

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**

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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.