1. Introduction:

Lumbar fusion is a frequently used technique to treat spinal disorders including symptomatic instability due to traumatic and iatrogenic causes, stenosis, spondylolisthesis and scoliosis. Traditional anterior or posterior approaches are chosen for direct exposure of the lumbosacral spine. These traditional approaches are often poorly tolerated by patients, because they require significant muscle dissection and retraction, ligamentous disruption, osseous stripping, neural retraction, annular disruption, sympathetic dysfunction, and bowel injury and the additional risk of vascular injury with anterior approaches. Additionally, traditional anterior spinal approaches place the abdominal viscera, ureters, retroperitoneal structures, sympathetic plexi, and great vessels at risk. The advent of minimally invasive spinal surgical techniques has allowed surgeons to perform interbody fusion and screw placement with less pain, less damage to muscles, decreased blood loss, improved postoperative length of stay, and fewer medications than open surgery.

Degenerative disease of the lumbar disc space frequently affects the anterior column of lower lumbosacral spine as normal loading of the lumbar spine directs over 80% of the axial load over the anterior column in the lower levels. As such, traditional open fusion treatment of spinal instability and back pain at the L4-5 and L5-S1 segments is extremely common. Because of the potential risks of open surgical approaches, technological advances employing small incisions and portals have allowed surgeons to perform lumbosacral fusion via posterolateral or anterior approaches through less invasive and tissue sparing techniques. Recently, a soft tissue sparing minimally invasive approach to the axial lumbosacral spine has been developed. The AxialLif (Trans-1; Wilmington, NC; USA) system combines the advantages of minimal invasive spinal surgical techniques with a novel corridor of approach. Via a 2 cm paracoccygeal incision, a trocar is advanced along the anterior surface of the sacrum using biplanar fluoroscopy, until a proper trajectory in the center of the L5-S1 intervertebral space is obtained. This minimally invasive approach to the lumbosacral spine also preserves the integrity of the muscles, ligaments, blood vessels and disc annulus.

Through the naturally existing presacral fat pad, ready access can be gained to the disc space while avoiding the anterior abdominopelvic cavity, great vessels, neural elements, facets, lamina, and the dorsal musculoligamentous complex completely. Significant segmental stiffness is immediately afforded by distraction across the disc space. As the ligaments and annulus are completely intact, this provides the strongest possible ligamentotaxis thereby affording the best interbody fusion construct stiffness.

Additionally, an important advantage is that there is no need for retraction of the vascular or neural elements to place the prosthesis, as the size is limited only by the diameter of the working portal. As distraction is achieved by the differential screw pitch at the ends of the cage, a wide variety of distraction heights can be obtained by simply altering the design of the implant. When combined with percutaneous pedicle screw instrumentation system, additional distraction, compression, and reduction maneuvers...
can also be applied to the spine as needed prior to threading the cage across the interspace (3). Similar to trans-sacral fibular dowel struts in the stabilization of high grade isthmic spondylolisthesis, axially placed cages such as the AxialLif trans-sacral cage provide excellent resistance to shear, translation, flexion, and extension that is far superior to traditional interbody constructs (3,8).

This paracoccygeal, trans-sacral approach to the L5-S1 interspace allows the surgeon to perform a near-total discectomy without violation of the annulus or surrounding ligaments thereby significantly increasing the stiffness of the motion segment with distraction. Additionally, this leaves the area around the disc, great vessels, and neural elements untouched and thus free of surgical scarring which is beneficial given that future operations may require revision or surgery at an adjacent level (3). Recent advances in this technique now allow the surgeon to extend the fusion to include the L4-S1 interspace and extend the fusion from L4 to S1. The development of this technology allows an expansion to the applications and indications for this technique.

2. Indications:

Degenerative disc disease, pseudoarthrosis, post-laminectomy instability, spondylolisthesis (grade 1 or 2), and unsuccessful previous fusion are the main indications for this transsacral approach.

