ProDisc®-L Total Disc Replacement over Time: Five-to-Nine 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 L2-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-nine year clinical results of the ProDisc®-L (Synthes Gmbh) TDR.

Methods: From 2000-2006, a prospective, controlled, consecutive case series of 602 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 46.7 years old; 52% were men and 48% women. Out of the 602 patients, 399 underwent single-level; 142 two-level; 57 three-level; 2 four-level; and 1 five-level surgery. The most frequently treated single-level was L5-S1 (62.6%). Of multi-level cases, two levels were most common (70.3%), with L4-S1 being the most frequent (69%) as in three levels the L3-S1 (73.6%). The baseline mean ODI score of 48.6 % ± 15.2 improved significantly at 3 months (30.8 % ± 19.5) and maintained this improvement at all follow-up time points (29.2% - 33.5%). At 3 months, the average VAS pain intensity score showed significant improvement from baseline (7.5 mm ± 3.9 mm) and maintained similar improvement out to 9 years (3 months: 3.6mm ± 2.4mm; then range 3.7mm - 4.3mm). 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 ± 6.4; 12 months 36.4 ± 9.6); the mental (MCS) component stayed consistent at all time points (baseline: 26.5 ± 9.1; 12 months 29 ± 8.9) and the total (baseline: 69.7 ± 14.5; 12 months 79.8 ± 15.8). Radiographic evaluation demonstrated that functional range of motion was preserved at all levels out to 9 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 with single and multilevel treatment. 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.