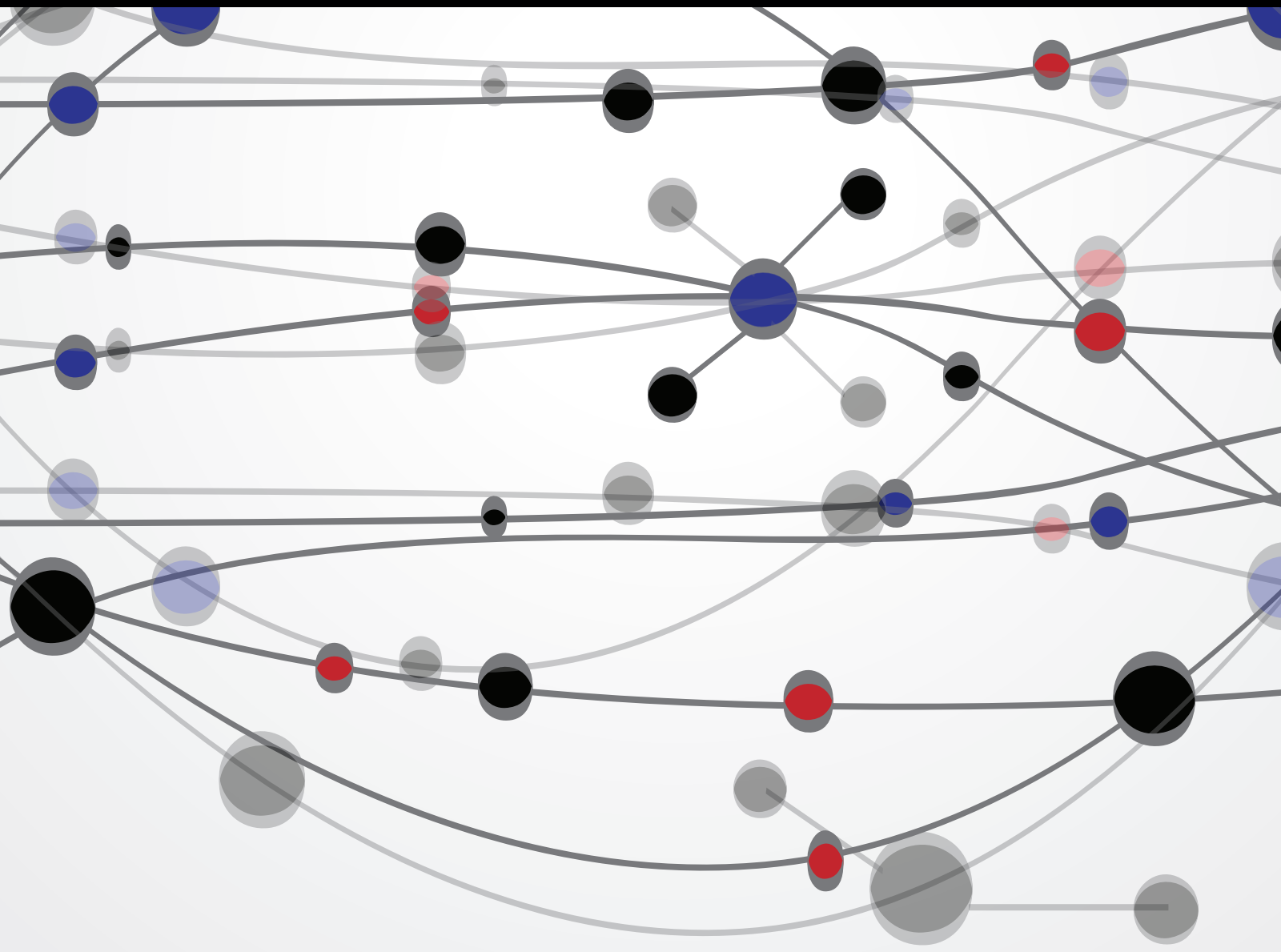
The Scientific World Journal

Lateral Access Surgery for the Thoracolumbar Spine

Guest Editors: Luiz Pimenta, William Smith, William Taylor, and Juan Uribe



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Editorial

Lateral Access Surgery for the Thoracolumbar Spine

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The advent of minimally invasive surgery has provided surgeons and patients the same good treatment alternatives. Within the field of spine surgery, techniques for lumbar interbody arthrodesis have shown enormous evolution. The retroperitoneal transpsoas lateral approach for the lumbar spine has revolutionized how interbody fusions can be performed more safely and with significantly less morbidity. In recent years, the role of minimally invasive transpsoas interbody fusion is strongly evolving. Lateral retroperitoneal approaches under direct visualization using expandable retractors have gained space and have been utilized for different purposes rather than interbody fusion. The objective of this special issue was to, for the first time in the literature, gather together articles on Lateral Access Surgery (LAS) and assemble unique peer-reviewed literature with basic and advanced reports focused in this emerging area.

The number of scientific articles about minimally invasive spine surgery (MISS) and specially about LAS is growing. The nature of the research tends to go to the same direction and evolve from single-center case reports to a higher level of evidence trials, once a recognized weakness in the MIS literature is the absence of randomized controlled trials. But by the other hand, randomizing patients were found to be challenging faced to patients' expectative and ethical principles. Given the challenges of conducting a randomized controlled trial and although more substantial research remains to be performed, nonrandomized concurrently controlled trials or prospective registries will provide valuable evidence-based medicine data. The level of evidence provided from the clinical and basic studies included in this special issue is not at the highest level of clinical trials, but though they represent different aims and indications for the lateral access, it can identify two patterns across them—safety and efficacy.

Among the table of content of this issue, V. S. Patel et al. go through overall indications and outcomes, while M. Malham et al. from Australia show results from their initial experience with the technique. The use of an allograft as bone graft option is well reported by A. G. Tohmeh et al. Basic science developments are illustrated with studies on biomechanics of interbody constructions and on the validation of an animal model. First developed for anterior based discectomy and interbody grafting in simple degenerative diseases, LAS has recently gained space for more complex indications. Over the years, it has been possible to address varied and complex scenarios. In this mindset, this special issue brings important reports that discuss advanced surgical applications of LAS—release of the ALL and sagittal reconstruction, degenerative scoliosis, application for revision surgery and thoracolumbar infection, and for L4-5 grade 2 spondylolisthesis.

We look forward to witness the evolution of spine surgery with the evidence based medicine to achieve the highest efficacy and safe to the patient who suffers from any spine-related condition.

Luiz Pimenta
William Smith
William Taylor
Juan Uribe

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Review Article

Use of Lateral Access in the Treatment of the Revision Spine Patient

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With the rate of spinal surgery increasing, we have seen a concomitant increase in the number of revision cases. It is, therefore, important to have a systematic approach to the management of these complicated patients with unique problems. A thorough understanding of the different pathologies affecting revision spine patients is critical to an effective treatment recommendation. Lateral access is a useful management approach since it can avoid the complications of operating through previous approaches. Furthermore, it possesses certain advantages for treatment in specific circumstances outlined in this paper. Long-term studies are needed to demonstrate the safety and efficacy of the lateral approach compared to the anterior and posterior approaches in the treatment of revision spine patients.

1. Introduction

With an aging population and increasing lifestyle expectations, advancing surgical techniques and improvements in perioperative care have resulted in a dramatic rise in surgical rates over the past two decades. From 1990 to 2001, rates of spinal surgery increased 220%, where most of this increase was following the approval of intervertebral cages for spinal fusion [1]. While most recent rates seem to have stabilized somewhat, the rates of complex spinal fusions compared with decompressions have continued to rise [2].

Although degenerative disease of the lumbar spine is similar to many other degenerative joint diseases, the spine possesses unique anatomical considerations compared to large joint disease. The spinal column is comprised of multiple motion segments in close proximity to each other, therefore, it is not surprising that what may affect one segment can subsequently affect another with or without surgery. Because of this, there exists no "definitive" spinal surgical procedure as problems may develop on the operated level(s) or at adjacent levels either as a result of surgery or from the natural history of the condition [3]. Not surprisingly, reoperation rates following primary spinal surgery have been reported between 10–18% [4–8].

Revision surgery poses specific challenges for the treating spinal surgeon since complications are more common compared to primary surgery [9]. As primary procedures may vary from minimally invasive to open surgical approaches with a variety of different instrumentation technologies, each has its potential complications. It is imperative that the surgeon possesses a systematic approach to the revision spine patient, a defined differential diagnosis, an understanding of deformity assessment, and an array of surgical revision strategies in their armamentarium. The purpose of this paper is to describe a concise approach leading to a differential diagnosis in the revision spine patient and to illustrate how lateral access techniques provide a useful method for treating these pathologies.

2. Initial Assessment

The initial assessment of the revision spine patient relies on a detailed history and physical examination. The chronological timeline of the symptoms with respect to the timing of prior surgeries is a key component in the assessment because it provides insights as to whether the new complaint is related to the previous procedures or a new phenomenon. Typically, complaints consist of isolated or a combination of pain, neurological deficits, and spinal deformity. In general, isolated back pain is a difficult entity to diagnosis due to the myriad of potential etiologies. Back pain at the site surgery can be due to pseudarthrosis, infection, prominent hardware, or adjacent segment degeneration (ASD). Persistent radiating pain to the legs in the same dermatomal distribution questions whether prior decompression was adequate, or stenosis is recurrent, whereas radiating pain in a new dermatomal pattern usually indicates new stenosis at another level.

Spinal imbalance after surgery can result from postsurgical instability, such as excessive facet and pars resection in post-laminectomy cases, adjacent level deformity, such as proximal junctional kyphosis (PJK), or progressive deformity through the original operative area from nonunions or subsidence. Inquiring about typical level of activity and functional limitations depicts the impact of the condition and provides a foundation to set realistic goals for treatment.

A detailed physical examination includes inspecting prior incisions to assess for prior or ongoing evidence of infection and the location of incisions (specifically in minimallyinvasive approaches) where future incisions may compromise skin vascularity. Similarly, the neurological evaluation must be comprehensive to consist of a complete sensory, motor, and reflex examination. Global coronal and sagittal spinal balance is assessed by having the patient stand upright. Pelvic obliquity and leg length discrepancy should also be noticed since this will affect surgical planning with respect to instrumentation. A complete assessment of spinal imbalance is beyond the scope of this paper and approaches to this problem have been published elsewhere [10].

Obtaining old records from the previous procedures including prior imaging studies and operative reports will allow the surgeon to appreciate the patient's presurgical condition, the operative approaches and the implants used and how the current presentation compares with their preoperative symptoms.

New imaging studies are obtained and compared to prior studies to evaluate the progression. Plain radiographs should include upright flexion and extension views to look for instability. Full-length 36-inch films that include the hip joints are necessary to evaluate spinal deformity to assess global coronal and sagittal balance. In the case of coronal imbalance or scoliosis, side-bending views to assess flexibility of curvature can be helpful. Computed tomography (CT) can be obtained to assess fusion mass and integrity of instrumentation. Magnetic resonance imaging (MRI) with gadolinium may depict recurrent stenosis, infection, and distinguish postsurgical changes. Post-myelographic CT is helpful in evaluating neurological compression in the setting of implant artifacts. Technetium bone scan with gallium can also elucidate the possibility of an infection.

Laboratory studies should include C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), and complete blood count with differential if infection is suspected. Vitamin D, calcium, complete lymphocyte count, and albumin levels portray current nutritional status and help direct perioperative dietary and medical management.

Table 1: The differential diagnosis of the revision spine patient.

	Same level	Adjacent level
Decompression	Infection CSF leak Stenosis Fracture Instability/deformity	Stenosis
Fusion	Infection Stenosis Fracture Symptomatic hardware Pseudarthrosis Instability/deformity	Stenosis Fracture Instability/deformity

3. Differential Diagnosis

The differential diagnosis for a revision patient can seem overwhelming at first; however, it can be considered more simplistically as a problem of location (operative or adjacent level) and index procedure (decompression or fusion). Potential complications in a previously decompressed area include infection, cerebrospinal fluid leak, restenosis, fracture, and instability. Likewise, potential problems after prior fusion are infection, pseudarthrosis, deformity progression, symptomatic hardware, and ASD (Table 1).

4. Treatment Options

Once a diagnosis is established, the surgeon has a variety of surgical approaches varying from minimally invasive to open procedures. Surgical approaches may be posterior, anterior, lateral, or a combination of several. The lateral transpsoas approach has gained popularity in place of the conventional anterior or posterior approaches to address anterior column support [11]. The advantages over other interbody techniques are that the lateral transpsoas approach can be less invasive and performed through a small window. Theoretically, the large interbody cage can provide a relatively bigger surface area for fusion while minimizing nerve root retraction compared with posterior interbody techniques and lower risk of vascular complications associated with anterior approaches. Revised anterior approaches have high complication rates since vascular complications can be as high as 57% [12]. Another reason for its growing popularity is the ability to bypass scarred tissue created by the typical posterior and anterior approaches. Mundis et al. [13] have also shown that when appropriate, minimally invasive lateral approaches yield lower blood loss and shorter hospital stay

compared to open anterior surgeries for patients with adult deformity. The disadvantage of this technique is approach-related thigh pain and weakness, steep learning curve, and the inability to access pathology at L5-S1 [11]. Moreover, although it might be able to indirectly decompress foraminal stenosis, posterior pathology like facet arthropathy needing direct decompression may be better addressed through a repeat posterior approach [14].

5. Indications Appropriate for Lateral Access

5.1. Infection. Postoperative infections are one of the most dreaded complications of spinal surgery. As with most surgical procedures, the risk is directly related to the length and complexity of the primary procedure. Surgical risk factors include arthrodesis, especially with posterior instrumentation, duration of surgery, and amount of blood loss [15, 16]. Patient risk factors include diabetes, smoking, malnutrition, obesity, age, corticosteroid use, and preoperative hospitalization greater than one week [17]. The causative organism is most often staphylococcal aureus, with methicillin-resistant Staphylococcus aureus reported in 34% of cultures in the series by Koutsoumbelis et al. [16]. Other causative organisms may be Staphylococcus epidermidis, enterococcus fecalis, and pseudomonas species.

Infection involving the anterior column, especially with retained interbody cages or total disc prosthesis that need to be removed and exchanged with new anterior column support, can be challenging to address through the previously operated approach due to scarring and anatomic constraints and can result in high rates of complications. The lateral access approach offers a new surgical avenue to address spinal infection, remove retained interbody devices and restore anterior column support [18, 19].

5.2. Pseudarthrosis. Patients at highest risk for pseudarthrosis are those with current nicotine use, poor bone quality, medical comorbidities (e.g., diabetes, immunosuppression), use of certain pharmacologic agents (anti-inflammatories), and even genetic predispositions. Risk factors related to surgical technique include the level of fusion, number of levels fused, use of instrumentation, and materials used for grafting [20, 21]. CT scans are the test of choice for detailing the osseous anatomy, however, false negatives have been estimated at 22% in a series of 175 patients [22] (Figure 1). Dynamic flexion/extension radiographs can also be helpful, but false negative rates are similar to CT at 27%. The gold standard of diagnosing pseudarthrosis remains re-exploration of the surgical site.

In cases where pseudarthrosis results from attempted posterolateral fusion, lateral access surgery can introduce better surface area for fusion through interbody fusion. For failed transforaminal or posterior lumbar interbody fusion, the lateral transpsoas approach can avoid scar tissue, remove old cages, introduce new cages, and allow for anterior fixation (Figure 2). In the presence of posterior pedicle screw and rod instrumentation, old impacted cages can be removed without removal of posterior instrumentation if desired.

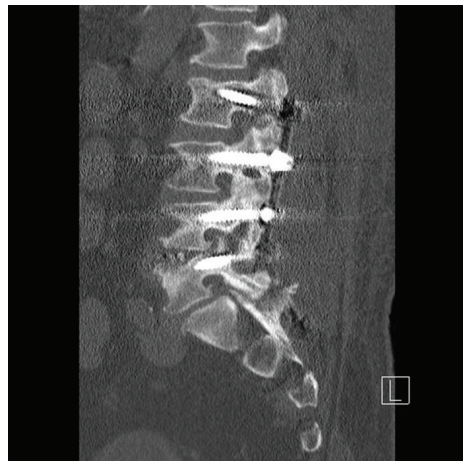
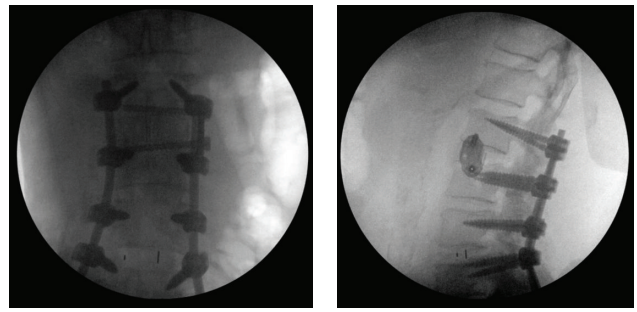


Figure 1: Sagittal view of CT scan showing loose L2 screws and a pseudarthrosis at the L2-L3 level.



(a) (b)

Figure 2: Intraoperative AP and lateral images showing L2-L3 interbody fusion and lateral plate fixation using the lateral transpsoas approach for pseudarthrosis.

5.3. Adjacent Level Degeneration. Adjacent segment degeneration (ASD) is defined as progressive degeneration above or below a prior fusion (Figure 3). ASD may manifest in back pain alone or may be associated with degenerative instability patterns such as spondylolisthesis, scoliosis, or kyphosis. The reported prevalence of adjacent level degeneration following lumbar fusion surgery has ranged between 5 and 43%, while the prevalence of operative interventions for these issues range between 2 and 15% [23].

Studies looking at adjacent level degeneration in spine fusions for scoliosis as well as longitudinal studies looking at fusions for degenerative lumbar disorders have shown increased incidence of degenerative processes in adjacent segments [24, 25]. Similarly, biomechanical cadaveric studies have also confirmed the increased stresses and motion at adjacent levels [26, 27].

Many patients can be treated conservatively as primary degenerative conditions. However, for those who fail these nonoperative measures or who have progressive deformity, extension of fusion will often be necessary. In single level disease, it may be possible to extend the fusion up by just one level. This could be performed in a variety of techniques such

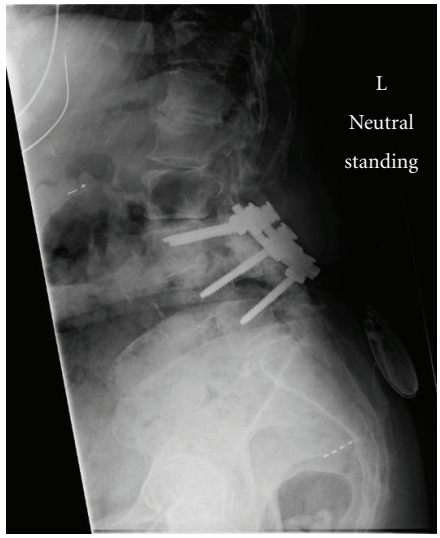


Figure 3: Lateral radiograph of the lumbosacral spine showing prior L3–L5 posterior fusion and instrumentation. However, there is adjacent segment degeneration cephalad to the instrumentation at L2-L3.

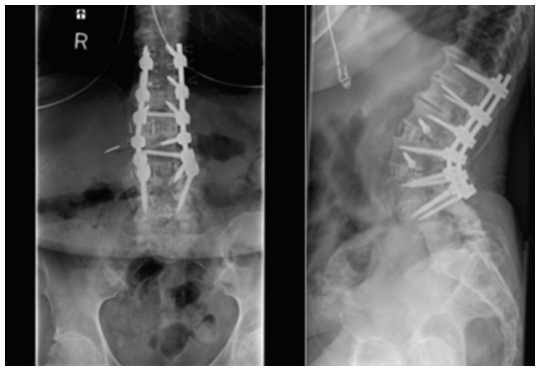


Figure 4: AP and lateral radiographs of the lumbosacral spine showing interbody fusion at L1-L2, and L2-L3 via the lateral approach and extension of posterior instrumentation and fusion from T11-L4. Notice improvement of lumbar lordosis and height restoration at the neuroforamina of L1–L3.

as transpsoas lateral, anterior, or revision posterior fusions. Lateral access can adequately stabilize this adjacent segment through interbody fusion and indirectly decompress the neural elements by distracting the disc space and ligamentum, which subsequently gives the neural foramen more space (Figure 4). The lateral approach allows the surgeon to avoid extension of the previous posterior instrumentation and avoid operating through previous scar tissue, thus reducing surgical time and its resulting morbidity.

5.4. Proximal Junctional Kyphosis. Proximal junctional kyphosis (PJK) is an adjacent level problem typically cephalad to a long posterior fusion resulting in a progressive kyphotic deformity. With the advent and introduction of more selective and segmental fusion techniques in treating spinal deformities, there has been increasing focus on the incidence of radiographically evident kyphosis between fused and mobile segments. Prior studies have estimated this incidence to be between 26 and 39% [28, 29].

Because PJK is generally caused by posterior instrumentation, either through radical dissection cephalad to the upper instrumented level or stopping the construct at a kyphotic junction, minimally invasive lateral interbody fusion is one method to reconstruct the anterior column aimed at restoring lordosis with or without supplemental posterior instrumentation. With anterior column lengthening through interbody height restoration, this technique may obviate the need for three-column osteotomies. Even in cases where osteotomies are necessary, lateral interbody fusions can be used to reconstruct the anterior column and reduce the risk of pseudarthrosis in retained disc spaces adjacent to pedicle subtraction osteotomies.

6. Surgical Pearls

While indications for the lateral approach for interbody fusion vary considerably in the revision patient, the technique remains similar to the primary situation. A detailed description of the basic technique is beyond the scope of this paper; however, certain technical pearls will be discussed.

In cases in which posterior instrumentation remains at a level with pseudarthrosis requiring interbody fusion, the surgeon must determine if there is a need for deformity correction or if the current position is acceptable. If the position is acceptable then the surgeon can carry out a lateral fusion in the standard way without distracting the disc space excessively. If deformity correction is required, then removal or loosening of instrumentation is required. This can either be performed with an initial posterior approach or in the lateral position with the appropriate screwdriver to loosen the set-screws and release the rod. It is especially helpful to obtain the screwdriver that exactly matches the current instrumentation to perform this percutaneous rod release. A second posterior stage is recommended to tighten or replace the posterior instrumentation in the new corrected position or perform further correction from the posterior approach.

In cases of infection or pseudarthrosis with posteriorly placed interbody cages, the surgeon should determine the side closest to the device in order to facilitate removal from the lateral approach. Careful attention to preoperative cross-sectional imaging will determine if lateral cage removal will result in neural element injury. In many cases, a partial corpectomy may be required to dislodge the retained cage. Bone hooks or threaded removal instruments may be needed and even fragmenting the cage is sometimes necessary if it does not come out in a single piece. After removal, a large lateral cage is recommended to ensure that it sits on both lateral cortices of the vertebral bodies to prevent subsidence into the cancellous bone beneath the endplates.

Patients with resultant coronal deformity are well treated with a lateral approach. Conceptually, it is usually preferable to approach from the concave side as correction is facilitated by positioning the patient on the convex side with bending the table over the operative level. Using this technique, a thorough lateral release on the ispilateral side can be performed. Contralateral release is also necessary for ideal

correction. Sequentially increasing trial sizes can dilate and expand the disc space, thus horizontalizing the cephalad vertebral body on the caudal one. In cases where the vertebral body has remodeled into a trapezoidal shape from longstanding erosive degeneration, a coronally tapered cage may be preferable.

Sagittal deformity following previous spinal surgery can be easily treated with interbody techniques since they provide anterior column lengthening. The lateral approach is an attractive method for achieving this since it may be performed in a less invasive way. Depending on the degree of deformity correction and the number of fusion levels planned, the correction may be easily addressed with standard size lateral cages. In general, a caudad to cephalad progression is easiest as the anterior column is reconstructed from the bottom up. In cases in which only a few fusion levels are planned and a large correction is required, the surgeon must decide if anterior interbody is the desired technique as opposed to an osteotomy. Newer techniques of anterior column reconstruction with release of the anterior longitudinal ligament and high lordotic cages are currently being developed and may be beneficial in select cases [30].

7. Conclusions

With the rate of spinal surgery increasing, the spine surgery community has seen a concomitant increase in the number of revision cases. It is, therefore, important to have a systematic approach to the management of these complicated patients with unique problems. A thorough understanding of the different pathologies affecting revision spine patients is critical to an effective treatment recommendation. Lateral access is a useful management approach since it can avoid the complications of operating through previous approaches. Furthermore, it possesses certain advantages for treatment in specific circumstances outlined in this paper. Long-term studies are needed to demonstrate the safety and efficacy of the lateral approach compared to the anterior and posterior approaches in the treatment of revision spine patients.

