M6-C artificial cervical disc

SUSTAINED CLINICAL IMPROVEMENT FOLLOWING CERVICAL DISC REPLACEMENT WITH A NOVEL, NEXT GENERATION ARTIFICIAL DISC: 12 MONTH PILOT RESULTS

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

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Summary

- These 12 month pilot findings suggest robust and consistent clinical improvement for all function, pain and quality of life outcomes.
- There has been sustained and durable effectiveness after implantation of this artificial disc with clinically relevant gains realized early postoperatively and maintained through 12 months of follow-up.
- This novel disc system has an excellent safety profile.

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Purpose

This single-arm, prospective feasibility trial evaluated the preliminary safety and effectiveness of a next generation artificial cervical disc (Spinal Kinetics, Sunnyvale, CA) in the treatment of patients with symptomatic cervical radiculopathy. This novel disc system replicates the anatomic, physiologic and biomechanical characteristics of the native disc by incorporating a compressible nucleus within a woven fiber annulus. These unique properties allow for natural kinematics including axial compression, translation independent of rotation, and progressive resistance to motion resulting from a physiologically restrained construct. Thus, the quality of motion closely mimics that of the native intervertebral cervical disc.

Methods

Thirty two patients (18 1-level, 14 2-level) have undergone standard decompressive discectomy and artificial disc implantation for persistent neurological symptoms associated with cervical radiculopathy, nonresponsive to at least 6 weeks of conservative management. Patient reported outcomes were measured prior to surgery as well as at 6 weeks, 3, 6 and 12 months. Condition-specific functional impairment was evaluated with the Neck Disability Index (NDI). Arm and neck pain severity was evaluated with a standard 10-point visual analog scale (VAS). Health-related quality of life was evaluated with the SF-36 Health Survey. Intervertebral range of motion (ROM) and disc height were determined independently from anteroposterior and lateral radiographs using proprietary, quantitative imaging software. Outcomes for the initial 15 patients with 12 months follow-up are provided.

Characteristics	Value (n=15)
Age, *mean ± SD, y*	41.2 ± 10.6
Female, *n (%)*	13 (86.7)
Duration of Non-operative Treatment, *mean ± SD, mo*	23.2 ± 16.6
Primary Diagnosis, *n (%)*	
Disc Herniation with Radiculopathy	15 (100.0)
Affected Level, *n (%)*	(n=20)
C3-C4	1 (5.0)
C4-C5	6 (30.0)
C5-C6	9 (45.0)
C6-C7	4 (20.0)
Previous Treatment(s), *n (%)*	
Cervical Traction	2 (13.3)
Bed Rest/Immobilization	2 (13.3)
Use of NSAIDS	15 (100.0)
Cervical Collar	6 (40.0)
Physical Therapy	12 (80.0)
Chiropractic Care	5 (33.3)
Acupuncture	2 (13.3)
Smokers, *n (%)*	6 (40.0)

Results

Thirteen (13) females and two (2) males with a mean age of 41.2 years are included in this analysis. All patients presented with cervical radiculopathy and were un-responsive to at least 6 weeks of non-operative treatment. Significant improvement was seen at 12 months for all clinical outcomes measured. The NDI score improved from 48.1% to 20.4% ($p<0.0001$) at 12 months. The arm pain VAS score decreased significantly with a mean change from 6.8 to 3.3 at 12 months ($p<0.0001$) and there was also a significant improvement in neck pain at 12 months with a change from 7.2 to 3.5 ($p=0.0014$). There have also been significant improvements in both the Physical Component Summary (PCS) and Mental Component Summary (MCS) scores of the SF-36.

Post-operative mean disc height has remained constant throughout follow-up and is 5.8mm at 12 months compared to 3.4mm at baseline. Global ROM has steadily improved to the baseline level at 12 months (47.3° to 47.7°) and the index level ROM has returned to near pre-operative motion levels. Device position has been maintained for all patients.

There have been no device-related adverse events, re-operations, revisions, removals supplemental fixation or evidence of device migration, expulsion or subsidence in this patient group.

Conclusions

These 12 month pilot findings suggest robust and consistent clinical improvement for all function, pain and quality of life outcomes. There has been sustained and durable effectiveness after implantation of this artificial disc with clinically relevant gains realized early postoperatively and maintained through 12 months of follow-up. This novel disc system has an excellent safety profile.

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