

# Outcomes after Percutaneous TranS1 AxiaLIF® L5-S1 Interbody Fusion for Intractable Lower Back Pain

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## Abstract

**Background:** Interbody fusion is an accepted treatment for patients with discogenic back pain originating from the L5-S1 disc space. The AxiaLIF® system was developed as a percutaneous, minimally invasive method to successfully perform an L5-S1 interbody fusion. **Methods:** A retrospective clinical evaluation was performed on 36 consecutive patients who underwent a minimally invasive L5-S1 interbody fusion using the AxiaLIF® system. Postoperative plain radiographs evaluated radiographic fusion rate. **Results:** Last follow-up, 14 patients (40%) had "resolution" of their pain and 19 patients (54%) claimed "significant improvement" of their pain. In a single patient, the symptoms worsened, and another patient the symptoms were felt unchanged. Thirty-one of the 36 patients had evidence of fusion based upon plain radiographs for an overall radiographic fusion rate of 86%. **Conclusion:** The AxiaLIF® procedure in combination with percutaneous pedicle screw placement was found to be a feasible and safe minimally invasive technique for L5-S1 interbody fusion with good clinical outcome.

## INTRODUCTION

Although the etiology of lumbar spinal pain remains poorly understood, research suggests that degenerating intervertebral discs are the primary source of low back pain.<sup>1</sup> Complete removal of the affected disc space followed by interbody fusion has now become an accepted treatment option for pain caused by an affected lumbar disc space.<sup>3-5</sup>

Interbody fusion has gained wider acceptance in an effort to maximize stability and subsequent fusion rates.<sup>6</sup> Some surgeons advocate the use of circumferential fusion with interbody graft and pedicle fixation.<sup>7</sup> Surgical treatment options for lower back pain include poster lumbar interbody fusion (PLIF), anterior lumbar interbody fusion (ALIF), transforaminal or transfacet lumbar interbody fusion (TLIF)<sup>8</sup>, artificial disc replacement and intradiscal Electrothermal Annuloplasty (IDET).<sup>9</sup>

The use of interbody devices has become increasingly popular because of improved rates of fusion, restoration of disc and foraminal height, and promotion of lordosis.<sup>10</sup> Good outcomes have been reported in 80 to 85% of patients.<sup>11</sup> The first successfully interbody posterior lumbar fusion was described by Cloward in 1985.<sup>12,13</sup> The United States Food and Drug Administration gave its final approval for the use of the interbody devices in the lumbar spine on September 20, 1996.<sup>8</sup> Later it was shown that similar result can be

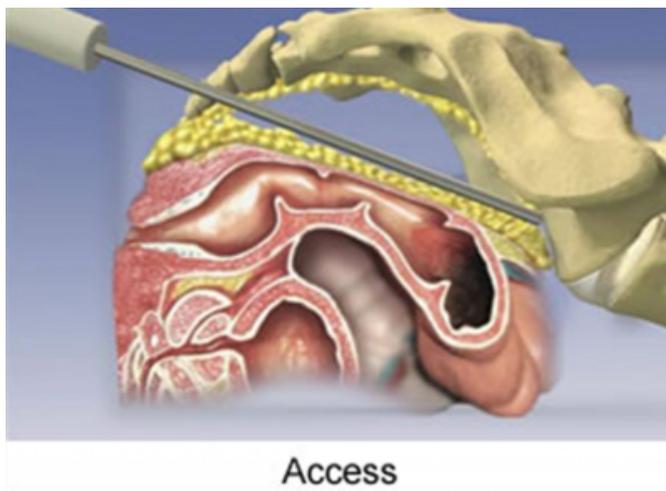
achieved with unilateral facetectomy with the graft placed with a more lateral trajectory.<sup>14</sup> Since that time, numerous lumbar interbody fusion techniques have been described in the literature for the treatment of degenerative spine disease.<sup>8</sup> However, significant morbidity has been associated with the exposure for these fusions.<sup>14</sup> Over the last decade, minimally invasive approaches employing tubular retractors<sup>15,16</sup> or standard ventral cervical retractor systems<sup>17</sup> using microscopy or endoscopy<sup>18</sup> for visualization were developed to minimize disruption of musculoligamentous support structures of the spine, which have been shown to have a major impact on outcome.<sup>19</sup> Besides preservation of the posterior arch and the musculoligamentous complex, minimally invasive techniques offer several other advantages, such as less nerve retraction, less blood loss, improved cosmetic results, and decreased length of hospital stay.<sup>15</sup> However, all these minimally invasive surgical approaches for lumbar interbody fusion employ the same surgical route and are simply smaller versions of the traditional open approaches. Hence, the patient is exposed to similar intraoperative and postoperative morbidities.

