Lumbar Facet Arthroplasty: An Analysis Comparing Two-Year Outcomes from a Prospective Randomized Clinical Trial Among Patients with Unstable vs Stable Spondylolisthesis

Evalina L Burger¹, Vikas Vanarsi Patel², Michael Patrick Steinmetz³, William C Welch⁴, Ahmad Nassr, Domagoj Coric⁵ ¹University of Colorado SOM, ²Univ of Colorado, Schl of Med, ³Cleveland Clinic, ⁴Univ of Pennsylvania Health System, ⁵Carolina Neurosurgery and Spine

INTRODUCTION:

Until recently surgical management for degenerative lumbar spondylolisthesis and stenosis has generally been limited to decompression-only or to decompression with fusion. When segmental instability is also present, decompression with fusion is often seen as the only option. The introduction of facet arthroplasty represents a new surgical modality that stabilizes a segment following complete decompression while maintaining a patient's normal biomechanical motion. Outcomes from a multi-center, prospective, randomized, Investigational Device Exemption (IDE) trial assessing the effectiveness of facet arthroplasty among subjects with degenerative Grade 1 spondylolisthesis have previously been reported however the effectiveness of this treatment has not been examined in subjects with unstable spondylolisthesis. METHODS:

This interim analysis examined 201 subjects that were randomly assigned to facet arthroplasty as part of the IDE trial. All subjects underwent decompressive laminectomy via a mid-line incision at one lumbar level followed by insertion of a facet arthroplasty device. Outcome measures after 24 months included the percentage of subjects that achieved minimal clinically important difference (MCID) in Oswestry Disability Index (ODI) and visual analog scale (VAS) for leg and back pain. These results were stratified by the presence of pre-operative segmental instability on flexion-extension defined rotation $\ge 5^\circ$ or translation ≥ 3 mm.

RESULTS:

Among the 201 subjects treated, 68 were identified as having pre-operative unstable spondylolisthesis and 139 were designated as having stable pre-operative spondylolisthesis). At 24 months, the percentage of subjects reporting a minimum 15-point improvement in ODI was 92% among the unstable cohort compared to 96% among the stable cohort. For VAS leg pain, 88% of subjects in the unstable cohort reported a minimum 20-point improvement compared to 96% of subjects in the stable cohort. Subjects reporting a minimum improvement of 20-points in VAS back pain was 82% for the unstable cohort compared to 84% for the stable cohort. No subjects in either cohort demonstrated a worsening of their spondylolisthesis from Grade 1 to Grade 2.

DISCUSSION AND CONCLUSION:

The interim results demonstrate excellent clinical outcomes in patients with either stable or unstable Grade 1 spondylolisthesis that were treated with facet arthroplasty. Additionally, subjects with pre-operative unstable Grade 1 spondylolisthesis that were treated with facet arthroplasty remained stable with no progression of spondylolisthesis through 24 months. Lumbar facet replacement appears to be a viable option for treatment of degenerative unstable spondylolisthesis. Continued follow-up is required to validate early findings and evaluate differences between facet arthroplasty and fusion.