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CerviCore® vs. Fusion: Two Year Clinical Results and Pain Medication Usage at Five IDE Study Sites

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Introduction: Anterior cervical discectomy and fusion (ACDF) is a common procedure for radiculopathy. This study compares the CerviCore® Intervertebral Disc to ACDF, for single-level treatment of cervical radicular symptoms, C3-C7, and presents some of the data supporting the concept of cervical spinal arthroplasty from five IDE study sites.

Methods: Functionality was assessed with NDI and neck pain was measured using VAS. At our 5 clinical sites, data is available for: 44 CerviCore® patients and 43 ACDF patients at baseline and 21 CerviCore® and 21 ACDF patients at 2 years. Pain medication usage was recorded at all follow-up visits. A signed rank test and a Kruskal-Wallis test were used to test for statistical differences.

Results: Within each treatment group, the mean NDI and Neck VAS results were significantly different from pre-op at all visits up to 2 years (p< .0001). Differences between groups were not significant. (CerviCore® vs. fusion): The mean NDI scores decreased by 41.7 points in the CerviCore® group as compared to a 33.4 point decrease in ACDF patients; (p=0.1772 between treatments). The mean VAS scores decreased by 58.3 points in the CerviCore® group as compared to a 46 point decrease in ACDF patients; (p=0.0894 between treatments). The percentage of patients using pain medication dropped by 46% in CerviCore® patients (p=0.002) as compared to 40.8% in the fusion group (p=0.012).

Conclusions: Although not statistically significant, CerviCore® clinical results, both NDI and neck VAS, showed greater improvement as compared to ACDF. Pain medication usage had a greater reduction in CerviCore® patients. These preliminary results suggest that the CerviCore® Intervertebral Disc may be an alternative treatment for radiculopathy. Full study data is needed to confirm the findings of this small sample size.