



Total Disc Replacement in the Failed Back Surgery Patient, Analysis of Prospective, Randomized, and Continued Access Cohorts

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Introduction

Patients with recurrent low back and leg pain following a failed lumbar decompression surgery (FLS) remain a treatment challenge. Historically these patients have frequently received fusion surgery. Following FDA-approval of the ProDisc-L Lumbar arthroplasty (Synthes Spine Company, L.P. West Chester PA.) in August 2006 many FLS patients have been receiving the arthroplasty option.

Methods

A total of 674 patients (161 randomized, 463 continued access and 50 training cases) received a lumbar TDR as part of the IDE clinical trial. 236 (35%) had prior lumbar surgery, including discectomy, laminectomy, laminotomy, foraminotomy and IDET including laser decompression. All patients were followed for at least two years.

Outcome measures included ODI, SF-36, VAS pain and satisfaction, adverse events, medication usage, recreational status and ROM. Multivariate analysis included Wilcoxon rank sum test, Fisher's exact test and two-way anova.

Results

Results: Preoperative demographics showed no statistical difference between those with (PS) or without prior surgery (NPS), although a greater number of patients with prior surgery had more than one year of pre-op symptoms. At a minimum 24-month follow-up there were no statistical differences in outcomes between the two groups. ODI improvement was similar in both groups. NPS 51.8%, PS 50.7%. VAS pain improvement was similar in both groups. NPS 53.1%, PS 54.8%.

Improvements in VAS satisfaction, SF-36, medication usage, recreational status and adverse events were all similar. Range of motion averaged 7.3 degrees in both groups.

When the individual prior surgery subgroups were analyzed only the IDET subgroup showed significantly less improvement in ODI ($P=0.0025$), VAS pain ($P=0.0119$) and VAS satisfaction ($P=0.0085$) compared to the remainder of the TDR group.

Conclusions

Conclusions: This outcome-based study shows that in properly selected patients with previously failed lumbar surgery. Total disc replacement can provide significant clinical improvement while maintaining normal range of motion.

Learning Objectives

Shows the importance and possibilities of new technology in treating patients with failed lumbar surgery.

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