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ProDisc®-L Total Disc Replacement over Time: Five-to-eight Year Follow-up

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Introduction: Lumbar total disc replacement (TDR) is an alternative to spinal fusion surgery for the treatment of degenerative disc disease (DDD) between L3-S1. It is intended to address discogenic pain and has the potential benefit of preserving functional motion in vertebral bodies; TDR may thus reduce long-term subsequent degeneration at adjacent disc levels, although continuing study results are needed to quantify this statement. The purpose of this study was to evaluate the five-to-eight year clinical results of the ProDisc®-L (Synthes GmbH) TDR.

Methods: From 2000-2004, a prospective, controlled, consecutive case series of 506 patients who received lumbar arthroplasty with the ProDisc®-L TDR was conducted. Patients were assessed pre-operatively and post-operatively at 3, 6, 12, 24 months, and yearly thereafter. Evaluations included Oswestry Disability Index (ODI), Visual Analog Scales (VAS) for pain and satisfaction, and SF-36 patient self-assessments, physical and neurological exams, and radiographic evaluation.

Results: The average age of patients was 45.8 years old; 51.2% were men and 48.8% women. Out of the 506 patients, 352 underwent single-level; 109 two-level; 40 three-level; 1 four-level; and 1 five-level surgery. The most frequently treated single-level was L5-S1 (64.2%). Of multi-level cases, two levels were most common (21.5%), with L5-S1 being the most frequent (68.5%). The baseline mean ODI score of 48.7 points improved significantly at 3 months (30 points; $p < 0.001$) and maintained this improvement at all follow-up time points. At 3 months, the average VAS pain intensity score showed significant improvement from baseline and maintained similar improvement out to 8 years (baseline: 7.6mm; 3 months: 2.3mm; $p < 0.01$). SF-36 scores indicated improvement in the physical (PCS) component at 12 months and remained similar at all subsequent follow-up points (baseline: 31.6; 12 months; 38.4; $p < 0.01$); the mental (MCS) component stayed consistent at all time points. Radiographic evaluation demonstrated that functional range of motion was preserved at all levels out to 8 years.

Conclusions: This longer term investigation shows clinical outcomes of the ProDisc®-L TDR past the 5-year follow-up point are maintained and provide significant improvement for patients. These results support earlier reports that ProDisc®-L is a safe and effective surgical treatment of discogenic pain in patients who meet the study criteria.