499

Coflex® Interlaminar Stabilization Compared to Posterior Spinal Fusion for Spinal Stenosis and Spondylolisthesis: Two-year Results from the Prospective, Randomized, Multicenter Food and Drug Administration IDE Trial

R.J. Davis[1], T.J. Errico[2], H. Bae[3], J.D. Auerbach[4]

[1]Greater Baltimore Neurosurgical Associates, Towson, MD, United States, [2]Hospital for Joint Diseases-NYU, New York, NY, United States, [3]The Spine Institute, Santa Monica, CA, United States, [4]Bronx-Lebanon Hospital Center, Department of Orthopaedics, Bronx, NY, United States

Introduction: Laminectomy and posterior spinal fusion are commonly performed for patients with degenerative spondylolisthesis and spinal stenosis with significant low back pain. Long-term untoward sequelae of lumbar fusion have led to the search for motion-preserving, less-invasive alternatives. The purpose of the current study is to evaluate the safety and efficacy of the coflex® interlaminar device compared to posterior spinal fusion in the treatment of 1- and 2-level spinal stenosis and degenerative spondylolisthesis.

Methods: Prospective, randomized, multicenter FDA IDE trial comparing direct decompression and coflex® interlaminar stabilization with laminectomy and posterior spinal fusion. Study inclusion consisted of moderate spinal stenosis with significant low back pain (VAS Back Pain≥50/100) and significant disability (ODI ≥40%), with up to Grade I spondylolisthesis, at spinal segments from L1-L5. Two hundred nineteen patients (146 coflex® and 73 fusion controls) were randomized and treated from 21 sites in the United States to receive direct decompression and coflex® interlaminar stabilization or laminectomy and posterolateral spinal fusion with spinal instrumentation in a 2:1 ratio. Perioperative data, ODI, VAS Back, VAS (worse) Leg, SF-12, ZCQ, and radiographic outcomes at minimum 2 years were evaluated. Overall device success was a composite of >15-point reduction in ODI, no reoperations, no major device-related complications, and no post-operative epidural injections.

Results: Patient follow-up at a minimum of 2 years was 96.6% and 98.6% for coflex® and fusion control groups, respectively. There were no group differences at baseline in any demographic, clinical, or radiographic parameter. Coflex® patients experienced significantly shorter operative times ($p< 0.0001$), estimated blood loss ($p< 0.0001$), and length of stay ($p< 0.0001$) compared with to fusion controls. At 2 years, mean ODI scores were significantly better in the coflex® cohort ($p=0.021$) with a trend towards a greater proportion achieving a 15-point reduction in ODI ($p=0.06$). Both groups demonstrated significant improvement in all VAS Back and Leg parameters. Coflex® patients had significantly greater improvement in SF-12 Physical Health outcomes ($p=0.027$) and similar Mental Health outcomes. Coflex® subjects had greater improvement in all ZCQ outcomes compared with fusion (Symptom Severity ($p=0.013$); Physical Function ($p=0.013$); Satisfaction ($p=025$)). Based on the stringent FDA composite for overall success, 66.4% of coflex® and 59.7% of fusions succeeded, respectively. The overall complication rate was similar between the groups. At 2 years fusion controls exhibited significantly increased sagittal plane translation ($p=0.05$) and angulation ($p< 0.0001$) at the superior adjacent level, while coflex® maintained normal operative and adjacent level motion.

Conclusions: Our results demonstrate safety, efficacy, and non-inferiority of decompression followed by coflex® interlaminar stabilization compared to fusion in the treatment of spinal stenosis and degenerative spondylolisthesis. Coflex® stabilization led to significantly improved perioperative outcomes, multiple clinical outcomes measures, and maintenance of motion at operative and adjacent levels compared with fusion at 2 years. Coflex® interlaminar stabilization is a safe and efficacious alternative, and provides several distinct advantages over lumbar spinal fusion with pedicle screw instrumentation.