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**Long-term Prospective Multi-center Clinical Cohort Evaluation of the AxiaLIF<sup>®</sup> Procedure**

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**Introduction:** There has been an evolution over the past decade in more minimally invasive approaches to allow for an L5-S1 interbody fusion. The purpose of this study was to evaluate the clinical outcomes, fusion rates, and complications of patients undergoing the percutaneous, presacral L5-S1 Axial Lumbar Interbody Fusion (AxiaLIF<sup>®</sup>) procedure (Trans1, Wilmington, NC).

**Methods:** A cohort of 178 patients from 5 centers (78 men, mean age 46 years, range 15-77 years) who underwent the AxiaLIF procedure at L5-S1 were prospectively evaluated. Inclusion criteria included failure of non-surgical therapy for at least 6 months. Preoperative and two-year visual analogue scale for pain (VAS) and Oswestry Disability Index (ODI) were collected and included for analysis. Fusion status was determined by dynamic lateral radiographics or thin cut multiplanar CT imaging. Complications were tracked from the time of surgery through the two years of follow-up.

**Results:** The primary indication for surgery was „pain of discogenic origin“ in 115 patients, „spondylolisthesis“ in 18 patients, „failed back surgery syndrome“ in 15 patients, and „other“ in 30 patients. Before surgery for the entire cohort, the mean VAS was 75 mm (range 63-90 mm) and mean ODI was 40% respectively (range 33-46%). The patient cohort at two years demonstrated a reduction in pain VAS by 71% and a reduction in ODI by 51%. Fusion rates by individual surgeon ranged from 78% to 100%. Mean blood loss was less than 50 ml. The most frequent complication was misplaced percutaneous pedicle screws. There were no vascular, neural, urologic, or bowel injuries recorded in this cohort.

**Conclusions:** This series represents one of the largest long-term follow-up evaluations to date on the AxiaLIF<sup>®</sup> procedure. The clinical and radiographic outcomes of patients undergoing L5-S1 interbody fusions using the AxiaLIF<sup>®</sup> procedure are comparable if not better to those recorded in the literature of more traditional open interbody fusion techniques.