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Original Article

Decompression and paraspinous tension band: a novel treatment method for patients with lumbar spinal stenosis and degenerative spondylolisthesis

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Abstract

BACKGROUND CONTEXT: Prior studies have demonstrated the superiority of decompression and fusion over decompression alone for the treatment of lumbar degenerative spondylolisthesis with spinal stenosis. More recent studies have investigated whether nonfusion stabilization could provide durable clinical improvement after decompression and fusion.

PURPOSE: To examine the clinical safety and effectiveness of decompression and implantation of a novel flexion restricting paraspinous tension band (PTB) for patients with degenerative spondylolisthesis.

STUDY DESIGN: A prospective clinical study.

PATIENT SAMPLE: Forty-one patients (7 men and 34 women) aged 45 to 83 years (68.2±9.0) were recruited with symptomatic spinal stenosis and Meyerding Grade 1 or 2 degenerative spondylolisthesis at L3–L4 (8) or L4–L5 (33).

OUTCOME MEASURES: Self-reported measures included visual analog scale (VAS) for leg, back, and hip pain and the Oswestry Disability Index (ODI). Physiologic measures included quantitative and qualitative radiographic analysis performed by an independent core laboratory.

METHODS: Patients with lumbar degenerative spondylolisthesis and stenosis were prospectively enrolled at four European spine centers with independent monitoring of data. Clinical and radiographic outcome data collected preoperatively were compared with data collected at 3, 6, 12, and 24 months after surgery. This study was sponsored by the PTB manufacturer (Simpirica Spine, Inc., San Carlos, CA, USA), including institutional research support grants to the participating centers totaling approximately US $172,000.

FDA device/drug status: Investigational (LimiFlex Spinal Stabilization System, aka LimiFlex Paraspinous Tension Band).

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RESULTS: Statistically significant improvements and clinically important effect sizes were seen for all pain and disability measurements. At 24 months follow-up, ODI scores were reduced by an average of 25.4 points (59%) and maximum leg pain on VAS by 48.1 mm (65%). Back pain VAS scores improved from 54.1 by an average of 28.5 points (53%). There was one postoperative wound infection (2.4%) and an overall reoperation rate of 12%. Eighty-two percent patients available for 24 months follow-up with a PTB in situ had a reduction in ODI of greater than 15 points and 74% had a reduction in maximum leg pain VAS of greater than 20 mm. According to Odom criteria, most of these patients (82%) had an excellent or good outcome with all except one patient satisfied with surgery. As measured by the independent core laboratory, there was no significant increase in spondylolisthesis, segmental flexion-extension range of motion, or translation and no loss of lordosis in the patients with PTB at the 2 years follow-up.

CONCLUSIONS: Patients with degenerative spondylolisthesis and spinal stenosis treated with decompression and PTB demonstrated no progressive instability at 2 years follow-up. Excellent/good outcomes and significant improvements in patient-reported pain and disability scores were still observed at 2 years, with no evidence of implant failure or migration. Further study of this treatment method is warranted to validate these findings.

Keywords: Degenerative spondylolisthesis; Flexion; Dynamic stabilization; Spinal stenosis; Tension band; Spinous process instrumentation

Introduction

Decompression alone was the standard surgical treatment for lumbar degenerative spondylolisthesis with spinal stenosis [1,2] until several landmark articles suggested that decompression and fusion was a superior mode of treatment [3–5]. Although there has been recent pressure to reduce the rates of spinal fusion, payers and medical societies consistently recommend that fusion be determined medically necessary for lumbar degenerative spondylolisthesis with spinal stenosis [6–8], and it remains the dominant procedure for this indication in the United States, shown by a 95% fusion rate in the Spine Patient Outcomes Research Trial study [9]. However, fusion is clearly an imperfect treatment because of the short-term morbidity involved in adding a fusion to the decompression and the longer term associated risk of adjacent-level degeneration and instability [10,11]. To circumvent these problems, ''dynamic stabilization'' systems were introduced [12,13], but most are pedicle screw based and associated with many of the same problems as instrumented fusion, notably complex implant loading [14–18] and facet joint violation during screw placement [19–21]. For this reason, simpler constructs have been suggested, such as that by Lee et al. [22,23], who reported a series of 65 patients with degenerative spondylolisthesis treated with decompression and posterior tension band stabilization using a figure of eight sutures. They found that back pain relief and functional improvement were significantly correlated with achievement of total and segmental lumbar lordosis after a mean follow-up of 72.5 months and equivalent outcomes could be achieved in comparison with posterior lumbar interbody fusion.

Based on the need for segmental stabilization in this patient population, the relative drawbacks of fusion and pedicle screw-based dynamic stabilization, and the promising outcomes of tension band stabilization reported by Lee et al. [22,23], a novel paraspinous tension band (PTB; LimiFlex Spinal Stabilization System; Simpirica Spine, Inc., San Carlos, CA, USA) has been developed to provide segmental sagittal plane stability through biasing the segment into lordosis. The facet joints are more engaged and afford more sagittal plane stability in segmental extension than in flexion because of the coronal orientation of the caudad portion of the joint [24] and thus, their biomechanics allow for this indirect mechanism of providing stability. The PTB utilizes titanium coil tension springs to restore segmental flexion stiffness and is attached to the spinous processes with ultra-high molecular weight polyethylene bands. A preclinical large animal implantation study demonstrated that the PTB is well-tolerated by the surrounding tissues and retains its function after anatomical incorporation [25]. Cadaveric biomechanical testing has demonstrated the restoration of the kinematics of a destabilized spinal segment to that of an intact segment, with increased flexion stiffness and reduced sagittal translation [26]. The device does not bear any axial loads, and therefore, the forces transmitted by the PTB to the spinal elements are, in an order of magnitude, less compared with pedicle screw-based systems. The PTB was designed to be easily implanted after a standard lumbar decompression with minimal additional exposure.

We aimed to prospectively assess the clinical and radiographic outcomes of patients treated with surgical decompression and stabilization with the LimiFlex PTB device over a 2-year follow-up period. We questioned whether these patients would become progressively more unstable from a radiographic standpoint over this length of follow-up and whether their clinical improvement in back and leg pain would deteriorate. This study was intended to provide initial data to demonstrate the clinical feasibility of this treatment method.