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Clinical Study

Early Outcomes of Minimally Invasive Anterior Longitudinal Ligament Release for Correction of Sagittal Imbalance in Patients with Adult Spinal Deformity

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The object of this study was to evaluate a novel surgical technique in the treatment of adult degenerative scoliosis and present our early experience with the minimally invasive lateral approach for anterior longitudinal ligament release to provide lumbar lordosis and examine its impact on sagittal balance. *Methods*. All patients with adult spinal deformity (ASD) treated with the minimally invasive lateral retroperitoneal transpsoas interbody fusion (MIS LIF) for release of the anterior longitudinal ligament were examined. Patient demographics, clinical data, spinopelvic parameters, and outcome measures were recorded. *Results*. Seven patients underwent release of the anterior longitudinal ligament (ALR) to improve sagittal imbalance. All cases were split into anterior and posterior stages, with mean estimated blood loss of 125 cc and 530 cc, respectively. Average hospital stay was 8.3 days, and mean follow-up time was 9.1 months. Comparing pre- and postoperative 36″ standing X-rays, the authors discovered a mean increase in global lumbar lordosis of 24 degrees, increase in segmental lumbar lordosis of 17 degrees per level of ALL released, decrease in pelvic tilt of 7 degrees, and decrease in sagittal vertical axis of 4.9 cm. At the last followup, there was a mean improvement in VAS and ODI scores of 26.2% and 18.3%. *Conclusions*. In the authors' early experience, release of the anterior longitudinal ligament using the minimally invasive lateral retroperitoneal transpsoas approach may be a feasible alternative in correcting sagittal deformity.

1. Introduction

Many factors are involved in the surgical management of adult spinal deformity, including maintenance of coronal and sagittal balance, as well as spinopelvic harmony [1–5]. Adult spinal deformity (ASD) is believed to develop because of asymmetrical degeneration of discs, osteoporosis, and vertebral body compression fractures [6]. Presenting symptoms of this condition primarily includes radiculopathy, chronic low back pain and neurogenic claudication caused by concurrent spinal stenosis [7, 8].

Studies by Schwab et al. [9] and Glassman et al. [10] have demonstrated that in the treatment of congenital and acquired deformity, correction of sagittal alignment to an SVA <5 cm leads to improved clinical outcomes. One of the multiple limitations of MIS techniques is that up till now they have been unable to improve sagittal balance significantly [11]. Sagittal imbalance is traditionally managed with posterior shortening osteotomies, anterior lengthening maneuvers, or both. Classically, closing wedge osteotomies include Smith-Peterson osteotomy (SPO), pedicle subtraction osteotomy (PSO), and vertebral column resection (VCR), which have been reported to have a 41% complication rate in ASD [12, 13]. Major complications in revision adult deformity surgery were reported by Cho et al. to be 34% in a retrospective review of 141 patients [14]. Sectioning the anterior longitudinal ligament (ALL) via the minimally invasive (MIS) lateral transpsoas approach with placement of a hyperlordotic cage has been proposed as an alternative to open traditional osteotomy for correction of sagittal plane deformity [15, 16]. Up to this point, literature on this subject has been scarce, and to the

authors' knowledge, the safety and early outcomes of this procedure have not yet been examined. In this paper, we describe our early clinical experience with ALL release (ALR) for the purpose of increasing lumbar lordosis and improving sagittal misalignment.

2. Materials and Methods

We retrospectively reviewed a prospectively acquired database of all patients with adult thoracolumbar degenerative deformity treated with an ALR via the minimally invasive, lateral retroperitoneal transpsoas interbody fusion (MIS LIF) at our institution. Parameters reviewed include patient demographics, preoperative/postoperative evaluations, spinopelvic parameters, sagittal vertical axis (SVA), procedure performed, operative time, blood loss (EBL), length of hospital stay, and complications. In order to quantitate early outcome measures, we compared preoperative and postoperative scores on the visual analogue scale (VAS) and the Oswestry Disability Index (ODI). These linear scales provide a percentage from 0 to 100%, with 0 representing no pain or disability and 100 representing complete disability and pain. Postoperative followup took place at weeks 2, 6, 12, 24, and 52 when available. If patients did not show up for a scheduled follow-up appointment, VAS and ODI scores were obtained over the telephone.

All patients in the cohort presented with mechanical back pain with or without radicular pain refractory to at least 12 months of nonoperative management and were in global sagittal malalignment. According to the Lenke-Silva classification for ASD, patients fell into levels 2, 3, 4, or 5 and were managed with a MIS version of their operative schema [17]. All patients with sagittally maligned ASD were evaluated for ALR although not all were candidates for this procedure. Patients with adolescent idiopathic scoliosis (AIS) or scoliosis secondary to neuromuscular conditions were excluded from the study.

3. Operative Technique

Prior to attempting this procedure in vivo, in order to minimize complications, we strongly encourage cadaveric dissection and a review of the literature focusing on the safe zones of the lateral approach [18–21]. In addition to the anatomical nuances regarding the lateral approach previously described, the anatomy of the ALL from the perspective of the lateral transpsoas approach is described by Deukmedjian et al. in a recent study [22]. The surgical procedure consisted of a variation of the previously described technique for the lateral retroperitoneal transpsoas approach to the lumbar spine [23]. After performing the discectomy with careful attention to endplate preparation, a slight curved custom retractor/dissector was gently passed along the anterior edge of the ALL and positioned between the large vessels/sympathetic plexus and the ventral aspect of the disc (Figure 1). Dissecting dorsal to the great vessels is the key step in this procedure, and although we have had no catastrophic complications, it would be possible at this step. Although there is a plane ventral to the ALL, a common pitfall we found during cadaveric dissection was to mistake the sympathetic plexus for the lateral edge of the ALL, which would lead to sectioning of the plexus. We are currently evaluating our patients for clinical ramifications of this for a future study. At this point, using a custom ligament blade and intradiscal distractor, the ALL was sectioned in a sequential fashion, easing the curved retractor across to the contralateral side of the disc space. With complete ALL sectioning, there was immediate mobilization and "fish-mouthing" of the adjacent vertebral body endplates. An appropriate sized hyperlordotic polyether-ether-ketone (PEEK) cage was selected at this point (CoRoent XL-Hyperlordotic, NuVasive, Inc., San Diego, CA, USA). These cages were packed with allograft (Osteocell, NuVasive, Inc., San Diego, CA, USA) and anchored to the adjacent VB with one or two screws to prevent ventral migration into the peritoneal cavity and loss of indirect decompression (Figure 2). In each case, pedicle screws were placed posteriorly to stabilize the construct, most commonly using a percutaneous technique.

4. Results

From 2010 to 2012, 7 patients (4 women, 3 men) underwent a MIS lateral retroperitoneal transpsoas approach to release the ALL in the treatment of sagittal imbalance in patients with ASD (Table 1). The mean patient age was 64.7 years (range 58–71). All patients successfully had 30-degree hyperlordotic cages placed in conjunction with standard cages at the other lumbar levels for anterior column support and interbody fusion (Figure 3). ALR was performed at 11 levels in the 7 patients (average 1.6 per patient), while a total number of 28 interbody fusions (average 4 per patient) were performed. 51 levels were fixated during a second stage with pedicle screws (average 7.3 per patient), all of which were done using the percutaneous technique except for one patient who had a revision surgery.

Average EBL was 125 cc for stage I and 530 cc for stage II, and the average length of hospital stay was 8.3 days (there was a minimum of 5 days between stage I and II). No patients required a blood transfusion and there were no catastrophic complications to report in our cohort. There were no durotomies, blood vessel or bowel injuries, and no patient had lasting postoperative weakness. One patient, however, did have a superficial wound infection in the lateral incision that was treated successfully with a wound washout and a short course of intravenous antibiotics.

During postoperative radiographic assessment, it was noted that there was an average increase in global and segmental lumbar lordosis of 24 and 17 degrees, respectively (Table 2). Overall sagittal balance improved by 4.9 cm, as measured on the SVA, going from 9 cm to 4.1 cm. Pelvic tilt (PT) decreased by an average of 7 degrees, from 32 to 25 degrees (Figure 4).

VAS and ODI scores were used as outcome measures, and average time from surgery to filling out the latest questionnaire was 9 months. VAS and ODI scores improved an average of 26.2% and 18.3%, respectively. VAS scores went

Table 1: Demographic and surgical data of cohort ($n = 7$).

Case	Age/sex	DOS	Level(s) of ALR	Interbody levels	Fixation levels	Blood loss (1st stage/2nd stage)	Complications
1	67 F	8/13/10	L2/3	L1-S1	T10-iliac	100/300	—
2	67 M	2/8/12	T12/L1 L2/3 L3/4	T12-S1	T10-S1	20/1100	—
3	71 F	10/26/10	L1/2	L1-5	T10-L5	100/500	—
4	69 F	3/16/11	L2/3	L2-5	L2-5	10/100	—
5	62 M	5/18/11	L2/3 L3/4	L1-5	T12-L5	100/300	—
6	58 F	2/16/11	L2/3 L3/4	L2-S1	L2-iliac	500/1100	Superficial infection
7	59 M	11/16/11	L3/4	L1-S1	T11-S1	50/300	—

Table 2: Pre- and postoperative spinopelvic parameters and outcome measures of the cohort.

Case	Preop LL	Postop LL	Preop SVA	Postop SVA	Preop PT	Postop PT	Preop VAS	Postop VAS	Preop ODI	Postop ODI
1	10	37	18	15	38	35	75	50	56	42
2	28	61	10	1.5	48	25	55	28	54	34
3	22	46	7.5	5.5	43	34	90	63	92	66
4	19	39	3.2	2.8	31	26	68	65	40	34
5	33	51	10.5	0	35	28	43	18	22	18
6	37	61	7	0.5	18	18	100	83	86	42
7	20	40	6.5	4	10	7	80	20	70	56
Mean	24	48	9	4.1	32	25	73	47	60	42

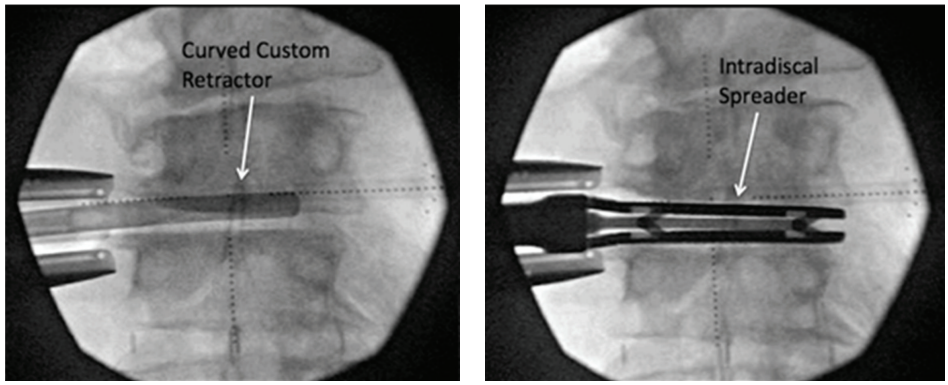
from an average of 73% to 46.8% after surgery, while the ODI scores improved from an average of 60% to 41.7% after surgery (Figure 5).

5. Discussion

With a growing elderly population demanding a longer active lifestyle, the impetus has been placed on spine surgeons to use innovations in technology to provide less invasive solutions to increasingly complex spinal deformities. Asymmetric degeneration of disc spaces in the thoracolumbar/lumbar spine is believed to be one of the causes that result in adult degenerative scoliosis/deformity. Symptoms of this class of spinal deformity may range from relatively asymptomatic to axial or radicular pain in 90% of patients [7, 8]. In many cases, patients with ASD are opting for surgical intervention when conservative measures fail. Traditional goals of adult deformity surgery are correction of coronal and sagittal balance and obtaining a solid fusion. However, treatment of adult spinal deformity is constantly evolving, and radiographic goals such as pelvic tilt <25 degrees and LL = PI ± 9 degrees have been established [4, 9, 24]. For the purposes of this study, we focus here on improving sagittal balance to an SVA <5 cm.

Although the importance of sagittal plane deformity has been well studied, especially in the context of flat back syndrome, we now have a guideline to keep sagittal balance, or SVA less than 5 cm to optimize clinical outcomes [25–28]. Sagittal plane correction is traditionally accomplished through posterior shortening techniques, such as a Smith-Peterson (SPO) or pedicle subtraction osteotomy (PSO), which, although effective, may be associated with significant morbidity [29–31]. Another option is the release of the anterior longitudinal ligament. Although not a new concept, it is relatively infrequently practiced because of significant approach-related morbidity [32–36]. Recently, however, the lateral retroperitoneal/retropleural approach to the thoracic and lumbar spine has provided spine surgeons with another, less invasive option in scoliosis surgery [37]. It has been shown previously that minimally invasive spine surgery results in less blood loss, reduced muscle dissection/trauma, shorter hospital stays, and faster mobilization and recovery after surgery [38].

5.1. Technical Aspects of MIS ALL Release. In this study we describe our experience with MIS ALR, and through our results show that it is not only a safe option but also one that provides significant improvements in sagittal balance with low morbidity. As with all new MIS techniques, there is a steep learning curve, and the most important factor is understanding the procedure and the surrounding anatomy. In addition to the usual risks associated with the lateral approach, unique perils associated with ALR include great vessel injury and damage to the sympathetic plexus [22]. However, the anatomical dissection plane is ventral to the ALL and dorsal to the sympathetic plexus and great vessels, making injury less likely. In addition, we avoid electrocautery and use a modified 15 blade to cut the ALL to minimize



(a) (b)

Figure 1: Intraoperative anterior-posterior radiographs demonstrating the curved retractor anterior to the disc space during dissection of the sympathetic plexus off the great vessels (a), and the intradiscal spreader in the disc space used to break the contralateral ALL remnant rather than blindly incising (b).

Figure 2: Photograph demonstrating the 30-degree hyperlordotic cage with attached screws to prevent ventral migration into the peritoneum.

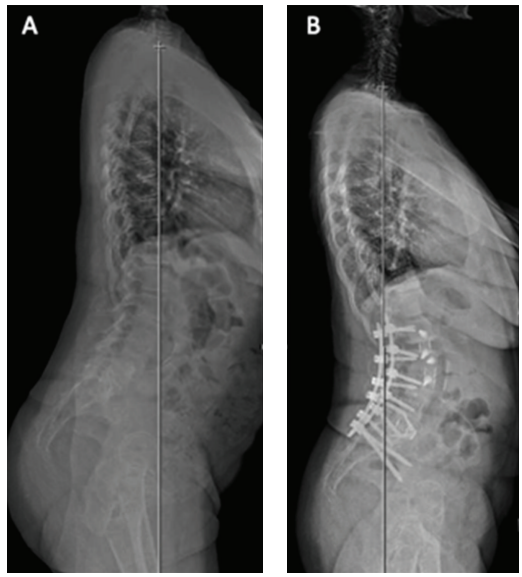
damaging surrounding tissues. Placing the patient in the left lateral decubitus position also allows better control of the inferior vena cava. In order to perform the final release of the ALL, use of the intradiscal distractor may avoid blind sectioning of the ligament on the contralateral side. After completion of the ALR, placing the hyperlordotic cage in the middle of the disc space may increase the disc height and provide indirect foraminal decompression. The cage is then secured into place with a screw to avoid anterior migration into the peritoneum.

5.2. Clinical Implications on MIS ALL Release. Although the average follow-up time in our series is only 9 months, we believe that this is adequate for the purposes of identifying the safety and efficacy of this procedure since the main results and complications occur during the immediate postoperative period. Ongoing analysis of these patients is being performed with the purpose of a future study to evaluate if the sagittal balance is maintained.

Short-term complications include vascular and neural injuries, while long-term complications include subsidence, pseudarthrosis, and adjacent segment failure, which are not unique to this surgery.

Length of hospital stay in our cohort was 8.3 days, similar to the 7.9 days reported by Schwab et al. in the group of patients without complications [39]. In our practice, surgery for adult deformity is generally done in two stages. The lateral approach for placement of interbody cages as well as sectioning the ALL if necessary is done during the first stage, and posterior fixation with either percutaneous or open pedicle screw placement is performed in the second stage. We recommend breaking large deformity cases into two stages for various reasons, including ease on patient in terms of operating time and related complications and ease on surgeon preventing long and difficult procedures. Another important factor is the ability to reassess the patients' spinopelvic parameters between stages to customize planning for the posterior procedure and assess need for hybrid constructs including an MIS SPO or open laminectomy/instrumentation versus percutaneous screw fixation.

Mean blood loss in our cohort during stage 1 was 125 cc, and during stage 2 was 530 cc, with a total of 655 cc. The International Spine Study Group recently published a study demonstrating that greater intraoperative blood loss (>2.4 L) is a major risk factor for perioperative complications [39]. This is another benefit of correcting sagittal balance through a minimally invasive approach. The global lumbar lordosis in our group improved by 24 degrees, from 24 to 48 degrees, while segmental lordosis at the levels where an ALR was performed improved an average of 17 degrees. Given that the SVA improved by 4.9 cm, from 9 to 4.1, and within the range established by Lafage et al., we expect postoperative outcome scores to be improved [40, 41]. This is in fact the case, as VAS and ODI scores improved by 26 and 18%, respectively. Another likely contribution to the overall



(a) (b)

Figure 3: (a) Pre- and (b) postoperative standing 36 inch lateral radiographs demonstrating improvement in sagittal vertical axis after two-level ALR plus multilevel MIS LIF with open posterior instrumentation.

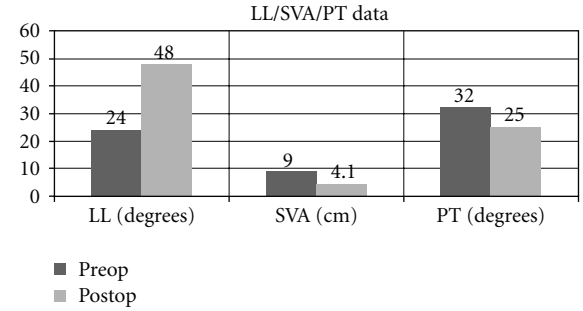


Figure 4: Graph demonstrating pre- and postoperative values for lumbar lordosis (LL), sagittal vertical axis (SVA), and pelvic tilt (PT) in our cohort.

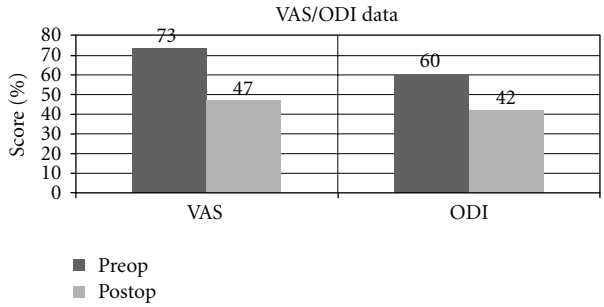


Figure 5: Graph demonstrating pre- and postoperative values for visual analogue scale (VAS) and Oswestry Disability Index (ODI).

patient improvement is that the pelvic tilt improved on average by 7 degrees, from 32 to 25 degrees, also within the recommended range of less than 25 degrees.

5.3. Complications. All techniques for restoration of sagittal balance have significant risk of complications and are technically challenging [14, 39]. We attribute our low rate of complication to multiple factors, the most important of which is understanding the regional anatomy. Before attempting an ALR which has a steep learning curve, we spent time in cadaveric dissection in the lab, isolating the sympathetic plexus as it runs along the anterolateral border of the lumbar vertebral bodies in order to determine if there was a plane between the ALL and the sympathetic plexus/great vessels. Only when it was determined to be feasible in cadaveric specimens were we willing to try it in our patients [15, 22]. After performing MIS LIF for five years on over a thousand levels and multiple dissections and publications, we felt confident in our ability to perform an ALR. As of yet there are no cases of subsidence, which is a potential complication with hyperlordotic cage placement.

In our cohort of 7 patients, we had no complications except for a superficial wound infection treated successfully with a wound washout and short course of intravenous antibiotics.

5.4. Limitations. During the dissection there is no adequate proximal and distal control of the great vessels. In case of injury to the aorta or inferior vena cava, the surgeon would likely need to extend the skin incision anteriorly and perform direct compression of the vascular structures followed by proximal and distal control, followed by direct repair of the defect.

The low number of patients ($n = 7$) in our cohort was a potential limitation in this study; however, we believe that it was adequate to demonstrate our results as well as the feasibility of this technique. At this point we must again stress the importance of understanding the surrounding

anatomy if attempting an ALR, as its true safety lies in the hands of the surgeon performing the procedure. The mean follow-up time of 9 months is also slightly below the 2-year standard, but in the context of a new surgical technique is sufficient for our goals. We believe that this technique requires further study to be able to draw general conclusions, and we will continue to follow these patients to assess long-term outcomes.

6. Conclusions

Sagittal imbalance is a causative factor of clinical impairment and is of great concern to spine surgeons. It can be managed through anterior lengthening procedures and posterior shortening techniques. Both are historically associated with significant morbidity. Our early experience using the MIS lateral retroperitoneal transpsoas approach to release the ALL and place a hyperlordotic cage shows that this approach may give up to 17 degrees of segmental lordosis and may be a feasible alternative to more traditional approaches such as posterior osteotomies.

Disclosure

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Clinical Study

Allograft Cellular Bone Matrix in Extreme Lateral Interbody Fusion: Preliminary Radiographic and Clinical Outcomes

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Introduction. Extreme lateral interbody fusion (XLIF) is a minimally disruptive alternative for anterior lumbar interbody fusion. Recently, synthetic and allograft materials have been increasingly used to eliminate donor-site pain and complications secondary to autogenous bone graft harvesting. The clinical use of allograft cellular bone graft has potential advantages over autograft by eliminating the need to harvest autograft while mimicking autograft's biologic function. The objective of this study was to examine 12-month radiographic and clinical outcomes in patients who underwent XLIF with Osteocel Plus, one such allograft cellular bone matrix. *Methods*. Forty (40) patients were treated at 61 levels with XLIF and Osteocel Plus and included in the analysis. *Results*. No complications were observed. From preoperative to 12-month postoperative followup, ODI improved 41%, LBP improved 55%, leg pain improved 43.3%, and QOL (SF-36) improved 56%. At 12 months, 92% reported being "very" or "somewhat" satisfied with their outcome and 86% being either "very" or "somewhat likely" to choose to undergo the procedure again. Complete fusion was observed in 90.2% (55/61) of XLIF levels. *Conclusions*. Complete interbody fusion with Osteocel Plus was shown in 90.2% of XLIF levels, with the remaining 9.8% being partially consolidated and progressing towards fusion at 12 months.

1. Introduction

Conventional surgical approaches for lumbar interbody fusion using open exposures have been associated with high rates of approach-related morbidity and extensive soft-tissue dissection [1–12]. Common complications include vascular, visceral, and reproductive complications after conventional direct anterior lumbar interbody fusion (ALIF) [1, 8–12] and nerve injury following posterior/transforaminal lumbar interbody fusion (P/TLIF) [11, 13–16]. Minimally invasive (MIS) approaches for lumbar interbody fusion have gained in popularity over the past decade as nonendoscopic MIS approaches have been developed to allow for greater reproducibility without extended learning curves [17–21].

These modern MIS approaches include mini-open direct anterior ALIF [17, 21], MIS TLIF [16, 22, 23], and mini-open lateral ALIF (extreme lateral interbody fusion (XLIF)) [19]. The miniopen lateral ALIF approach accesses the lumbar spine through a mini-open, 90° off-midline, retroperitoneal, transpsoas approach and largely avoids vascular, visceral, reproductive, and neural complications common to conventional direct anterior ALIF and P/TLIF approaches, with minimal incidence of infection, transfusion, and markedly shorter hospitalization when compared with traditional open approaches [24, 25]. The primary potential risk when performing the XLIF procedure is injury or irritation to nerves in and around the iliopsoas muscle. However, the risk to motor nerves is mitigated through the use of advanced neurophysiologic monitoring, which provides real-time, surgeon-directed, discrete threshold electromyographic responses in directional orientations, to supply geographic information on the position and distance of motor nerves relative to instrumentation [26–29]. As a result, the most commonly reported complications following the XLIF procedure have been mild hip/thigh numbness and hip-flexion weakness, which typically resolve within 6 weeks following surgery [24, 26, 30–32].

The XLIF procedure preserves the anterior and posterior longitudinal ligaments and the exposure allows for broad disc space preparation and placement of a wide intervertebral cage that spans the lateral borders of the ring apophysis, resting on cortical bone to resist implant subsidence. The large aperture of the interbody cage allows for the placement of bone graft material and a large surface area for fusion.