3. Contraindications:

Spondylolisthesis (grade 3 and 4), pararectal infection, and exceptional patient body habitus are the main contrindications for transsacral approach.

Two patients must garner specific attention: the thin patient and the patient with a flat sacrum. The thin patient may have minimal presacral fat, thus the surgeon must closely monitor the relationship between the introducer and the rectal air shadow on the lateral view. Additionally, an ideal trajectory is much more difficult in patients with a flat or hooked sacrum, so manual advancement of the dilator should be done carefully in these patients.

4. Surgical Procedures

4.a. Surgical Equipment

Several items of equipment are needed to perform a transsacral AxialLif fusion. First, the draped C-arm fluoroscopy and monitor are essential for verifying the position and localization of the patient during surgery. The transsacral AxialLif set (Trans1 Inc; Wilmington, NC) is necessary to perform the operation. Additionally, standard posterior lumbar minimal invasive surgery instruments are essential for the operation (Figure 1).

4.b. Operating room set up

A standard set up for posterior lumbar surgery is used with the spine surgeon standing on the left or right side of the patient with a operation technician and a surgical assistant. The C-arm and monitor is placed according to the localization of the surgeon (Figure 2a,2b).
4.c. Patient positioning:
The patient is positioned under general anesthesia prone on a suitable radiolucent spine operative table (Figure 2c). A 20-French catheter may be inserted into the rectum and the balloon insufflated with 10-12 ml air to provide visualization of the rectum and to minimize the risk of bowel injury during the process under lateral fluoroscopy. The anus is covered with an occlusive dressing that to separate it from the paracoccygeal working area which is more dorsal. Intraoperative EMG and/or SSEP may be used for neurophysiological monitoring for surveillance of neural integrity during decompression, interbody distraction, and screw placement. A fluoroscopic C-arm is located in the surgical field to provide real-time lateral and A-P imaging. The operation area is then washed and draped in the usual sterile fashion.

4.d. Surgical Technique:
A 15-20 mm incision is performed 20 mm caudal to the left or right paracoccygeal notch after local anesthesia (Figure 3a-1, 3a-2). Finger dissection may be used to ensure that the fascia is appropriately opened. The Guide Pin Introducer/Stylet Assembly is inserted into the incision with a suitable angle and slowly advanced along the anterior midline of the sacrum. Direct tactile feedback is obtained from the stylet to control continuous bony contact of the introducer tip. The presacral fat and anterior contents are swept off away from the bony floor of the pelvis with a rhythmic little oscillating movement under biplanar fluoroscopic control (Figure 3b-1,2,3,4). The Guide Pin Introducer is then engaged properly on the anterior cortex of the S1-S2 junction. After preliminary contact with the inferior aspect of the S1-S2 junction, a trajectory plan is made through the sacrum, L5-S1 disc space, and the L5 body under biplanar fluoroscopy.
This will be the final path for placement of the AxiaLif threaded cage. The trajectory of the stylet will pass through the middle and anterior portions of the L5-S1 intervertebral disc space while still ending in the anterior column of the L5 body.

The A-P plane of the fluroscopy must provide that the ultimate trans-discal trajectory will be near the midline and not too far off laterally in either direction. After the planning of optimal trajectory, the blunt guide introducer is exchanged for the sharp guide pin on a handle and then docked on the S1-S2 junction.

After the confirmation of trajectory, the Guide Pin is inserted through the sacrum (Figure 3c) with a cannulated slap-hammer. Serial dilators are used which will dilate the presacral soft tissue as well create the bony working channel the sacrum itself after the removing of the guide pin and handle.

