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

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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 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.