ORIGINAL ARTICLE

Percutaneous Axial Presacral Lumbar Interbody Fusion: A Preliminary Case Series (Three Cases)

Shashivadhanan Sundaravadhanan

Abstract

Introduction: Traditional surgical management of lumbosacral spondylolisthesis is technically challenging and is associated with significant complications. The combination of percutaneous pedicle screw reduction and an axial presacral approach for lumbosacral discectomy and fusion offers an alternative procedure for the surgical management of low-grade lumbosacral spondylolisthesis. In an attempt to alleviate many of the limitations of previous lumbar fusion techniques, a presacral approach to the lumbosacral junction has been investigated. This study attempts to analyze the feasibility and efficacy of percutaneous 360° axial lumbar interbody fusion (AxiaLIF) as a standard procedure for lumbar fusion.

Materials and methods: A total of three patients were evaluated in this study. The AxiaLIF system (TranS1, Inc., Wilmington, NC) was used for this new fusion technique which combines a minimally invasive technique with a novel corridor approach. Results were compared preoperatively and following the surgery at 3 and 6 months.

Observation: There was a significant improvement in the pain scores. No complications were recorded and Magnetic Resonance Imaging revealed satisfactory implant placement with no neural compromise.

Conclusion: The AxiaLIF is a feasible procedure which will require long term studies before it can be validated as a standard technique for lumbar fusion.

Keywords: Interbody fusion, Percutaneous, Presacral axial lumbar.

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Aim

The aim of this study is to analyze the feasibility and efficacy of percutaneous 360° AxiaLIF as a standard procedure for lumbar fusion.

Materials and Methods

This study was conducted in a Government Tertiary Care Hospital of India. Three patients were offered this procedure. The patients included in this study had at least 2 years of intractable lumbar pain. They had already tried all other conservative modalities of treatment for low back pain. The patients included in the study had only vertebral pain with no associated sciatica. On radiology, the pathology was limited to the L5–S1 segment only. Up to grade II, spondylolisthesis cases were included in this study. Magnetic resonance imaging (MRI) of the lumbosacral spine was carried out and all those with abnormal sacral anatomy, like flat or hooked sacrum, very less presacral fat, or anomalous presacral vessels, were excluded from this study. Two patients were first offered posterior pedicle screw fixation followed by presacral fusion. In one patient with L5 spondylolysis without listhesis, the presacral approach was performed as a standalone procedure (Fig. 1).

Brief Outline of Operative Technique

The trajectory of the axial rod was planned on MRI sagittal images before the operation. A 2 cm paracoccygeal skin incision (palpating the tip of the coccyx) was made and the presacral approach was performed to place the anterior axial rod. The entry point was selected under fluoroscopic guidance close to the S1–S2 junction (on the lateral images) and close to the midline (on the anteroposterior images) so that the extension of a straight line from the entry point would cross the center of the L5–S1 disc. The trajectory was further adjusted under fluoroscopic guidance. Till the guide pin was placed within the body of S1, one has to stay in midline constantly making a deliberate attempt to stay beneath the presacral fascia constantly scraping against the sacral bone as the probe is being advanced till S1–S2 junction. On reaching the junction, the blunt-tipped probe is replaced by a beveled pin which is advanced through the bone by turning the bevel of the guide pin in the desired direction. Initially, a volumetric discectomy was performed by using specially designed radial cutting-loop devices and disc extractors. Next, bone graft consisting of a mixture of bone morphogenic protein and autograft harvested during trajectory creation is inserted into the disc space to create interbody fusion. The threaded axial rod was advanced along with the guide pin through S1 and into the L5 vertebral body. The superior aspect of this threaded rod, designed to engage the L5 vertebral body, had a wider thread pitch than the inferior S1 portion of the device, allowing intervertebral distraction by a reverse lag-type screw action. The rod was further advanced into the L5 vertebral body. By design, the axial rod can provide 1–6 mm of distraction of the spinal interspace, thereby indirectly widening the neural foramina. Once the axial rod was advanced to its final position, the handheld

Department of Neurosurgery, Command Hospital Air Force Bangalore, Bengaluru, India

Corresponding Author: Shashivadhanan Sundaravadhanan, Department of Neurosurgery, Command Hospital Air Force Bangalore, Bengaluru, India, Phone: +91 7042296201, e-mail: drshashivadhanan@gmail.com

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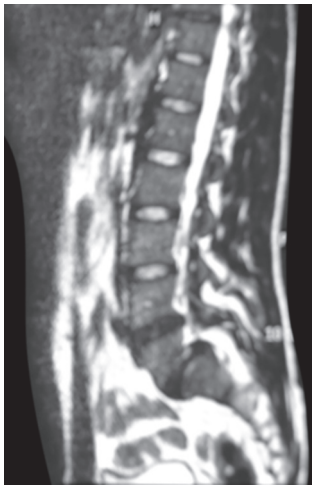

