Axial Lumbosacral Interbody Fusion Appears Safe as a Method to Obtain Lumbosacral Arthrodesis Distal to Long Fusion Constructs

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Abstract *Background:* Current methods to achieve lumbosacral interbody fusion have been complicated by approach-related morbidity, nerve root or cauda equina injury, or difficulty in implanting a large lordotic graft posteriorly. There is little information in the literature evaluating the presacral axial approach to the lumbosacral disc space. *Questions/Purposes:* What are the short-term clinical and radiographic outcomes in patients undergoing axial lumbosacral interbody fixation and fusion at the end of long fusion constructs using the AxiaLIF implant (Trans1 Inc., Wilmington, NC, USA)? Furthermore, what complications are associated with this procedure? *Patients and Methods:* We performed a retrospective evaluation of nine patients who underwent presacral axial lumbosacral interbody fixation and fusion at the end of long fusion constructs using the AxiaLIF implant. Preoperative diagnoses included adjacent segment degeneration below a long fusion construct for adult scoliosis and progressive sagittal plane deformity. *Results:* There were two pseudoarthroses, one at L4–5 and one at L5–S1. No major complications occurred. There were no significant differences in coronal or sagittal plane alignment at the time periods measured. There was no significant difference in implant position between immediate postoperative and final follow-up periods. There were significant postoperative improvements in Scoliosis Research Society-22 scores, specifically in the pain, self-image, and satisfaction with management domains. *Conclusions:* The axial lumbosacral interbody fusion is a

minimally invasive and safe method to obtain lumbosacral fixation and arthrodesis distal to a long fusion construct. Longer follow-up of larger numbers of patients are needed prior to recommending this procedure as a routine method to fuse L4–5 or L5–S1.

Keywords presacral lumbosacral interbody fusion · degenerative · AxiaLIF

Introduction

The extension of fusion constructs for adult scoliosis to the sacrum is often required in cases where there is lumbosacral disc degeneration, spondylosis, degenerative spondylolisthesis, or a fractional lumbosacral curve greater than 15° in magnitude [1, 10, 14]. To protect distal fixation, particularly S1 screws, Galveston-type fixation into the iliac wings and the addition of anterior lumbosacral interbody support is recommended for load sharing purposes [3, 7, 20].

There are at least four established methods to fuse the L5–S1 disc space. The anterior lumbar interbody fusion allows for the release of the anterior longitudinal ligament and the placement of a lordotic cage with a large footprint which can help restore sagittal alignment, decompress neuroforamina, and enhance fusion rates. However, the approach risks injury to major vascular structures and the sympathetic plexus which can cause retrograde ejaculation in males [9, 16]. The PLIF and TLIF cages are smaller compared to ALIF cages and thus contain less graft for fusion. In addition, nerve root and cauda equina injury can result from retraction to place these cages [15, 18]. The posterior transsacral approach using a fibular dowel or graft-filled cage has been well described for the treatment of high-grade spondylolisthesis [4, 19]. This procedure requires laminectomies and dural retraction to place the

Level of Evidence: Therapeutic Study Level IV.

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implant and thus adds unnecessary morbidity if posterior decompression or reduction of spondylolisthesis is not needed. Finally, the direct lateral interbody fusion in the majority of cases cannot be performed at the lumbosacral disc space because of obstruction by the iliac crest and traversing roots of the lumbosacral plexus [17].

Obtaining lumbosacral fusion distal to a long fusion construct is challenging. Emami and colleagues performed a retrospective study of long fusion to the sacrum using three different fixation techniques: (1) Luque–Galveston technique (11 patients), (2) combined iliac and sacral screws (36 patients), and (3) sacral screws (12 patients). Pseudoarthrosis developed in ten patients, four in group 1, five in group 2, and one in group 3. The average Scoliosis Research Society-22 (SRS-22) total score was 74% for group 1, 71% for group 2, and 63% for group 3. The authors recommended sacral screws with an anterior interbody support in patients with good bone stock and adding iliac fixation if bone stock is poor [7]. Weistroffer and colleagues performed a retrospective study of 50 patients with long fusions to the sacrum. Pseudoarthrosis was seen in 24% of the patients; most of these were at the lumbosacral junction and only 25% of which were detected within the first 2 years [20]. The authors concluded that the use of anterior support and iliac screws has decreased but not eliminated the pseudoarthroses rate [20].

