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One-year clinical and radiographic outcomes for a next-generation, tri-lobed, polycrystalline diamond cervical artificial disc

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ONE-YEAR CLINICAL AND RADIOGRAPHIC OUTCOMES FOR A NEXT-GENERATION, TRI-LOBED, POLYCRYSTALLINE DIAMOND CERVICAL ARTIFICIAL DISC

Background: A next-generation Cervical Artificial Disc is being studied. The disc, manufactured from polycrystalline diamond, is designed for unrivaled wear resistance. Due to its two-piece, tri-lobe design, it closely mimics natural spinal motion while enhancing stability.

Research Question: What are the clinical, biomechanical, and radiographic outcomes of this next-generation cervical disc?

Design: The following is an interim analysis of a one-year post-market clinical follow-up (PMCF) study. It employs a prospective, single-arm, multi-center design, targeting patients requiring one- or two-level cervical spine reconstruction due to intractable symptomatic cervical disc disease (SCDD).

Methods: Data collected at multiple intervals up to 12 months assessed various metrics, including Neck Disability Index (NDI) and Visual Analogue Scale (VAS) for neck and arm pain. The study has enrolled 118 of 150 subjects, with 77 subjects having six-month follow-up and 38 with 12-month evaluations.

Results: At 12 months, 92.1% of patients exceeded the minimal clinically important difference (MCID) for NDI (improvement of ≥15 points). Mean NDI scores were reduced from 59.4 at baseline to 9.1 at 12 months. Significant reductions from baseline in VAS neck and arm pain scores were reported at 12 months (7.3 to 1.9 and 7.2 to 0.9, respectively). One-level vs. two-level treatments revealed no statistically significant differences in outcomes.

Radiographic analyses demonstrated maintained angular motion in 96.3% of treated segments (mean = 5.9°). Sagittal alignment improved from 2.8° of kyphosis at pre-op to 1.4° of lordosis at 12 months. The index level center of rotation closely approximated physiological norms, supporting natural biomechanical motion and alignment.

Discussion: Preliminary findings suggest that this unique disc significantly improves pain, functionality, and spinal biomechanics up to 12 months postoperatively, with minimal potential for wear debris-related issues.