At first, the bevelled 6 mm tubular dilator is slid over the Guide Pin using the Slap Hammer with the bevel facing ventrally to move the visceral contents anteriorly and away. When the dilator is in contact with the sacrum, it is rotated 180-degrees to match the bevel with the inclination of the sacrum. It is then inserted directly through the sacral surface and countersunk several mm to firmly seat it within the sacrum.
The 6 mm dilator is removed and changed with a 8 mm dilator to repeat the same series of steps. A 10 mm dilator is inserted after removal of the 8 mm dilator (Figure 3d). Finally, a thin walled Dilator Sheath is inserted over the 10 mm Dilator Body to assemble the dilators. This Dilator Sheath is anchored firmly in the sacrum using the slap-hammer under biplanar fluoroscopic confirmation. All assembly is removed except dilator sheath thereby establishing the safe, secure presacral, trans-sacrum working corridor for subsequent intervertebral access, discectomy, reaming, distraction, and threaded cage placement.

A 9 mm threaded reamer is inserted down the working portal into the sacrum to create the bony channel into the L5-S1 disc space (Figure 3e). Superior end-plate of S1 and L5-S1 disc space is passed with gently rotation of the reamer and then stopped on the inferior endplate of L5 without penetrating it at this moment. The reamer is then removed with the bone contained in the threads saved for later use as autologous bone graft material. The cutting-loop devices and disc extractors made from Nitinol memory-metal is specifically designed for a transsacral approach and it is used to perform a partial volumetric discectomy (Figure 3f-1,2,3). These cutting loops are passed into the L5-S1 sequentially with a preset angle and curvature to allow for a variety of cutting angles and lengths under fluoroscopic guidance to complete a rotational type discectomy. Additionally, cartilaginous endplates are carved off to create bleeding for the arthrodesis of cortical surfaces with forward and back-angled rotation of loops under manual pressure. The fragmented disc material is captured with a special wire brush type capture device (Figure 3g-1,2). So, radial removal of the disc nucleus is achieved while maintaining outer annular integrity.

After discectomy, a funnel-type cannula is inserted into the disc space to introduce the bone graft material. Optimally, a graft material is chosen with
the combination of autologous bone obtained during reaming, iliac crest bone marrow aspiration with or without concentration into a carrier matrix, demineralized bone matrices, and calcium triphosphates. After the impaction of 10-15 cc of graft material directly into the interbody space (Figure 3h), a smaller 7.5 mm diameter drill is inserted through the working sheath and penetrated directly into the L5 vertebral body. The 7.5 mm bit is then rotated and advanced to within 1 cm of the superior L5 endplate under biplanar fluoroscopy (Figure 3i). A final guide pin is inserted through the dilator sheath after removing the reamer.

A larger cannula is then slid over the final guide pin to allow placement of the 3D-Axial Rod prosthetic device (Figure 3j). This rod is a specially fabricated titanium prosthesis such that the threaded rod has two portions with different thread pitches. The superior part of the threaded cage that will engage into the L5 body has a diameter of 11 mm with a wider thread pitch as compared to the inferior S1 portion of the device which has a larger 14 mm diameter and a narrower thread pitch. The different diameter and thread pitch leads to distraction of the intervertebral disc space height as it is threaded between the S1 and L5 bodies. An appropriate sized screw is also used by measuring the distance of the guide pin as well as by adding the amount of desired segmental distraction.

The appropriate sized 3D-Axial Rod is then methodically inserted with a gentle movement over the previously introduced guide pin. It is then gradually rotated through the sacrum and into the intervertebral space with a T-handle. The differential pitch creates the distraction mechanism across the disc space as it enters the L5 body. The guide pin is then removed, when the 3D-Axial rod is advanced to the L5-superior endplate under biplanar fluoroscopy. Additional injection of iliac crest bone marrow aspirate, bone morphogenic protein, or other material can be injected through the center of the rod into the intervertebral space. The injection portal is then disengaged with a inserted threaded plug to prevent graft extrusion. The working incision is then irrigated with antibiotic impregnated irrigation after removing the rod introducer cannula. After this processes, the incision is closed gently.

