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Novel lumbosacral axial fixation techniques

Eric H Ledet[†], Allen L Carl and Andrew Cragg

For patients with low back pain secondary to pathological motion of an unstable lumbar motion segment, interbody fusion may be indicated. Numerous open and minimally invasive techniques have been traditionally used, but all suffer from shortcomings related to biomechanics or inherent iatrogenic destabilization. A novel transaxial approach to the lumbosacral junction has recently been described which appears to obviate many of the limitations of previous techniques. Preliminary results of the transaxial approach to lumbosacral fixation appear promising.

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Low back pain, neck pain and related spinal disorders are ubiquitous in industrialized nations, and there is a broad spectrum of clinical pathology associated with degenerative disorders of the lumbar spine. Low back pain can emanate from the paraspinal muscles, the facet joints, the spinal ligaments, from failed endplates or from degeneration of the intervertebral disc.

Disc degeneration often results in collapse and loss of disc height, with concomitant pathological instability. Segment instability is broadly defined as pathological hypermotion when a motion segment is subjected to normal physiological loads. This can be characterized quantitatively by an increase in total range of motion or by an increase in the amount of laxity near neutral position (neutral zone).

The etiology of disc degeneration remains controversial, but there is evidence indicating a correlation between exposure to repeated mechanical loads and the extent of pathology in the lumbar spine [1]. The lumbosacral junction presents a uniquely challenging biomechanical environment owing to the high axial compressive forces due to body weight and high bending moments from trunk motion. Subsequent to the onset of degeneration at the lumbosacral junction, an unstable degenerative spondylolisthesis may result due to the high anterior–posterior shear forces unique to that level of the spine. Milburn and colleagues

reported axial compressive loads nearing 8000 N and anterior–posterior shear forces of 350 N at L₅–S₁ during everyday activities [2].

Available therapeutic approaches

Current treatment strategies for an unstable degenerative disc are largely aimed at alleviating the symptom, that is, pain, and not at treating the disease itself. For patients who fail conservative treatment, surgery may be an option. For patients with degenerative instability as a source of pain, a fusion procedure may be indicated to eliminate pathological motion. A successful fusion eliminates intersegmental motion and may alleviate pain if the source is associated with an unstable degenerative spine [3].

Current indications for spinal fusion are broad. With improvements in technology and development of more minimally invasive surgical techniques, there is a large body of literature that advocates arthrodesis and fusion for the treatment of degenerative disc disease, internal disc disruption, segmental instability, revision of failed spinal surgery or reconstruction following excision of tumor or infection.

In 1997, there were approximately 150,000 fusion candidates, and an estimated 70,000–80,000 fusion surgeries in the USA [4]. The number of fusion procedures in the USA has risen rapidly, with a reported 77% increase between 1996 and 2001 [5]. Reported pseudarthrosis rates range from 5 to 35% [3,6,7].

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Although fusion procedures have been advocated for many pathologies, fusion remains controversial as treatment for discogenic pain, with little differences in long-term outcomes relative to nonoperative care [8,9]. Data also indicate that fusion procedures for patients with herniated discs or radicular pain may have no better outcome than discectomy alone [10].

Fusions have been shown to be particularly beneficial when used to treat degenerative pathology common at the L₄–L₅ and L₅–S₁ motion segments. However, fusion procedures at the lumbosacral junction are challenging with complication rates reported up to 37% [11,12].

Posterior pedicle screw-based systems, posterior hook- and rod-based systems, posterior wiring techniques, rods with placement into the iliac wings, lumbosacral plates and translaminar facet screws have been utilized for instrumented posterior lumbosacral fixation and correction of spinal deformities with a history of success [13]. The mechanical demands on these posterior systems are significant because they are not only loaded axially, but are also loaded significantly in bending because they are placed at a distance from the instantaneous axis of rotation [14]. Owing to the mechanical demands, posterior instrumentation used as a stand-alone treatment at the lumbosacral junction may result in residual intersegmental motion and hardware loosening or failure [15].

Forces developed in the lumbar spine are primarily transmitted through the disc and anterior structures with only a small fraction transmitted through the facet joints and posterior elements [16,17]. Thus, instrumentation via the interbody space has mechanical advantages for restoring segmental stability, particularly at the lumbosacral junction [18].

Anterior interbody fixation is mechanically advantageous because the graft or implant is loaded primarily in compression due to its proximity to the instantaneous axis of rotation [19]. Interbody implant failure is rare, but subsidence remains an issue, varying substantially on implant design, surface area of contact and material composition [4].

