SPINAL KINETICS M6®-C: INITIAL CLINICAL AND RADIOGRAPHIC OUTCOMES FOR AN ADVANCED GENERATION ARTIFICIAL CERVICAL DISC

As presented at the Global Symposium on Motion Preservation Technology • 9th Annual Meeting • April 28 - May 1, 2009 London/England

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Summary

- The M6-C US IDE feasibility study is a three center, prospective, single arm study intended to evaluate the initial safety and clinical performance of the M6-C artificial cervical disc for the treatment of cervical radiculopathy secondary to cervical disc disease at one or two levels.
- The mean NDI score has decreased from 67.8% to 22.7% at 6 months and 29 patients (96.7%) had a decrease in NDI of at least 15 percentage points at the most recent follow-up visit.
- Device position has been maintained for all patients with no evidence of device migration, expulsion or subsidence.
- Initial clinical and radiographic results from a US IDE study of the M6-C artificial cervical disc indicate encouraging clinical and radiographic outcomes.

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PUBLICATIONS

Introduction

Cervical arthroplasty provides the ability to preserve motion and is an alternative to fusion for the treatment of cervical radiculopathy. The M6®-C artificial cervical disc (Spinal Kinetics, Sunnyvale, CA) is an advanced generation artificial disc developed to replace an inter-vertebral disc damaged by cervical disc degeneration. 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 progressive resistance to motion and a controlled range of motion.

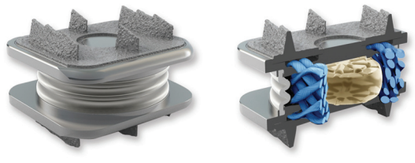


Figure 1: M6-C Artificial Cervical Disc

This unique design allows the M6-C prosthesis 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).

Methods

The M6-C US IDE feasibility study is a three center, prospective, single arm study intended to evaluate the initial safety and clinical performance of the M6-C artificial cervical disc for the treatment of cervical radiculopathy secondary to cervical disc disease at one or two levels. Patients were evaluated pre-operatively and post-operatively at 6 weeks, 3 months and 6 months and will continue to be followed annually for up to 5 years. Evaluations at each visit include routine neurological examinations, x-rays (radiographic analysis, Medical Metrics, Inc, Houston, TX), the Neck Disability Index (NDI), arm and neck pain assessments (VAS) and the SF-36v2. Adverse events were monitored to evaluate safety.

Results

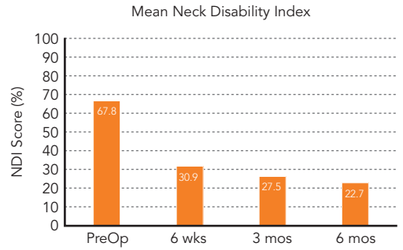
Thirty patients (11 female; 19 male) were enrolled with a mean age of 45 years (females=44 yrs; males=46yrs).

Gender	Male	19 (63.3%)
	Female	11 (36.7%)
Age	yrs.	45.1 ± 8.1
Height	in.	68.3 ± 4.1
Weight	lbs.	188.2 ± 42.4

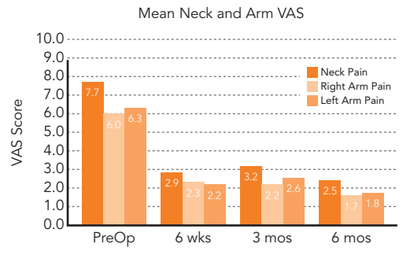
Table 1: Patient Characteristics

Eighteen (18) patients were treated at two levels and twelve (12) at one level for a total of 48 implanted discs. There were 7 implants at C4/C5, 27 at C5/C6, and 14 at C6/C7.

The mean NDI score has decreased from 67.8% to 22.7% at 6 months and 29 patients (96.7%) had a decrease in NDI of at least 15 percentage points at the most recent follow-up visit.

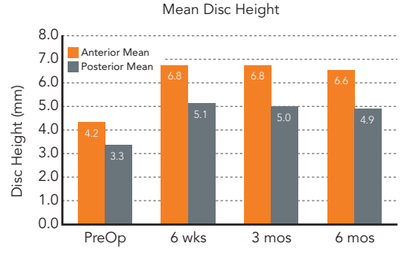


The mean neck pain VAS score has decreased from 7.7 to 2.5, the right arm pain VAS score from 6.0 to 1.7 and the left arm pain VAS score from 6.3 to 1.8.