The major advantage of the axial interbody fusion is its minimally invasive approach. In carefully selected patients, without prior retroperitoneal surgery or other risk factors for intra-abdominal adhesions and MRI evidence of a presacral corridor devoid of major neurovascular structures, the AxiaLIF approach can be safely used to fix and fuse the lumbosacral disc space [1–3, 6, 7, 11, 13]. Biomechanically, the implant may not provide as much stability in flexion and extension in L4–5 compared to L5–S1; therefore, supplemental posterior fixation may be needed when fusing L4–5 [8].

There is little information in the literature on the use of the AxiaLIF to obtain lumbosacral fixation and fusion distal to long fusion constructs. The AxiaLIF technique has several advantages including minimal dissection, muscle-sparing approach, complete preservation of the annulus, and access through the relatively safe prevascular corridor. In selected patients, the placement of a large axial implant with annular and muscular preservation has the theoretic potential to achieve fusion rates comparable to the ALIF and direct lateral approaches without the concerns of vascular injury, retrograde ejaculation, or nerve root injury [2, 3, 6, 9, 11–13, 16–18]. However, the approach is not without risk. High rectal perforation has been reported as a complication of the AxiaLIF procedure [5]. This occurred in a 44-year-old female patient with a history of previous anterior and posterior spinal surgeries, pelvic inflammatory disease, and previous diverticulitis who eventually needed a diverting colostomy. The authors of that report recommend that patients with risk factors for adhesion formation undergo a pelvic CT with rectal contrast before surgery to identify aberrant anatomy.

The primary aim of this report is to present our preliminary data on our experience with the presacral

approach to lumbosacral interbody fixation and fusion below long fusion constructs using the AxiaLIF implant (Trans1 Inc., Wilmington, NC, USA). Specifically, we are asking the following questions: (1) What are the short-term radiographic changes in alignment after undergoing axial lumbosacral interbody fixation and fusion at the end of long fusion constructs using the AxiaLIF implant (Trans1 Inc.)?; (2) What are the short-term clinical outcomes in patients after implantation of the AxiaLIF as measured by the SRS-22 and Oswestry Disability Index?; and (3) What complications are associated with this procedure?

Patients and Methods

This retrospective case series included nine patients who underwent the AxiaLIF procedure to perform either a one-level interbody fusion at L5–S1 or a two-level interbody fusion at L5–S1 and L4–L5. These were the first nine consecutive cases performed at our institution from June to December 2009. No patient was lost to follow-up. A total of 14 disc levels were instrumented in nine patients: four one-level procedures at L5–S1 and five two-level procedures at L4–5 and L5–S1. All patients had clinical and radiographic evidence of lumbar spondylosis with extension to the L5–S1 level. In six patients, the degenerative changes followed a previous long fusion which stopped short of L4 resulting in adjacent segment degeneration. In three patients, the lumbar spondylosis was associated with progressive sagittal imbalance. All patients had failed nonsurgical management including activity modification, nonsteroidal anti-inflammatory medication, and physical therapy. All patients had a preoperative MRI performed to demonstrate a clear fat plane devoid of vascular structures separating the visceral peritoneum and rectum from the anterior sacral wall. If extensive vasculature is seen in this plane, or if patients have had prior retroperitoneal surgery with scarring in this area, this percutaneous procedure is contraindicated as it cannot be safely performed.

There were two males and seven females in the study with an average age of 53 years (range 19–66). Average length of follow-up was 12.2 months (range 6–16 months). In all cases, the AxiaLIF was performed at the end of a long fusion to the sacrum. The proximal extent of the fusion was T3 in one case, T4 in one case, T8 in one case, T10 in three cases, T12 in one case, L1 in one case, and L2 in one case (Table 1).