While synthetic interbody implants are generally sufficient to maintain intervertebral disc height, there is controversy as to whether interbody cage implants are sufficient to facilitate fusion as stand-alone devices [20–22]. Interbody implants are generally poor at resisting extension which is further complicated by the necessary removal of the anterior anulus for insertion.

For patients who might be at high risk for pseudarthrosis, particularly in the face of the challenging biomechanics of the L₅–S₁ level, a circumferential fusion may be indicated [23]. Fusion rates for circumferential procedures are higher than those for stand-alone posterior or anterior procedures [23], but even this remains controversial [9]. A circumferential fusion is mechanically advantageous, particularly in a segment with concomitant degeneration of the facets and intervertebral disc.

New therapeutic paradigm: axial interbody procedures

Placement of interbody implants through an anterior, posterior or lateral approach necessitates compromise of the anulus, an inherently destabilizing procedure. Minimally

invasive techniques may reduce morbidity, but do not eliminate iatrogenic destabilization because the anulus is still compromised.

Biomechanical testing has shown that a large box anulotomy or microdiscectomy will significantly reduce motion segment stiffness [24,25]. These data are well recognized; yet interbody fixation methods have universally required anulotomies and thus disruption of the inherent stabilizing tissues [26]. These approaches can reduce the intrinsic stability of the motion segment, particularly in extension [27].

To minimize disruption of the native stabilizing structures of a motion segment while capitalizing on mechanical advantages of interbody fixation, transdiscal fixation of the L₅–S₁ space has been demonstrated with promising early results [28,29]. One technique utilizes placement of pedicle screws through the S₁ pedicle, then through the L₅–S₁ disc space and into the L₅ vertebral body. This technique, which spans the disc space axially, has been shown to be mechanically advantageous relative to posterior instrumentation alone owing to the high strength of the cortical endplate bone [30]. Compromise of the anulus is avoided using transdiscal screws for interbody stabilization. However, this technique does necessitate wide exposure and the need for posterolateral bone grafting [31].

MacMillan and colleagues describe a minimally invasive technique for fusing the lumbosacral junction via placement of long 9-mm diameter screws from the ileum through the S₁ endplate into the L₅ vertebra. The transiliac–sacral approach was shown to be safe and early clinical results were excellent [32]. Leong and colleagues studied stability following placement of sacral screws in various configurations, concluding that two divergent screws affords the most stability of the configurations tested [33].

Cunningham and colleagues described transvertebral fixation of L₅–S₁ using threaded dowels and threaded cages in an *in vitro* biomechanical study [34]. The instrumentation passes through the L₅ vertebral body from anterior–superior to posterior–inferior across the L₅–S₁ disc space. When augmented with posterior L₄–S₁ pedicle screws, the system demonstrated higher stiffness than L₅–S₁ pedicle fixation alone. Although advantageous biomechanically, the transvertebral approach described requires open trans- or retroperitoneal exposure.

Minimally invasive axial interbody fusion

For patients who are appropriately indicated for interbody fusion at L₅–S₁, an axial percutaneous approach to the lumbosacral spine (AXLIF) has recently been described by Cragg and colleagues [35]. Using this technique, vertical access to the lumbosacral spine is achieved percutaneously via the presacral space. This approach allows for a novel means of access and fixation of the L₅–S₁ space axially. The technique spares the need for a large anterior abdominal exposure and avoids disruption of muscles, ligaments and, most importantly for stabilization, the anulus of the L₅–S₁ level.

The axial approach to the spine, as shown in FIGURE 1, is performed under fluoroscopic guidance using specialized instrumentation and bony landmarks of the ventral coccyx and

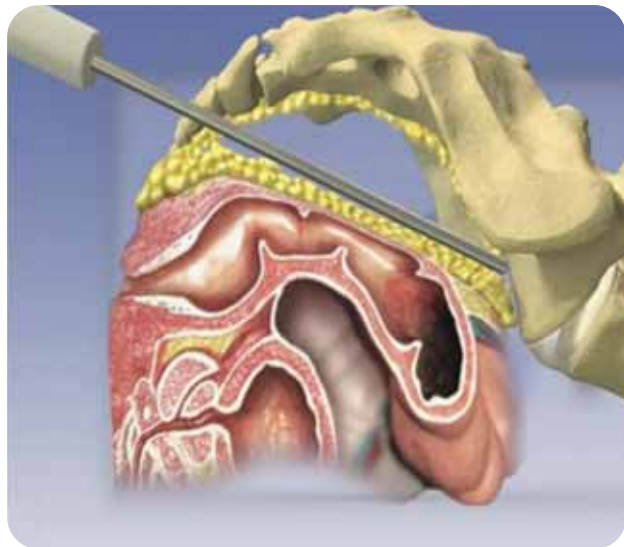


Figure 1. Axial approach to the spine. Blunt dissection is used to traverse the presacral space and access to the anterior sacrum percutaneously.

