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5-year Results of the Prospective, Randomized, Multicenter Food and Drug Administration Investigational Device Exemption ProDisc®-C Clinical Trial

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Purpose: Cervical total disc replacement (TDR) is intended to address pain and preserve motion between vertebral bodies in patients with symptomatic cervical disc disease (SCDD). TDR may prevent subsequent accelerated degeneration at adjacent disc levels. Previously, the 2-year follow-up results from the investigational device exemption (IDE) clinical trial of the ProDisc®-C (Synthes USA Products, LLC, West Chester, PA) cervical total disc replacement (TDR) were reported.¹ Up until now, follow-up results of the ProDisc®-C study were only available to this 2 year time point, with longer term results not known. With continued follow-up of the same patient population as in the reporting of the 2-year results, the purpose of this study was to evaluate safety and efficacy of ProDisc®-C TDR compared to anterior cervical discectomy and fusion (ACDF) surgery for treatment of 1-level SCDD between C3 and C7 at 5 years.

Methods: A prospective, randomized, multicenter, Food and Drug Administration (FDA)-regulated IDE clinical trial was conducted at 13 sites, utilizing a 1:1 randomization ratio. A total of 236 patients (103 ProDisc®-C; 106 ACDF) were treated. Patients were evaluated pre-operatively, and post-operatively at 6 weeks, 3, 6, 12, 18, 24, 36, 48, and 60 months. Assessments included Neck Disability Index (NDI), Visual Analog Scales (VAS) for pain and satisfaction, SF-36, physical and neurological exam, and radiographic evaluation.

Results: Demographics were similar between the two groups (ProDisc®-C: 42.1 ± 8.4 years, 44.7% males; ACDF: 43.5 ± 7.2 years, 46.2% males). The most commonly treated level was C5-C6 (ProDisc®-C: 56.3%; ACDF: 57.5%). Baseline NDI values were not different between treatment groups (p=0.3551); NDI scores significantly decreased for both groups at 6 weeks follow-up (p < 0.0001) and maintained improvement out to 60 months. VAS pain assessment showed significant improvement from pre-operative levels regardless of treatment (p< 0.0001). SF-36 scores improved out to 60 months for both groups. NDI, VAS and SF-36 scores of ProDisc®-C patients showed greater improvement out to 60 months than those of ACDF patients, though not significantly. Out to 60 months, a greater difference in VAS satisfaction improvement in ProDisc®-C compared to ACDF patients was seen. At 24 months, 84.4% of ProDisc®-C patients achieved ≥4 degrees of motion or maintained functional motion (relative to baseline) at the operated level, remaining consistent to 60 months. Within 60 months, the number of secondary surgeries differed significantly; 0.2% of ProDisc®-C compared to 8.8% of ACDF patients (p = 0.006) needed a re-operation, revision, or supplemental fixation.

Conclusions: Data shows that significant clinical improvement was maintained in ProDisc®-C patients out to 5 years with no deterioration of outcomes from 2-year results. Specifically, ProDisc®-C patients were significantly less likely to require further surgical treatment than ACDF patients. These findings support earlier reports that ProDisc®-C TDR is a safe, effective treatment in patients who meet the study criteria.

Reference: 1. Murrey D, Janssen M, Delamarter R, Goldstein J, Zigler J, Tay B, Darden B: Results of the prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc®-C total disc replacement versus anterior discectomy and fusion for the treatment of 1-level symptomatic cervical disc disease. *Spine J.* 2009;9:275-286.