A standard bowel preparation was performed the day before surgery. The patient drinks 2 L of GoLyteLy the day before surgery. The patient may drink clear liquids the day before surgery and is NPO after midnight. The patient is positioned prone on a Jackson frame with a pillow elevating the pelvis. Preoperative antibiotics are administered. Biplanar fluoroscopy is used. The sacrococcygeal region is prepped and draped in the standard sterile fashion. When the AxiaLIF is performed in conjunction with additional posterior spinal procedures (as was done in all nine cases), the posterior wound was closed and dressed, the patient was repositioned, and the distal sacrococcygeal region was re-

Table 1 Summary of individual patient data

Patient (age, sex, diagnosis)	Fusion levels	AxiaLIF levels	Iliac screws	ODI (preop/final)	SRS-22 total (preop/final)	Complications
LE (19 yrs old, female, adolescent idiopathic scoliosis, adjacent segment degeneration)	L2–S1	L4–S1	Right	46/41	3.2/3.7	None
LK (66 yrs old, male, lumbar spondylosis, postlaminectomy kyphosis)	T10–S1	L5–S1	None	46/13	3.0/4.6	None
SD (66 yrs old, male, lumbar spondylosis, ankylosing spondylitis)	T10–S1	L4–S1	Right	26/18	3.2/4.7	None
MD (45 yrs old, female, lumbar spondylosis, flat back)	T10–S1	L4–S1	Left	38/6	3.2/4.3	None
LT (62 yrs old, female, adult scoliosis adjacent segment degeneration)	L1–S1	L5–S1	None	54/70	2.2/2.3	L5–S1 pseudoarthrosis
SM (56 yrs old, female, adult scoliosis adjacent segment degeneration)	T4–S1	L4–S1	Right	50/42	2.2/3.0	L4–5 pseudoarthrosis
LW (57 yrs old, female, adult scoliosis adjacent segment degeneration)	T3–S1	L5–S1	Left	32/6	3.5/3.5	None
SK (50 yrs old, female, adult scoliosis adjacent segment degeneration)	T8–L4	L4–S1	Right	52/28	3.4/3.8	None
NH (61 yrs old, female, adult scoliosis adjacent segment degeneration)	T12–S1	L5–S1	None	32/10	2.7/4.5	None

prepped and draped. We suggest that this two-step prepping and draping be performed to (1) minimize risk of infection and (2) allow for optimal patient positioning in lumbosacral lordosis for accurate targeting of the implant into the L5 vertebral body (and into L4 if it is necessary to fuse L4–5). The technique was performed essentially as described by the manufacturer (Trans1 Inc.). Prone position is the natural position to perform this procedure in as (1) the procedure often follows posterior instrumentation and fusion and (2) the positioning allows for optimization of lumbar lordosis. For a right-handed surgeon, it is easier to stand on the left side of the prone patient, with the C-arm coming in from the patient's right side. The screen is opposite the surgeon. A left-handed surgeon can set up the image in the opposite manner. At the right side of the coccyx, a 3-cm incision transverse incision was made and carried through the subcutaneous tissue with cautery. The ligamentous fascia is exposed bluntly to the presacral region using a curved Kelly clamp turned toward the anterior surface of the sacrum. Under fluoroscopy, a blunt dissecting tool (TranS1) then advanced along the midline of the sacrum to the S1–S2 level. At this point, the inner blunt stylet is exchanged for a guide pin and is tapped into the S1 vertebral body using a mallet, across the L5–S1 disc space and 1–2 mm into the L5 vertebral body under direct visualization. A series of dilators are then passed over the guide pin to dilate the sacral osseous path; a working cannula is then secured into place to allow for drilling of an osseous path from the anterior sacrum through S1 into the L5–S1 disc space. Discectomy is performed using radial and down-cutting blades. After discectomy, the disc space was bone grafted with local bone removed from the vertebral body and Grafton demineralized bone matrix (Osteotech, Eatontown, NJ, USA). In cases where the L4–5 disc space was to be fused, a drill was passed through a working sheath to enter the L4 endplate. Discectomy and bone grafting at L4–5

were performed in a manner identical to that described for L5–S1. A guide pin was used to measure implant length and the appropriate length AxiaLIF implant was inserted over a guide pin through a protective cannula transfixing the L4–5 level. A second implant was then passed, docking into the end of the L4–5 implant, transfixing the L5–S1 disc space. A locking plug was placed to secure the implants, the guide wires and cannulas were removed, and the wound is irrigated and closed in layers.

