M6 Artificial Cervical Disc: Results from Two IDE Investigation Centers for One Level Cervical Arthroplasty at 2 Years.

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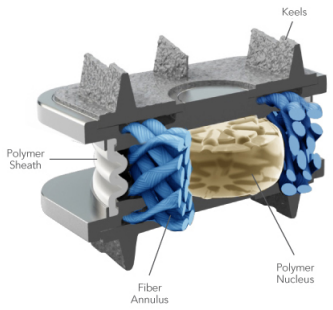
Introduction

A next generation cervical disc replacement which mimics the natural disc structure and its biomechanical qualities is being evaluated in a FDA IDE clinical trial. Unlike ball-and-socket cervical discs, this next generation cervical disc allows the motion inherent in a natural disc including axial compression, flexion-extension, lateral bending, translation, and axial rotation.

M6-C Artificial Cervical Disc Cutaway



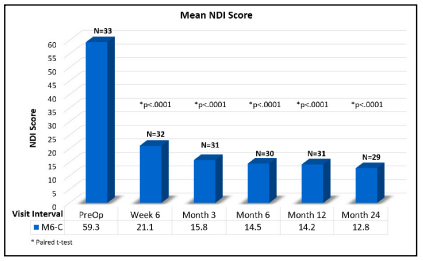
M6-C Artificial Cervical Disc Cutaway

Methods

The two centers participated in a prospective, multi-center, FDA IDE study of subjects with cervical radiculopathy who had not improved with conservative care of at least six-weeks. Skeletally mature subjects were implanted with the cervical disc at one-level from C3 - C7. Subjects were required to have preoperative neck or arm pain Visual Analogue Scales (VAS) = 4, Neck Disability Index (NDI) =30% and other entry requirements similar to prior cervical disc FDA IDE studies.

Patient Characteristics

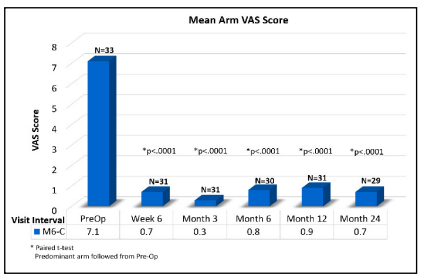
Characteristic		M6-C
	N →	33
Gender (N, %)	Male	19 (51.3%)
	Female	14 (48.8%)
Age	Years	44
Implanted Level	C5/C6	91%
Surgical Duration	Minutes	78
Hospital Stay	Days	1



VAS neck pain was reduced from 7.2 preoperative to 1.5 ($p<0.0001$) at two-years, and mean predominant preoperative arm VAS pain was 7.1 versus 0.7 ($p<0.0001$) at two-years.

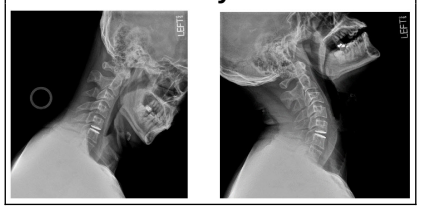
Results

Thirty-three subjects were implanted. The mean age was 44 years, and 19 were males. Ninety-one percent were implanted in the C5 to C7 levels. Mean surgical time was 78 minutes, and mean hospital stay was one day. Mean preoperative NDI was 59 which decreased to 12.8 ($p<0.0001$) at two-years.



There have been no discs revised or removed. Two subjects experienced minimal caudal subsidence by two-years and maintained good clinical outcomes. One subject had a mild radiolucency at two-years. No migrations were reported. Mean index level ROM was 9.3 degrees preoperative versus 6.8 degrees at two-years, and mean index level disc angle improved from 3.6 preoperative to 9.5 degrees at two-years. Mean disc height increased at two-years to 5.7 mm vs 3.2 mm preoperative.

Two Year Flexion and Extension X-Rays of the M6-C



Conclusions

The M6-C is currently being investigated in an FDA approved IDE study in the US. The early experience of two investigational centers suggests that the device performs as intended from both clinically and radiographically for treatment of symptomatic cervical radiculopathy.

Learning Objectives

The objective of this study was to determine the safety and effectiveness outcomes of a cervical M6-C next generation arthroplasty at 2 years follow up.