In addition to minimizing approach-related morbidity through the use of mini-open approaches, synthetic and allograft materials have been increasingly used to decrease donor-site pain and complications secondary to autogenous bone graft harvesting [33, 34]. One such example is allograft cellular bone matrix (ACBM), which retains its native bone-forming cells, including mesenchymal stem cells and osteoprogenitor cells. Like autograft, ACBM provides all three physiologic mechanisms that are instrumental in normal bone healing, including osteoconduction, osteoinduction, and osteogenesis [35, 36].

The clinical use of allograft cellular bone graft has potential advantages over autograft in spinal fusion procedures by eliminating the need to harvest autogenous bone graft—which can lead to infection, increased blood loss and operative time, chronic donor-site pain, and iliac crest fracture, in addition to the fact that the immediate postoperative pain associated with bone harvesting defeats the purpose of minimally invasive surgery [33, 34]—while still providing all three elements necessary for bone healing. Of note, the mesenchymal stem cells (MSCs) contained in ACBM, which have multipotential differentiation abilities in vivo, can differentiate into mesenchymal tissues, namely, bone and cartilage through osteogenesis and chondrogenesis, respectively.

The object of this study was to examine 12-month radiographic and clinical outcomes in patients who underwent extreme lateral interbody fusion with ACBM as the sole bone growth substrate.

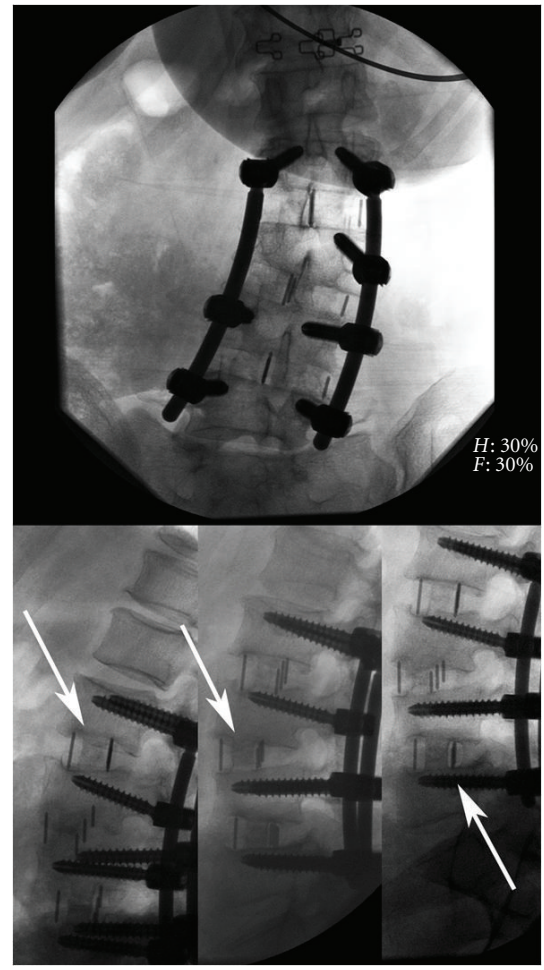

Figure 1: Anterior and lateral fluoroscopy-guided, level-by-level radiography. Note that parallel endplates were obtained on lateral radiography using this technique (white arrows), avoiding X-ray parallax.

2. Methods

Clinical and radiographic data were collected through a prospective registry examining patient outcomes after undergoing XLIF (NuVasive, Inc. San Diego, CA, USA) for lumbar interbody fusion using Osteocel Plus (NuVasive, Inc.) ACBM at a single institution in Spokane, WA, USA, from February 2009 to February 2011. Neurophysiologic monitoring was performed in all cases using NV JJB/M5 (NuVasive, Inc.). Inclusion criteria in the current post hoc analysis included having been treated with XLIF at any level with ACBM as the sole bone graft material, having had at least 12-month followup with fluoroscopy-guided, level-by-level, radiography (FGX) (to eliminate parallax and make accurate PER-level assessments, Figure 1) or computed tomography (CT) assessed by a third-party reviewer to determine extent of bony fusion in XLIF levels. Fusion criteria used are as follows.

(i) Complete Fusion. Complete ossification with some component of endplate involvement.

(ii) Incomplete/Progressing Fusion. Ossification in cage that abuts one or both endplates without evidence of endplate involvement or continuous bridging bone.

(iii) Indeterminate. Clear lucencies at endplates with or without ossification in the cage.

In total, forty (40) patients met all inclusion criteria and were included in these analyses. Thirty-nine (98%) patients had fusion status evaluated using FGX, while one (3%) was assessed by CT. Of the 40 patients assessed for fusion, 35 (88%) had both preoperative and 12-month postoperative functional outcome scores, which were evaluated as a subset of the sample.

Mean age of the patients was 60 years (range 36–82 years) with a mean body mass index of 28.1 (range 20–38). Comorbidities were common, with 48% of patients having a history of heart disease, 20% with diabetes mellitus, 13% were smokers, and 65% had undergone prior lumbar spine surgery. Of those with prior spine surgery, a total of 20 surgeries had been performed: one (5%) discectomy,

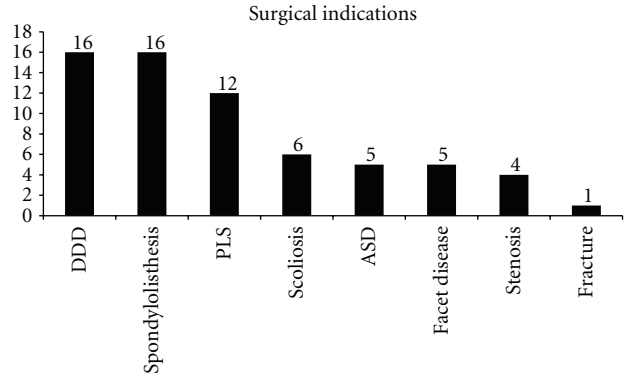

Figure 2: Graph showing the number of patients with each indication.

7 (25%) instrumented fusions, and 18 (70%) laminectomies. Sixty-five (65) indications for treatment were noted in the 40 patients (mean 1.6 per patient). The most common diagnoses (multiple per patient) were degenerative disc disease (DDD) (40%), spondylolisthesis (40%), and post-laminectomy syndrome (30%). A listing of all diagnoses can be found in Figure 2 and full baseline characteristics are included in Table 1.

In total, 68 levels were treated in 40 patients (mean 1.7 levels per patient, range 1–3) between L1 and S1. Of these, 61 levels from L1 to L5 were treated with XLIF and 7 levels at L5–S1 underwent TLIF. The most common levels treated were L4-5 (48%) and L3-4 (30%). A complete listing of XLIF levels treated is included in Figure 3. Supplemental internal fixation was used in all patients and included lateral plating in 38% and bilateral transpedicular fixation in 63% of patients. A direct decompression was performed in 13 (33%) patients. In all cases the sole biologic material used was Osteocel Plus. Complete treatment characteristics are included in Table 2.

For a historical control, a review of the literature was performed to examine fusion and pseudoarthrosis revision rates in lumbar spinal fusion using autograft as the bone graft material. A total of 24 peer-reviewed articles [8, 13, 15, 18, 37–56] following 2,026 patients treated with lumbar fusion using autograft were reviewed and analyzed. Articles reviewed were determined to have the following levels of evidence: [57] I : 7 (27%), II : 3 (14%), III : 2 (9%), and IV : 11 (50%) and procedures examined included conventional direct anterior ALIF in 11 (50%) studies, TLIF in 2 (9%), PLIF in 5 (23%), and posterolateral fusion in 5 (23%).

Table 1: Demographic information.

Characteristic	Statistic $n = 40$
Mean age in years (stdev) (range)	60.4 (12.2) (36–84)
Female (%)	20 (50)
Mean body mass index (BMI), (stdev) (range)	28.1 (4.4) (20–38)
Comorbidities (mean number per patient)	63 (1.6)
Comorbidity type	
Tobacco use (%)	5 (12.5)
Coronary artery disease (%)	19 (47.5)
Diabetes (%)	8 (20)
Chronic obstructive pulmonary disease (COPD) (%)	2 (5)
Steroid use (%)	3 (8)
Any prior lumbar/thoracic spine surgery (%)	26 (65)
Prior surgery type	$n = 26$
Discectomy (%)	1 (5)
Laminectomy (%)	18 (70)
Fusion (%)	7 (25)
Diagnoses (mean number per patient)	65 (1.6)
Degenerative disc disease (%)	16 (40)
Spondylolisthesis (%)	15 (38)
Postlaminectomy syndrome (%)	12 (30)
Adjacent segment disease (%)	5 (13)
Scoliosis (%)	6 (15)
Retrolisthesis (%)	1 (3)
Facet disease (%)	5 (13)
Stenosis (%)	4 (10)
Fracture (%)	1 (3)

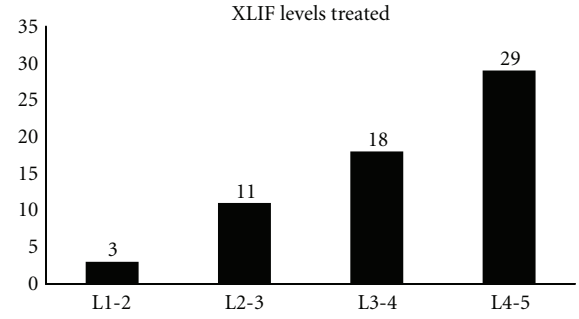

Figure 3: Graph showing the number of each level treated with extreme lateral interbody fusion.

3. Results

Mean initial patient positioning from induction of anesthesia to initial incision was 32 minutes, mean interbody procedure time (all levels) was 57 minutes, mean repositioning for posterior procedure time (where applicable) was 27 minutes, and mean posterior/fixation procedure time was 73 minutes. Mean total positioning time was 59 minutes (range 25–109 mins), mean total operative time was 122 minutes (range 49–274 mins), and mean total time in the operative field was 178 minutes (range 75–342 mins). Mean XLIF blood loss was 54 cc per patient, with mean 129 cc for combined anterior and posterior procedures (Table 2). No complications were observed. One patient underwent reoperation at an adjacent level with XLIF for DDD. A second patient has developed new symptoms in an L5–S1 distribution, with a potential pseudoarthrosis at an L5–S1 TLIF, though symptom etiology and course of treatment are currently unknown.

Table 2: Treatment information.

Characteristic	Statistic $n = 40$
Mean initial positioning time (anesthesia to incision) (mins.) (range)	32 (18–57)
Mean anterior procedure time (incision to anterior close/completion) (mins) (range)	57 (24–145)
Mean repositioning time (for second procedures) (mins) (range)	27 (0–82)*
Mean second procedure time (incision/fixation start to final close) (mins) (range)	73 (6–205)*
Mean total procedure time (anterior and fixation) (mins) (range)	122 (49–274)
Mean total operating room time (mins) (range)	178 (49–342)
Mean anterior procedure estimated blood loss (EBL) (cc) (range)	47 (10–110)
Total number of levels treated	68
Mean number of levels per patient (range)	1.7 (1–3)
Levels treated	*n* (% of levels)
L1-L2	3 (4)
L2-L3	11 (16)
L3-L4	18 (26)
L4-L5	29 (43)
L5–S1 (TLIF)	7 (10)
Supplemental internal fixation (%)	40 (100)
Lateral plating (%)	11 (38)
Bilateral pedicle screws (%)	25 (63)
Direct decompression	
Yes (%)	13 (33)
No (%)	27 (67)
Biologics used	
Osteocel Plus	40 (100)

*In lateral plating following XLIF, repositioning time is zero, as the XLIF exposure is used for placement. Lateral plating also accounts for short second-procedure times in the range. Longer second-procedure times include, in some cases, posterior lumbar interbody fusion at L5–S1 and multilevel posterior fixation, which accounts for the high variability.

Thirty-five (35) patients also had pre- and 12-month postoperative functional outcome scores. From preoperative to 12-month postoperative followup, Oswestry disability index (ODI) improved 41% (45.7 to 27.1), low back pain (LBP) (visual analog scale (VAS)) improved 55% (7.4 to 3.4), leg pain (LP) improved 43% (6.8 to 3.8), and quality of life (SF-36) improved 55.6% (41.8 to 65.0). All clinical variables were statistically significantly different from pre- to postoperative time points, $P < 0.05$. Of the 36 (90%) of patients who completed a satisfaction questionnaire at 12-month postoperatively, 92% reported being either "very" or "somewhat" satisfied with their outcome and 86% reported being either "very" or "somewhat likely" to have undergone the same procedure had their outcome been known in advance.

Complete fusion was observed in 90.2% (55/61) of XLIF levels. Five (5) levels were assessed as incompletely fused, where ossification was present in the cage, but complete trabecular bridging had not yet occurred. In these instances, 3 of 6 were in multilevel cases (two 3-level, one 2-level case). One level was assessed as indeterminately fused or showing clear lucencies at endplates with or without ossification in the cage. Examples of completely fused XLIF levels can be found in Figures 4 and 5. Any evidence ($\geq$1 mm) of radiographic subsidence was observed in 20 of 61 levels (32.8%) (Figure 4), though symptoms did not correlate with subsidence and no revisions occurred.

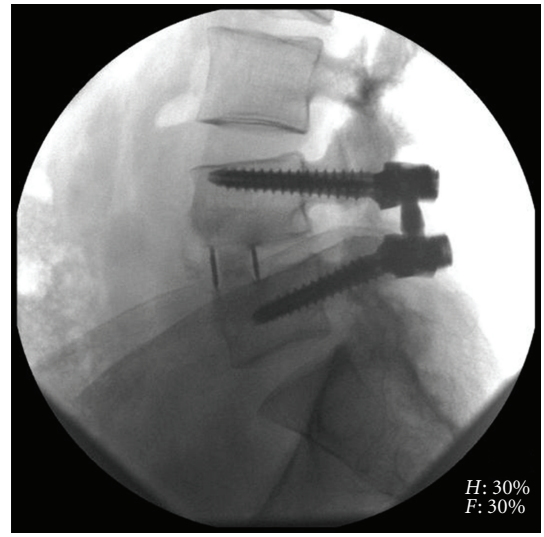

Figure 4: Lateral radiograph of L4-5 extreme lateral interbody fusion with Osteocel Plus at 12-month postoperative.

3.1. Literature Review. In the review of 24 studies and 2,026 patients undergoing lumbar fusion using autograft, the weighted average for fusion rate was 87.6% (range 44%–100%) and the pseudoarthrosis revision rate was 3.8% (range 0%–28.1%) [8, 13, 15, 18, 37–51, 53–56].

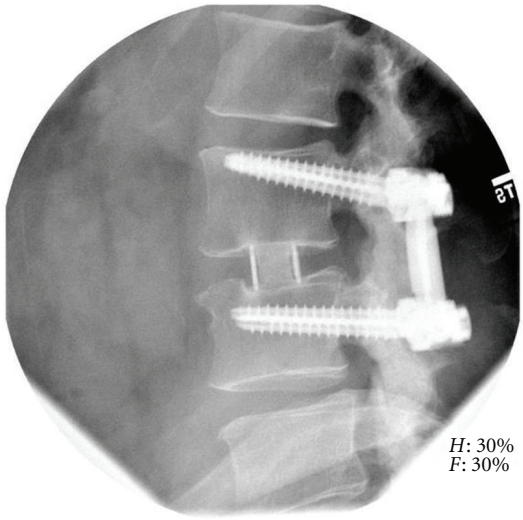

Figure 5: Lateral radiograph of L3-4 extreme lateral interbody fusion with Osteocel Plus at 12-month postoperatively.

4. Discussion

Evidence of bony fusion following lumbar fusion procedures is an important measure to gauge the long-term integrity of the fused segment and, as such, is generally valued alongside clinical outcomes as a primary surgical outcome. Historically, the "gold standard" biologic graft material to assist in the fusion process in spine fusion has been autograft, due to its inherent biologic properties of osteoconduction, osteoinduction, and osteogenesis, which are all required to form bone [35, 36]. However, the morbidity associated with autologous bone graft harvest from the iliac crest can be substantial and long lasting. In a review by Dimitriou et al. [33] of 81 studies of iliac crest bone graft (ICBG) harvesting in 6,449 patients, the authors found an ICBG harvest-related morbidity rate of 19.4%, the primary complications being chronic donor-site pain (7.8%), persistent dysesthesias at the harvest site (4.8%), hematomas/seromas (2.1%), and infection (1.4%). Similarly, Kim et al. prospectively followed 104 patients for one year to examine long-term pain and complications related to iliac crest harvesting for autologous bone graft in lumbar fusions [34]. At 12 months, the authors found that 16.5% of patients reported continued harvest-site pain and 29.1% reported persistent numbness. With respect to physical ability, the following activities were listed as difficult to perform due to continued harvest-site pain: 15.1% walking, 5.2% employment, 12.9% recreation, 14.1% household chores, 7.6% sexual activity, and 5.9% experienced harvest-site irritation when in contact with clothing [34].

Despite the associated morbidity, the precedent of ICBG as the standard bone graft material resulted, naturally, from there being limited allograft or synthetic alternatives until recently [35, 36]. And with allograft or synthetic materials, few inherently have all of the biological components required for fusion (and those few are only recently available, in the form of ACBMs), requiring combinations of materials to complete the biologic environment for the fusion cascade. One such example is osteoinductive graft material, such as bone morphogenic protein (rhBMP-2, Medtronic Sofamor Danek, Memphis, TN, USA), with osteoconductive ceramic synthetics and osteogenic bone marrow aspirate. Unfortunately, the use of rhBMP-2 in the spine has been shown in some studies to have a complication profile similar or greater than ICBG harvesting, though generally with high fusion rates. In a review of 31 articles discussing complications following BMP use in spine surgery, Mroz et al. [58] found a 44% mean rate of resorption/osteolysis, 25% rate of graft subsidence, 8% rate of ectopic bone growth, 27% rate of cage migration, 29% incidence of new onset radiculitis, and an inflammatory response to the collagen carrier in 29% of patients [58, 59].

As part of this study an extensive literature review was undertaken, for historical control, examining fusion and reoperation rates for pseudoarthroses in the autograft in spine fusion literature. In total, 24 peer-reviewed articles were included covering 2,026 patients. Overall fusion rate, using weighted average, was 87.6% with a range of reported fusion rates from 44% to 100%. Fusion rate in these studies was generally assessed at 24-month postoperatively or greater. Surgically revised pseudoarthroses occurred in a weighted average of 3.8% percent of cases with a range of 0%–7%. In one representative study from the review, McAfee et al. [52] and Blumenthal et al. [38] described 99 patients treated with the BAK-threaded cage through conventional direct anterior ALIF as the control group of the Charité randomized control FDA trial. In these patients with 2-year followup, the authors observed a fusion rate of 90.9% and pseudoarthrosis revision rate of 9.1%. Mean ORT was 114 minutes, blood loss was 209 cc, with an overall complication rate of 46.5% (minor and major), an 8% infection rate, 5.5% rate of retrograde ejaculation, and 18.2% rate of donor-site pain from ICBG harvest with a 30.5% improvement in ODI.

With respect to the current findings of MIS lateral ALIF with ACBM at 12-month followup, we observed a 90.2% solid fusion rate in 55/61 XLIF levels and 9.8% rate of incomplete or ongoing fusion in the remaining 4 (9.8%) levels. These data represent, to our knowledge, the first reported fusion results of ACBM in the human spine. There were no complications in this series, though there was a reoperation in one (3.7%) patient at the level above the index fusion for adjacent segment disease. Clinical outcomes, evaluated in a subset of patients, at 12 months showed an improvement on disability (ODI) of 41% and LBP and LP improved 55% and 43%, respectively, with a 56% increase in quality of life. In 92% of patients their general surgical outcome was rated as excellent or good and 86% would have undergone the same procedure again had their outcome been known in advance. With respect to fusion rate, the current results are higher than the weighted average from the historical control, and in-line with the high-end of the range of values of autograft in spine fusion, despite the fact that the literature generally reported 24-month or greater fusion rate compared to the 12-month followup of the current study. The high variability in the historical control is likely due to the lack of evaluation control and the retrospective nature

of some of the literature, which is mitigated in part both by the relatively large number of publications and the resultant large patient series included.

Limitations of the current study include the lack of a parallel control group with autograft or other bone graft material to directly compare fusion performance at the same institution. Additionally, final fusion is more typically assessed at 24-month postoperatively, which may account for our progressing fusion rate in 9.8% of patients. However, since this was designed as an early fusion assessment in a novel biologic graft material for fusion, we have limited claims in the conclusion to better reflect the preliminary nature of the results.

5. Conclusion

As of this writing, this work represents the first report of fusion and clinical results of allograft cellular bone matrix in the human spinal fusion procedures. These results, however, are preliminary, being only 12-month postoperatively in a relatively small number of patients. No complications were observed in this series of patients treated with XLIF for degenerative conditions of the lumbar spine. Functional outcomes, from a subset of the current series, improved significantly in pain, disability, and quality-of-life measurement from preoperative to 12-month postoperatively. The vast majority of patients reported being both satisfied with their outcome and would have chosen to undergo the procedure again had their outcome been known in advance. Complete interbody fusion, facilitated by allograft cellular bone matrix, was shown in 90.2% of XLIF levels, with 8.2% being partially consolidated. One level was of an indeterminate status. None of the index fused levels were revised. Subsequent work examining larger case series and comparisons with other biologic materials are needed to supplement these early favorable results.

Conflict of Interests

Potential conflicts of interest do exist where commercial party (NuVasive, Inc.) related directly or indirectly to the subject of this paper has relationships in the form of consultancies, stock, royalties, speaker's bureau, and travel with one of more of the authors of this paper.

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Research Article

Biomechanics of Lateral Interbody Spacers: Going Wider for Going Stiffer

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This study investigates the biomechanical stability of a large interbody spacer inserted by a lateral approach and compares the biomechanical differences with the more conventional transforaminal interbody fusion (TLIF), with and without supplemental pedicle screw (PS) fixation. Twenty-four L2-L3 functional spinal units (FSUs) were tested with three interbody cage options: (i) 18 mm XLIF cage, (ii) 26 mm XLIF cage, and (iii) 11 mm TLIF cage. Each spacer was tested without supplemental fixation, and with unilateral and bilateral PS fixation. Specimens were subjected to multidirectional nondestructive flexibility tests to 7.5 N·m. The range of motion (ROM) differences were first examined within the same group (per cage) using repeated-measures ANOVA, and then compared between cage groups. The 26 mm XLIF cage provided greater stability than the 18 mm XLIF cage with unilateral PS and 11 mm TLIF cage with bilateral PS. The 18 mm XLIF cage with unilateral PS provided greater stability than the 11 mm TLIF cage with bilateral PS. This study suggests that wider lateral spacers are biomechanically stable and offer the option to be used with less or even no supplemental fixation for interbody lumbar fusion.

1. Introduction

The lateral transpsoas approach for lumbar interbody spinal fusion has gained popularity in recent years for a variety of indications [1–8]. The approach provides wide access to the lateral aspect of the disc allowing extensive discectomy, preservation of the anterior and posterior longitudinal ligaments, annulus and posterior elements, and placement of a large interbody spacer [9].

The biomechanical stability of a lumbar fusion construct is determined by the extent of resection of local bone and ligament, implant size and positioning, and the type of supplemental internal fixation used. Previous biomechanical assessment has demonstrated the stability of an 18 mm anterior-posterior (A-P) width extreme lateral interbody fusion (XLIF) interbody cage [10]. XLIF cages with larger anterior-posterior widths (22 mm and 26 mm) have been developed in order to reduce the risk of subsidence in osteoporotic patients by distributing load over a greater area of the endplate. These larger cages potentially provide additional stability over standard 18 mm spacers by blocking motion.