![Figure 3e: A 9 mm threaded reamer is inserted down the working portal into the sacrum to create the bony channel into the L5-S1 disc space.](image-url)

Minimally invasive screw fixation at L5-S1 is performed after anterior L5-S1 interbody fusion. The pedicles of L5 and S1 are localized and marked with an 11-gauge needle under A-P and lateral fluoroscopy guidance. The skin and fascia is incised with 2 bilateral small incisions. A #11 jamshidi needle placed at the top of the pedicle and advanced into the pedicle through under biplanar fluoroscopic confirmation. The trocar is removed and exchanged for a kirschner wire. This technique has been previously described in combination with transacral fixation, but does not differ from most currently described percutaneous pedicle fixations. The pedicle is tapped and an appropriately-sized cannulated screw and extender sleeve is placed into the pedicle and vertebral body.
and grafting at the L5-S1 space are carried out essentially in the same manner as with one level fusion. However, prior to placement of the implant, the surgeon now drills through the L5 vertebral body. Given the distance covered in the two-level technique, trajectory is extremely important in the AxiaLIF 2L procedure. The trajectory used should be that the rod will be positioned within the L4 body, staying at least one diameter away from the anterior vertebral wall. Once the surgeon has drilled to the L4-L5 interspace, radial disectomy and bone grafting are done exactly as described for L5-S1.
Figure 3g: 1-2:
Cartilaginous endplates are carved off to create bleeding for the arthrodesis of cortical surfaces with forward and back-angled rotation of loops under manual pressure. The fragmented disc material is captured with a special wire brush type capture device.

Figure 3h:
10-15 cc of graft material is impacted directly into the interbody space.

Figure 3i:
A smaller 7.5-mm diameter drill is inserted through the working sheath and intervertebral space and penetrated directly into the L5 vertebral body.

Figure 3j:
A larger cannula is then slid over the final guide pin to allow placement of the 3D-Axial Rod prosthetic device.
Placement of the L4/L5 threaded dowel is guided by the use of the implant template and continuous fluoroscopic guidance. A L4/L5 dowel must be selected in which section B of the implant perfectly matches the height of L4 VB. Further, the template must be adjusted to accommodate both sections A and B of the implant such that the transition point between these two regions lies just cephalad to the superior endplate of L5. A 7.5-mm 2-level reamer is inserted. This is used to penetrate through the sacrum, both the L5-S1 and L4-L5 interspaces, L5 body, and into the L4 vertebral body. An accurate depth of reaming into the L4 VB is determined by the template, however, in general this terminates far before the L3-L4 interspace. The reamer is removed in a counterclockwise fashion. This ensures that the previously placed bone graft is not dislodged.

An appropriate implant is chosen. The template used to determine the L4/L5 implant is also used to determine the proper size of the sacral portion of the implant. This depends upon the desired degree of distraction as well as the sacral anatomy. In general, an implant with 25 mm length in the sacral component is often sufficient. However, in cases where greater distraction is desired, a 30 mm sacral length can be used. When both sections of the implant are determined, a 2-level guide pin is placed through the dilator sheath and left in place. An exchange cannula is advanced over this wire and rotated 180 degrees to match the sacral face. The L4/L5 implant should be advanced in place over the guide-pin under fluoroscopic guidance. Proper placement of the implant should place the portals of the rod within the L4/L5 disc space and the proximal end of the implant at the caudal L5 endplate. The S1 implant section is advanced through the exchange cannula until it engages the sacrum. The S1 implant is moved anteriorly through the sacrum and into the proximal portion of the L4/L5 rod. When the S1 implant is engaged with the L4/L5 implant, it can be rotated continuously to obtain the desired degree of distraction. The distraction mechanism of the implant is created by the differential pitch of the implant, which helps to restore both the height of the intervertebral disc and open the neural foramina to achieve indirect compression. An implant plug is threaded to seal the inferior portion of the implant and the incision site is closed in a routine fashion.

