What Specific Questions are Responsible in Driving NDI Superiority of Two-level Anterior Disc Replacement Over Two-level Fusion. Post Hoc Item Analysis of Self-reported Outcomes of Two-level Cervical Disc Arthroplasty (CDA, Mobi-C®) vs. Two-level ACDF Treated Patients From The IDE US-RCT.

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Disclosures:

Introduction: Investigational Device Exemption (IDE) trial of two-levels treated with Cervical Disc Arthroplasty (CDA) vs. Anterior Cervical Discectomy Fusion (ACDF) demonstrated statistical superiority of 'Overall Success' in 66.0% of CDA treated patients compared to 36% ACDF treated patients at 48 months. The neck disability index (NDI) total score was the most significant component in determining patient-based overall success. The purpose of this study was to determine what specific NDI questions or clusters of questions distinguished CDA vs. ACDF improvement. Also do these questions reflect a valid clinical difference in patients who received two level arthroplasty vs. fusion. The study design was a post-hoc item analysis of a comparison of differences in self-reported NDI questionnaire items for patients treated at two-levels with CDA vs. ACDF. The original study was a prospective, randomized 2:1 CDA vs. ACDF, multi-center, US-FDA IDE RCT at 24 sites. Selfreported outcome measures were NDI, VAS neck pain and VAS arm pain.

Methods: There were 330 patients with DDD treated at two contiguous levels, 225 CDA (Mobi-C®) patients (investigational) vs. 105 ACDF patients (control). Clinical evaluations and self-reported outcome measures were collected pre-operatively and postoperatively at 6 weeks, 3, 6, 12, 18, 24, 36, and 48 months. The post hoc NDI item analysis included prospectively collected data from pre-operative (0 months), 24, and 48 month follow-up visits. A patient-based difference score was calculated for each NDI item (pre-operative value subtracted from follow-up value). Averages were calculated by treatment group and ranked. Improvements as NDI item difference scores were evaluated as a function of treatment (ANOVA,GLM-SAS). Patterns of change were assessed with Mantel-Haenszel Chi-Square.

Results: Separate analysis of the 10 NDI items revealed significantly more improvement (less disability) at 48 months compared to pre-op for CDA treated patients compared to ACDF treated patients in Recreation (-2.39 vs -1.96, p< 0.04), Lifting (-1.93 vs -1.39, p< 0.02), Reading (-1.80 vs -1.40, p< 0.02), Headaches (-1.43 vs -0.86, p< 0.01), Work (-1.95 vs -1.44, p< 0.01). The least amount of improvement was reported for Personal Care (-1.24 vs -0.86, p< 0.01). Ranking separately by treatment, the NDI items with the greatest average improvement were Recreation (-2.39), Pain (-2.27) and Sleeping (-2.04) for CDA patients and Pain (-2.04), Recreation (-1.95), and Sleeping (-1.68) for the ACDF treated patients.

Discussion: This post hoc analysis identified Recreation and other potentially important NDI items associated with the greatest improvements for CDA versus ACDF treated patients. Overall, the CDA treated patients reported greater improvement than ACDF patients statistically significantly on Recreation, Lifting, Reading, Headaches, Work and Personal Care. The effect of fusion of two levels seems to have the most impact in these activities. These differences were not apparent in the concurrent one level CDA vs. ACDF trial.

Significance: The Mobi-C IDE trial was multi-centered, prospective, and controlled. The NDI was used to assess the effect of pain on daily life. Of the ten items assessed, the NDI item analysis at 48 months revealed greater improvement in Recreation, Lifting, Reading, Headaches, Work and Personal care in the CDA group.

Acknowledgments: Mobi-C IDE trial


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