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Direct Neurologic Decompression Improves Functional Neurologic Outcomes in Spinal Stenosis and Low-grade Spondylolisthesis: A Comparison of Coflex® Interlaminar Stabilization, Laminectomy and Spinal Fusion, and X STOP

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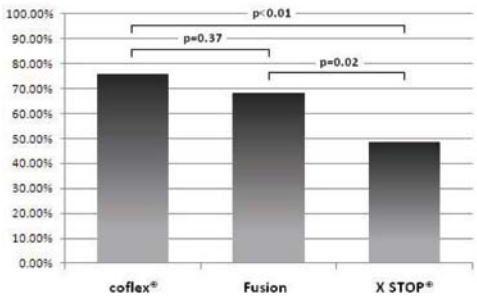
Introduction: Interspinous process device technologies have been developed to complement conservative care, laminectomy, and laminectomy with or without spinal fusion as treatment options for spinal stenosis and low grade degenerative spondylolisthesis. While the X STOP interspinous implant relies upon indirect decompression and fixation to the spinous processes, the coflex® interlaminar stabilization device is implanted following a direct neurologic decompression, and is fixated to the stronger laminar bone. The purpose of this study is to compare 2-year functional outcomes in patients treated with X STOP, coflex® interlaminar stabilization device, or spinal fusion in the treatment of spinal stenosis with up to Grade 1 spondylolisthesis.
Methods: Comparative analysis of the results of two separate, independent, randomized, prospective, multicenter Food and Drug Administration Investigational Device Exemption trials comparing:
1) conservative care with X STOP, and
2) direct decompression and coflex® interlaminar stabilization with decompression and fusion.
In the coflex® IDE trial, a total of 219 patients (146 coflex® and 73 fusion controls) were randomized and treated from 21 US sites to receive direct decompression and coflex® interlaminar stabilization or laminectomy and posterolateral spinal fusion with spinal instrumentation in a 2:1 ratio. In the X STOP IDE trial, a total of 191 patients (100 X STOP and 91 controls) were randomized and treated from 9 US sites to receive X STOP or to continue with conservative treatment. The primary outcome measure was Zurich Claudication Questionnaire, a patient-reported validated functional outcomes instrument for spinal stenosis and neurogenic claudication. Composite success criteria required a 0.5 point improvement in ZCQ-Physical Function and ZCQ-Symptom Severity, and < 2.5 in ZCQ-Patient Satisfaction.
Results: At 2 years, Composite ZCQ success was achieved in 75.7% of coflex® patients, compared with 68.3% of fusion controls, and 48.4% of X STOP patients. The proportion of patients achieving success was significantly higher in the coflex® cohort than in the X STOP cohort (p< 0.001). Similarly, fusions also significantly outperformed the X STOP cohort (p=0.019). There were no significant differences between the coflex® and fusion cohorts (p=0.37).



[Table: Comparison of Composite ZCQ Success at 24 m]

Conclusions: Coflex® interlaminar stabilization following direct decompression facilitated superior ZCQ composite success at 2 years compared with X STOP to treat spinal stenosis and degenerative spondylolisthesis, and nonsignificant improvements over laminectomy with spinal fusion. Similarly, laminectomy with spinal fusion led to significant improvements over X STOP. Our data highlights the fact coflex® and X STOP are intended for different patient populations, and also suggests that there are clear benefits of direct neurologic decompression that is facilitated with either coflex® interlaminar stabilization or with laminectomy and fusion over indirect decompression alone with the X STOP interspinous implant.