The AxiaLIF® system (TranS1, Inc., Wilmington, NC) was developed as a minimally invasive method to perform an L5-S1 interbody fusion to treat low back pain of discogenic origin at the level of the L5-S1 disc space. The AxiaLIF® approach is a percutaneous alternative to the anterior,

posterior, or transforaminal lumbar interbody fusion techniques. This makes it the first truly minimally invasive, percutaneously placed lumbar interbody device using the presacral fat bed. (Picture 1)

**Figure 1**

Figure 1: Trajectory for the minimally invasive, percutaneously placed lumbar interbody device using the presacral fat bed.



The specific surgical technique has been described by Marotta et al.<sup>20</sup> The TranS1 AxiaLIF® System is intended to provide anterior stabilization to the segment between the fifth lumbar vertebrae and the sacrum. The device is indicated for degenerative disc disease (DDD) with or without radicular symptoms, pseudoarthrosis from a prior unsuccessful fusion, and/or spondylolisthesis (Grade 1 or 2).

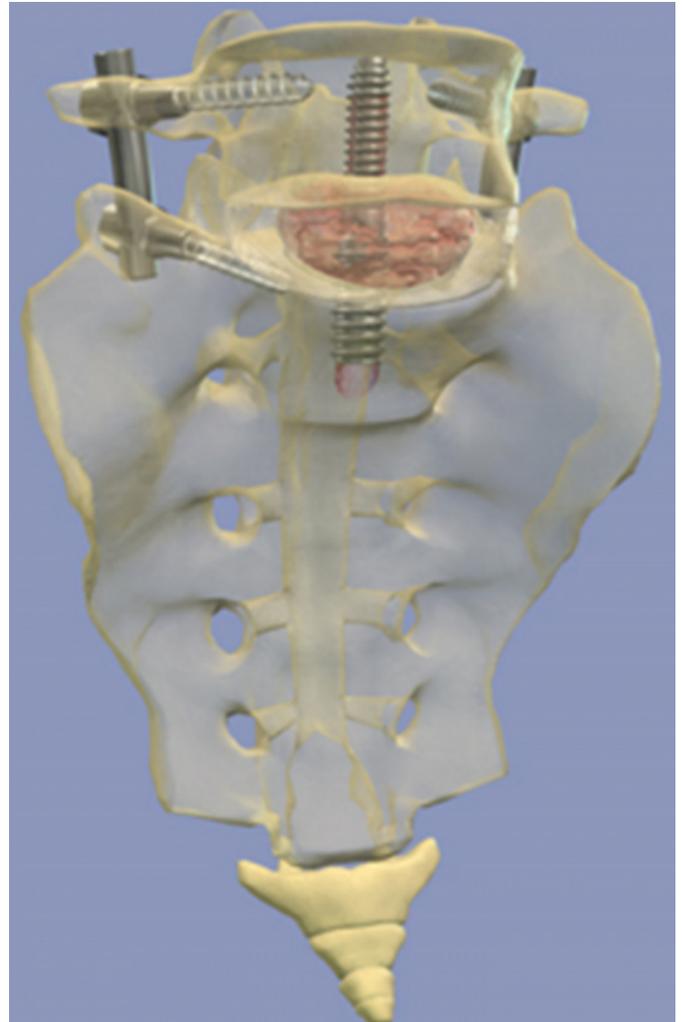
While the safety of AxiaLIF® placement and the minimally invasive technique have been described previously<sup>20</sup>, there is currently a paucity of clinical outcome evaluations of this technique. Therefore, we investigated the safety and clinical improvement of LBP in a consecutive series of patients who underwent an AxiaLIF® fusion.