Fig. 1: Preoperative T2-weighted sagittal view image of the lumbosacral spine showing grade II spondylolisthesis

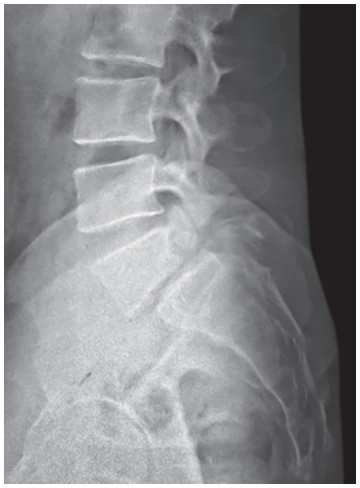

Fig. 2: Lateral view plain X-ray showing the bony outline of the same patient with grade II spondylolisthesis L5 over S1

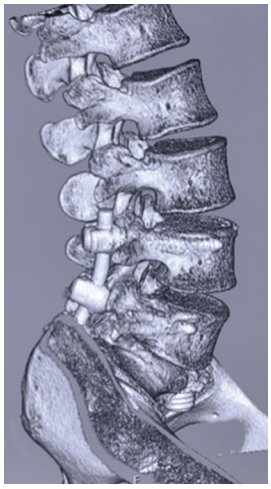

Fig. 3: Postoperative 3D reconstruction CT image with implant *in situ*

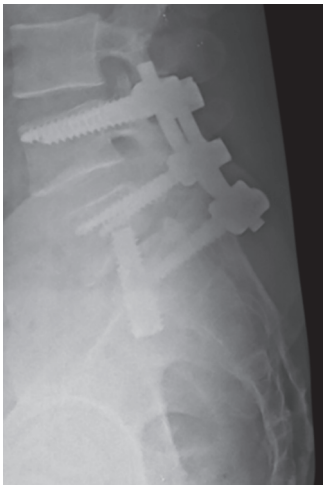

Fig. 4: Postoperative plain rontegenogram lateral view with implants *in situ*

screwdriver along with the sheath is withdrawn and the small wound is closed in a single layer (Fig. 2).

A total of three patients were subjected to this study. In one patient with L5–S1 spondylolysis, it was offered as a standalone procedure and in two patients with grade I spondylolisthesis L5 over S1, the procedure was supplemented with posterior pedicle screw fixation. In the preoperative planning, the MRI sagittal images were reviewed for trajectory planning. Dynamic X-rays covering lateral views were done of the lumbosacral spine to look for any translational mobility of the diseased segment. In the preoperative preparation, the bowel was prepared, and informed consent was taken which included consent to conduct any alternative procedure in case the proposed procedure failed. The pre- and postoperative neurological status, radiology, and pain scores were compared (Fig. 3).

Observation

Following the procedure, no patient developed any complication or any neurological deficit. The visual analog score which was 8 before the procedure improved to 4 at 3 months and, subsequently, improved to 2 at the end of 6 months following the surgery. Imaging with MRI showed the satisfactory placement of the implant with no evidence of fresh neural compromise. Marked clinical improvements were realized in back pain severity with no additional morbidity (Fig. 4).

Result

The percutaneous 360° AxiaLIF technique achieves satisfying therapeutic effects in the short term, although it has fairly narrow indication and needs a long-term follow-up observation before it can be validated as a standard procedure for lumbar fusion. The procedure offers the advantage of being a minimally invasive procedure for L5–S1 interbody fusion. It maintains the integrity of the bilateral facet joints, the anterior/posterior longitudinal ligament, and the annulus fibrosus and other support structure which provide strong ligament support for interbody fusion (Fig. 5).

Discussion

The presacral retroperitoneal ALIF was introduced in the United States, after the FDA clearance was obtained, in the late 2004 for L5–S1 interbody fusion.[1,2] Lumbar spine is a finely balanced biomechanical wonder that relies on the integration of intervertebral height, joint mobility proprioception, muscle balance, and

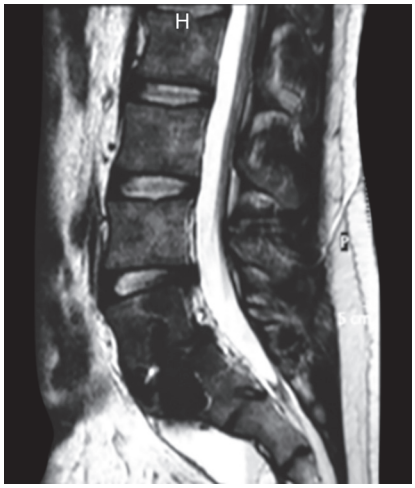

Fig. 5: Postoperative MRI T2-weighted sagittal image with implant *in situ* where it was offered as a standalone procedure for L5–S1 spondylolysis

