Prospective, Randomized Controlled FDA Study of Lumbar Facet Replacement vs. Transforaminal Lumbar Interbody Fusion for Degenerative Spondylolisthesis: Two-Year Outcomes

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INTRODUCTION:
Lumbar facet replacement is a novel motion-preserving procedure that can be used to treat degenerative spondylolisthesis with spinal stenosis. There is an ongoing multicenter, prospective, randomized, controlled US Food and Drug Administration (FDA) Investigation Device Exemption (IDE) trial evaluating the clinical and radiographic outcomes of lumbar decompression followed by an investigational facet replacement device (TOPS) versus transforaminal lumbar interbody fusion (TLIF) with pedicle screws.
METHODS:
Patients with Grade I degenerative spondylolisthesis and spinal stenosis were 2:1 randomized to TOPS versus TLIF. A minimum of 24 months follow up was required for inclusion in this study. The primary clinical outcome measures included percentage of subjects achieving minimum clinically importance difference (MCID) in the Oswestry Disability Index (ODI) and visual analog scale (VAS) for back and leg pain. Radiological assessment included standing and dynamic x-rays, MRI, and bone density.
RESULTS:
At the time of this analysis, 249 patients have been enrolled (TOPS =170; TLIF= 79) and a total of 118 patients have reached 24 months of follow up (TOPS=84, TLIF=34). At 24 months the percentage of subjects reporting minimum 15-point improvement in ODI demonstrated a significant difference (p-value=0.037) between TOPS (94.0%) and TLIF (79.4%). There was no significant difference between groups in the percentage of patients reporting a minimum 20-point improvement on VAS back (TOPS=81.0; TLIF=69.7) and leg pain (TOPS=88.1; TLIF=87.9) scales. Among all 249 subjects that were enrolled, the rates of supplemental surgical intervention for facet replacement and the TLIF control were 5.9% and 8.8%, respectively.
DISCUSSION AND CONCLUSION:
The preliminary results of the TOPS System demonstrate better clinical outcomes at the immediate postoperative visit through 24 months. Reoperation rates are consistent with literature for surgical treatments to address spondylolisthesis with stenosis. Lumbar facet arthroplasty appears to be a viable option for treatment of degenerative spondylolisthesis. Continued long-term follow up is required to validate early findings and evaluate differences between facet arthroplasty and fusion.