Abstract: 90
5-year Results of the Prospective, Randomized, Multicenter Food and Drug Administration Investigational Device Exemption Study of the ProDisc®-L Total Disc Replacement versus Circumferential Fusion for the Treatment of 2-level Degenerative Disc Disease

1The Spine Institute at St John’s Health Center, Santa Monica, CA, USA, 2Texas Back Institute, Plano, TX, USA, 3Pennsylvania Hospital, Philadelphia, PA, USA, 4NYU/Hospital for Joint Diseases, New York, NY, USA, 5CORE Orthopaedic Medical Center, Encinitas, CA, USA, 6St Mary's Spine Center, San Francisco, CA, USA, 7Yale University, New Haven, CT, USA, 8Haider Spine Center Medical Clinic, Inc, Riverside, CA, USA, 9Orthopedic Spine Associates, LLC, Eugene, OR, USA, 10Hospital for Special Surgery, New York, NY, USA, 11Texas Spine and Joint Institute, Tyler, TX, USA, 12Michigan Brain & Spine Institute PC, Ypsilanti, MI, USA, 13Watkins Spine Group, Marina Del Ray, CA, USA, 14SUNY Syracuse, Syracuse, NY, USA, 15Twin Cities Orthopedics, Edina, MN, USA, 16William Beaumont Hospital, Royal Oak, MI, USA

Purpose: Previously, the results from the investigational device exemption (IDE) clinical trial of the ProDisc®-L (Synthes USA Products, LLC, West Chester, PA) lumbar total disc replacement (TDR) were only available to the 2-year time point, with longer term outcomes not known. With continued follow-up of the same patient population as in the reporting of the 24 month results, the purpose of this study was to evaluate the safety and effectiveness of the ProDisc®-L TDR compared to circumferential spinal fusion for the treatment of discogenic pain at two vertebral levels between L3-S1 at 5 years.

Methods: A prospective, randomized, multicenter, clinical trial was conducted at 16 sites. A total of 237 patients were treated on protocol, randomized in a 2:1 ratio (ProDisc®-L: Fusion). Patients were assessed pre-operatively and post-operatively, at 6 weeks, 3, 6, 12, 18, 24, 36, 48, and 60 months. Each visit included patient self-assessments, physical and neurological examinations, and radiographic evaluations.

Results: Overall patient demographics showed no statistically significant differences between treatment groups. The most commonly treated levels were L4-S1 (ProDisc®-L: 90.9%; Fusion: 88.9%). Intra-operative data showed the ProDisc®-L group was significantly lower statistically and clinically relevant, with regard to intra-operative time and estimated blood loss (p < 0.0001, p = 0.0013, respectively). Baseline pre-operative ODI values were not different (ProDisc®-L: 64.7 ± 11.4; Fusion: 64.8 ± 9.54; p = 0.8261). Patients in both groups improved significantly at 6 weeks follow-up (p < 0.0001) and maintained improvement out to 60 months. At 24 months, the mean score of the ProDisc®-L group was 30.0 ± 24.5 points for an average improvement from baseline of 34.4 points (53.6%); the mean score of the Fusion group was 39.1 ± 24.0, for an average improvement from baseline of 27.0 points (39.7%). Average improvement continued out to 60 months (ProDisc®-L: 56.7%; Fusion: 43.2%), trending toward significance in the ProDisc®-L group compared to the Fusion group (p = 0.05732). The VAS pain assessment showed statistically significant improvement from pre-operative levels regardless of treatment (p< 0.0001). VAS pain showed a greater improvement, although not significant, in ProDisc®-L patients at 24 months (ProDisc®-L: 31.9mm; Fusion: 38.4mm). At 60 months, ProDisc®-L patients continued to improve, whereas Fusion patients declined slightly (ProDisc®-L: 29mm; Fusion: 39.8mm). There was a statistically significant difference at 24 months in VAS satisfaction score improvement favoring the ProDisc®-L group (p=0.0126), as well as at the 60-month time point (0.0391). At 60 months, 93.0% of ProDisc®-L patients compared to 89.2% of Fusion patients reported that they would have this surgery again.

Conclusions: This is the first reported 5-year study following 2-level TDR patients. The data shows that significant clinical improvement was achieved and maintained in the ProDisc®-L patients out to 60 months; in properly chosen patients, ProDisc®-L has been shown to be superior to circumferential fusion at two levels by multiple clinical outcomes. These results support earlier reports that ProDisc®-L TDR is a safe and effective surgical treatment of discogenic pain at two vertebral levels in patients who meet the study criteria.