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Results from the Prospective, Randomized, Multicenter IDE Study of 2-level ProDisc®-L: Randomized Patients versus Continued Access Patients at 2 Years

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Purpose: The ProDisc®-L total disc replacement (TDR) was approved for market in the US in 2006 by the Food and Drug Administration for treatment of 1-level degenerative disc disease (DDD). Additionally, a cohort of the prospective, randomized, multicenter IDE trial comparing ProDisc®-L to fusion at 2 vertebral levels was conducted. Results from both of these cohorts have been previously reported. The purpose of this report was to present data on 302 ProDisc®-L TDR cases at 2 contiguous vertebral levels as part of the 2-level cohort, as either randomized (R) or continued access (CA) patients. Demographic, intra-operative, and 24 month outcome data was collected and compared between the two groups.

Methods: A total of 165 patients were randomized to ProDisc®-L at 16 sites. After enrollment of the randomized portion of the IDE trial was completed, 259 patients that met the original study criteria received the ProDisc®-L as a "continued access" series. Inclusion/exclusion criteria included 2-level DDD that was non-responsive to conservative care for at least 6 months, and an Oswestry Disability Index (ODI) score > 20/50 (40%). Patients were assessed pre-operatively, and post-operatively at 6 weeks, 3, 6, 12, 18, and 24 months. Clinical outcome data included ODI, Visual Analog Scale (VAS) pain, VAS satisfaction, and SF-36 self-assessments, and reoperations.

Results: The two groups were similar in age, gender and body mass index (R: 41.8±7.7 years, 57.6% males, 27±4.5 BMI; CA: 40.5±7.4 years, 60.2% males, 26.3±4 BMI). Intra-operative time (R: 160.2±73.3 min; CA: 162.3±69.4 min) and blood loss (R: 398.1±451.5cc; CA: 390.1±473.6cc) were similar in both groups. The most commonly treated levels were L4-S1 (R: 90.3%; CA: 88.8%). Baseline ODI scores were statistically similar between the two groups (R: 64.7±11.4; CA 63.2±10; p = 0.1865). ODI, VAS pain, and SF-36 were significantly lower at all follow-up time points compared to baseline (p < 0.0001). ODI scores showed no difference in the amount of improvement at 24 months between groups (R: 34.4%; CA: 34.8%; p=0.8898). At 24 months, both groups also exhibited similar improvements in VAS pain scores from baseline (R: 43.3%; CA: 43.2%; p = 0.7758). At 24 months, VAS satisfaction scores were similar between the two groups (R: 77.7; CA: 78.7; p = 0.549). Reoperations occurred in 4 (2.4%) patients in the randomized group and 16 (6.2%) patients in the continued access group.

Conclusions: There have been limited controlled studies demonstrating multi-level use of TDRs in the lumbar spine. This large patient study demonstrates that "continued access" patients of the 2-level ProDisc®-L TDR IDE had results comparable to the randomized group; both groups achieved significant improvements in all clinical outcomes at the 24-month follow-up.