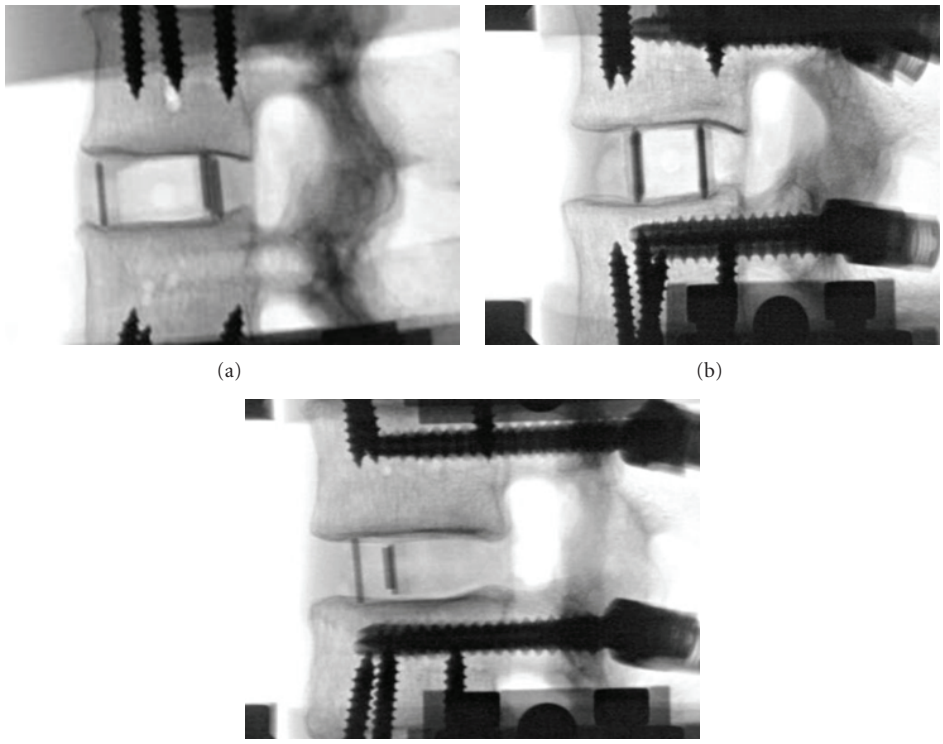
The objective of this cadaveric study was to compare the stability of different A-P width XLIF cages with and without supplemental pedicle screw (PS) fixation. A more conventionally used transforaminal interbody fusion (TLIF) group was included for reference purposes.

2. Material and Methods

Twenty-four L2-L3 functional spinal units (FSUs) were dissected from fresh-frozen human spines (average age: 50.1, range 21–76 years; 22 male, 2 female). A-P and lateral radiographs were used to exclude deformity and degeneration. Bone mineral density (BMD) was assessed prior to dissection of each specimen using standard lumbar dual energy X-ray absorptiometry (DEXA) scans (Discovery C, Hologic

(a) (b) (c)

Figure 1: Axial view of cages used in testing (CoRoent, NuVasive, Inc, San Diego, CA): (a) 26 mm XLIF cage, (b) 18 mm XLIF Cage, and (c) 11 mm TLIF cage.



(a) (b) (c)

Figure 2: Lateral fluoroscopy images during testing of (a) 18 mm XLIF cage, (b) 26 mm XLIF cage, and (c) 11 mm TLIF cage, implanted at L2-L3 intervertebral space.

Inc., Bedford, MA). The FSUs were divided into 3 BMD-matched subgroups of 8 FSUs, each with an average BMD of 0.89 g/cm^2. The caudal and cephalad ends of each specimen were mounted in polyurethane casting resin (Smooth-Cast 300; Smooth-On, Inc., Easton, PA), with the disc space positioned horizontally. Each group was tested with a different interbody spacer (Figures 1 and 2): (i) 18 mm A-P width XLIF cage (CoRoent XL, NuVasive, Inc, San Diego, CA), (ii) 26 mm A-P width XLIF cage (CoRoent XL-XW; NuVasive, Inc.), or (iii) 11 mm A-P width TLIF cage (CoRoent LC; NuVasive, Inc.). Discectomy, endplate preparation, and cage insertion were performed following usual XLIF [2] and TLIF [3] techniques.

Each FSU was subjected to multidirectional nondestructive flexibility testing using a custom 6 degree-of-freedom spine test system controlled by LabVIEW (National Instruments, Austin, TX). Specimens were subjected to a standard protocol consisting of 3 fully reversed cycles of flexion extension, lateral bending, and axial rotation to 7.5 N·m without an axial load or follower load [11, 12], under the following conditions: (i) intact, (ii) intact disc with bilateral pedicle screw (PS) fixation, (iii) interbody cage alone, (iv) cage + unilateral PS fixation, and (v) cage + bilateral PS fixation.

Infrared light-emitting diode marker arrays were fixed to the L2 and L3 vertebral bodies. Intervertebral (L2-L3) range of motion (ROM) was measured using an Optotrak Certus system (Northern Digital Inc., Waterloo, ON, Canada). Data from the third motion cycle was analyzed. ROM was normalized to the intact condition (percent intact ROM). ROM differences were first examined within groups (per cage) using repeated-measures ANOVA and Holm-Sidak

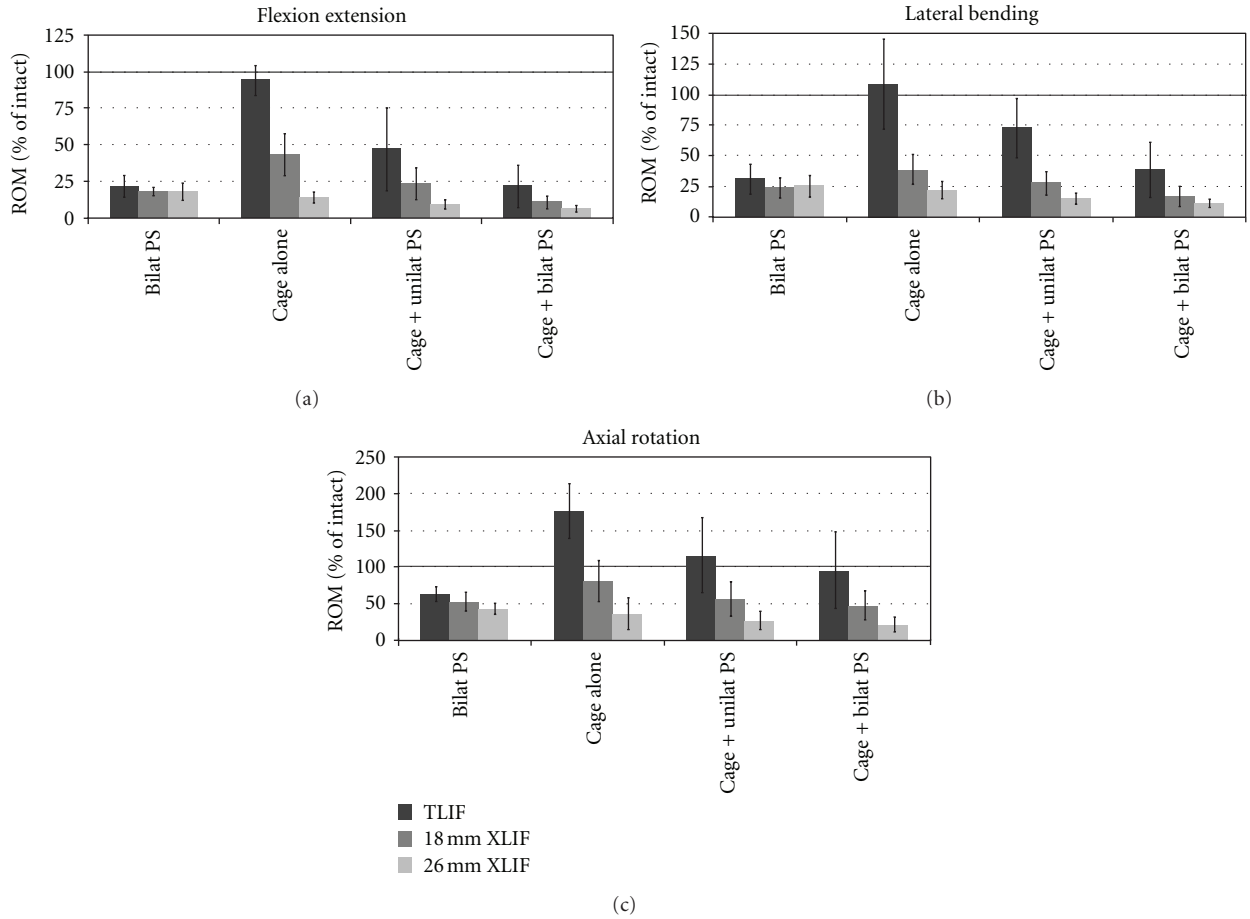


Figure 3: Range of motion (ROM) results normalized to intact motion: (a) flexion extension, (b) lateral bending, and (c) axial rotation. Bars represent means ±1 standard deviation. Intact spine ROM (100%) indicated by solid line.

post hoc comparisons. Differences between cage groups were then evaluated using non-repeated-measures ANOVA and Dunn-Sidak comparisons. The stand-alone TLIF cage condition was excluded from this part of the analysis since the ROM values were significantly higher than the other test groups it was being compared against. A significance level of $P < 0.05$ was used for all analyses.

3. Results

Addition of bilateral pedicle screws to the intact discs created similar stability across all three test groups, with an average 81% reduction in flexion extension ROM, 73% reduction in lateral bending, and 48% reduction in axial rotation. Decreased ROM corresponds to increased construct stiffness.

After removing the rods from the pedicle screws, the appropriate approaches and discectomies were performed, and the interbody cages were inserted. Without supplemental fixation, both XLIF cages (18 and 26 mm) significantly reduced ROM with respect to intact in all directions ($P < 0.026$). The TLIF cage alone condition allowed ROM similar to intact in flexion extension (Figure 3(a)) and lateral bending (Figure 3(b)), but significantly greater ($P < 0.001$) in axial rotation (Figure 3(c)).

Addition of unilateral PS to the stand-alone cages produced a significant decrease in ROM in all cases ($P < 0.015$), with the exception of the 26 mm XLIF cage in axial rotation ($P = 0.106$). Addition of bilateral PS to the cages led to significant decreases in ROM, compared with the standalone cages, in all cases ($P < 0.008$). Comparing unilateral and bilateral PS fixation, there were significant reductions in ROM only in flexion extension and lateral bending for the 18 mm XLIF ($P < 0.002$) and TLIF ($P < 0.021$) cages.

The two bilateral pedicle screw conditions (initially without, and then with an interbody spacer) displayed no significant differences for the 18 mm XLIF ($P > 0.076$) and TLIF ($P > 0.091$) cages. However, the combination of a 26 mm XLIF cage with bilateral PS provided a significant decrease in ROM compared to the bilateral pedicle screws alone ($P < 0.001$).

Looking at the results between cage groups, the 26 mm XLIF cage provided greater stability than the 18 mm XLIF and TLIF cages when examining the cages alone, or under each of the supplemental fixation conditions. On average, the 26 mm XLIF cage alone was more rigid than TLIF with bilateral pedicle screws ($P < 0.05$ in axial rotation; flexion extension and lateral bending were not significant). The 26 mm XLIF cage alone provided a statistically significant

reduction in ROM compared with TLIF with unilateral screw in all directions ($P < 0.05$). The 26 mm XLIF spacer with unilateral PS was significantly more rigid ($P < 0.05$) than TLIF with unilateral screws in all directions and bilateral PS in lateral bending and axial rotation. The 26 mm XLIF cage with bilateral pedicle fixation was also significantly more rigid ($P < 0.05$) than TLIF with unilateral screws in all directions and TLIF with bilateral PS in lateral bending and axial rotation.

The 26 mm XLIF cage in the stand-alone condition was significantly more rigid in flexion extension ($P < 0.05$) than the 18 mm XLIF cage. On average, the 26 mm XLIF cage alone was more rigid than the 18 mm XLIF spacer with unilateral pedicle screws, in all directions tested, although statistically significant differences were not detected. The 26 mm XLIF cage with both unilateral and bilateral PS was more rigid than the 18 mm XLIF cage alone ($P < 0.05$).

Finally, the 18 mm XLIF cage in the stand-alone condition provided greater stability than TLIF with unilateral PS in all directions tested ($P < 0.05$ in lateral bending; flexion extension and axial rotation were not significant). The 18 mm XLIF spacer with both unilateral and bilateral pedicle screws provided significant reductions in ROM over TLIF with the unilateral PS in all directions ($P < 0.05$). XLIF with the 18 mm cage and bilateral PS was more rigid than TLIF with the same fixation ($P < 0.05$) in axial rotation. TLIF with bilateral pedicle screw was more rigid than the 18 mm XLIF cage alone in flexion extension ($P < 0.05$).

4. Discussion

This biomechanical study analyzed the stability of different lateral constructions for lumbar interbody fusion. TLIF constructs were tested to establish a baseline for a commonly used technique. Both XLIF interbody spacers, with and without pedicle screw fixation, provided improved stability over the TLIF constructs. Additionally, the 26 mm XLIF cage also reduced ROM to a greater extent than the 18 mm XLIF cage. These biomechanical results suggest that the stability provided by the XLIF spacers, with adequate cage height sizing and good bone quality, may allow for less supplemental fixation than a more destabilizing approach such as TLIF thus avoiding posterior muscle dissection and adjacent facet joint injury.

The reduced stability observed with the TLIF approach compared to XLIF in the current study is likely due to resection of stabilizing structures such as the facet joint, ligamentum flavum, and posterior longitudinal ligament in order to insert the interbody spacer. These structures are all retained during XLIF. Additionally, XLIF allows taller interbody implants to be placed across the disc space since TLIF cage sizing is typically limited by the approach, which is constrained by the proximity of the nerve roots and the often smaller intervertebral space posteriorly. The XLIF cages distract the disc space and generate tension in the retained ligaments, which contributes to stability. Potentially, improved stability over the results obtained here using a TLIF approach may be possible using different cage designs or insertion techniques.

Previously, two groups studied the biomechanical stability of XLIF constructs [10, 13]. Despite some differences in testing methodology (e.g., the tested lumbar level), the ROM results with the 18 mm XLIF cage obtained in the present study were similar to those previously observed. Bess et al. [13] investigated 18 mm XLIF cages as a stand-alone construct and with various instrumented constructs (lateral plate, unilateral or bilateral PS). They observed that the XLIF implant, with or without supplemental fixation, provided significantly decreased ROM in all loading modes compared with intact. Cappuccino et al.[10] and the current study confirmed these findings.

Laws et al. [14] compared direct lateral interbody fusion (DLIF), similar to XLIF, with anterior lumbar interbody fusion (ALIF). Cage width was not provided; however, stand-alone DLIF was shown to demonstrate greater stability than stand-alone ALIF in all directions tested. In a historical literature comparison [10], Cappuccino et al. also noted substantially less motion with XLIF over ALIF [15] with the greatest differences in flexion extension and lateral bending. Minimal differences were demonstrated between the groups if supplemental fixation was added to ALIF, TLIF, or an 18 mm XLIF cage. In the present study, we demonstrated that 26 mm XLIF interbody spacers can potentially provide 1.5 (flexion extension) to 2.7 (axial rotation) times as much stability as a TLIF construct with bilateral pedicle screws.

Stand-alone fusion constructs have historically been seen to be biomechanically insufficient to provide stabilization in all directions [16], whether the technique is ALIF [15, 17], TLIF [17], or PLIF [18], or even in lateral approach (using a cylindrical threaded cage) [19]. As previously discussed, TLIF involves removal of posterior anatomic structures, while ALIF requires removal of the anterior longitudinal ligament (ALL). The importance of ALL retention in interbody fusion construct stability was seen after its resection following a laterally inserted ALIF cage, which led to increased ROM by 59% and 142% in axial rotation and flexion extension, respectively [17].

Unlike ALIF and TLIF, stand-alone lateral interbody fusion has been performed in an off-label fashion with success for cases without instability [3–5, 20–22]. Despite the greater stability over other approaches, and the ability to insert a long cage that spans the strongest lateral bone of the ring apophysis [23], subsidence of stand-alone 18 mm XLIF cages has been observed, which can impair disc space distraction and indirect decompression [5]. With the wider 22 mm and 26 mm XLIF spacers, greater endplate area is covered which decreases the pressure on the vertebral endplate and should increase the load required to cause subsidence. The result of this was seen as a lower rate of subsidence comparing 18 and 22 mm XLIF cages in some clinical studies [24, 25].

Cage shape also appears to play an important biomechanical role in stability of the fusion construct. In the study by Le Huec et al. [19], a stand-alone construct with a cylindrical laterally placed interbody cage was not able to provide as much stability as the intact spine. Only after the addition of a lateral plate was the stability sufficiently improved, with stiffness increased by 3.1 times relative to the intact spine.

Cylindrical cages likely provide limited stability since there is limited implant-endplate contact area to resist motion. In contrast, the rectangular XLIF spacers provide much greater implant-endplate contact area, which blocks motion and hence gives greater stability. This was further demonstrated by the increased stability provided by the 26 mm XLIF spacer compared with the 18 mm.

Although our cadaveric study design provided well-controlled biomechanical results, there are some inherent limitations associated with the study design. For the current study, L2-L3 lumbar levels were used. This may bias stability results towards the larger XLIF cages compared with testing at more caudal vertebral levels, since the vertebrae are smaller at L2-L3 and the same size interbody implants will occupy a greater proportion of the endplate area. Each interbody cage type was studied independently in three different groups, which will introduce additional specimen variability. Effects of this were minimized by creating groups with similar BMD and selecting specimens with good bone quality and minimal degeneration or deformity. The pure moment loading applied to the specimens in order to measure ROM is typical of physiologic levels; however, it does not investigate the stabilizing effect of surrounding musculature seen *in vivo*, which may alter the results. In addition, the current study demonstrates immediate postoperative stability of the construct and does not take into consideration the long-term impact of cage settling, bone ingrowth, or cyclic loading.

The transpsoas lateral approach is an evolving technique in minimally invasive spine surgery. Studies presenting initial results with 22 mm XLIF cages have been reported [3, 24, 25]. Development of new implants for specific patient groups and/or indications can be very useful and should first be evaluated experimentally to ensure intended benefits, such as biomechanical stabilization, are realized. These findings should be confirmed in clinical studies. Clinical considerations for using larger 26 mm XLIF cages over the 18 mm devices include larger psoas exposure and need for appropriate neuro-monitoring [26].

With the results found in this work and in the literature, it can be suggested that the stability of a lumbar interbody fusion construct can be modified to a lesser or greater extent by: (1) removal of bone/ligament structures, (2) cage positioning, (3) cage design/size, and (4) supplemental fixation options. In the lateral XLIF approach, maintenance of the ALL and a stand-alone wide cage is sufficient to significantly reduce intervertebral motion. In some cases, this may be sufficient to allow bone growth and fusion to take place; however, other factors such as existing instability, bone quality, and patient activity level should first be evaluated when considering fixation options.

Disclosure

CoRoent PEEK intervertebral fusion cages are not FDA-cleared for use without supplemental fixation.

Conflict of Interests

L. Pimenta and M. D. Peterson have a stock and stock option ownership and are both Consultants at NuVasive, Inc. A. W. L. Turner, Z. A. Dooley, and R. D. Parikh are all salaried employees at NuVasive, Inc, and also possess a stock and stock option ownership at the same company.

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Review Article

Lateral Transpsoas Fusion: Indications and Outcomes

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Spinal fusion historically has been used extensively, and, recently, the lateral transpsoas approach to the thoracic and lumbar spine has become an increasingly common method to achieve fusion. Recent literature on this approach has elucidated its advantage over more traditional anterior and posterior approaches, which include a smaller tissue dissection, potentially lower blood loss, no need for an access surgeon, and a shorter hospital stay. Indications for the procedure have now expanded to include degenerative disc disease, spinal stenosis, degenerative scoliosis, nonunion, trauma, infection, and low-grade spondylolisthesis. Lateral interbody fusion has a similar if not lower rate of complications compared to traditional anterior and posterior approaches to interbody fusion. However, lateral interbody fusion has unique complications that include transient neurologic symptoms, motor deficits, and neural injuries that range from 1 to 60% in the literature. Additional studies are required to further evaluate and monitor the short- and long-term safety, efficacy, outcomes, and complications of lateral transpsoas procedures.

1. Background

Spinal fusion has been used extensively in the thoracolumbar spine for tumors, spinal instability, deformity, and stenosis. Recent developments and advancements in minimally invasive spine surgery have created new technologies that can help avoid the morbidity of traditional open anterior or posterior surgery. Anterior surgery has been associated with complications with its approach, which include vascular complications, retrograde ejaculation, postoperative colonic obstruction, lymphocele, or injury to the sympathetic chain [1–3]. Posterior surgery, for example, posterolateral fusions, posterior lumbar interbody fusions, and transforaminal lumbar interbody fusions, have been associated with paraspinal muscle denervation, dural tears, and neural complications, such as radiculitis from malpositioned screws or retraction during the surgery to allow placement of the intervertebral cage [4–7].

As an alternative to anterior and posterior surgery, lateral interbody fusion was described by Pimenta in 2001 as a minimally invasive procedure for the management of lumbar spine disease [8]. Lateral interbody fusion (XLIF: NuVasive, Inc., San Diego, CA ARIA: Stryker, Inc., Kalamazoo, MI, COUGAR: Depuy Spine, Inc., Rynham, MA Ravine: K2 M, Inc., Leesburg, VA DLIF: Medtronic, Inc., Minneapolis, MN Transcontinental: Globus Medical Inc., Audubon, PA) is performed through a lateral, retroperitoneal, transpsoas approach to the disc space. Key to this approach is real-time neuromonitoring to ensure safe passage through the psoas muscle, avoiding the nerves of the lumbar plexus [9–13]. Potential benefits of the lateral approach compared with anterior and posterior approaches include the avoidance of vascular, visceral, and sexual dysfunction complications sometimes experienced in open anterior procedures, and paraspinal denervation, dural tear, and neural injuries in posterior approaches. As with anterior lumbar spine approach, the lateral approach capitalizes on the larger surface area available for fusion compared to a posterolateral fusion. In contrast, however, the anterior and posterior longitudinal ligaments remain intact, providing inherent stability during the formation of bone in fusion.

2. Indications

The original indication for lateral interbody fusion delineated by Ozgur et al. was for patients with low back pain associated with degenerative disc disease but without severe central canal stenosis. In the original description of the procedure, Ozgur et al. described the contraindications to the procedure as being patients with significant central canal stenosis, significant rotatory scoliosis, and moderate to severe spondylolisthesis. However, recent reports have utilized lateral interbody fusion in conjunction with posterior instrumentation for those previous contraindications [14–16].

Current indications include degenerative disc disease, spinal stenosis, degenerative scoliosis, nonunion, trauma, infection, and spondylolisthesis (grade I or II) [9, 14, 16–20]. Some of these indications also require posterior fixation. Figure 1 is an example of an XLIF performed at L1-2 for a nonunion at the proximal aspect of a long adult deformity.

Contraindications to this technique for standalone applications include severe spinal stenosis, vascular abnormalities, and significant spondylolithesis. Relative contraindications include previous retroperitoneal surgery and severely collapsed disc spaces [21, 22].

3. Technique

The lateral procedure, as originally described by Ozgur et al. and demonstrated in Figure 2, is performed under general anesthesia with the patient in the lateral decubitus position on a radiolucent table. Preoperative evaluation of the spine and vascular anatomy on imaging dictate a right or left lateral decubitus approach. Neuromonitoring is essential for this approach due to the lumbar plexus anatomy in the psoas. Because monitoring is needed, paralytic anesthetics must be avoided during the approach. Once the patient is positioned, intraoperative fluoroscopy is used to obtain a perfect lateral and AP radiograph. Next using blunt dissection, the retroperitoneal space is entered using one or two incisions. Using a series of sequential dilators, the psoas is entered down to the center of the disc space. During this exposure, neuromonitoring is used to ensure the safety of the working channel. Discectomy and disc space preparation are then performed using standard techniques with a combination of pituitary rongeurs and ringed curettes under direct visualization. After complete preparation of the disc space, an intervertebral cage that spans the space with a wide aperture that is prefilled with bone graft is inserted into the disc space between the two end plates. The external oblique fascia, subcutaneous layer, and skin are then closed.

4. Results and Complications

One of the earliest series of patients that underwent a lateral approach was reported by Rodgers et al. in 2007 [17]. Indications for surgery were for various degenerative conditions. They reported the procedure was safe and reproducible with a low complication rate of 2% overall, with no major complications. Rodgers et al. noted a decrease in the VAS pain scores of 68%. In another series, Knight et al. in 2009 reported on 58 patients who underwent a lateral interbody arthrodesis for degenerative disc disease [23]. Compared to Rodgers et al, they reported longer operative times, mean of 161 minutes, and a higher complication rate, 22.4% overall. Of the 13 patients who experienced complications, 9 of them were approach related with ipsilateral L4 nerve root injury in two cases, irritation of the lateral femoral cutaneous nerve in 6 patients and significant psoas muscle spasm that required extended hospitalization in two patient. Of the four other complications, three were medical and one was an acute subsidence of the implant. Rodgers et al. published another series on 100 patients who underwent XLIF for adjacent level degeneration adjacent to a prior spinal fusion surgery with similar improvement in VAS as their previous report. They reported nine complications for a total complication rate of 9%, with two patients each having postoperative urinary retention, cardiac complications, and ileus, one patient having transient tibialis anterior weakness that resolved in two weeks, one nonunion, and one vertebral body fracture. Of note, one patient had transient thigh symptoms postoperatively, which they did not count as complications [18]. Berjano et al. recently published their results of 97 patients who underwent lateral interbody fusion for a variety of indications, most commonly degenerative disc disease in 78 patients [24]. They reported no permanent neurological, vascular, or visceral injuries. Transient neurological symptoms were present in 7% of cases, though they all resolved within 1 month from surgery. Transient thigh discomfort was observed in 9%, and the overall complication rate was 12%. Clinical success was reported in 90% of the patients at six months postoperatively. Ozgur et al. published one of the first studies with a two-year followup for lateral interbody fusion in 62 patients. They reported a 19% minor complication rate, though a significant number of patients had transient hip flexion weakness and upper thigh numbness that resolved in most by six weeks. Functional improvements were maintained out to two years of followup [25].

