37 - 5-year Outcomes for Single-Level Total Disc Replacement with a Novel Viscoelastic Artificial Cervical Disc Compared to Anterior Cervical Discectomy and Fusion (ACDF)

Friday, June 3, 2022 11:28 AM – 11:32 AM ET Location: Poseidon III & IV

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Abstract: Background Context:
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 and has previously demonstrated favorable clinical outcomes out to 4-years post-implantation.

Purpose:
To evaluate 5-year safety and effectiveness of the M6-C artificial cervical disc compared with ACDF.

Study Design/Setting:
A prospective, multicenter, controlled, IDE clinical trial is ongoing. 12 M6-C sites and 11 ACDF sites are participating in the study, with pre-operative assessments followed by assessments at 6 weeks, 3 months, 6 months, 1 year, and annually out to 10 years post-implantation. 160 M6-C and 189 ACDF subjects were enrolled.

Patient Sample:
Study subjects presented with one-level symptomatic degenerative cervical radiculopathy, and received either M6-C or ACDF at a single level.

Methods:
The M6-C and ACDF cohorts were propensity matched. Follow-up assessments are planned out to 10-years post-op.

Results:
Neck Disability Index Scores are available for 106 M6-C and 93 ACDF subjects at 5 years. At 5 years post-op, M6-C subjects had a mean NDI score of 8.0 - significantly better than the mean of 18.0 observed in the ACDF group. M6-C subjects experienced a mean NDI improvement from baseline of 47.5 points at 5-years, compared to 33.4 for the ACDF cohort, significantly better for the M6-C group. At 5 years post-op, a statistically higher percentage of M6-C subjects experienced a 15-point improvement from baseline (98.1%) compared to the ACDF cohort (84.9%.)

Neck Pain and Shoulder/Arm Pain VAS Scores are available for analysis for 105 M6-C and 93 ACDF subjects at 5 years. At 5 years post-op, M6-C subjects had a mean Neck Pain VAS Score of 0.6, which was significantly better than the mean of 1.9 observed in the ACDF control group. M6-C subjects experienced a mean improvement from baseline of 6.5 points at 5-years post-op, compared to 5.1 for the ACDF cohort, significantly better for the M6-C group. Similarly significant results were observed in Shoulder/Arm Pain VAS Scores (worst side) at 5-years, with a mean of 0.5 for M6-C and 2.1 for ACDF, and a mean improvement from baseline of 6.8 for M6-C and 5.2 for ACDF.

Through 5 years post-op, 5 M6-C subjects experienced Supplemental Surgical Interventions (SSI) at the index level. These included 3 Removals, 1 Reoperation, and 1 Supplemental Fixation. Of the removals, 2 were performed due to persistent neck and arm pain (with 1 being

replaced by a new M6-C,) and 1 was performed due to osteolysis associated with a confirmed infection. 11 ACDF subjects underwent SSIs through 5 years post-op.

Conclusions:
The significant benefits in NDI and Neck Pain and Shoulder/Arm Pain VAS Scores associated with M6-C in earlier follow-up periods, compared to ACDF controls, appear to be maintained at 5-years post-op. SSI were lower in the M6-C group. When the M6-C was used at a single level, revisions for sterile osteolysis were not observed at 5-years post-op. The safety and performance of M6-C in this cohort will continue to be monitored out to 10-years post-op.