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550: Lumbar Motion Is Maintained with Paraspinous Tension Band for Degenerative Spondylolisthesis: Results from 24-month FDA Study

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Introduction: Durable outcome for degenerative spondylolisthesis (DS) usually requires decompression and fusion. Fusion, however, places greater stress at adjacent levels with increased incidence of adjacent segment disease. A novel interspinous tension band is proposed for segmental stabilization after decompression for DS, as an alternative to fusion. An FDA IDE study (NCT03115983) compares decompression and stabilization with the tension band (treatment group) to decompression and transforaminal interbody instrumented fusion (control group) for symptomatic DS.

Methods: Prospectively enrolled IDE study subjects with 24 months postoperative radiographic follow-up were included in this analysis. X-rays obtained during the follow-up period for both the treatment (n=75) and control (n=52) groups were reviewed by an independent Core Laboratory for flexion/extension range of motion (ROM) and translation at the index, supradjacent and subjacent levels.

Results: For the treatment group, pre-op to 24-month post-operative ROM was reduced 33% ($p<0.01$) and translation was reduced 29% ($p<0.01$). The control group as expected showed a significantly greater decrease in ROM (68%, $p<0.01$) and translation (77%, $p<0.01$) at the index level. Both treatment and control groups did not have statistically significant change at supradjacent and subjacent levels. At 24 months, considering the ranges of motion at the index and adjacent segments, adjacent segments accounted for 73% of motion in the treatment group and 87% in the control group.

Conclusion: Unlike fusion, paraspinous tension band for DS maintained both stability and the anatomic range of motion and translation at the index levels out to 24 months. Thus, less incidence of adjacent segment disease may be expected with DS treated with paraspinous tension as opposed to fusion. These results should be confirmed with a longer follow-up including clinical outcomes in propensity score-matched patients.