The previous reports included patients with various degenerative conditions. As the lateral approach has gained more acceptance into the spine community, newer and more specific indications have been found. One of these indications is adult degenerative scoliosis. Historically, the surgical treatment for adult degenerative scoliosis has been associated with significant complications, including neurologic deficits, pulmonary embolism, infection, and death. Complication rates have reached as high as 30% in older patients. Utilizing an anterior approach for adult degenerative scoliosis, Daubs et al. reported a 10.9% incidence of vascular injury [20]. Isaacs et al. presented the first large multicenter series using a minimally invasive approach in the treatment of adult scoliotic deformity with 107 patients with 75.7% percent of the cases including posterior supplemental instrumentation with 64.2% of those cases placed using minimal access posterior surgical techniques; 35.8% using standard open techniques, and the rest without posterior surgery. They noted a major complication rate of 12.1% overall, with no vascular complications observed [26]. Of the major

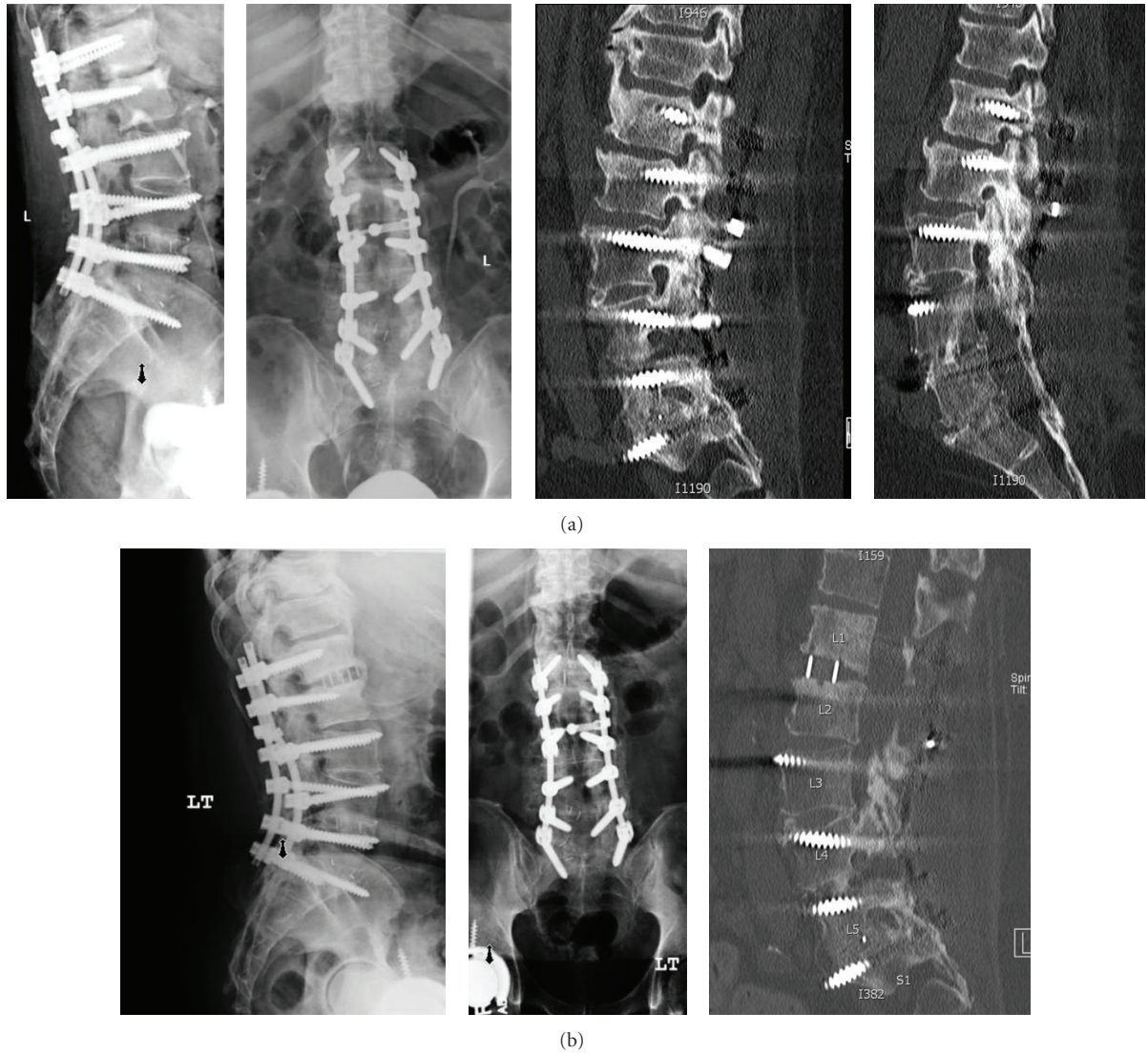
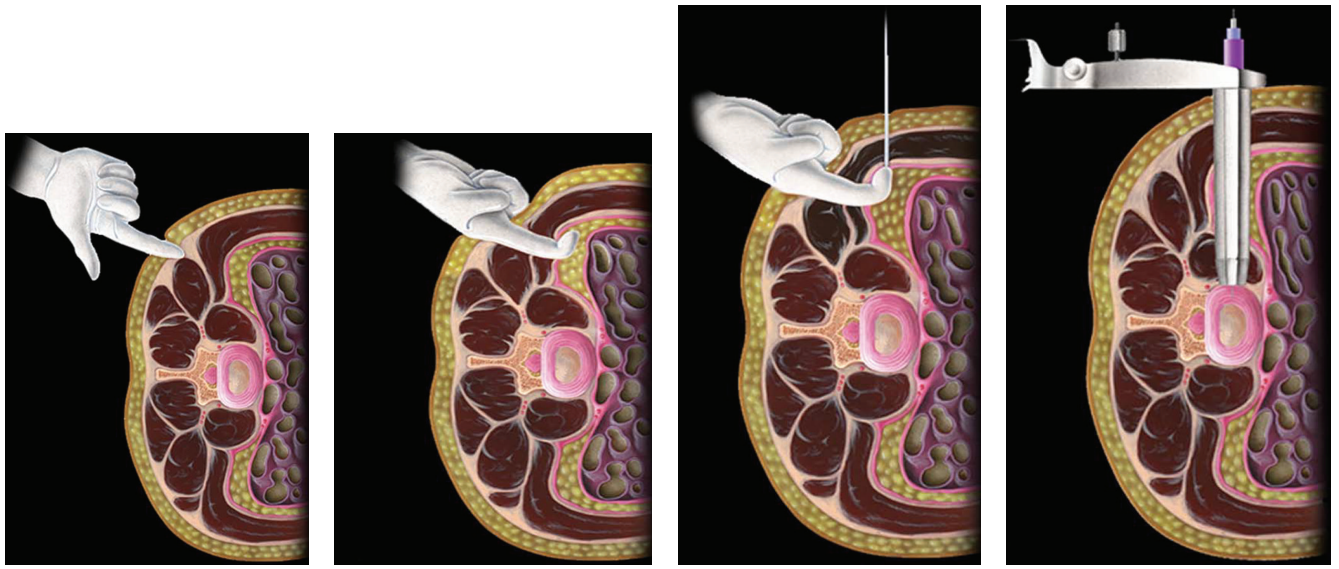


Figure 1: (a) Preoperative X-rays demonstrating nonunion at L1-2 after posterior instrumented fusion and decompression from L1-S1. (b) Postoperative X-rays demonstrating XLIF at L1-2.

complications, two were medical with one case of an MI and the other sepsis. The other twelve major complications were surgical, with one case of a kidney laceration, 3 wound infections, 1 DVT, and 7 motor deficits. Furthermore, 36 patients (33.6%) reported weakness after surgery; and of those, 29 reported hip weakness that the authors attributed to the transpsoas approach. Fortunately, 86.2% of the patients with weakness had resolution by six months of followup. Predictor of any major complication was strongly correlated to the number of levels of surgery. Interestingly, patients that underwent an isolated minimally invasive lateral interbody fusion had fewer major complications in the perioperative period than those undergoing supplemental open posterior fusion.

In addition, Anand et al. reported on 12 patients who underwent combined posterior instrumentation and minimally invasive procedures for the treatment of adult degenerative scoliosis that included lateral interbody fusion [14]. The study reported pain reduction of 32.4%, though a lower blood loss than historically reported for traditional scoliosis surgeries. Furthermore, Anand et al. reported 25% of the patients with dyesthesias over the thigh, and even one patient with quadriceps weakness, though they all resolved within six weeks. In a longer follow-up paper (22 months), Anand et al. published on 28 patients with degenerative scoliosis. They found continued significant improvement in VAS pain (57%) and ODI functional outcome (82.1%) scores. Of note, they found that the incidence of thigh discomfort and numbness in up to 74% of the patients, though overall, 100% of the patients maintained correction of their deformity with verification of a solid fusion on radiographs at last followup [15]. Lastly, Dakwar et al. reported similar results in a series of 25 adult deformity patients with mean 11-month followup [16]. Despite the fact that 24 of the patients underwent multiple level lateral interbody fusion, their reported mean operative time was short at 108 minutes,



(a) (b) (c) (d)

Figure 2: Two incision technique for a lateral transpsoas approach. (a) Surgeon's Finger traversing paraspinal muscle incision site, (b) finger identifying the retroperitoneal space, (c) surgeon's finger guiding the first dilator onto the psoas major, and (d) dilator in place traversing the psoas major directly over the intended intervertebral disc space (image reprinted with permission from Nuvasive Inc., San Diego, CA).

with minimal mean blood loss of 53 mL. They reported a complication rate of 24% overall, with 12% of the patients experiencing transient postoperative anterior thigh numbness ipsilateral to the side of approach in the distribution of the anterior femoral cutaneous nerve. The patients had a mean improvement of 5.7 point in the VAS and 23.7% in the ODI. Clinical outcomes reported included 70.4% and 44.2% improvement in pain (VAS) and function (ODI), respectively. Of the 25 patients, 20 had minimum 6-month followup, all of whom had evidence of spinal fusion on CT scan or flexion/extension radiographs.

As stated previously, another indication of lateral interbody fusion is for indirect decompression of the spinal canal and neuroforamen. Oliveira et al. performed a lateral interbody at 43 levels in 21 patients with the primary diagnosis of lumbar stenosis with degenerative disc disease and grade I or II spondylolisthesis with good preliminary results [27]. They found the central and foraminal decompression was statistically significant, with an average 41.9% increase in disc height, 13.5% increase in foraminal height, 24.7% increase in foraminal area, and 33.1% increase in central canal diameter. Of note, two of the 21 patients needed additional posterior decompression as their symptoms of stenosis continued postoperatively. Elowitz et al. reported similar results in their series of 25 spinal stenosis patients with instability who underwent lateral transpsoas interbody fusion without laminectomy [28]. Their radiographic evaluation found a statistically significant increase in dural sac dimension of 54% in the anterior-posterior plane and 48% in the medial-lateral plane. Unlike Oliveira et al., they also evaluated clinical parameters, and found a statistically significant decrease in the ODI. Lastly, Kepler et al. analyzed pre- and postoperative CT scans in 29 patients who underwent lateral interbody fusion through a lateral transpsoas approach [29]. They found an average increase in the foraminal area of 35%, with posterior intervertebral height increasing 70%. Significant improvement was seen in SF-12 and ODI scores, but these improvements did not correlate significantly with increases in the foraminal areas, which they concluded reflected the multifactorial nature of symptom improvement.

An additional complication recently reported in the literature is that of an incisional hernia in a 75-year-old patient who underwent a one level XLIF [30]. While incisional hernias are a common complication of anterior abdominal surgery, with incidence rates from 2 to 14% [31], it had previously never been described as a complication of XLIF. Galan et al. recommended placing the surgical incision for XLIF as far posterior as possible into the thicker transversalis fascia, and then repairing the fascia with nonabsorbable suture at the end of the case.

Ultimately, the most common and serious complication following a lateral transpsoas approach is postoperative thigh symptoms, that range from numbness of the thigh to frank motor deficits. The rate of thigh symptoms as shown in Table 1 ranges from 1% [18] to 60% [15]. The symptoms generally resolves weeks to months after the surgery.

5. Conclusion

Lumbar fusion has been shown to be clinically and cost effective for the treatment of instability, lumbar spondylotic disease, disc degeneration or herniation, facet degeneration, spondylolisthesis, stenosis, or scoliosis [21, 32]. Despite its benefits, both anterior and posterior surgeries have significant complications, which include the potential for vascular and neurologic injury, deep vein thrombosis, wound complications, infection, and even death. The open posterior approach to the lumbar spine for decompression and

Table 1: Summary of published neurologic XLIF complications.

	Transient neurologic symptoms	Motor deficit
Anand et al. [14]	25%	Not recorded
Anand et al. [15]	60%	Not recorded
Rodgers et al. [17]	1%	Not recorded
Knight et al. [23]	9%	3%
Rodgers et al. [18]	1%	Not recorded
Isaacs et al. [26]	27%	33.6%
Dakwar et al. [16]	12%	Not recorded
Berjano et al. [24]	7%	Not recorded
Youssef et al. [36]	Not recorded	1%

supplemental fixation requires extensive dissection of the posterior paraspinal musculature and has been shown to lead to permanent denervation of the muscles in rats [33–35] and chronic incisional pain. There have been reports as well that have shown higher infection rates with the open posterior approach compared to minimally invasive approaches [35].

Due to the disadvantages of the traditional approaches, minimally invasive approaches have been developed, of which include lateral interbody fusion. Initially, lateral interbody fusion was indicated for the treatment of degenerative disc disease without significant central canal stenosis, spondylolisthesis or rotatory scoliosis. However, as surgeons have become more adept at this procedure, the indications have broadened to encompass many more pathologies. Before definitive conclusions can be made, longer term followup will be needed, but it certainly does appear promising.

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Clinical Study

Clinical Outcome and Fusion Rates after the First 30 Extreme Lateral Interbody Fusions

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Introduction. The lateral transpsoas approach for lumbar interbody fusion (XLIF) is gaining popularity. Studies examining a surgeon's early experience are rare. We aim to report treatment, complication, clinical, and radiographic outcomes in an early series of patients. *Methods*. Prospective data from the first thirty patients treated with XLIF by a single surgeon was reviewed. Outcome measures included pain, disability, and quality of life assessment. Radiographic assessment of fusion was performed by computed tomography. *Results*. Average follow-up was 11.5 months, operative time was 60 minutes per level and blood loss was 50 mL. Complications were observed: clinical subsidence, cage breakage upon insertion, new postoperative motor deficit and bowel injury. Approach side-effects were radiographic subsidence and anterior thigh sensory changes. Two patients required reoperation; microforaminotomy and pedicle screw fixation respectively. VAS back and leg pain decreased 63% and 56%, respectively. ODI improved 41.2% with 51.3% and 8.1% improvements in PCS and MCS. Complete fusion (last follow-up) was observed in 85%. *Conclusion*. The XLIF approach provides superior treatment, clinical outcomes and fusion rates compared to conventional surgical approaches with lowered complication rates. Mentor supervision for early cases and strict adherence to the surgical technique including neuromonitoring is essential.

1. Introduction

The lateral transpsoas approach for anterior lumbar interbody fusion (extreme lateral interbody fusion (XLIF)) was developed as a less-invasive alternative to conventional anterior and posterior approaches for interbody fusion [1]. Similar to anterior exposures for lumbar interbody fusion, the lateral approach allows for placement of a wide footprint intervertebral cage with wide apertures to provide superior anterior column realignment [2, 3] as well as a healthy fusion environment [4], without anterior and posterior longitudinal ligament (ALL and PLL) resection. In addition, the lateral approach mitigates many of the risks more common to traditional approaches, namely, vascular and visceral risks associated with anterior approaches [5–8] and the neural complications and bony resection common to posterior approaches [9, 10]. However, safe passage through the psoas muscle requires neuromonitoring to identify the nerves of the lumbar plexus, the injury of which represents a significant risk of the approach.

Since the introduction of the approach in the literature in 2006 [1], the procedure has increased in popularity, and reports of safety and outcome continue to be needed to fully validate the approach, especially during early cases of a new approach where a learning curve may be present [11, 12]. The purpose of this study was to examine clinical and radiographic outcomes in the first thirty patients treated with the XLIF approach by one surgeon in Melbourne, Australia.

2. Materials and Methods

Data were collected through a prospective registry, with retrospective analysis performed of the first 30 (consecutive) patients treated with extreme lateral interbody fusion (XLIF, NuVasive Inc., San Diego, CA, USA) by a single

surgeon (GM) in Melbourne, Australia from February 2011 to October 2011. Patients were treated only after failure of extended conservative therapy and imaging studies, including dynamic (flexion, extension, and lateral bending) radiography, computed tomography (CT) coregistered with bone scans, magnetic resonance imaging (MRI), and bone mineral density (DEXA) scans, as appropriate. Data were collected preoperatively and then postoperatively at standard follow-up intervals for one year postoperatively.

Baseline patient information included basic demographic information as well as the primary indication for surgery and baseline medical comorbidities. Treatment information included levels treated, biologics and fixation used, and the presence of any procedural side effects, complications, or reoperations. Patient-reported outcomes included minimum, maximum, and average back and leg pain (LBP and LP) (visual analogue scale (VAS)), disability (Oswestry Disability Index (ODI)) and quality of life (SF-36 physical and mental component scores (PCS and MCS)). Fusion was assessed using high definition (HD) CT (Somatom scanner) taken one to two days postoperatively to assess instrumentation placement and then between six and twelve months postoperatively to assess fusion status. Fusion was defined as the presence of bridging interbody trabecular bone [13] and was determined by a third-party radiologist from within the treating institution.

The surgical procedure has previously been described [1] but involves a 90° off-midline retroperitoneal approach to the anterior lumbar spine with blunt dissection through the fibres of the psoas muscle to the lateral border of the disc space. Passage through the psoas muscle, avoiding the nerves of the lumbar plexus, is accomplished using a neuromonitoring system (NV JJB/M5, NuVasive, Inc.) integrated into approach and procedural instrumentation. Neuromonitoring with this system provides real-time and surgeon-directed discrete-threshold electromyographic responses to provide geographic information about the presence of motor nerves relative to procedural instrumentation [14, 15]. One thoracic level was treated (T6-7), and a similar procedure to the lumbar XLIF procedure was followed, though using a transpleural lateral approach, as has also been previously described [16, 17]. Direct decompressions were performed when required.

All patients were fitted with intervertebral polyetheretherketone (PEEK) cage(s) (CoRoent, NuVasive, Inc.) filled with a combination of bone morphogenetic protein (rhBMP-2 (BMP), Infuse, Medtronic, Inc., Memphis, TN, USA) and Mastergraft β-TCP granules (Medtronic, Inc.). BMP has a fixed concentration of 1.5 mg/cc, and the dose used per level was volume dependent (i.e., the internal volume of cage equalled BMP volume in cc), using (a small kit of BMP (2.8 cc providing a 4.2 mg dose), per the manufacturers recommendation, following a one-hour absorption into the carrier period. No BMP was placed outside the cage. Supplemental internal fixation was applied as needed.

Statistical analyses included frequency testing for demographic and treatment variables, paired t-tests comparing clinical outcomes from preoperative levels, and fisher exact tests for comparisons of the frequency of events between groups. Statistical analysis was carried out using SPSS v. 19.0 (SPSS IBM, Chicago, IL, USA) with statistical significance measured at $P < 0.05$.

3. Results

The first thirty (30) patients treated with XLIF were included in the analysis and had a mean age of 63 years with a mean body mass index (BMI) of 26.7, and 20 (67%) were female. Baseline comorbidities included tobacco use (20%), diabetes mellitus (13%), and prior lumbar spine surgery (20%). The most common primary diagnoses included degenerative disc disease (41%), spondylolisthesis (31%), and degenerative scoliosis (24%). In 30 patients, 43 levels (1.4 per patient, range 1–3) were treated with the most common levels being L3-4 and L4-5 (in 57% of patients, each). Supplemental internal fixation was used in 15 (50%) patients and included pedicle screw fixation in 13 and interspinous plating in two patients. Staging of secondary procedures (decompressions and/or fixation) occurred in 47% of cases. A summary of baseline and treatment information is included in Table 1.

Average operating time per level was 60 minutes with a mean blood loss of 50 mL per level (range 10–150 mL).

Four (13%) complications were observed. One large bowel injury occurred in a thin 53-year-old female patient who underwent a left-sided approach for a L3-5 XLIF with posterior instrumentation for disabling low back pain above a previous L5-S1 fusion. The patient had a past history of midline laparotomy for bowel obstruction performed 20 years previously. On day three postoperatively the patient developed left lower quadrant abdominal pain with tenderness and tachypnoea. Chest and abdominal plain radiographs were indeterminate for free air, but abdominal CT demonstrated intraperitoneal air (Figure 1). Urgent laparotomy found that the descending colon had been perforated adjacent to the L4-5 level on the side ipsilateral to the approach. One patient developed a new motor deficit immediately evident postoperatively with 4/5 power quadriceps due to a posteriorly placed cage which resulted in a L2 radiculopathy that partially resolved with persistent 4+/5 weakness at 12 months. One instance of symptomatic subsidence was observed in the form of unilateral disc space collapse with a 22 mm-wide cage inferior to a prior fusion, and while a reoperation was not required, fusion was not evident at 12 months. Finally, there was one instance of cage breakage following an attempted forceful impaction of an 8 mm cage into a collapsed L3-4 disc space. In addition, three cases of asymptomatic (radiographic) subsidence (<25% height loss) were observed without sequelae. Of the four instances of cage subsidence, three included 18 mm cages (two standalone, one bilateral pedicle fixation) and one with 22 mm (standalone).

Side effects of the approach were observed, with five cases of anterior thigh sensory changes (dysesthesias), four of which had resolved by six weeks postoperative and one of which was persistent at last followup (12 months). Of these,

Table 1: Listing of patient demographic and treatment information.

Characteristic	Statistic $n = 30$
Mean age in years (stdev) (range)	62.7 (10.5) (30–81)
Female (%)	20 (66.7)
Mean body mass index (BMI), (stdev) (range)	26.7 (5.4) (17.6–37.9)
Comorbidities	
Comorbidity type	
Tobacco use (%)	6 (20)
Diabetes (%)	4 (13)
Any prior lumbar spine surgery (%)	6 (20)
Lami/MLD (%)	4 (67)
Fusion (%)	2 (33)
Primary diagnosis	$n = 29$ (1 missing)
Degenerative disc disease (%)	12 (41)
Herniated nucleus pulposus (%)	1 (3)
Spondylolisthesis (%)	9 (31)
Scoliosis (%)	7 (24)
Levels treated (mean per patient) (range)	43 (1.4) (1–3)
T6-7 (% of levels) (% of patients)	1 (2) (3)
L1-L2 (% of levels) (% of patients)	1 (2) (3)
L2-L3 (% of levels) (% of patients)	6 (14) (20)
L3-L4 (% of levels) (% of patients)	17 (40) (57)
L4-L5 (% of levels) (% of patients)	17 (40) (57)
Biologics used	
rhBMP-2 (%)	30 (100)
Fixation type (%)	
Interspinous plating (%)	2 (7)
Transpedicular fixation (%)	13 (40)
Unilateral (%)	2 (15)
Bilateral (%)	11 (85)
Standalone (%)	15 (50)
Staged fixation?	
Yes (%)	14 (47)
No (%)	16 (53)

n: number of patients; stdev: standard deviation; Lami: laminectomy; MLD: microlumbar discectomy.

Table 2: XLIF fusion rates.

Time postoperatively	Fusion rate
6 months	46% (12/26)
9 months	58% (15/26)
12 months	85% (22/26)

three occurred within the first 10, and none occurred in the last 10, patients of the series. Complications and side effects are included in Table 3.

Two patients required reoperation: one underwent a microforaminotomy for a posteriorly placed cage and a second underwent bilateral pedicle fixation for symptomatic facet arthropathy.

