neutral zone between intact segments and implanted M6-C.

Center of Rotation Comparison



Bogduk, Mercer
Clin Biomech, 2000

Cervical spine center of rotation location.