## **METHODS**

All consecutive patients who underwent the AxiaLIF® interbody procedure in combination with percutaneous pedicle screw placement using the Sextant System (Medtronic Sofamor Danek, Memphis, TN) between March 2006 and June 2007 were included in this study.

**Figure 2**

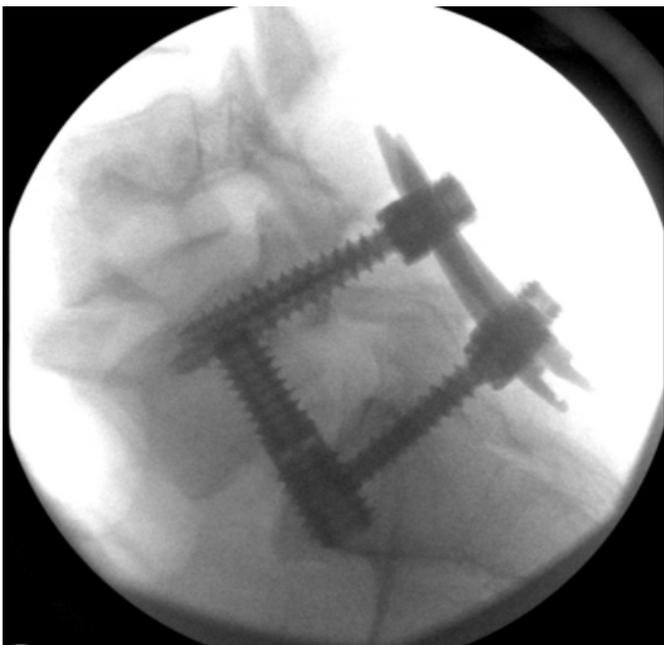
Figure 2: The AxiaLIF® interbody fusion device in combination with percutaneous pedicle screw placement (2a). The same construct is demonstrated radiographically on intraoperative anterior-posterior and lateral fluoroscopic images (2b, 2c).



**Figure 3**



**Figure 4**



(Picture 2a-c)

All patients were treated at the University of Pittsburgh Medical Center, Pittsburgh, PA, and the protocol was approved by the University of Pittsburgh's institutional review board. Pain relief was assessed by the patient's subjective report about the pain status as noted by the physician at the time of the outpatient visit. The outcome was divided into four categories (Table 1) and analyzed at 3-6 month follow-up, 6-11 month follow-up, and  $\geq 12$  month

follow-up. Descriptive methods were employed for statistical analysis.

All patients also underwent plain radiographs after surgery as part of their routine post-operative care. These radiographs were reviewed to determine radiographic fusion rate.

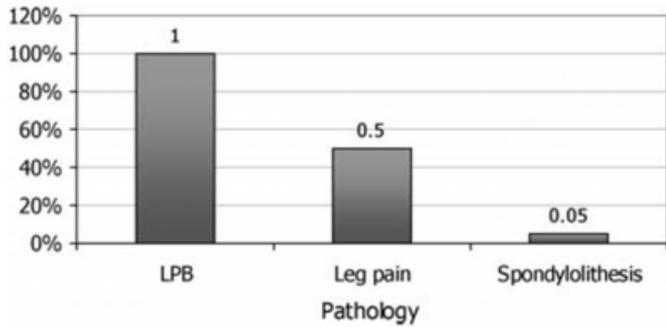
The indications for performing the L5-S1 AxiaLIF® interbody fusion included intractable discogenic back pain of greater than one year's duration due to degenerative disc disease, post-discectomy pain, or symptomatic Grade 1 or 2 spondylolisthesis at the L5-S1 level. All patients had LBP greater than lower extremity radicular pain. LBP was defined as "intractable" when the patient was under treatment by a pain management physician, and other non-surgical therapeutic interventions such as epidural steroid injects, facet injections, and/or active and passive physical therapy were unsuccessful in providing significant and sustained symptomatic improvement. The symptomatic L5-S1 disc space level was confirmed by magnetic resonance imaging appearance and reproduction of concordant pain on provocative discography.