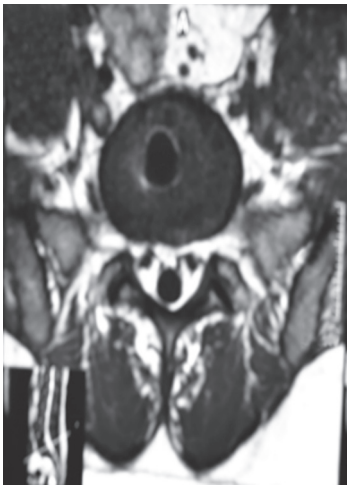

Fig. 6: Postoperative MRI T2-weighted axial view of the same patient showing the implant within the vertebral body

osseoligamentous constraint to allow us to function without pain.[3] This is the guiding philosophy of the AxiaLIF system as it attempts to immobilize the diseased segment with minimal destruction of the surrounding soft tissue structures. Interbody fusion (arthrodesis) in the lumbar spine is performed to treat painful symptoms caused by the instability of the vertebrae, lumbar vertebral pain due to spondylolisthesis, spinal stenosis, or degenerative disc disease.[4] Methods of spinal fusion include procedures in which bone grafts or metal implants are placed anteriorly, posteriorly, or laterally. However, the insertion of these implants is not without surgical risk. Numerous open and minimally invasive techniques have been developed but all of these approaches experience the same shortcomings related to biomechanics and inherent iatrogenic destabilization. In an attempt to alleviate many of the limitations of previous techniques, a presacral approach to the lumbosacral junction has been investigated in other countries. Transaxial anterior lumbar interbody fusion is an emerging minimally invasive spinal fusion procedure used to treat patients with chronic lower back pain resistant to conservative management.[5] This procedure is an alternative to traditional fusion techniques that utilize anterior or posterior approaches to directly expose the lumbosacral spine. In the case of transaxial anterior lumbar interbody fusion, the spine is accessed percutaneously *via* the anterior surface of the sacrum. The AxiaLIF system (TranS1, Inc., Wilmington, NC) combines a minimally invasive technique with a novel corridor approach.[6,7] Proponents of this approach report minimal risk to adjacent vital structures and no annular disruption.[8–14] The percutaneous presacral route may provide an alternative access route to the L5–S1 interspace in those patients who may have unfavorable anatomy or contraindications to the traditional open anterior approach (Fig. 6).[10,11,15,16]

This procedure offers the advantage of causing minimal soft tissue disruption of the Osseo ligamentous structures. It provides an alternative route for those patients with unfavorable anatomy. Theoretically allows better biomechanical fusion and adjacent level motion preservation. Lei He et al. evaluated the stress distribution over lumbosacral vertebrae and axial trans-sacral rod by means of a finite element analysis. They concluded that the standalone AxiaLIF offers sufficient stress resistance and, thus, meets the basic requirements for normal activities of patients. In comparison with other surgery-simulated models, only insignificant influence is exerted on load transfer in patients with spondylolysis or unilateral facet deficit.[4] In case one is planning the posterior approach also, then both procedures can be performed in the same sitting.

This procedure also has certain limitations; in that, it is applicable to only a certain selected group of patients. The procedure can be offered only to a selected group of patients. Preoperative imaging should be thoroughly evaluated with emphasis on perirectal fat pad thickness, identification of the rectum/sacrum interface, aberrant vasculature, and anticipated trajectory. All these findings preclude the placement of an axial rod through the lower lumbar segments and, hence, constitute unfavorable anatomy. The AxiaLIF system is not intended to treat severe scoliosis, severe spondylolisthesis (grade III or IV), tumor, or trauma. Contraindications for use include coagulopathy, bowel disease, pregnancy, and sacral agenesis. The use of the AxiaLIF system is limited to the anterior fusion of the lumbar spine at L5–S1 in conjunction with legally marketed posterior fixation systems. The AxiaLIF system should not be used with facet screws when spinal stenosis correction requires the removal of significant portions of the lamina or any portion of the facets. Its role as a standalone procedure is debatable. Like any new minimally invasive procedure, this has a learning curve. The long-term functional outcomes are yet to be seen as current published literature and trials are inconclusive. Guidance from the National Institute for Health and Clinical Excellence (NICE, 2011) concluded that current evidence on the efficacy of transaxial interbody lumbosacral fusion is limited in quantity but shows symptom relief in the short term in some patients.[17]

In the ultimate analysis, one can infer that the presacral approach is a novel minimally invasive approach for achieving lumbar fusion. However, it has not yet been established as the standard of care. Its use remains confined to a selected group of patients with chronic low back pain.

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