sacrum. The skin access site for the technique is paracoccygeal. This is usually 5–10 cm from the anus and is easily protected from contamination by surgical preparation and barrier dressing. Blunt dissection is used to traverse the presacral space with the rectum insufflated to minimize the risk of bowel injury. Serial dilators are used for inferior access to the anterior sacrum percutaneously. A transosseous tunnel is formed through the sacrum across the L_5 – S_1 disc space using a hand drill. Radial disc cutters are inserted through the axial tunnel and are used to completely remove the nucleus pulposus and decorticate the endplate. A bone graft inserter is then passed through the osseous tunnel and bone graft or other osteoinductive material is inserted into the disc space. Once the bone graft is placed in the debrided disc space, the tunnel is continued through the disc into L_5 with a smaller concentric hole drilled into L_5 . The Axial Fixation Rod, as shown in FIGURE 2, is then inserted, as shown in FIGURE 3. The tapered rod can facilitate distraction of the motion segment if the distal thread is a more fine pitch than the proximal thread, as shown in FIGURE 4. After rod insertion, additional flowable osteoinductive material may be inserted through the cannulated rod via the radial ports in the central unthreaded portion of the rod.

The ‘footprint’ of the implant occupies approximately only 10–15% of the area of the endplate. Bony fusion is facilitated within the margins of the debrided nucleus and inner anulus by the contained graft material, allowing the outer anulus to remain intact.

In a recent biomechanical study, Ledet and colleagues evaluated the Axial Fixation Rod *in vitro* to determine its effects on stiffness, range of motion and neutral zone in axial compression, flexion, extension, lateral bending and torsion as a stand-alone device [36]. The effects of drilling the axial channel through the L_5 – S_1 disc space were also evaluated. Data from

the study indicate that axial placement of an Axial Fixation Rod as a stand-alone device significantly increased the stiffness of motion segments in all testing modes in comparison with the intact specimen. Data also indicate that the effects of drilling for placement of the Axial Fixation Rod were minimal. The minimal changes resulting from axial drilling are unique relative to other procedures which necessitate large anulotomies and compromise of ligamentous structures. Thus, there appears to be minimal iatrogenic destabilization from the transaxial approach to the L_5 – S_1 disc space.

When compared with previously reported biomechanical data for stand-alone interbody cages including the BAK device, BAK Proximity™, Ray TFC™, Danek Threaded Lumbar Interbody Spinal Fusion Device, Harms cage, Brantigan Planar Laser Induced Fluorescence (PLIF) cage, Brantigan Anterior Lumbar Interbody Fusion (ALIF) cage, femoral ring allograft, bone dowel and InFix® device, the Axial Fixation Rod had the highest stiffnesses in flexion and lateral bending, while only the femoral ring allograft was more stiff in axial compression [37]. A comparison of data is shown in FIGURE 5.

Transaxial technology is being developed by TranS1, Inc [101]. The TranS1 AxiaLIF™ System has recently received US FDA market approval for anterior supplemental fixation of the lumbar spine at the L_5 – S_1 motion segment in conjunction with pedicle screw systems. Preliminary clinical results appear promising with good maintenance of disc height (up to 1 year). Early clinical data indicate evidence of bone formation in the interbody space around the implant, as shown in FIGURE 6.

In early clinical evaluations, some surgeons have used the AxiaLIF fixation rod as a stand-alone device (with no pedicle or facet screws) for stabilization, but there are no data available on the outcomes. The device is currently intended for use with posterior fixation to provide maximum stability.



Figure 2. The TranS1, Inc. Axial Fixation Rod is shown in three different lengths.



Figure 3. A transosseous tunnel is formed through the sacrum across the L₅–S₁ disc space and the Axial Fixation Rod is inserted.

There has been no incidence of infection in preliminary clinical follow-up. The salvage procedures in the face of infection would include removal of the implant through the same path as insertion, or via anterior exposure and removal at the sacral entry point (via unscrewing). Removal of the implant axially would leave a 12 mm channel through the vertebrae and disc. An ALIF or transforaminal lumbar interbody fusion (TLIF) technique could be used as a revision procedure. If axial removal is prohibitive, the device could be removed anteriorly via discectomy and partial corpectomy.