## **RESULTS**

Between March 2006 and June 2007, 36 consecutive patients underwent the percutaneous L5-S1 AxiaLIF® interbody procedure in combination with percutaneous pedicle screw placement. The mean age of the cohort was 44 years (range 20 to 61 years). Twenty patients (56%) were male, and 16 (46%) were female. The mean duration of reported LBP for the entire patient cohort was 6 years (minimum of one year). Eighteen patients (50%) reported a component of unilateral or bilateral radicular leg pain in addition to their LBP. Two patients (6%) suffered from mechanical lower back pain secondary to Grade 1 spondylolisthesis at the L5-S1 level (Graph 1).

**Figure 5**

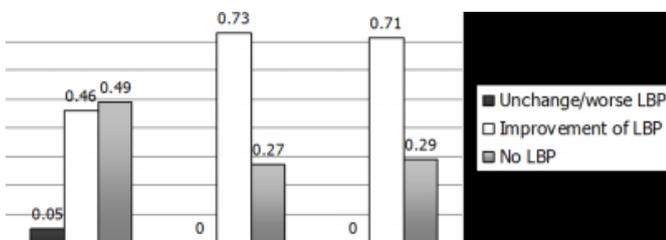
Graph 1: Primary indications for patients undergoing the AxiaLIF® procedure. Legend: LBP=lower back pain



The mean follow-up for the cohort was 8 months (range 3 to 20 months). Three to six month follow-up was available in 35 patients (97%); 6 -12 month follow-up was available in 11 patients (31%) patients; ≥ 12 month follow-up was available in 7 patients (22%). Based upon the last follow-up available, 14 patients (40%) had “resolution” of their pain and 19 patients (54%) claimed they had “significant improvement” of their low back pain In a single patient the symptoms worsened, and in another patients the symptoms were felt to be unchanged (Graph 2).

**Figure 6**

Graph 2: Pain outcomes for the three postoperative periods. Legend: LBP=lower back pain 100% is 35 patients



For patients in the 3-6 month follow-up period, LBP was felt to be completely resolved in 17 patients (49%), improved in 16 patients (46%), unchanged in 1 patient (2.5%), and worse in another (2.5%). This patient with worsening symptoms was involved in a motor vehicle accident postoperatively. The other patient who did not improve after the L5-S1 fusion subsequently underwent a second operation with extension of his fusion to incorporate the L4 level. For patients with 6 to 12 months follow-up, LBP was gone in 3 patients (27%) and improved in 8 patients (73%). For patients with greater than 12 months of follow-up, LBP was gone in 2 patients (29%) and improved in 5 patients (73%). Five patients (14%) developed a new, different quality lower back pain during the follow-up period that was treated with non-invasive modalities in all cases.

All patients underwent plain radiographs after surgery as part of their routine post-operative care. Thirty-one of the 36 patients had evidence of fusion based upon plain radiographs for an overall radiographic fusion rate of 86%.

No major complications occurred in this cohort. One patient developed a wound infection treated with intravenous antibiotic therapy. A single patient developed intractable pain felt to be caused by the pedicle screw instrumentation. The posterior instrumentation was removed on an elective basis after radiographs had demonstrated a solid fusion at the L5-S1 level.

**DISCUSSION**

Chronic lower back pain is one of the most common and difficult disease processes to treat. The prevalence of lower back pain has been reported to be 20-30% in the adult population. Eight percent of all adults will have at least one episode of acute back pain during their lifetime. LBP is the largest single cause of lost work days, and the social-economic costs have been estimated to be as high as \$2 billion.<sup>21</sup> In only 5-10% of people, LBP will progress to chronic lower back pain over time. The national lower back pain study followed 2,374 patient referred for neurosurgical or orthopedic evaluation. Although 79% of the patients had a radiological abnormality on their imaging study, only 20% ultimately underwent surgical intervention.<sup>2</sup> For chronic lower back pain without lower extremity radicular pain, the percentage of patients who are candidates for surgery may even lower.