Several radiographic parameters were measured to evaluate the position of the interbody fusion as well as the trajectory of the implant (Table 2). Preoperative, postoperative, and final follow-up standing radiographs were evaluated. The following radiographic parameters were measured: lumbosacral lordosis (L1 superior endplate to S1 superior endplate), sagittal angulation at L4–5 and L5–S1 (measuring adjacent endplates), overall sagittal plane alignment measuring the sagittal vertical axis (distance between the plumb line from the vertebral body of C7 and the superior sacral vertical line (SSVL) drawn vertically from the posterior–superior endplate of S1), and overall coronal plane alignment measuring the coronal vertical axis (distance between the plumb line from spinous process of C7 and the central sacral vertical line (CSVL) drawn vertically from the midpoint of the sacrum). AxiaLIF screw position was assessed by measuring the sagittal distance from the implant and the anterior vertebral cortex (AVC) at L4, L5, and S1. Angulation in the sagittal and coronal planes is assessed by measuring the angle the implant makes with the SSVL and the CSVL, respectively (Fig. 1a, b). In the coronal plane, the distance between the tip of the implant and the CSVL was also measured.

Fusion was assessed clinically and defined as the absence of pain at the lumbosacral junction with flexion and extension, and radiographically defined as the presence of bridging bone across the disc space with no radiolucencies around the AxiaLIF implant, and the absence of

Table 2 Radiographic measurements after AxiaLIF implantation

	Preop	Postop	Final follow-up
L5–S1 sagittal angulation	22.7±16.2 (9–57)	22.2±12.9 (0–49) <i>p</i> =0.94	22.2±13.2 (3–49) <i>p</i> =0.94
L5–S1 sagittal translation	0±0 (0–0)	1±3 (0–9) <i>p</i> =0.332	1.3±4 (0–12) <i>p</i> =0.344
L4–L5 sagittal angulation	9.3±5.7 (1.2–3.6)	10.2±2.4 (7–13) <i>p</i> =0.75	7.8±4.7 (1–12) <i>p</i> =0.661
L1–S1 sagittal angulation	35.2±17.3 (9–65)	46.6±22.3 (11–69) <i>p</i> =0.24	42.3±16.8 (12–63) <i>p</i> =0.39
Sagittal vertical axis	47.8±33.2 (0–112)	49.1±29.8 (10–97) <i>p</i> =0.93	65.3±26 (37–100) <i>p</i> =0.23
Coronal vertical axis	5.1±13.9 (–22–24)	1.7±24.4 (–51–34)	–1±30.5 (–63–37) <i>p</i> =0.59
Implant–AVC at L4		8.4±8.6 (2–21.2) <i>p</i> =0.66	8.3±8.6 (1.9–21) <i>p</i> =0.99
Implant–AVC at L5		16.5±6.8 (4.6–24)	13.7±8.5 (0–25.7) <i>p</i> =0.452
Implant–AVC at S1		9.7±5.1 (2–15.4)	10.5±5.9 (3.9–19.5) <i>p</i> =0.75
SSVL–implant angulation		23.3±6.9 (11.5–31.3)	22.6±7.3 (15.3–34) <i>p</i> =0.837
Implant tip–CSVL distance		4.1±5.2 (0–14)	4.3±5.2 (0–16) <i>p</i> =0.94
CSVL–implant angulation		6.0±6.0 (0–19)	5.1±5.3 (0–17.5) <i>p</i> =0.97

All the values are in degrees ± standard deviation (range)

pedicle or iliac screw loosening or fracture. Clinical outcomes were measured by the SRS-22 and Oswestry Disability Index (ODI) scores. Means and standard deviation

were obtained for measured parameters in the preoperative, postoperative, and final follow-up subgroups. Measurements were compared using Student's *t* test with statistical significance set at a *P* value<0.05.