The axial approach to the lumbosacral junction may be advantageous to other interbody techniques in that it spares muscle, internal organ displacement and outer annular disc

tissue and preserves other future surgical options. The axial approach may have advantages for access to the L₅–S₁ disc space for single-level fusion and may be utilized for two-level fusions involving L₄–L₅ and L₅–S₁ using the same access.

For patients who are appropriately indicated for interbody fusion at the L₅–S₁ disc space, percutaneous axial interbody fusion may be advantageous relative to traditional methods due to the biomechanical advantage and minimal morbidity.

Optimal therapy

The etiology of back pain and instability in the lumbosacral spine remains unclear. Thus, optimal therapy for alleviating pain and restoring function to the disc cannot yet be defined. As knowledge of the pathology evolves, so too will more optimal therapy. Based on the current understanding of the physiology and mechanics of disc degeneration, the optimal fusion therapy is one which:

- Restores stability acutely
- Does not promote long-term bony resorption or subsidence
- Requires a short hospital stay and immediate return to everyday activities
- Allows for reconstruction, realignment or maintenance of the disc space
- Provides a delivery mechanism for osteoinductive and/or osteoconductive materials
- Promotes long-term bony fusion
- Will not fail mechanically in the face of pseudarthrosis
- Does not promote adjacent level disease
- Does not preclude future revision procedures
- Reduces surgery time, complications and morbidity relative to traditional methods
- Is cost-effective



Figure 4. The tapered rod can facilitate distraction of a motion segment as seen comparing (A) the preoperative image with (B) the postoperative image. Placement of the Axial Fixation Rod resulted in a gain in disc height postoperatively.

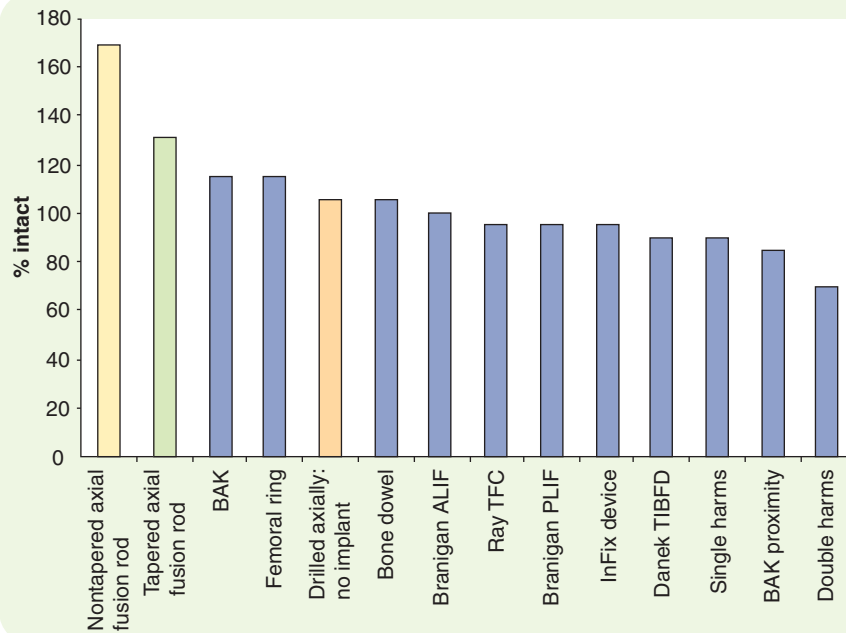


Figure 5. Mean flexural stiffness represented as a percentage of intact values for the Axial Fixation Rod and other interbody cage implants.

ALIF: Anterior lumbar interbody fusion; PLIF: Planar laser induced fluorescence; TIBFD: Threaded lumbar interbody spinal fusion device.

Appropriate patient selection is paramount as several factors can influence successful fusion rate including hormones, smoking, income, age, diabetes, immunocompromisation, previous surgery, workers' compensation status, fusion site preparation, blood supply, bone mineral density, mechanical environment, use of electrical stimulation and the use of growth factors [6,40,41]. Appropriate patient selection based on these factors is key to success.

Conclusion

Surgical techniques are often employed in the lumbosacral spine to eliminate pain and restabilize the affected segment. Numerous open and minimally invasive techniques have been used traditionally, but all suffer from inherent shortcomings either related to biomechanical disadvantage or inherent iatrogenic destabilization. The transaxial approach to the lumbosacral junction appears to obviate many of the limitations of previous

Currently, no therapy exists that embodies all of these desired characteristics. Early results indicate that minimally invasive transaxial fixation of the lumbosacral junction may afford additional benefits relative to traditional techniques for L₅–S₁ fusion, but the optimal therapy remains elusive.