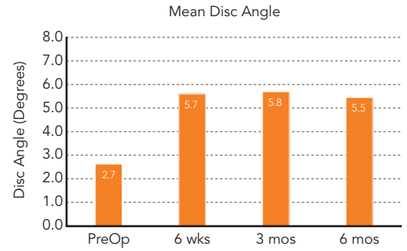


There have been no serious device related adverse events, revisions, removals or need for supplemental fixation. One (1) patient required re-operation at 1 day post-op for removal of a partially retained wound drain.

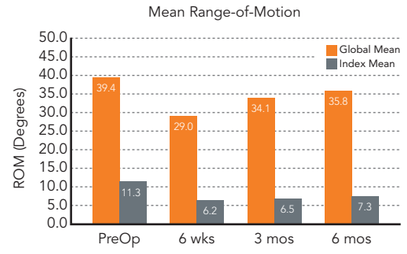
Both anterior and posterior mean disc height increased significantly post-op and have been maintained through the 6 month follow-up.



A slightly higher increase in anterior disc height has resulted in a positive increase in disc angle at the index level.



Although there was a decrease in mean index level and global ROM in the early post-op time period by 6 months there is a trend toward returning to the baseline level.



Device position has been maintained for all patients with no evidence of device migration, expulsion or subsidence.

Conclusion

Initial clinical and radiographic results from a US IDE study of the M6-C artificial cervical disc indicate encouraging clinical and radiographic outcomes. Further assessment of this cohort and additional larger studies should be performed to confirm these early results.

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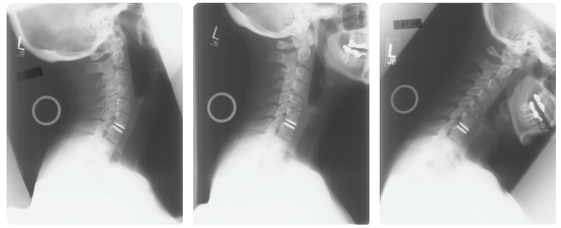
M6-C US IDE Study Case Presentations

One Level M6-C Implant: 55 y/o female presented with a history of intermittent neck and right arm pain over a period of 5 years with right arm numbness over the past 15 months. There was a loss of disc height (C6-C7: anterior=3.7mm, posterior=2.6mm) confirmed radiographically. Pre and post-op Clincial Outcomes are as follows:

Clinical Outcomes	Pre-Op	6 week F/U	3 month F/U	6 month F/U
Right arm VAS	8.4	2.1	3.6	3.0
NDI (%)	72	30	42	38

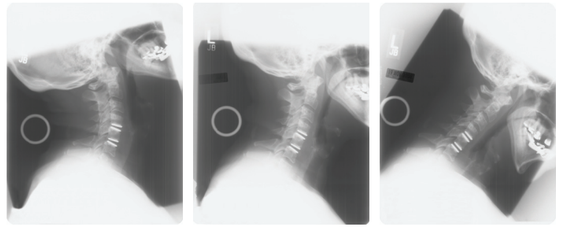


Index Level	Anterior Disc Height (mm)	Posterior Disc Height (mm)	Disc Angle (degrees)	Index Level ROM (degrees)	Global ROM (degrees)
C6-C7	6.9	4.7	8.7	8.2	
					38.6

Table 2: 6 Month Radiology Assessment

Two Level M6-C Implant: 48 y/o female presented with a 24 month history of right arm pain with intermittent numbness and loss of disc height (C4-C5: anterior=5.1mm, posterior=3.6mm; C5-C6: anterior=4.9mm, posterior=3.6mm) confirmed radiographically. Pre and post-op Clincial Outcomes are as follows:

Clinical Outcomes	Pre-Op	6 week F/U	3 month F/U	6 month F/U
Right arm VAS	7.9	3.4	3.0	4.0
NDI (%)	50	34	8	24



Index Level	Anterior Disc Height (mm)	Posterior Disc Height (mm)	Disc Angle (degrees)	Index Level ROM (degrees)	Global ROM (degrees)
C4-C5	8.3	5.1	10.7	4.3	
C5-C6	8.0	6.8	4.5	10.4	
					34.0

Table 3: 6 Month Radiology Assessment