Fig. 1. **a** Shown is an anteroposterior radiograph of the lumbosacral spine demonstrating a well-positioned AxiaLIF implant and fusion of the L5–S1 disc space. The CSVL implant angle measurement is shown. **b** This lateral radiograph shows the SSVL–implant angle (*a*), implant–AVC distance at L4 (*b*), implant–AVC distance at L5 (*c*), and implant–AVC distance at S1 (*d*)

Results

For one-level AxiaLIF fusions (L5–S1), the average operative time was 94 min (range 60–120 min). For two-level AxiaLIF fusions (L4–S1), the average operative time was 150 min (range 120–180 min). Supplemental iliac screws were used in six cases, including all of the two-level fusions. At final follow-up, seven patients demonstrated fusion clinically and radiographically (Fig. 1a, b).

There were no significant radiographic changes in alignment after implantation of the AxiaLIF. Specifically, there were no significant differences in sagittal angulation or translation at L5–S1, sagittal angulation at L4–5, lumbar lordosis (L1–S1 sagittal alignment), or the overall sagittal and coronal vertical axes in the preoperative, postoperative, or final follow-up radiographs (Table 2). In addition, there were no significant differences in the AxiaLIF screw position in the immediate postoperative period and final follow-up based on implant–anterior vertebral cortex measurements at L4, L5, and S1, angulation between the implant and the SSVL or CSVL, and the distance between the tip of the implant and the CSVL.

Over the 1-year follow-up period, clinical outcomes in patients who underwent implantation of the AxiaLIF improved as measured by the SRS-22 scores and were unchanged as measured by the Oswestry Disability Index. There were no significant differences in the ODI scores measured preoperatively, postoperatively, or at final follow-up. The patients demonstrated significant improvements in their SRS-22 scores

at final follow-up specifically in the pain, self-image, and satisfaction with management domains (Table 3).

Overall, there were two complications in two patients, both pseudoarthroses. One patient, a 62-year-old female with a history of adult scoliosis and posterior spinal fusion, demonstrated a painful pseudoarthrosis at L5–S1 (Fig. 2). This was treated 14 months after the AxiaLIF procedure with revision L4–S1 instrumented posterior spinal fusion using iliac crest autograft. The second case, a 55-year-old female, also with a history of adult scoliosis and posterior spinal fusion, demonstrated a symptomatic pseudoarthrosis at L4–L5. This patient had iliac screw fixation on the right side. She underwent revision surgery 12 months after the AxiaLIF procedure with L4–S1 instrumented posterior spinal fusion using recombinant human bone morphogenetic protein (INFUSE, Medtronic Sofamor Danek, Memphis, TN, USA).

Discussion

In this report, we asked the following questions: (1) What are the short-term radiographic changes in alignment after undergoing axial lumbosacral interbody fixation and fusion at the end of long fusion constructs using the AxiaLIF implant (Trans1 Inc.)?; (2) What are the short-term clinical outcomes in patients after implantation of the AxiaLIF as measured by the SRS-22 and Oswestry Disability Index?; and (3) What complications are associated with this procedure? We observed no significant differences in sagittal angulation or translation at L5–S1, sagittal angulation at L4–5, lumbar lordosis (L1–S1 sagittal alignment), or the overall sagittal and coronal vertical axes in the preoperative, postoperative, or final follow-up radiographs (Table 2). There were no significant differences in the AxiaLIF screw position in the immediate postoperative period and final follow-up based on implant–anterior vertebral cortex measurements at L4, L5, and S1, angulation between the implant and the SSVL or CSVL, and the distance between the tip of the implant and the CSVL. Clinical outcomes in patients who underwent implantation

Fig. 2 This radiograph demonstrates a pseudoarthrosis at L5–S1 after one-level AxiaLIF. **a** Lateral radiograph taken 1 year after AxiaLIF implantation demonstrates a lack of bridging bone at the L5–S1 interspace (arrow). **b** A coronal reformatted CT image demonstrating radiolucency around the AxiaLIF implant

of the AxiaLIF improved as measured by the SRS-22 scores and were unchanged as measured by the Oswestry Disability Index. There were no significant differences in the ODI scores measured preoperatively, postoperatively, or at final follow-up. The patients did demonstrate significant improvements in their SRS-22 scores at final follow-up specifically in the pain, self-image, and satisfaction with management domains (Table 3). We had two pseudoarthroses, one at L4–5 and one at L5–S1. One of these patients had a positive sagittal balance of 97 mm after AxiaLIF. It is possible that the sagittal imbalance contributed to pseudoarthrosis (at L4–5) in this patient. There were no other differences noted in terms of overall spinal alignment or implant position between the successful fusions and the two pseudoarthroses; however, the numbers are too small to make statistical significant conclusions.