Factors likely to affect choice of therapy or patient response

Lumbosacral fusion is not a new procedure; however, the available techniques have evolved rapidly over the last 20 years. Many techniques and implants have been adopted in spite of limited knowledge of the disease process and limited long-term review of clinical outcomes. Thus, the factors most likely to affect clinical outcomes for contemporary implants may not be adequately identified until long-term objective assessments can be made.

In a recent review, Bono reported 89% of all one-level fusion procedures were successful, whereas only 69% of two-level procedures went on to fuse [7]. The use of instrumentation (vs uninstrumented) to facilitate fusion increases fusion rate, but does not affect overall clinical outcome.

Design of instrumentation can also have a significant affect on fusion outcomes. Long-term clinical outcome data have been reported recently for interbody cage use. Data indicate that implants with stiffnesses much higher than the surrounding tissue may cause resorption of adjacent bone. This stress shielding effect can result in bone resorption followed by implant subsidence, loss of disc height and a poor clinical outcome necessitating a revision procedure [38]. Implants which have stiffnesses similar to the host tissue allow load sharing with newly formed bone, possibly stimulating enhanced bone formation [38,39].



Figure 6. Plain radiographs indicate evidence of bone formation in the interbody space around the Axial Fixation Rod at 1 year postoperatively.

techniques. Preliminary results indicate that using the Axial Fixation Rod via the transaxial approach to lumbosacral fixation is promising.

Expert commentary

Like other areas of surgery, there is a trend toward less invasive surgical solutions for lumbar spinal fusions. Early results from the minimally invasive axial approach to lumbar fusion show patients with early mobilization and that return home the next day. This is likely due to the reduced morbidity associated with the minimal muscle dissection. The novel technique also avoids potential revision problems including abdominal scarring and potential vascular injury (especially venous). It may also offer a unique avenue for placement of nucleus pulposus replacements and total disc replacements in the future. The axial approach may also be the avenue for drug delivery and tissue regeneration in the future.

Just as the transaxial axial fixation technique obviates many of the inherent shortcomings of traditional fusion procedures, there is potential for a motion-preserving implant to be placed using the same access. Thus, single-level L₅–S₁ disc replacement or two-level L₄–L₅ and L₅–S₁ disc replacement will be performed minimally invasively – perhaps as an outpatient – with no disruption of the outer anulus and minimal morbidity. Transaxial access to the lumbosacral junction suggests a new treatment genre for which a family of implants and procedures will be developed in the future.

Five-year view

The future of the spine is focusing on regenerative technologies. This is a break from the past in which the focus was on accelerating the degenerative process. It remains to be seen as to whether the pain cascade concomitant with degeneration can be altered or slowed and whether this will lead to a more successful result. There are more complex intertwined movable parts in the spine than in other more peripheral joints. This would make the smaller disruptive procedures more enticing, especially if peripherally associated functional damage can be minimized. The lack of biochemical insight in this arena also may slow progress and development of novel therapies. The thinking minds in spine are now starting to branch out in more than one direction but still mainly

focusing on structural and mechanical solutions. Further progress will be made once genetics, immunology and chemistry make advances for this field.

As the causes of degenerative diseases of the spine are elucidated, the focus of therapies will be shifted from the treatment of the end-stage symptom (pain), to prevention and reversal of the disease process. Yet, it is likely that there will remain a significant patient population who will require replacement or neutralization of irreversibly diseased tissue. For these patients, fusions or motion preserving stabilization techniques will remain options. Like other new therapies, there will be many early adaptors of disc replacement procedures. As long-term results are reported by unbiased investigators, the shortcomings of first-generation motion-preserving devices will become clear. Like fusion implants, the second- and third-generation implants and techniques will eliminate some of the complications and drawbacks of early disc replacements, and outcomes will continue to improve for those suffering from degenerative diseases of the lumbar spine.

Key issues

- Placement of interbody implants through an anterior, posterior or lateral approach necessitates compromise of the anulus – an inherently destabilizing procedure. Minimally invasive techniques may reduce morbidity, but do not eliminate iatrogenic destabilization because the anulus is still disrupted.
- To minimize disruption of the native stabilizing structures of a motion segment while capitalizing on mechanical advantages of interbody fixation, transdiscal fixation of the L₅–S₁ space has been proposed with promising early results.
- The axial percutaneous approach to the lumbosacral spine allows for a novel means of access and fixation of the L₅–S₁ space axially. The technique spares the abdominal muscles, ligaments and outer anulus of the L₅–S₁ level.
- Axial percutaneous access to the lumbosacral spine may be a delivery mechanism for future therapies to stabilize and treat degeneration of the lumbar spine.

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