The introduction of the lumbar interbody procedure improved the treatment for degenerative disc disease (DDD).<sup>22</sup> Anterior lumbar interbody fusion (ALIF) was first introduced by Muller et al.<sup>23</sup> However, a study by Stauffer in 1972 showed a low clinical success rate with this approach as well as a 44% rate of pseudoarthrosis.<sup>24</sup> The ALIF as a stand alone procedure fell out of favor until threaded cylindrical cages were introduced. The fusion rates subsequently increased to 56-93% with the BAK titanium cage.<sup>8, 24</sup> As expected with the removal of the degenerated intervertebral disc, the ALIF was demonstrated to be superior to postero-lateral fusion alone to achieve pain control in patients with discogenic back pain.<sup>3</sup>

The posterior lumbar interbody fusion (PLIF) is also a well established surgical approach for the treatment of DDD and discogenic back pain. Because of its relative invasiveness, it is seen as a rescue procedure only if other non-surgical treatment options fail.<sup>25</sup> Both the ALIF and PLIF

procedures are associated with muscular and ligamentous injury, manipulation of vascular and visceral structures and neural elements, and have the potential for significant complications and subsequent long-term morbidity.<sup>26</sup> It has been shown that disruption of the lower back muscles and ligament is negatively correlated with good outcome after posterior fusion for LBP.<sup>19, 27</sup> Although tubular retractor systems may minimize the trauma to the posterior musculoligamentous complex during surgery, the same structures are nevertheless violated.<sup>20</sup> Newer minimally invasive approaches for posterior interbody fusions are still not truly “percutaneous” and may result in clinically significant muscle damage.

The AxiaLIF® interbody system is noteworthy because it is the first truly percutaneous minimally invasive interbody fusion technique for the L5-S1 level. Because the AxiaLIF® system uses a presacral corridor, typical morbidities seen from postoperative muscle fibrosis after posterior approaches are eliminated. For this procedure, the L5-S1 intervertebral space can be accessed over the presacral fat pad while preserving the integrity of the posterior musculoligamentous support structures.<sup>28</sup> This provides strong ligamentotaxis, interbody fusion construct stiffness, and promotes successful fusion formation according to Wolff’s law.<sup>20</sup> Additionally, the AxiaLIF® interbody system, by being an axially placed cage, provides certain theoretically superior biomechanical features over an ALIF or PLIF. Slosar et al. demonstrated that axially placed cages grant better resistance to translation, flexion, extension, and shear forces<sup>29</sup> than traditional cages.

AxiaLIF® interbody fusion can be used for patients requiring fusion to treat pseudoarthrosis from unsuccessful prior fusion, spondylolisthesis Grade 1 or 2, and degenerative disc disease causing discogenic back pain. The procedure is approved for the anterior supplemental fixation of the lumbar spine at the L5-S1 level in conjunction with a posterior fixation system. Although well established surgical techniques for the treatment of discogenic back pain exist and have acceptable results, this study attempted to demonstrate that LBP might be significantly improved using a safe and effective percutaneous minimally invasive technique.

The current case series demonstrated both the safety as well as the efficacy of the AxiaLIF® procedure. Pain was improved or ameliorated in all but two patients. These clinical outcomes are comparable to those reported using both ALIF and PLIF approaches. Furthermore, the procedure

was found to be safe and very well tolerated by the patients. Further follow-up of the patients who undergo this procedure will help to further define the long-term clinical outcomes of this surgical approach. These results indicate that the AxiaLIF® procedure in combination with supplemental percutaneous pedicle screw placement is a feasible and safe technique for L5-S1 interbody fusion which results in good clinical outcomes.

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