Clinical: Cervical new motion preservation technologies

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Will an Advanced Generation Artificial Cervical Disc Provide Normal Post-operative Kinematics?


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Introduction: The M6-C artificial cervical disc (Spinal Kinetics, Sunnyvale, CA) is an advanced generation artificial disc intended to treat degenerative cervical radiculopathy. It is designed to replicate the anatomic structure of a natural disc by incorporating an artificial nucleus and annulus. The compressible polymer nucleus of the M6-C is designed to simulate the function of the native nucleus, while the surrounding multi-layer high tensile strength fiber annulus is intended to provide controlled range of motion. This unique design allows the M6-C device to have all 6 degrees of freedom to include angular motion in flexion-extension, lateral bending and axial rotation as well as allowing independent translations along the 3 anatomic planes (anterior-posterior, side-to-side and axial compression). The hypothesis of the study is that the novel design of the M6-C device will provide normal post-operative kinematics.

Methods: The M6-C US IDE feasibility study and the M6-C German Post-Market Registry were single-arm, prospective studies intended to evaluate the initial safety and clinical performance of the M6-C artificial cervical disc for the treatment of intractable cervical radiculopathy at one or two levels. Patients were evaluated pre- and post-operatively at predetermined intervals through 24 months. Radiographic images included AP, Lateral, Flexion-Extension and, in the US, Left-Right Bending. Validated, computer-assisted methods (QMA®: Medical Metrics, Inc., Houston, TX) were used to quantify intervertebral motion in the sagittal and coronal planes, including center-of-rotation (COR).

Results: Radiographic analysis was performed in 72 patients from nine clinical sites with a mean age of 45 years. Fifty patients were treated at one level and 22 at two levels for a total of 94 implanted levels. Intervertebral rotation from flexion to extension at the index level at 2 years (7.3 ± 5.1 deg) was not significantly different than at pre-op (9.2 ± 4.5 deg, P=0.13). There was also no significant difference between 1-level and 2-level patients (P=0.76). Intervertebral translation averaged 1.0 ± 0.7 mm at pre-op and 0.7 ± 0.6 mm at 2 years (P=0.052). Intervertebral rotation in left-right bending averaged 5.8 ± 3.9 deg at pre-op and 5.0 ± 3.8 deg at 2 years (P>0.99). In flexion-extension, the anterior-posterior position of the COR did not change significantly from pre-op (P>0.99). The cephalocaudal position of the sagittal plane COR shifted cranially by approximately 2 mm (P<0.001) but remained within or below the disc in all patients. In left-right bending, there was a trend for the COR to shift caudally between pre-op and 2 years (P=0.21), but the COR remained within or above the disc in most patients. Post-operatively, the index level COR in the sagittal and coronal planes significantly overlapped the 95% confidence intervals for asymptomatic populations.

Conclusion: Two years following implantation of the M6-C, the quantity of intervertebral motion is preserved in most patients. The M6-C also generally appears to provide for a quality of motion that is within previously established limits for asymptomatic volunteers. The ability of the implant to support a COR that is below the disc in the sagittal plane and above the disc in the coronal plane suggests that it may support a helical axis of motion consistent with true, 6 degree-of-freedom kinematics.