Seven-Year Outcomes for Single-Level Total Disc Replacement with a Novel Viscoelastic Artificial Cervical Disc

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INTRODUCTION:

The M6-C Artificial Cervical Disc, with a compressible viscoelastic nuclear core and an annular structure, is substantially different from first generation articulating surface designs.

METHODS:

A prospective, multicenter, controlled, IDE clinical trial is currently in long-term follow up. Twelve M6-C sites are participating in the study, with preoperative assessments followed by 6 weeks, 3 months, 6 months, 1 year, and annually out to 10 years post-implantation. In total, 160 M6-C subjects were enrolled. Study subjects presented with one-level symptomatic degenerative cervical radiculopathy.

RESULTS:

NDI and Pain Scores are available for 93 M6-C subjects at 7 years postoperative. M6-C subjects had a mean Neck Disability Index Scores (NDI) score of 9.3 on a 100-point scale, indicating mild disability. M6-C subjects experienced a mean NDI improvement from baseline of 46.5 points at 7-years. Similarly, M6-C subjects had a mean Neck Pain VAS Score of 0.8 (out of 10) and a mean Shoulder/Arm Pain VAS Score (worst side) of 0.5.

Through 7 years postop, 11 of the 160 enrolled M6-C subjects (6.9%) experienced Supplemental Surgical Interventions (SSI) at the index level. These included 9 Removals, 1 Reoperation, and 1 Supplemental Fixation. Five of the removals were associated with osteolysis, with confirmed or suspected infection reported for all 5 subjects. The mean timeframe for removal for osteolysis was 73 months postop (range 54-86 months.) The mean timeframe for SSI for other causes was 35 months (range 1-77 months.)

DISCUSSION AND CONCLUSION:

The reduction in disability and pain associated with M6-C in earlier follow-up periods are maintained at 7-years postop. Seven-year SSI rates are comparable to other commercially-available artificial discs. The safety and performance of M6-C in this cohort will continue to be monitored out to 10-years postop.