The limitations of this study include its retrospective design, the limited number of patients, and the limited follow-up. While a prospective randomized design may help compare outcomes between transsacral fixation and

Table 3 Clinical outcome scores at final follow-up

	Preop	Postop	Final follow-up
Oswestry Disability Index	43±10 (26–54)	44.7±12.3 (30–63) <i>p</i> =0.75	28.3±21.6 (6–70) <i>p</i> =0.083
SRS-22 (total)	2.9±0.5 (2.2–3.4)	3±0.6 (2.1–3.7) <i>p</i> =0.71	3.8±0.8 (2.3–4.7) <i>p</i> =0.011
SRS-22 (function)	2.8±0.8 (1.2–3.6)	2.9±0.8 (1.4–3.8) <i>p</i> =0.79	3.5±1.2 (1.8–4.6) <i>p</i> =0.165
SRS-22 (pain)	2.5±0.6 (1.8–3.4)	2.5±0.6 (1.8–3.4) <i>p</i> =1	3.4±1.1 (1.6–4.8) <i>p</i> =0.047
SRS-22 (self-image)	2.7±0.3 (2.2–3.2)	3.1±0.8 (1.8–3.6) <i>p</i> =0.18	3.8±0.9 (2.4–4.8) <i>p</i> =0.03
SRS-22 (mental health)	3.6±1.1 (1.6–4.6)	3.8±0.8 (2.8–5) <i>p</i> =0.67	4.1±0.7 (3–5) <i>p</i> =0.27
SRS-22 (satisfaction with management)	2.8±1.2 (1.5–5)	3.1±1.6 (1–5) <i>p</i> =0.66	4.4±0.8 (3–5) <i>p</i> =0.04

All the values are in degrees ± standard deviation (range)

other techniques of L4–S1 interbody fusions, the retrospective design still provides valuable information on the safety and complication rate of the AxiaLIF procedure. Larger numbers of patients and longer follow-up are needed to determine the fusion rate after AxiaLIF. However, this study identifies two pseudoarthroses within the first year, which are concerning and may require technique modifications, such as iliac screw fixation in cases where bone quality is poor.

There is only one other report [2] in the literature which includes patients in which AxiaLIF was performed caudal to long fusion constructs in 17 patients (21 levels) and followed for an average of 22 months. There were no complications related to the AxiaLIF in this study. Radiographic alignment was not specifically investigated in this paper. The authors report a 100% union rate in this study. Of note, the most proximal vertebrae in their study was T10, while three of our nine cases had fusion extending proximal to T10. With fusions as long as the ones in our study, it is possible that strain on the AxiaLIF implant may need to be supported by supplemental iliac screw fixation.

There was no change in the ODI scores in our patients. There were changes in the pain, self-image, and satisfaction with management domains of the SRS-22. This is likely because the latter parameters, which are very subjective measurements, are noted within the first few months to 1 year after surgery. Longer follow-up is likely necessary to see changes in ODI scores.

Based on our small series, the percutaneous presacral axial interbody fusion can be safely performed to fix and fuse L4–5 and L5–S1 below long fusion constructs. There were no major complications in this small series. Achieving proper sagittal balance is likely important to the success of the AxiaLIF procedure. As the major limitation in our study is the small number of patients with 1-year follow-up, a larger number of patients with longer follow-up are required before this procedure can be recommended for routine lumbosacral fusion. Furthermore, CT scans at final follow-up may be helpful to confirm fusion.

Disclosures One author (O.B-A.) certifies that he has received or may receive payments or benefits from a commercial entity related to this work.

Each author certifies that his or her institution has approved the reporting of these cases, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participating in the study was obtained.

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