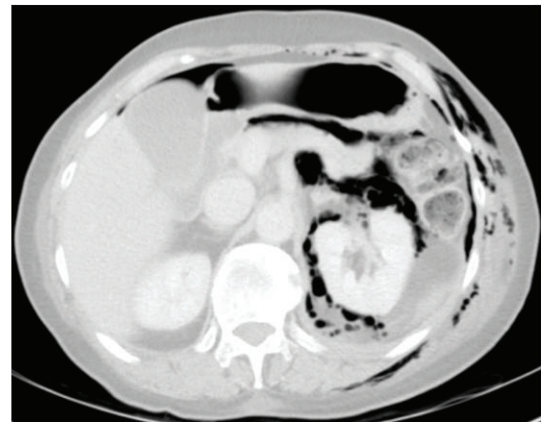

Figure 1: Abdominal axial computed tomography (CT) showing intraperitoneal free air following unrecognized bowel perforation.

Four patients were lost to followup. All patients or their representatives were contacted by phone for followup, and reasons for noncompliance included one who is a workers compensation case and refused followup, another is an elderly women who was satisfied with her outcome but was unable to travel to the office, and another whose son reported that the patient had become morbidly obese (130 kg) and was now agoraphobic and unable to leave the house. One patient was unable to be contacted.

Of those able to be followed (26), average followup was 11.5 months (range 9–12). Average back and leg pain (in those with leg pain) improved 6.9 and 6.6 to 2.9 and 2.9, representing a 63% and 56% improvement, respectively (Figures 2 and 3). Disability (ODI) improved from 56.9 preoperatively to 33.5 at last followup (41.2%) with PCS and MCS improving 51.3% (27.0 to 40.8) and 8.1% (46.9 to 50.7), respectively (Figure 4). All clinical results were statistically significantly improved from baseline ($P < 0.001$) except for MCS ($P = 0.200$). Fusion rate confirmed on HD CT coronal views (Figure 5) progressed from 46% (12/26) at 6 months to 58% (15/26) at 9 months and 85% (22/26) at 12 months postoperatively (Table 2). In patients with supplemental internal fixation, a 92% (12/13) fusion rate was observed, while without fixation only 77% (10/13) of patients exhibited complete fusion at 12 months, a difference which was not statistically significant ($P = 0.593$).

4. Discussion

The primary indications for the XLIF procedure are thoracolumbar pathology from approximately T4 through L5 (limited superiorly by the axilla and interiorly by the iliac crest) and include symptomatic disc degeneration [18], degenerative scoliosis [19, 20], spondylolisthesis, adjacent segment disease [21], as well as traumatic, tumor, and infection pathologies [22–24]. Relative contraindications for XLIF included L5-S1 pathology, retroperitoneal adhesions, and early bifurcation of the iliac vessels. Preoperative assessment

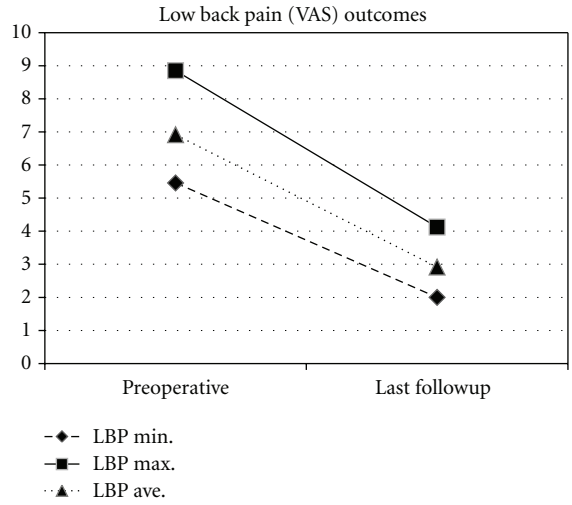

Figure 2: Change in minimum, maximum, and average low back pain (LBP) from preoperative to last followup (mean 11.5 months).

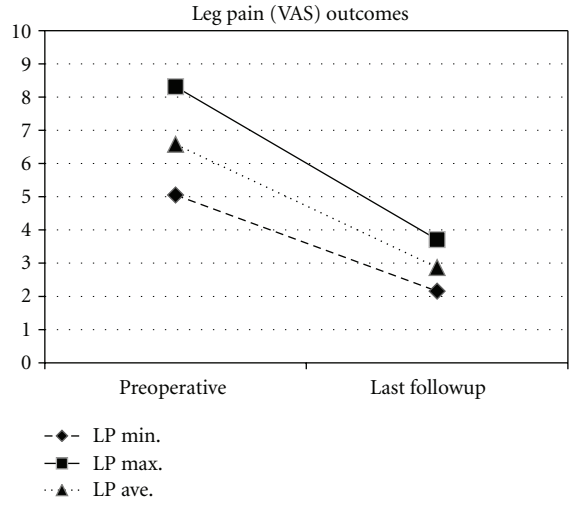

Figure 3: Change in minimum, maximum, and average leg pain (LP) from preoperative to last followup (mean 11.5 months).

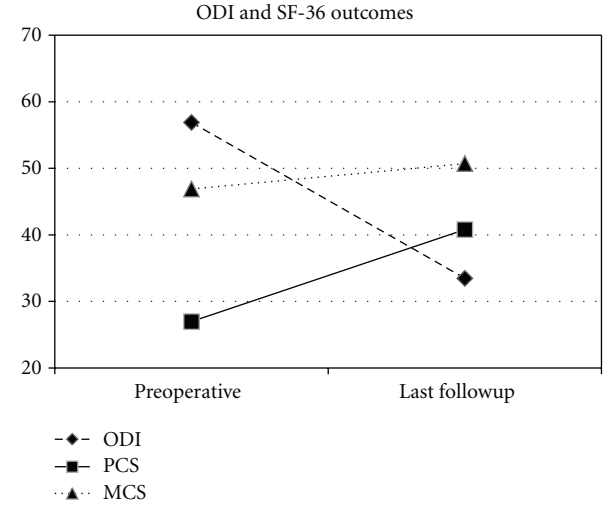

Figure 4: Change in average disability (ODI), and physical and mental quality of life (PCS and MCS) from preoperative to last followup (mean 11.5 months).

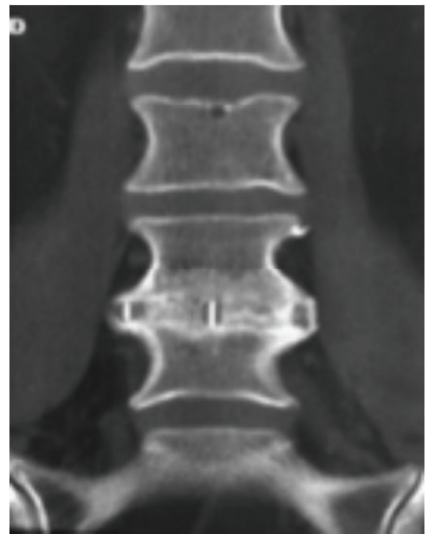

Figure 5: Coronal computed tomography (CT) showing solid arthrodesis at 12 months postoperative following L4-5 XLIF.

of the neurovascular complex at each level to be treated on axial MRI is essential to have a preoperative understanding of regional anatomy as it relates to the lateral approach [25].

In the first 30 cases of XLIF at one institution, the authors observed a 13% complication rate in 30 patients with two reoperations occurring. Mean followup was 11.5 months and low back and leg pain decreased by 63% and 56%, respectively, with similar improvements in disability (41.2%) and physical and mental quality of life (51.3% & 8.1%, resp.).

In comparison with alternative approaches for lumbar interbody fusion, complications rates with transforaminal and posterior lumbar interbody fusion (T/PLIF) have generally been reported in elevated ranges compared to the current series. In 2009, Rihn et al. [9] reported on a series of 119 TLIF cases performed at Thomas Jefferson University Hospital. An overall complication rate of 46% (55) was observed in 35% (40) of patients. While 10 complications were attributed to iliac crest bone graft harvesting, there was a 10.9% rate of new postoperative radiculitis, a 5% infection rate, and a 10.1% reoperation rate. Similarly, Okuda et al. [26] in 2006 reported the surgical complications of 251 PLIF patients treated at a single institution. In this series, the authors found an intraoperative complication rate of 10.3% with a new postoperative neurologic deficit rate of 8.3% (21; 19 motor, 2 sensory), with 32% of those classified as slight, 47% severe, and 21% permanent. Results in the current series, having observed a 13% complication rate, is favorable to these similar study-design historical results, even when factoring in that cases in the current series represented the adoption of a new procedure [11, 12]. In total, six (20%) neural adverse events occurred, one motor complication and 5 sensory

Table 3: Complications and side effects.

Patient number	Levels (mean)	Dysaesthesia	Motor deficit	Reoperation	Subsidence	Cage breakage	Bowel injury
1–10	1.1	3	1	1	0	0	0
11–20	1.3	2	0	0	2	0	0
21–30	1.5	0	0	1	2	1	1
Totals	42	5	1	2	4	1	1

side-effects, rates which are consistent with high-quality prospective multicenter studies of XLIF performed using surgeons already familiar with the procedure [14]. Tohmeh et al. [14] observed a 17.5% rate of transient anterior thigh sensory changes postoperatively with a 2.9% new motor deficit rate in 102 XLIF patients treated at L3-4 and/or L4-5. In addition, the single incidence of motor injury occurred as a result of a misplaced cage (case 6) rather than during direct injury by procedural instrumentation during the approach for procedure. When considering the generally transient nature of the expected sensory nerve irritation, the incidence of neural events (the most apparent anatomical risk during the procedure) also compares favorably to posterior approaches.

Anatomically, the sensory nerves at risk with this operation are the ilioinguinal, iliohypogastric, lateral femoral cutaneous, and genitofemoral nerve [27]. The first three nerves are at risk of injury in the approach to the psoas. The genitofemoral nerve arises from the L1 and L2 nerve roots, traverses the psoas, and descends along the anteromedial border of the psoas deep to its fascia [28]. The nerve crosses the L2-3 disc space and may be injured anywhere along its course [28, 29] though the risk is somewhat mitigated by more posterior docking on the lateral aspect of the disc space, enabled by neuromonitoring of the more-posterior motor nerves of the lumbar plexus [15]. The patients in this series that experienced the side effect of genitofemoral irritation, which are relatively common with this procedure, usually resolve within 6 weeks, but persistence has been reported [14, 30] as in one of the five cases in this series. In the current series, we observed a reduction in the incidence of sensory side effects from early cases (20% rate in the first 20 cases) compared to later (0% in last 10 cases) though the difference in rate was not statistically significant ($P = 0.140$). Potential reasons for the decrease in these events may include decreased duration of time and the psoas muscle was under retraction (procedural efficiency) and increased comfort with more posterior docking (avoiding the more anterior genitofemoral nerve) with incremental adherence to neuromonitoring.

Radiographic subsidence was observed in three cases, with one instance of both radiographic and clinical subsidence. Factors thought to contribute to cage subsidence are the narrower 18 mm cages, osteoporosis, the use of BMP-2, the use of standalone cages, and iatrogenic endplate violation [31, 32]. Three of the four cage subsidence in this series occurred with 18 mm standalone cages. The symptomatic subsidence occurred six weeks postoperatively after the insertion of a 22 mm standalone cage packed with BMP-2 inferior to a previous fusion in a patient with normal bone density. This may reflect increased biomechanical stress at the L4-5 level as well as the osteolytic, inflammatory phase of BMP-2 [32].

In the patient who experienced the unrecognized bowel injury, the injury likely occurred during placement of the initial dilator, which was delivered at an angle from the plane perpendicular to the floor, in a deviation from the prescribed surgical technique. The patient required a Hartmann's colostomy that was reversed two months later. She recovered without infection and reported significant improvement in low back pain and mobility. Bowel injury following XLIF has previously been reported as a complication of the approach, both acute and delayed [33].

Clinical and radiographic outcomes were consistent with previously-reported results which showed fusion rate ranges between 91% and 100% (though generally with more extended followup), 37% to 80% reduction in low back pain, and a 39% to 82.1% reduction in disability (ODI) [34]. These results are similar or superior to conventional surgical approaches. Blumenthal et al. [35], as a part of the Charité artificial lumbar disc Food and Drug Administration (FDA) investigation, reported a 47.6% improvement in low back pain at 24 months postoperative in the ALIF fusion control group with a 41.5% improvement in ODI. Similar results were seen in ALIF by Kuslich et al. [36] in 1998, showing an improvement of 42% in pain and 31.5% in disability at 24 months postoperatively.

In the current series, the relatively lower early fusion rate seen in standalone cases may suggest an extended healing period due to the less-rigid segmental environment to promote fusion [37]. While this has yet to be formally studied, several studies of standalone XLIF show that some consistency with this notion though, also of note, is that progression to complete fusion does generally occur [38–41].

5. Conclusion

In summary, these data represent generally superior treatment (blood loss and operative time), clinical (pain, disability, and quality of life), and fusion rates using the XLIF approach compared to conventional surgical approaches with substantially lowered complication rates. With specific training, mentor supervision for early cases, and strict adherence to surgical technique including neuromonitoring, surgeons can anticipate low perioperative morbidity even in the early period following the adoption of the approach.

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Clinical Study

Treatment of Thoracolumbar Spinal Infections through Anterolateral Approaches Using Expandable Titanium Mesh Cage for Spine Reconstruction

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Pyogenic vertebral osteomyelitis (PVO) is still a rare pathology. However, its incidence is on the rise. This is due to an increasing population with predisposing factors. Also, the availability of more effective diagnostic tools has brought it increasingly to the surgeon's attention. In this study the patients were treated in the Neurosurgery Division of the Department of Neurological Sciences and Psychiatry of the Sapienza University of Rome, between 2001 and 2009. They had thoracolumbar pyogenic spondylitis. This study was undertaken in order to identify the correct diagnostic and therapeutic treatment needed in such cases. From the cases studied here, it is evident that spinal infections can be extremely insidious and that diagnosis tends to be reached late. Surgery, along with the antibiotic treatment, allows for eradication of the causes of the pathology by the reclamation of the affected region. Surgery is also fundamental in helping to recover vital functions and in restoring as much as possible the correct curvature of the rachises. The use of an anterolateral approach is dictated by the necessity of obtaining 360° stability as well as by the need to clear away extensive infections, which are not always reachable using a posterior approach.

1. Introduction

Spinal infections are quite rare pathologies, that is, 2% to 7% of all osteomyelitis [1]. Nevertheless predisposing factors such as diabetes, immune-depression, and advanced age can favour their appearance.

These infections are usually caused by saprophytes which are normally present in human organisms. In certain conditions they can become pathogens [2]. One germ in particular must always be taken into consideration in a differential diagnosis and that is the BK. Its frequency is on the increase due to the migration of people from developing to industrialised countries [3].

The diagnosis of spinal infection occurs late as these infections arise insidiously generally with the appearance of localised pain which gradually worsens. When there is radicular or spinal cord compression, the infection has already reached an advanced stage. The patient usually comes to the surgeon's attention once medical therapy has failed and thus when the infection is fairly advanced [4].

The treatment of the spondylodiscitis is essentially medical. However, when the infection fails to decrease or it progresses, intervention becomes necessary. Once neurological defects become apparent surgery is called for.

There are no specific guidelines on what would be the most appropriate surgical treatment [5].

Therefore, these cases were reexamined retrospectively in order to evaluate the clinical and medical aspects to take into consideration when deciding on the appropriate therapy for patients affected by spinal infections.

2. Materials and Methods

This study is based on the review of 16 clinical charts of patients affected by thoracolumbar pyogenic (tuberculotic and nontuberculotic) spondylitis (Table 1). They were

Table 1: This table shows general data regarding our patients including sex, age, origin, and presence of other pathology that can favourite the onset of infection. In the table are also indicated the affected levels, the responsible microorganisms, and the level treated whit stabilization. There are also summary data regarding pre-operative and post-operative neurological status valuated with Frankel Scale (*Grade A*: complete neurological injury—no motor or sensory function clinically detected below the level of the injury. *Grade B*: preserved sensation only—no motor function clinically detected below the level of the injury; sensory function remains below the level of the injury but may include only partial function (sacral sparing qualifies as preserved sensation). *Grade C*: preserved motor nonfunctional—some motor function observed below the level of the injury, but is of no practical use to the patient. *Grade D*: preserved motor function—useful motor function below the level of the injury; patient can move lower limbs and walk with or without aid, but does not have a normal gait or strength in all motor groups. *Grade E*: normal motor—no clinically detected abnormality in motor or sensory function with normal sphincter function; abnormal reflexes and subjective sensory abnormalities may be present. There are also summary data regarding duration of symptoms and duration of followup.

Patients	Sex	Age	Birth place	Comorbidity	Levels of infection	Organisms	Instrumented levels	Neurological status preop/postop	Followup	Duration of symptoms
1	M	56	Italy	Obesity, thoracic aortic prosthesis	T7–T9	Culture negative	T4–T12	C/D	18 months	2 weeks
2	M	75	Italy	Lumbar aorto-iliac prosthesis	L3–L5	*Staphylococcus aureus*	T11-ileum (sacro-iliac screw)	C/D	24 months	12 weeks
3	F	80	Italy	Diabetes mellitus	T7-T8	*Staphylococcus aureus*	T5–T10	E/E	33 months	4 weeks
4	M	61	Italy	Drug abuser	T8-T9	Culture negative	T6–T11	C/C	24 months	10 weeks
5	M	21	Somalia	Debility	T9	BK	T7–T11	E/E	48 months	16 weeks
6	M	34	Ethiopia	Debility	T11-T12	BK	Only anterior approach	D/E	36 months	12 weeks
7	M	35	Italy	Drug abuser	T9-T10	BK	T7–T12	C/E	23 months	3 weeks
8	F	64	Peru	None	L2-L3	*Staphylococcus aureus*	D11-S1 (spondilolistesi L5-S1)	E/E	40 months	12 weeks
9	M	59	Ethiopia	Diabetes mellitus	T7–T9	Culture negative	T5–T11	D/E	37 months	6 weeks
10	F	47	Kenya	Hiv+	T8-T9	*Staphylococcus epidermidis*	T6–T11	C/D	25 months	10 weeks
11	F	53	Italy	Thoracic aortic prosthesis	T11-T12	Culture negative	T9-L2	C/C	42 months	2 weeks
12	M	65	Somalia	Debility	T9-T10	Culture negative	T8–T11	D/E	30 months	8 weeks
13	M	48	Italy	None	L3-L4	*Staphylococcus aureus*	Only anterior approach	E/E	45 months	16 weeks
14	M	57	Romania	Alcohol abuser	L2-L3	Culture negative	T12-L5	A/A	28 months	1 week
15	F	69	Romania	Drug abuser	L3-L4	Culture negative	L1-S1	C/E	28 months	3 weeks
16	F	80	Italy	Diabetes mellitus	L2-L3	*Staphylococcus epidermidis*	T12-L5	D/E	44 months	12 weeks

treated surgically from 2002 to 2009 in the Neurosurgery Division of the Department of Neurological Sciences and Psychiatry of the University "La Sapienza", Rome. Fourteen patients were operated on using an anterolateral and posterior column approach with the placement of an expandable titanium mesh (ETM) and pedicle screws. Two of these patients were treated using solely the anterolateral approach. None of the patients had had any previous operations on their spinal columns.

Prior to the operation, the patients were questioned as regards the duration of symptoms with especial attention paid to back pain, radicular pain, and paraesthesia. They then submitted to a neurological exam to evaluate their tendon reflexes, any signs of radicular or spinal cord compression, and the presence of neurological sphincter defects, sensitive, and/or motor impairment.

The patients were evaluated in the preoperative and in postoperative course with the Frankel scale: *Grade A*: complete neurological injury—no motor or sensory function clinically detected below the level of the injury. *Grade B*: preserved sensation only—no motor function clinically detected below the level of the injury; sensory function remains below the level of the injury but may include only partial function (sacral sparing qualifies as preserved sensation). *Grade C*: preserved motor non-functional—some motor function observed below the level of the injury, but is of no practical use to the patient. *Grade D*: preserved motor function—useful motor function below the level of the injury; patient can move lower limbs and walk with or without aid, but does not have a normal gait or strength in all motor groups. *Grade E*: normal motor—no clinically detected abnormality in motor or sensory function with normal sphincter function; abnormal reflexes and subjective sensory abnormalities may be present.

The laboratory exams included a complete blood cell count with differential, erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) evaluation, in addition to peripheral blood cultures.

In three cases a CT guided biopsy with a needle via the pedicle was undertaken (in only one case a germ was isolated). All patients before the operation underwent an MRI in the T1 sequence with and without contrast, T2 and STIR, CT and a standard X-ray, this was to evaluate the extent of the infection, the possible compression of nerve structures, and the degree of bone erosion and kyphosis.

In selected cases a preoperative angiography with identification of the artery of Adamkiewicz was done.

During the operation samples were taken for histological exams and cultures.

Following the operation antibiotic treatment was administered intravenously for four weeks and after that it was administered orally.

In the first week following the operation, a CT was performed to check the screw fixation system. Then, during followup, the patient was X-rayed in an upright position so as to control the reduction of the preop kyphosis and the possible shift or movement of the ETM or the positioning screws.

The Laboratory exams included a complete blood count, erythrocyte sedimentation rate (ESR), and C-reactive protein (CRP). These were evaluated to check on the infection and to determine the end of the antibiotic therapy.

The follow-up period ranged from 18 months to 4 years (mean: 32.8 months).

3. Results

The data obtained from the 16 cases is resumed in Table 1. The average age of the patients was 56.5 (range 21 to 80 years old), 10 patients (62.5%) were male and 6 (37.5%) were female. Fourteen patients (87.5%) had other pathologies. Eight patients (50%) came from non-European countries.

All presented with back pain or lumbar pain associated with radicular pain. In 12 patients, 75% of the cases, there were also neurological defects.

In all the patients the ESR and CRP were above the normal range, in 8 cases the white blood cell count was elevated.

The average duration of symptoms prior to surgical intervention was of 8 weeks (range 1 to 16 weeks).

Fourteen out of 16 patients (87.5%) noted an improvement in their pain symptomology following the operation. Nine out of 16 patients who had preoperative neurological defects presented clinical improvement following the operation, 4 patients who had no neurological disorders remained free postoperatively, and 3 patients who had moderate or severe neurological disorders (Frankel A and C) did not present clinical improvement in the postoperative course.

In 3 cases, an intravascular aortic prosthesis was placed following a ruptured aneurism.

Fourteen of the cases had come to the neurosurgery department after having previously visited other specialists and having followed a course of antibiotics for a number of weeks.

In 7 cases the cultures were negative, in 6 cases the germ identified belonged to the staphylococcus family while in 3 cases it was the bacillus of Koch. In 12 cases the cultures obtained during the operation were negative and the germ responsible was isolated following a further cultural exam.

Out of the 12 patients who presented involvement of the dorsal rachises, 8 on the radiography exams showed a kyphosis of the spinal tract affected by the infection (range from 38° to 45°). Among the 4 patients with an involvement of the lumbar rachises, in one case the radiography showed a 62° increased lordosis, while for the rest of the patients there was a significant decrease in lordosis (range from 37° to 30°). In all the patients there was a postoperative reduction of the preoperative deformation ranging from 2° to 15°.

Four patients had had to be operated on urgently following the sudden onset, within the last 24 hours, of sphincter impairments and motor deficits in the lower limbs.

The patients were first operated on anterior laterally and subsequently using a posterior approach. In 2 patients only the anterolateral approach was used. In 6 cases (42.8%) the two approaches were undertaken on the same day, whereas in the other cases, and taking into account the clinical condition of the patients as well as the comorbidity, the second operation took place 3-4 days later.

In 10 cases a lateral thoracotomy was performed and in 6 cases a retroperitoneal lumbar approach was used.

The retroperitoneal approach, when possible and taking into consideration the laterality of the paravertebral access, took place from the left. This was due to the presence on the right of the vena cava and because of the greater accessibility to the vertebral field.

For the thoracolumbar option a left side thoracotomy was performed. This was due to the presence on the right of the liver thus making it easier to dislocate the diaphragmatic crura and retract the diaphragmatic cupola downwards.

In all the cases a debridement was done and an expansion mesh was placed.

In the cases operated on using the posterior approach a posterior lateral fusion with an heterologous bone was done.

The suppurating material was always removed. The site was continuously washed using a 0.9% physiological solution and a drainage tube was placed for both types of operations whether using an anterolateral or a posterior approach. The drainage tubes were removed within 24–72 hours.

The patients were immobilized with a corset for about 2 months. An antibiotic therapy was imposed and followed up by colleagues from infectious diseases. It was then suspended on normalisation of the inflammatory markers (white blood cells, ESR, and CRP). The follow-up X-rays took place every 30 days for the first 3 times and then once every six months.

One patient developed a thrombosis to the lower limbs (this was despite the use in all the patients of antithrombosis socks and heparin therapy); the problem resolved itself following further heparin treatment.