5. Postoperative Care:

The patient is returned to the supine position immediately after the operation. We routinely given a muscle relaxant systematically during the first postoperative day. The day after the surgery, the patient can be mobilized. We often obtain daily abdominal radiographs during the first post-operative days. Often the patient can be discharged 2-3 days after the operation. However, select patients may be discharged earlier. The resumption of previous activities is encouraged and we suggest a return to work 3-4 weeks after the operation.

6. Complications and Avoidance:

A number of complications are possible with this technique, but with care and anticipation, most can be avoided.

Neural structures in presacral space include the hypogastric nerves 1 cm lateral to the midline at the sacral promontory, parasympathetic nerves that arise from the ventral roots of S3-S4 in the male and S2-S4 in the female. Although the hypogastric nerves are located several centimeters laterally at S1-S2, the surgeon must be careful to avoid damage to these neural structures.

Vascular structures in the presacral space are the middle sacral artery and veins. Bleeding from the transverse sacral vein or the midline sacral artery is also possible, but at S2 the midline sacral artery is often small or non existent. The risk of venous bleeding is low as the technique begins with sweeping the soft tissues off the sacrum with a blunt dilator.
Minimally-Invasive Lumbosacral Axial Instrumentation Technique

Spinal infection is one of the possible complications but we believe the risk of infection related to the paracoccygeal approach has been low because the procedure is brief, percutaneous, and results in very little devitalized tissue and anatomic dead space.\(^9\)

Bowel perforations, re-operations, and implant breakage are rare but potential complications of this technique.

7. Case illustrations:

Case 1:
A 62-year-old obese male with severe low back pain was admitted to the neurosurgery department. The patient had no previous history of prior back surgery or trauma. Physical examination revealed no abnormalities. Plain radiographs, CT and MRI of the lumbosacral spine revealed narrowing and degeneration at the L5-S1 disc space without motion in flexion and extension (Figure 4a,b). Additionally, discography was positive at L5-S1 level and negative at the L4-5 level. The patient underwent a transsacral fusion with AxialLif (Trans-1; Wilmington, NC; USA) system with a combination of posterior minimal invasive stabilization (Pathfinder, Abbott Spine; Austin, TX; USA). Surgery was completed in 3 hours; blood loss estimated at 100 cc. He was discharged from the hospital 2 days following the surgery. Three weeks after surgery, he was off narcotic pain medications and had returned to work.

Case 2 (AxiaLIF, Two-level Technique):
This 15 year-old girl presented to our institution following a high-speed motor vehicle accident complaining of severe lower back pain with weakness and numbness in bilateral lower extremities. Her

Figure 4a:
Preoperative x-ray graphies and T2-weighted sagittal MRI demonstrates the significant loss of height and degenerative disc disease at the L5-S1 disc space.

Figure 4b:
Preoperative x-ray graphies and T2-weighted sagittal MRI demonstrates the significant loss of height and degenerative disc disease at the L5-S1 disc space.
Figure 5a:
Preoperative MRI showing the severe spinal canal stenosis.

Figure 5b,c:
Post-operative imaging demonstrated appropriate placement of the L4-S1 implant, removal of canal bone fragments, and placement of adjacent pedicle screws.

exam revealed saddle anesthesia and a L5 sensory level, muscle strength was diminished against resistance in the lower extremities and rectal tone was decreased. Imaging demonstrated a burst fracture of L5 with retropulsed bony fragments causing severe spinal canal stenosis (Figure 5a), a left-sided pneumothorax, and retroperitoneal hematoma. She was taken for emergent decompression with initial minimally invasive bilateral L5 laminectomies and partial transpedicular L5 corpectomy, followed by pedicle screw fixation at L4 and S1 with minimally invasive Pathfinder (Abbott Spine, Austin, TX) screw fixation. From the same position, a L4-S1 interbody fusion was done with the AxialLIF trans-sacral system. Post-operative imaging demonstrated appropriate placement of the L4-S1 implant, removal of canal bone fragments, and placement of adjacent pedicle screws (Figure 5b-c). At six month follow-up, the patient had regained full strength and sensation. She continues to do well 1 year from her surgery.

8. References