

Minimally-invasive Axial Pre-sacral L5-S1 Interbody Fusion: Two Year Clinical and Radiographic Outcomes

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ABSTRACT

Study Design. Retrospective case series.

Objective. The primary aim of this study was to evaluate and report the two year clinical and radiographic outcomes associated with a L5-S1 interbody fusion procedure that employs an axial pre-sacral surgical approach.

Summary of Background Data. There are a number of lumbar interbody fusion procedures used to treat painful, degenerated discs. However, despite their procedural differences (e.g., anterior vs. posterior), all of the current surgical approaches are undertaken in the same anatomical plane which requires disruption of musculoligamentous and osseous support structures as well as vascular and neurologic tissue to gain access the intervertebral disc space. The pre-sacral procedure is distinct in that it uses an approach along an axis essentially perpendicular to the anatomical plane of traditional fusion procedures.

Methods. One hundred fifty six patients from four clinical sites were selected for inclusion if they underwent a L5-S1 interbody fusion via the pre-sacral approach with the AxiaLIF® System (TranS1, Wilmington, NC) and had both pre-surgical and two year radiographic or clinical follow-up. Back pain and functional impairment were evaluated with an 11-point numeric scale and the Oswestry Disability Index (ODI), respectively, pre-operatively and at two years. Standard radiographic imaging techniques were used to determine fusion status.

Results. Marked clinical improvements were realized in back pain severity and functional impairment through two years of follow-up. Mean pain scores improved from 7.7 ± 1.6 (n=155) pre-operatively to 2.7 ± 2.4 (n=148) at 24 months, reflecting an approximate 63% overall improvement ($p < 0.001$). Mean ODI scores improved from $36.6 \pm 14.6\%$ (n=86) pre-operatively to $19.0 \pm 19.2\%$ (n=78) at 24 months, or approximately 54% ($p < 0.001$). Two year clinical success rates based on change relative to baseline of at least 30% were 86% (127 of 147) and 74% (57 of 77) for pain and function, respectively. The overall radiographic fusion rate at two years was 94% (145 of 155).

Conclusion. Findings from this clinical series of patients treated with a pre-sacral interbody fusion procedure, stabilized with the AxiaLIF® rod, reflect favorable and durable outcomes through two years of follow-up.