All the patients who had shown preoperative deficits underwent physiotherapy in a rehabilitation clinic.

The cage settling ranged from 0 to 3 mm.

In none of the patients was it necessary to reintervene surgically.

Here, we present two illustrative cases. One of a patient who presented severe preoperative deformities and needed an urgent operation on the lumbar region using a 360° approach. The other of a younger patient who was treated on the dorsal area using the anterior approach. This approach alone was enough to reduce and contain the preoperative rachis deformity.

4. Illustrative Cases

4.1. Case 1. This was the case of a 75-year-old male (Case 2, Table 1). Fifteen months earlier, due to the rupture of an abdominal aortic aneurism, this patient had undergone an operation, by intravascular technique, for the placement of an aortic-iliac lumbar prosthesis. For 6 months he had been suffering from lower back pain. The analgesic treatment provided had only eased the pain momentarily. In the last 15 days prior to his operation a progressive weakening of the lower limbs had led to the patient needing a wheel chair.

Unfortunately, it was in this condition that the patient arrived at the hospital's ER.

A CT angiography of the aorta did not show any loss of contrast to the aortic wall while a lumbar-sacral MRI with mdc (Figure 1) revealed a VO involving the vertebral bodies of L3-L4-L5 with invasion of the spinal canal and an important compression of the dural sack.

A colleague from vascular surgery did not attempt the removal of the prosthesis due to the high risk of laceration to the vassal wall.

Due to the gravity of his neurological condition (Frankel C) the patient had to be operated on urgently. Under general anaesthesia, with the patient in a lateral position, a left side retroperitoneal lumbar approach was used. The vertebral field was reached by dislocating the aorta, the abdominal viscera, and the urethra medially. A debridement with resection of all infected and necrotic tissues was effected so as to visualise the inferior end plate of L2 and the superior end plate of S1. Samples were taken for histological exams and cultures. An expansion mesh was then placed (Figure 2); it was gradually expanded so as to reduce as much as possible the kyphosis (measurements as to the size of the mesh were based on the preoperative CT). Numerous washes (2000cc) with a 0.9% physiological solution were done and a drainage tube was placed. Then, with the patient in a prone position, the transversal processes were exposed, the pedicle screws were inserted from T11 to the ileum. A decompressive laminectomy of L3, L4, and L5 then followed.

Finally a lateral posterior arthrodesis with autologous and heterologous bone was undertaken and, here too, a drainage tube was placed. The drainage tubes were removed 48 hours after the operation.

The patient began his physiotherapy and was seated with a corset on the second postoperative day.

The antibiotic treatment was administered intravenously for the first four weeks and then orally for a further 6 months until normalisation of the haematic inflammatory markers.

The first radiological checkup, a CT, took place within 7 days of the operation and was followed by a standard X-ray in two projections. The last checkups, radiological and haematological, 24 months later, have shown no alterations (Figure 2).

4.2. Case 2. This was the case of a 34-year-old detainee with back pain which had not been alleviated by pharmacological treatment. The patient was extremely debilitated.

During the neurological exam the patient presented no motor or sensory deficits.

He underwent a lumbar MRI with and without contrasts that showed an extended accumulation of suppurating matter in the paravertebral region which involved T11-T12 (Figure 3). This was eroding them and causing the beginning of a kyphosis of the rachis. Initially the patient was treated with the placement of a drainage tube, using the technique of interventionist radiology. The result obtained was unsatisfactory as it failed to reduce pain and it failed to reduce the accumulated suppuration.

It was then decided that the patient should undergo an operation, a right side lateral thoracotomy, under general anaesthesia. The patient was positioned in lateral decubitus with his right arm raised. An oral-tracheal tube was placed so as to omit the right side lung. The vertebral field was reached by dislocating the lung and the diaphragmatic cupola. There then was a debridement with resection of all infected and

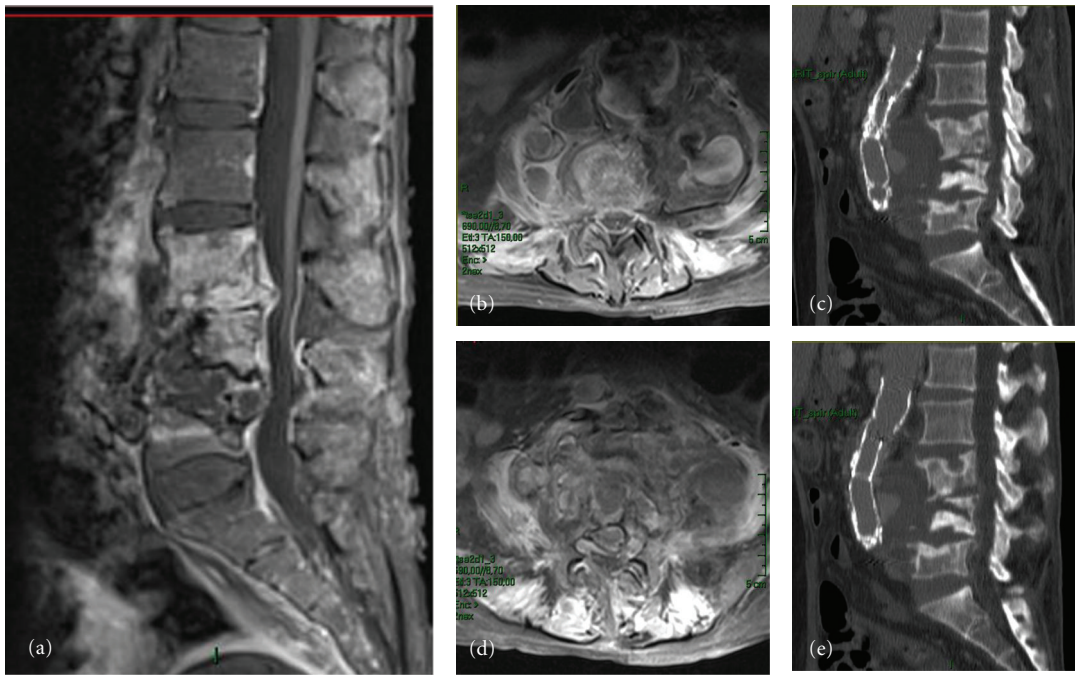
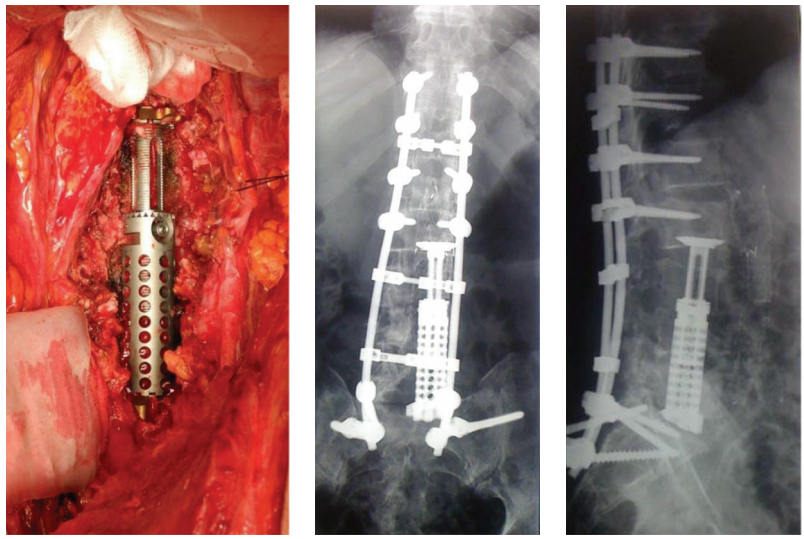


Figure 1: (a) Sagittal MRI, T1 showing the extension of the infectious process to three vertebral bodies L3-L4-L5 and to the intervertebral discs, as in a case of spondylodiscitis. ((b) and (d)) Axial MRI, T2 showing the paravertebral extension of the infection as well as an important compression of the sack and roots by the infection. ((c) and (d)) Sagittal CT showing the erosion and an extended rehashing of the bone as well as the involvement of the aortic prosthesis which has in part been pushed forwards by the infection. The CT also shows the integrity of the vertebral plain of the vertebrae adjacent to the damaged ones.



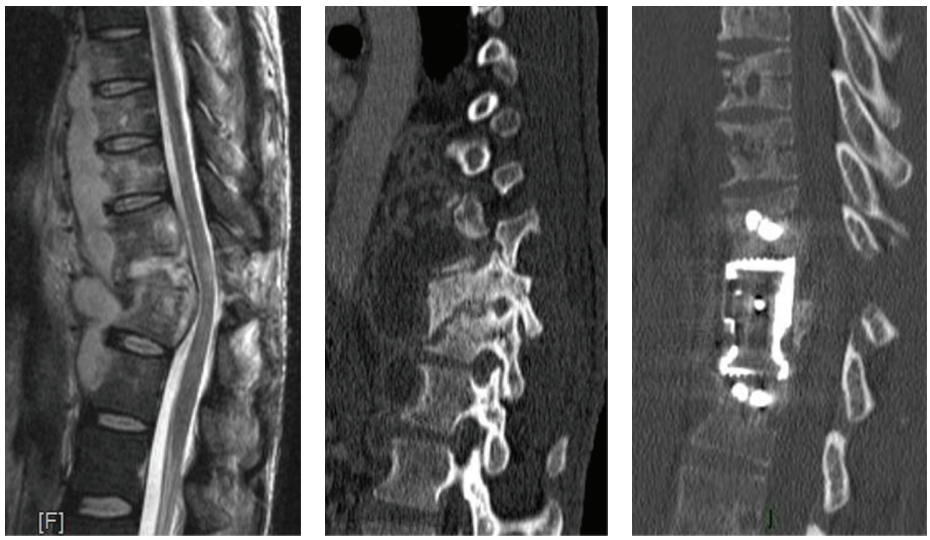
(a) (b) (c)

Figure 2: (a) Intraoperative picture showing the placement of the expansion mesh. ((b) and (c)) Follow-up pictures taken 12 months apart. They show the correct placement of the fixation system. The mesh is in place with a 3 mm settling. To be noted here is the natural inclination of the mesh on the inferior end plate. This has allowed for restitution of a partial lordosis to the lumbar-sacral column.

necrotic tissue so as to visualise the inferior end plate of T10 and the superior end plate of L1 (Figure 4).

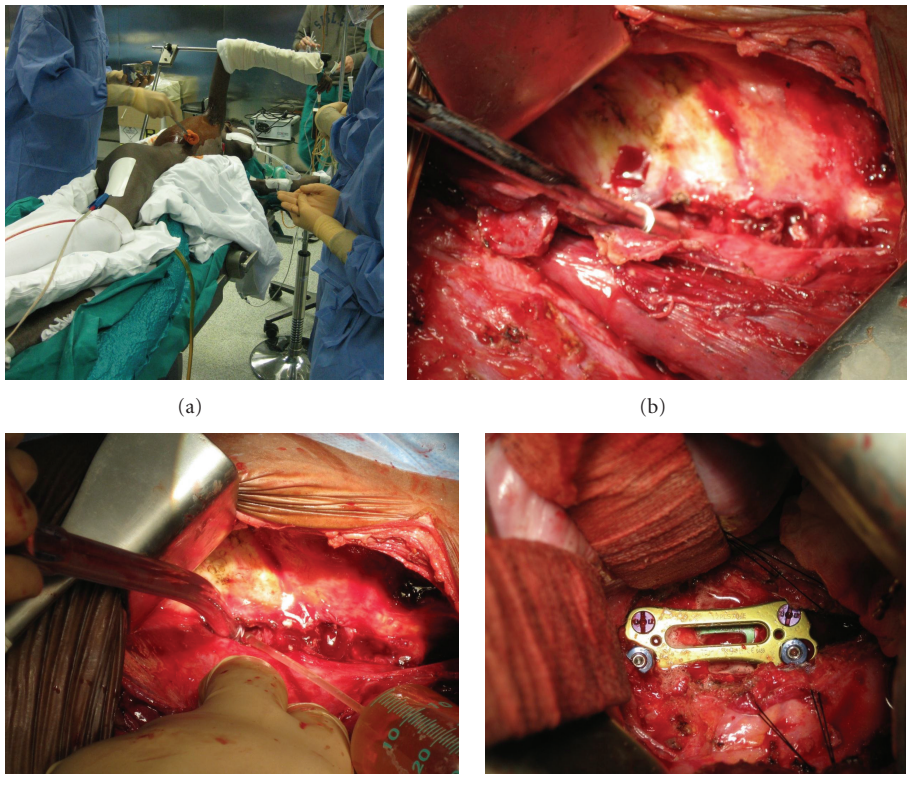
Samples were collected for the histological and bacteriological exams as well as cultures.

An expansion mesh was placed; it was gradually expanded so as to reduce as much as possible the kyphosis (measurements of the mesh were determined by the preop CT). There then followed numerous washes (2000cc) using a 0.9% physiological solution and a thoracic drain was placed. This latter was removed after about 7 days on complete normalisation of the thoracic region. The patient, wearing a corset, was able to get up 8 days after the operation.



(a) (b) (c)

Figure 3: (a) Sagittal MRI T2: here the infectious process has involved two vertebral bodies with an initial tightening of the canal even if it is still possible to identify signs of the liquor around the spinal cord. The paravertebral extension is clearly visible. (b) Sagittal CT: it highlights the marked kyphotic deformation caused by the complete erosion of the bone by the infection, in particular to the inferior vertebral body. (c) Postoperative sagittal CT: highlighted here is the correct positioning of the mesh as well as the restitution of the correct curvature to the dorsal rachises.



(a) (b)

(c) (d)

Figure 4: (a) Picture of the position of a patient in the operating room for the lateral thoracotomy approach, with the ipsilateral arm raised. (b) Intraoperative picture showing bone erosion by the infection. (c) During the surgical procedure the site is repeatedly washed with 0.9% physiological solution so as to clear as much as possible the surgical field. (d) Final intraoperative picture. It shows the placement of the mesh and the plaque.

This patient also had to undergo antibiotic therapy for tuberculosis. The bacteriological exam undertaken during the operation had revealed a tubercular infection. This was confirmed by further cultures. The treatment was carried on for further 6 months.

It was decided that no posterior stabilisation needed to be done considering the age of the patient and the good degree of kyphosis reduction after the initial operation.

In all successive checkups, at the last 36 months, the patient has shown maintenance of the rachises curvature without any signs of kyphosis.

5. Discussion

5.1. Epidemiology. Spinal infections, also denominated vertebral osteomyelitis (VO), and spondylodiscitis have been known since the end of the XIX century [6, 7]. In the past, in preantibiotic times, they were associated with a high rate of mortality and often were diagnosed postmortem [6, 7].

Spinal infections represent less than 4% of all bone infections [1]. Nowadays the mortality rate has been greatly reduced [4, 8]. However, it remains a challenging pathology to diagnose and treat.

In medical literature the ratio of male to female is 2 M to 1F, which corresponds to our data [9]. The average age of diagnosis in our cases was of 56.6, again in line with the data found in the literature [10].

The majority of patients with spinal infections presented some comorbidity (Table 1): diabetes, debility, drug abuse, and HIV+ [11]. Those patients found positive for the bacillus of Koch often came from countries where tuberculosis was present (Table 1).

The lumbar and dorsal segments were the most frequently affected regions followed in decreasing order by the cervical tract and then the cervicothoracic one [9].

5.2. Clinical. The clinical presentation of thoracolumbar VO is generally insidious. It usually begins with back pain, followed later by radicular pains, sensitive/motor deficits, going on to paraparesis and sphincter defects. This gradual escalation of the infectious process is one of the reasons for the late diagnosis [12].

5.3. Diagnostic. Laboratory evaluation is fundamental. It included a complete blood cell count, erythrocyte sedimentation rate (ESR), and C-reactive protein (CRP) evaluation, in addition to peripheral blood cultures [13]. These analyses were used to evaluate the efficiency of the medical and surgical treatments. Their normalisation was necessary to suspend antibiotic treatment.

The radiological exams included standing plain radiographs, MRI with gadolinium and CT. The first one at the beginning of the pathology can come up negative or be difficult to interpret. The MRI with gadolinium, is the optimal exam as it can show bone and disc involvement, the presence of paravertebral accumulations and epidural abscesses, spinal cord compression, and any possible ischemic lesions [14, 15]. The CT is needed to program the surgical intervention and for the placement of the prosthesis as the information obtained regards the density and erosion of the bone.

The percentage of positive results from the computed tomography-guided needle biopsy is between 29%, 51%, and 96% [5, 8, 9]. Also the percentage of microbiological diagnosis following an intraoperative biopsy has a high degree of variability in literature 80%, 18%, and 59%; [8–10] in our case studies the cultures were 56% positive.

This was due to the fact that a lot of patients came to the surgeon's attention following the onset of neurological problems and after having already begun an antibiotic therapy.

81% (13 cases) of the patients came to our department after having seen other specialists in the field and after having been administered antibiotics for a number of weeks.

5.4. Treatment. To date there are no guidelines regarding medical treatment associated or not with surgical treatment. Moreover, with regard to surgical treatment, there is no agreement on whether to follow only a debridement or to position an allograft strut grafting, or to use a prosthesis in different materials (stainless steel and titanium) [16, 17]. Different surgical approaches may be used anteriorly, posteriorly, or both.

Traditional medical treatment calls for the administration of intravenous antibiotics for 4 weeks, then orally (3–12 months) until normalisation of the inflammatory markers associated with the positioning of a corset [1].

As stated above there is, as yet, no agreement on how or when to intervene surgically [5]. In our institute, we maintain, along with some authors, that surgical treatment is indicated in failure of nonoperative treatment (persistent pain, persistent abnormal ESR e CRP, and persistent or increase of the abscess in MRI), extensive bone destruction, kyphosis, and neurological deterioration (motor deficits, paraparesis or paraplegia, and bladder dysfunction). The policy in our institute is to intervene surgically within 24 hours on patients who are deteriorating neurologically.

In this study 75% (13) of the patients had preoperative motor deficits. But, whatever the case, surgical treatment must always be associated with the administration of antibiotics.

A few years ago the use of spinal instrumentation in VO was a much discussed topic [18–20]. Now many papers on the use of anterior stabilisation with debridement associated with or without posterior stabilisation have been published [16, 17].

The advantages of this technique would be the reduction of vertebral deformities, the reduction of pain, an earlier patient mobilization, and the decompression of neural structures.

Few studies have been undertaken on which materials to use. But it would seem that the adherence and persistence of bacteria are higher with stainless steel devices than with titanium [17]. In addition to this, biofilms tend to form more frequently on stainless steel than on titanium [21, 22].

In our case studies 16 patients were operated on using an anterolateral approach. It was not always possible to perform both the anterior and posterior approach on the same day due to the clinical condition and comorbidity of the patient.

In approaches to the dorsal rachises it is very important to do, when possible, a spinal angiography so as to know the origin of the artery of Adamkiewicz. This serves to avoid damaging it and to reduce vascularization of the spinal cord in patients who often already have a neurological damage. It also serves to link the intercostal artery, if necessary, after the origin of the artery itself.

In our cases we found no relevant complications nor any need to reintervene surgically.

The inferior and superior sides of the mesh should be placed on vertebral end plates which are not affected by the infection and not on the cancellous bone even if this latter is healthy, as some authors show [5, 17]. This is so as to avoid excessive settling, in our cases this was from 0 to 3 mm.

In the majority of works, regarding treatment with anterior surgery, there have been published accounts of cases of VO involving one or two adjacent vertebral bodies and their discs.

In these papers 2 cases were described, one lumbar and one thoracic, of triple corpectomy for an infection which involved three vertebral bodies. In both cases the spinal infection was secondary to an adjacent infected aortic graft. In our cases we did not remove any vascular prosthesis as they had been in place for over a year and the risk of damage to the vassal wall was too high. However, these patients followed an antibiotic therapy of 9 months and successive checkups showed that the haematic inflammatory markers were within the norm.

One of the first authors to talk about spinal fusion by anterior approach for patients with spinal infections caused by the BK was Hodgson in 1960 [23]. The anterolateral thoracotomy or retroperitoneal approach allows direct access to the vertebrae and thus to the infection which helps to reduce more efficiently the vertebral deformities. In our cases it was decided to perform a posterior approach as well when it was necessary to reduce a significant kyphosis; in obese patients, an important spinal cord compression was present which necessitated decompression both anteriorly and posteriorly by laminectomy.

The anterior and posterior approach would normally be followed in the same operation [16] to reduce the risk of infection, to reduce blood risk, to reduce the length of hospitalisation, to allow for precocious mobilization, and so as to avoid that the patient undergoes two anaesthesias.

Unfortunately this may not always be possible as certain patients present comorbidity and are medically unstable. In our case studies, whether the patients had one or two operations, the outcome was always good.

6. Conclusion

Spinal infections are insidious pathologies which can lead to motor and sphincter damages. In their early stages they can be difficult to diagnose if an MRI with gadolinium is not done, as standard radiography results can come up negative.

The anterolateral surgical treatment with placement of a device associated or not with a posterior stabilisation is indicated for patients unresponsive to traditional treatments, with a significant deformation of the rachis which necessitates 360° stabilisation, in the presence of neurological damage which requires decompression of the spinal cord or the roots either by an anterior or a posterior approach. In fact, surgical treatment may even become urgent if there has been significant neurological deterioration in the last 24 hours. The anterolateral approach allows access to all the vertebral bodies involved in the infection so as to follow a complete debridement, especially in extended infections, and to place a prosthesis in the absence of complication and with a rapid clinical improvement for the patient.

The expandable titanium mesh cage allows through gradual distension to reduce important vertebral deformities with the effective absence of risk of infection to the prosthesis itself.

The retrospective analysis of our cases leads to the conclusion that there are two principal objectives to be reached:

(1) an extended drainage of the area affected by the infective process;

(2) a reduction of the rachises deformation, if present, and a stabilisation of the vertebral column.

Both these objectives are reachable by using a combined posterior and anterior approach.

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Clinical Study

Grade 2 Spondylolisthesis at L4-5 Treated by XLIF: Safety and Midterm Results in the "Worst Case Scenario"

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Spondylolisthesis is one of the most common indications for spinal surgery. However, no one approach has been proven to be more effective in treating spondylolisthesis. Recent advances in minimally invasive spine technology have allowed for different approaches to be applied to this indication, notably extreme lateral interbody fusion (XLIF). The risk, however, of using XLIF in treating grade II spondylolisthesis is the ventral position of the lumbar plexus, particularly at L4-5. *Objective*. This study reports the safety and midterm clinical and radiographic outcomes of patients with grade II lumbar spondylolisthesis treated with XLIF. *Methods*. 63 patients with grade II spondylolisthesis and spinal stenosis were treated with XLIF and were available for 12-month followup. Of those, 61 (97%) were treated at L4-5. Clinical (VAS, complications, and reoperation rate) and radiographic (anterolisthesis, disk height, and fusion) parameters were assessed. *Study Design*. Data were collected via a prospective registry and analyzed retrospectively. *Results*. Sixty-three patients were available for evaluations at least one year postoperatively. Average pain (visual analog scale) decreased from a score of 8.7 at baseline to 2.2 at 12 months postoperatively. Average anterior slippage was reduced by 73% and was well maintained. Average disk height (4.6 mm pre-op and 9.0 mm post-op) nearly doubled after surgery. Slight settling (average 1.3 mm) occurred over the twelve-month follow-up period. There were no neural injuries and no nonunions noted. *Conclusions*. XLIF is a safe and effective minimally invasive treatment alternative for grade II spondylolisthesis. Real-time neurological monitoring and attention to technique are mandatory.

1. Introduction

Spondylolisthesis remains one of the most common indications for surgery on the spine. The efficacy of surgical treatment for this condition has been repeatedly confirmed [1], most notably in the Spine Patient Outcomes Research Trial (SPORT) study [2–4] and as such, fusion is frequently recommended for patients with degenerative spondylolisthesis [5, 6]. While the long-term benefits of surgical treatment over nonoperative care for this indication have been shown, only recently has the cost-effectiveness of this procedure been proven in high-level data [7]. Recent reports have discussed and compared a variety of fusion procedures, including anterior lumbar interbody fusion (ALIF), posterior lumbar interbody fusion (PLIF), [8] transforaminal lumbar interbody fusion (TLIF) [9], and minimally invasive (MIS) TLIF and MIS ALIF [10]. Despite a great deal of investigation, no approach has proven more effective than the others, and no universal treatment guideline can be proposed [5].

Recent advances in MIS technology are now being applied to spinal pathologies. One of these techniques, extreme lateral interbody fusion (XLIF) has been suggested as a safe, minimally invasive alternative to traditional open fusion procedures. The technique has previously been described in detail Figure 1 [11] and several reports with long-term outcomes and large-series samples are emerging, showing the efficacy of the approach with fewer morbidities than conventional approaches [12–18].

