

Lumbar Facet Arthroplasty for Spondylolisthesis and Stenosis: Three-Year Outcomes from a Prospective FDA Randomized Clinical Trial

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INTRODUCTION:

In June 2023, a new lumbar facet replacement technology was approved by FDA following an analysis of two-year outcomes from a multi-center, prospective, randomized, Investigational Device Exemption trial. Longer term results are needed to validate these early results at two years.

METHODS:

The IDE clinical trial included three-hundred-five subjects that were randomly assigned (2:1) to either facet arthroplasty or transforaminal lumbar interbody fusion (TLIF) at one lumbar level. Subjects enrolled into this study continue to be followed and are seen annually through five years. The primary clinical outcomes for this analysis includes improvement in Oswestry Disability Index (ODI) and visual analog scale (VAS) for leg and back pain, as well as re-operation rate at 3 years of follow-up.

RESULTS:

At 36 months, the mean reduction in ODI scores were -46.7 ± 17.0 and -39.3 ± 20.1 for the facet arthroplasty and fusion groups, respectively, equating to a between-group difference of -7.4 (95% CI -13.3 to -1.6). VAS back pain scores showed a mean reduction of -54.1 ± 31.0 and -44.2 ± 34.7 for facet arthroplasty and fusion, respectively, equating to a between-group difference of -9.9 (95% CI -20.3 to 0.6). VAS leg pain scores for the facet arthroplasty group showed the mean reduction of -71.6 ± 22.7 while fusion group -70.3 ± 26.5 , equating to a between-group difference of -1.3 (95% CI -9.0 to 6.5). Rates of reoperation were 8.6% for the facet arthroplasty and 14.6% for the fusion group.

DISCUSSION AND CONCLUSION: Outcomes after 3 years demonstrate that lumbar facet replacement appears to be a viable alternative for treatment of degenerative spondylolisthesis with better improvements in subject disability and lower rates of re-operation. Continued long-term follow-up is necessary to validate these findings.