

Zigler JE, Glenn J, Delamarter RB. Five-year adjacent level degenerative changes in patients with single-level disease treated using lumbar total disc replacement with ProDisc-L versus circumferential fusion. J Neurosurg Spine 2012;17:504-511.

Design: Five year follow-up of a randomized clinical trial

Population/sample size/setting:

- 236 patients (116 men, 120 women, mean age 39) treated for degenerative disc disease (DDD) of the lumbar spine as part of an FDA IDE study of a lumbar disc prosthesis
- Inclusion criteria were back and/or leg (radicular) pain with radiographic confirmation either (1) instability with ≥ 3 mm translation or $> 5^\circ$ angulation, (2) loss of disc height of > 2 mm, (3) scarring/thickening of the anulus fibrosis, (4) herniated nucleus pulposus, (5) vacuum phenomenon; other criteria were Oswestry score ≥ 40 , failure of at least 6 months of conservative therapy, ability to adhere to protocol, and written informed consent
- Exclusion criteria were having DDD at more than 1 level, vertebral endplates too small for the artificial disc, allergy to disc components, prior fusion at any vertebral level, compromised vertebral bodies at the affected level due to trauma, radiographic facet joint disease or degeneration, lytic spondylolisthesis or spinal stenosis, osteoporosis with DEXA ≤ 205 , back or leg pain of unknown etiology, metabolic bone disease, pregnancy, BMI > 40 , use of drugs which may inhibit bone or soft tissue healing (such as steroids), and several systemic or autoimmune diseases

Main outcome measures:

- The study followed the population in the FDA IDE trial out to 5 years to compare rates of adjacent level disease (ALD) following the total disc replacement (TDR) versus circumferential fusion
- ALD was assessed on the basis of disc height loss, endplate sclerosis, osteophytes, and spondylolisthesis, with a total ALD score based on a weighted sum of the four observed characteristics
- ALD was measured preoperatively and 5 years after surgery
- The change in ALD from the preoperative measurement (Δ ALD) was much lower in the TDR group (9.2%) compared to the fusion group (28.6%)
- In a stepwise logistic regression model, adjusted for smoking (more common in the fusion than in the ADL group), prior surgery, and initial degeneration, the likelihood of Δ ALD was 4.5 times greater in the fusion than in the TDR group
- Adjacent level surgery was rarely done during the 5 years of follow-up; it was done in 3 of 161 TDR patients and in 4 of 75 fusion patients

Authors' conclusions:

- Compared to circumferential fusion, TDR has a statistically significant sparing effect on adjacent-level degenerative disease over a 5 year period
- This analysis was done post hoc, not as part of the original study protocol, and should be interpreted with appropriate caution

Comments:

- The 17-center study enrolled 236 patients (161 TDR and 75 fusion), but the 5 year ALD was available for only 119 TDR and 42 fusion patients
- This represents more than 26% attrition for the TDR group and 44% attrition for the fusion group
- This level of differential attrition adds considerable uncertainty to the estimate of the treatment effect on adjacent level disease, making it unwise to quote a particular risk ratio, but the reported differences between groups are unlikely to be obliterated by biases arising from the high loss to follow-up
- The 4.5 fold likelihood reported in the results section was done with a logistic regression model, which estimates odds ratios rather than likelihood (probability) ratios; odds ratios may inflate probability ratios when the outcome (Δ ALD) is common, and the probability ratio is likely to be less than 4.5
- The post hoc nature of the analysis, the impossibility of blinding the interpretation of radiographic imaging, and the close similarity of adjacent level surgery between groups, collectively create qualifications regarding the clinical importance of Δ ALD with the two operations

Assessment: Adequate for some evidence that total disc replacement of the lumbar spine reduces the 5-year risk of adjacent level degeneration compared to circumferential fusion