XLIF has been recommended for spondylolisthesis up to grade 2 [11, 13] but the concerns about neural complications associated with the lateral approaches to the spine [19–21] beg the question of safety. These concerns are most pronounced at the L4-5 level, where the lumbar plexus is most ventral anatomically [8, 22–27]. Significant anterolisthesis at this level only exacerbates the risk.

To our knowledge, no reports have specifically addressed the treatment of grade 2 spondylolisthesis at L4-5 with XLIF.

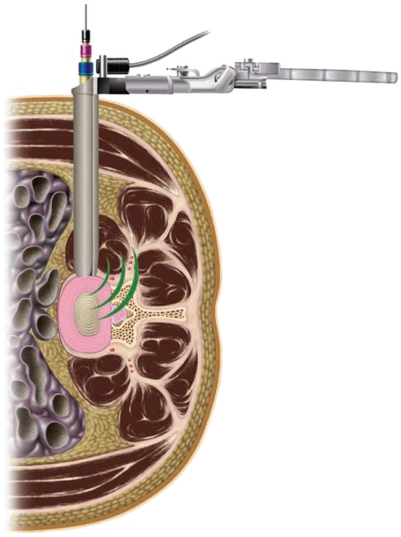


Figure 1: Illustration of XLIF technique.

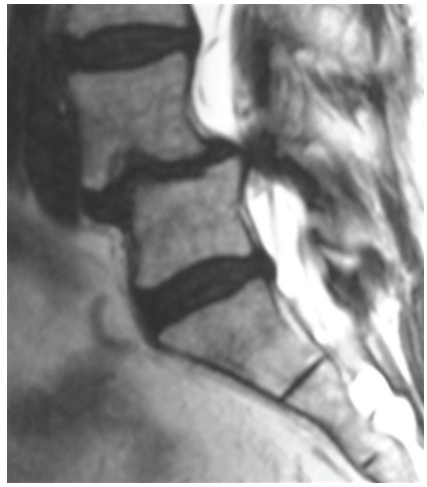


Figure 2: MRI scan showing spinal stenosis and spondylolisthesis.

Herein, we report on our early and intermediate term results in applying this technique to what is arguably its "worst case scenario."

2. Methods

2.1. Patient Population. Sixty-three patients (10 men and 53 women; mean age 64.5 years) available for 12-month followup after undergoing XLIF for grade 2 spondylolisthesis were treated with XLIF at a single institution between November 2006 and March 2011. In all cases supplemental posterior instrumentation was applied. No posterior direct decompression was performed, relying solely on the indirect decompression achieved through disk height restoration and reduction of slip. Demographics, diagnosis, previous surgery, body mass index (BMI), and preexisting comorbidities were recorded. Under Saint Mary's Health Center Institutional Review Board (IRB) approval, clinical and radiographic outcomes were prospectively collected and evaluated at pre-op, post-op, 3 months, 6 months, and 12 months followup.

2.2. Radiographic Evaluation. Standing anteroposterior (AP), static lateral, and flexion-extension lateral radiographs were obtained preoperatively and at two weeks, three months, six months, and twelve months after surgery. Measurements of disk height (mm) and anterolisthesis (mm) were taken. Spinal stenosis was confirmed by preoperative CT or MR imaging. Radiographic analysis was performed by a physician other than the operating surgeon.

Fusion was defined as the presence of bridging bone across the disk space (modified Lenke grade 1 or 2) [28] and the absence of significant motion (<5 degrees, <2 mm interspinous widening) on dynamic radiographs.

2.3. Clinical Evaluation. Visual analog scale (VAS) pain measurements were obtained at each time point through the completion of patient outcomes questionnaires administered by the research staff. Intraoperative and postoperative complications were recorded by the evaluating physician. At twelve months postoperatively, patients were asked to complete an additional questionnaire assessing the presence of new back or leg pain (pain not present prior to surgery), their degree of satisfaction with the result, and their willingness to have the procedure again.

2.4. XLIF Surgical Technique. Extreme lateral interbody fusion, or XLIF, is a 90° off midline or true lateral approach that allows for large graft placement and excellent disk height restoration and provides indirect decompression at the stenotic motion segment. This approach can be performed using two 3 cm to 4 cm skin incisions. Safe passage to the retroperitoneal space is assured by gentle blunt dissection. As the psoas muscle is traversed, the lumbosacral plexus is protected by the use of automated electrophysiology. Exposure is achieved with an expandable three-bladed retractor, which allows for direct illuminated visualization facilitating diskectomy and complete anterior column stabilization using a large load-bearing implant. In patients with significant listhetic deformity, the adherence to procedural technique, including careful patient positioning, gentle retroperitoneal dissection, and meticulous psoas traverse using advanced neurological monitoring before performing a complete discectomy and placing a properly size interbody spacer is essential [13] where neural structures are pulled ventrally by the slipping L4 vertebral body (Figure 2).

It is impossible to overemphasize the importance of reliable, timely monitoring of the neural elements as the surgeon traverses the psoas muscle. Visual identification of the lumbar plexus is not possible but the plexus can be protected by using an automated real-time electrophysiology technology (Figure 3).

3. Results

The demographic, diagnosis, and comorbidity data for the total cohort are summarized in Table 1. For all patients,

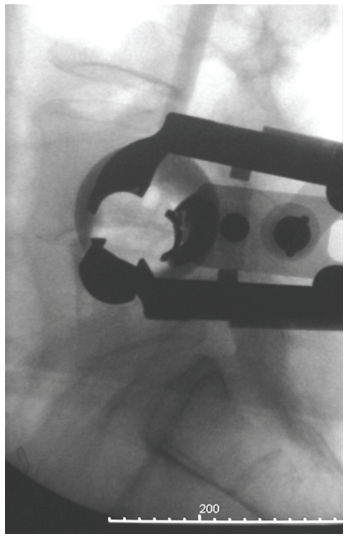


Figure 3: Lateral fluorogram showing dorsal retractor placement.

Table 1: Patient demographics of grade II spondylolisthesis patients treated with extreme lateral interbody fusion (XLIF).

Characteristic	Statistic ($n = 63$)
Mean age in years (range)	66.4 (25–88)
Number of females (%)	53 (84.1)
Mean body mass index (BMI) (range)	30.8 (16.9–48.4)
Comorbidities	
Tobacco use (%)	47 (74.6)
Coronary artery disease (%)	39 (61.9)
Diabetes (%)	9 (14.3)
Chronic obstructive pulmonary disease (COPD) (%)	3 (4.8)
Preoperative steroid use (%)	9 (14.3)
Cancer (%)	7 (11.1)
Any prior lumbar surgery (%)	45 (71.4)
Prior surgery type	$n = 45$
Laminectomy (%)	11 (61.1)
Fusion (%)	4 (22.2)
Anterior lumbar interbody fusion (ALIF)	3 (16.7)
Diagnoses (primary only)	
Spondylolisthesis (%)	45 (71.4)
Stenosis with instability (%)	132 (46.6)
Degenerative scoliosis (%)	2 (3.2)

hospital stay averaged 1.2 days and hemoglobin decreased 1.4 g on average. There were two (3.4%) complications in the total cohort, one patient experiencing postoperative ileus, the second having a broken pedicle screw on radiographs obtained after a motor vehicle accident 14 months after surgery. CT imaging showed a solid fusion and the patient was asymptomatic. There were no infections. Although early postoperative transient upper thigh pain and hip flexion weakness were common, as expected consequences to operative trauma to the psoas muscle, these symptoms were not persistent. There were no neurologic deficits. Two (3.4%) patients of the total cohort underwent further surgery within one year: both for adjacent segment disease, one treated with PLF, the other with XLIF.

Table 2: Treatment characteristics.

Characteristic	Statistic ($n = 63$)
Number of levels treated (average per patient)	80 (1.3)
L2-L3 (% of patients)	2 (3.2)
L3-L4 (% of patients)	15 (23.8)
L4-L5 (% of patients)	61 (96.8)
L5-S1 (AxiaLIF) (% of patients)	2 (3.2)
Number of GII spondy levels (average per patient)	63 (1.0)
Number of total levels treated per case	
One	49 (77.8)
Two	11 (17.5)
Three	3 (4.8)
Graft material	
Beta-TCP/HA (%)	6 (9.5)
DBM + allograft (%)	6 (9.5)
DBM + CCC (%)	49 (77.8)
Allograft cellular bone matrix (%)	2 (3.2)
Supplemental fixation (GII levels)	
Unilateral pedicle screws (%)	53 (84.1)
Bilateral pedicle screws (%)	9 (14.3)
Total pedicle screw fixations (%)	62 (98.4)
Transpedicular facet fixation (%)	1 (1.6)
Internally fixated implant (%)	10 (15.9)
No supplemental fixation (stand alone) (%)	0 (0)
Mean hemoglobin change from pre- to postoperative (g) (range)	−1.4 (−3.8–0.5)
Mean length of hospital stay (days) (range)	1.21 (0–4)

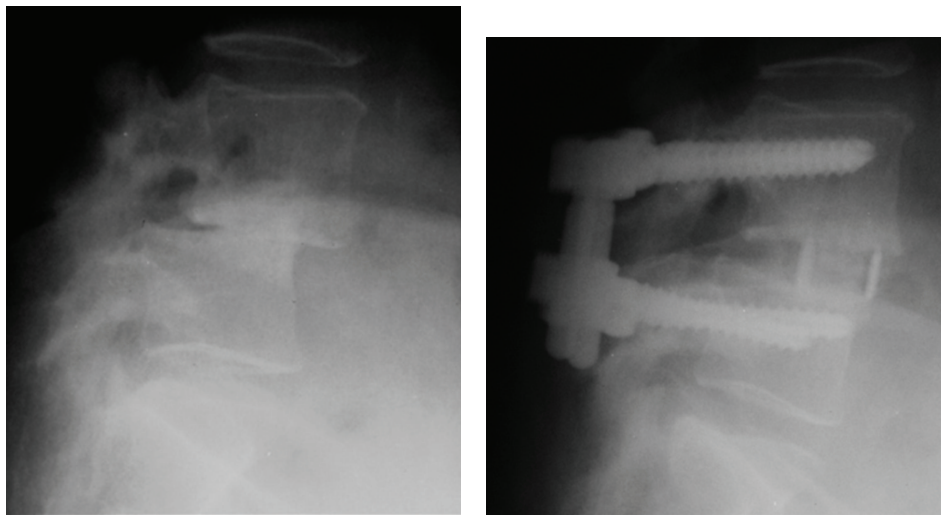
Grade II spondylolistheses were most commonly present at L4-5 (97%), though in a single level each, L2-3, and L3-4 were indicated. A total of 80 levels (1.3 per patient) were treated (63 for grade II spondylolisthesis). One-, two-, and three-level procedures were performed in 78%, 18%, and 5% of cases, respectively. Biologic materials varied, but most included demineralized bone matrix (87%). Transpedicular fixation was used in all but one instance of grade II spondylolisthesis, where transpedicular facet fixation was used. Treatment variables are included in Table 2.

Clinical and radiographic outcomes are shown in Table 3. At 12 months, there was no radiographic instability noted on dynamic radiographs and all patients appeared to have bridging bone across the interbody space (Figures 4(a) and 4(b)). Eight patients underwent CT imaging. All were judged to be fused by an independent radiologist (Figure 5).

Table 3: Average clinical and radiographic outcome data of patients with at least 12 months followup.

	Preop	Postop	3 months	6 months	12 months	P
VAS (pain) (stdev.)	8.7 (1.3)		2.2 (2.0)	2.3 (22.0)	2.2 (2.0)	<0.001
Disk height (mm) (stdev.)	4.6 (2.2)	10.3 (2.6)	9.7 (2.6)	9.3 (2.6)	9.0 (2.5)	<0.001
Slip (mm) (stdev.)	11.1 (1.7)	3.0 (2.0)	3.3 (2.2)	3.6 (2.3)	3.6 (2.3)	<0.001
Lenke			1.9 (0.5)	1.4 (0.4)	1.1 (0.3)	

Mm: millimeters, stdev: standard deviation.



(a) (b)

Figure 4: (a) Preoperative lateral radiograph. (b) Lateral radiograph 12-months postoperative.

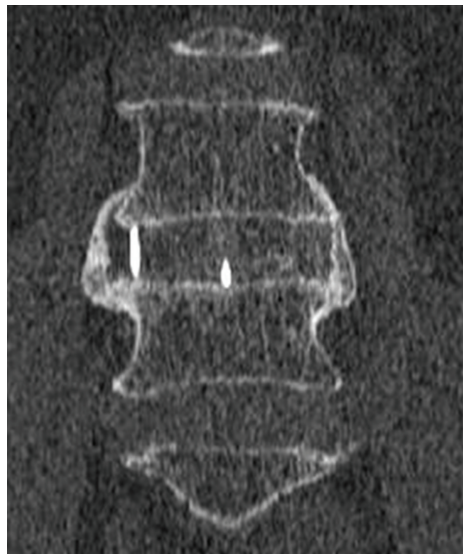


Figure 5: CT image demonstrating fusion.

Neither radiographic (slip) nor VAS improvement and maintenance at last followup were influenced by age, BMI/obesity, preexisting comorbidities, prior surgery, levels treated, or unilateral versus bilateral fixation ($P > 0.05$). Patient satisfaction and willingness to have undergone the procedure again were, however, dependent on slip improvement ($P = 0.011$ and $P = 0.008$, resp.). A summary of slip and VAS findings by demographic and treatment variables is included in Table 4. Although average correction was well maintained, 6.4% of patients had lost more than 3 mm of listhetic correction and 6.4% had lost more than 3 mm of disk height.

At last followup, 89.3% rated themselves as "satisfied" or "very satisfied" with their results and 92.9% stated that they would choose to have the procedure again.

4. Discussion

The purpose of this study was to examine the safety and efficacy of XLIF in the treatment of grade 2 spondylolisthesis. The use of XLIF to treat degenerative conditions has been documented, as has the procedure's reduced complication rate when compared to traditional open approaches, either anterior [29] or posterior [30, 31]. Analysis of our results shows excellent reduction in listhetic deformity and improvement of disk height with maintenance of these radiographic outcomes over time. Progression toward fusion appears to be routine. Likewise, clinical outcomes denote marked improvement in VAS with persistent improvement at one year. Patient satisfaction with the procedure approaches 90% in most studies, a finding confirmed by our results. These clinical measures attest to the resolution of stenotic

Table 4: Breakdown of spondylolisthesis reduction and 12-month pain (VAS) by demographic and treatment variables.

Grouping variable (n)	Slip reduction from preoperative (%)			12-month VAS (mm)		
	No	Yes	P	No	Yes	P
Gender (female/male)	67% (53)	75% (10)	0.228	2.2 (48)	2.1 (10)	0.933
Obese	68% (36)	68% (27)	0.925	2.1 (24)	2.2 (34)	0.840
Smoke	68% (47)	67% (16)	0.862	2.1 (44)	2.2 (14)	0.915
Diabetes mellitus	69% (54)	62% (9)	0.345	2.1 (50)	2.4 (8)	0.677
Coronary artery disease	68% (39)	68% (24)	0.934	1.9 (34)	2.5 (24)	0.249
Chronic obstructive pulmonary disease	69% (60)	56% (3)	0.273	2.2 (55)	2.3 (3)	0.856
Steroid use	67% (54)	76% (9)	0.149	2.1 (49)	2.2 (9)	0.916
Cancer	68% (56)	70% (7)	0.714	2.2 (52)	2.0 (6)	0.760
Prior surgery	69% (45)	66% (18)	0.680	2.1 (43)	2.3 (15)	0.800
Levels treated (1 or 2)	67% (49)	71% (11)	0.637	2.1 (44)	2.6 (11)	0.508
Unilateral versus bilateral fixation (uni/bi)	68% (53)	70% (8)	0.799	2.3 (49)	1.7 (7)	0.445
Satisfaction	49% (6)	70% (50)	**0.011**	5.7 (6)	1.7 (45)	**0.016**
Redo	43% (4)	70% (52)	**0.008**	5.3 (4)	1.8 (47)	**0.041**

VAS: visual analog scale, mm: millimeters, uni: unilateral, and bi: bilateral.

symptoms through the indirect decompression and stabilization achieved.

However, the concerns regarding the safety of lateral transpsoas approaches to the lumbar spine remain. In a frequently cited study, [19] the authors reported a 27% incidence of groin numbness (but no motor deficits) using an endoscopic transpsoas approach without neurologic monitoring. It should be noted that this study has been mistakenly referenced [19] as a description of the XLIF approach, which is minimally invasive but not endoscopic and mandates the use of real-time neurologic monitoring. Another study [21] noted two L4 nerve root injuries (3.4%) in a series of 58 lateral fusion cases (and a 22.4% complication rate). This paper reported cases using both XLIF and direct lateral interbody fusion (DLIF) without delineating the number of each type of procedure or distinguishing the complications by procedure. Since the recommended technique is somewhat different in the two procedures and the duration of hospitalization was so prolonged (XLIF: 6 days; DLIF: 4 days), one might argue that this study was a learning curve comparison and should not be cited as definitive. In the largest published series to date, 600 patients treated with XLIF experienced a length of hospitalization averaging 1.21 days and a 6.2% complication rate (rate of transient motor deficit—0.7%) [18].

Nonetheless, neurologic deficits associated with lateral approaches are an area of great discussion. As has been documented anatomically and radiographically, the lumbar plexus migrates ventrally as one descends caudally from L2-3 to L4-5 [8, 22–27]. This places the plexus at greatest risk in a transpsoas approach at the L4-5 level. In addition, anterolisthesis of the superior vertebral body carries the plexus even more ventral, heightening safety concerns. However, as shown by our data, in the presence of real-time neurologic monitoring and with attention to the details of the technique mentioned above, grade 2 listhetic segments, especially at L4-5, can be treated successfully without neurologic injury. The importance of monitoring and technique cannot be overemphasized.

Clinically, surgery for spondylolisthesis has been shown to yield better patient outcomes than nonoperative treatment in large randomized trials [2–4]. Multiple techniques have been employed—decompression alone, [32] PLF, [6] instrumented PLF [33] PLIF [34], ALIF [35], TLIF [9], as well as MIS ALIF [10], or MIS TLIF [19] procedures—without a clear consensus emerging [5]. In addition to clinical effectiveness, recent results of a randomized controlled trial have shown that instrumented fusion for the treatment of degenerative spondylolisthesis is substantially cost effective compared to conservative care [32]. This study noted a quality-adjusted life-year (QALY) gain of 0.39 in the fusion cohort at a cost of $54,500 (down from 0.23 QALY and $115,600 cost per QALY gained at two years postoperative) per QALY gained. With the threshold for cost effectiveness in the United States at $100,000 per QALY gained, [36, 37] this proves that in the treatment of degenerative spondylolisthesis, instrumented lumbar fusion is solidly cost effective compared to conservative care at four-years postoperative. However, no breakdown of the 344 fusion surgeries (269 with instrumentation) by type of procedure was provided but, based on the timeframe of the study, it may be inferred that the vast majority of those fusions were performed using traditional open techniques. As we have shown in this study, the complications associated with MIS XLIF fusion for spondylolisthesis are notably less than the complications reported with traditional open approaches. Furthermore, open spinal fusions have been reported to have much longer hospitalizations (ALIF: 3.9 days [28], PLIF: 9.7 days [29], or TLIF: 5.5 days [38]) than the 1.2 days we report herein. A recent study, compared the operating costs for a hospital performing XLIF and open PLIF in the treatment of two-level degenerative spinal conditions showed a decrease in operating costs by 9.6% (including the higher price for XLIF implants) with a 1.2 compared with 3.2 day hospital

stay (resp.) with significantly fewer transfusions and residual events [39]. A similar study of open and miniopen posterior found significantly lower hospital charges, complications, length of stay, and transfer to inpatient rehabilitation using minimally invasive posterior lumbar interbody fusion (PLIF) compared with open PLIF [40]. It stands to reason that modern surgical fusion options—utilizing direct visualization, miniopen approaches—would be expected to yield a markedly decreased dollar cost per QALY gained because these MIS techniques require shorter hospital stays and result in fewer expensive complications.

5. Conclusion

XLIF is safe and effective for the treatment of grade 2 spondylolisthesis at L4-5. The use of this technique results in marked clinical and radiographic improvement which is maintained over time. The use of real-time neurologic monitoring and careful attention to technique are mandatory.

Disclosure

W. Rodgers serves as a Consultant to NuVasive, the designers of the XLIF procedure. He is an inventor on four pending patents. He has been paid for teaching, receives royalties, owns NuVasive stock, serves on the advisory board, and is paid research support and travel expenses. He is also a Consultant to Exactech, makers of the majority of the bone grafting material used in the procedures discussed in this paper. Exactech also provides research support to W. Rodgers and and supports travel expenses.

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Clinical Study

Clinical Outcomes of Extreme Lateral Interbody Fusion in the Treatment of Adult Degenerative Scoliosis

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Introduction. The use of extreme lateral interbody fusion (XLIF) and other lateral access surgery is rapidly increasing in popularity. However, limited data is available regarding its use in scoliosis surgery. The objective of this study was to evaluate the clinical outcomes of adults with degenerative lumbar scoliosis treated with XLIF. *Methods*. Thirty consecutive patients with adult degenerative scoliosis treated by a single surgeon at a major academic institution were followed for an average of 14.3 months. Interbody fusion was completed using the XLIF technique with supplemental posterior instrumentation. Validated clinical outcome scores were obtained on patients preoperatively and at most recent follow-up. Complications were recorded. *Results*. The study group demonstrated improvement in multiple clinical outcome scores. Oswestry Disability Index scores improved from 24.8 to 19.0 ($P < 0.001$). Short Form-12 scores improved, although the change was not significant. Visual analog scores for back pain decreased from 6.8 to 4.6 ($P < 0.001$) while scores for leg pain decreased from 5.4 to 2.8 ($P < 0.001$). A total of six minor complications (20%) were recorded, and two patients (6.7%) required additional surgery. *Conclusions*. Based on the significant improvement in validated clinical outcome scores, XLIF is effective in the treatment of adult degenerative scoliosis.

1. Introduction

Adult degenerative scoliosis has an estimated prevalence of 6% in people over the age of 50 [1]. Patients classically present with back pain, sagittal imbalance, or radicular symptoms. Though conservative management is recommended as an initial treatment, outcomes are frequently unacceptable [2].

When nonoperative treatment fails, adult degenerative scoliosis presents significant surgical challenges. Decompression may be the treatment of choice in mild deformity or minimal instability. However, decompression alone has been associated with a risk of iatrogenic instability and progression of deformity [3, 4]. For this reason, an instrumented arthrodesis is often indicated [4–7].

Interbody fusion has been demonstrated to be an effective method of deformity correction in adult scoliosis [8, 9]. Approaches to interbody fusion include posterior lumbar interbody fusion (PLIF), transforaminal lumbar interbody fusion (TLIF), and anterior lumbar interbody fusion (ALIF). In 2006, a lateral transpsoas approach to the lumbar spine was described [10]. This approach has been popularized as "extreme lateral interbody fusion (XLIF)." Advantages of the lateral approach may include decreased blood loss, accelerated recovery, and decreased cost [11–13].

Recently, authors have described the use of lateral interbody fusion for the treatment of a variety of lumbar conditions [14–23]. The indications for lateral access surgery continue to expand as more surgeons adopt the technique. However, with this increase in popularity comes a need for more clinical data. In an attempt to address this need, this study describes a single surgeon's experience with XLIF in the treatment of adult degenerative scoliosis.

2. Methods

2.1. Study Design. The study herein was an institutional review board-approved evaluation of adult degenerative scoliosis treated by a single surgeon at a major academic institution. During the study period, thirty consecutive patients underwent XLIF with supplemental posterior instrumentation. Validated clinical outcome scores were obtained preoperatively and at most recent followup for comparison purposes. Complications were recorded.

2.2. Subjects. Thirty patients were followed up for an average of 14.3 months (Table 1). Inclusion criteria required a diagnosis of symptomatic degenerative adult scoliosis that had failed at least a year of conservative treatment. Patients were required to have a coronal Cobb angle of at least 10° for inclusion. The average age was 65.9 years (range 53–76 years). The study included 11 men and 19 women with an average BMI of 28.8 (range 19–38). 18 patients had apex-left deformity, and 12 had apex-right. Nine patients were active smokers at the time of surgery. 15 patients (50%) had undergone prior lumbar spine surgery at one or more levels: 6/30 laminectomy, 1/30 interspinous spacer placement, 1/30 microdiscectomy, 1/30 anterior/posterior fusion, and 6/30 posterolateral fusion.

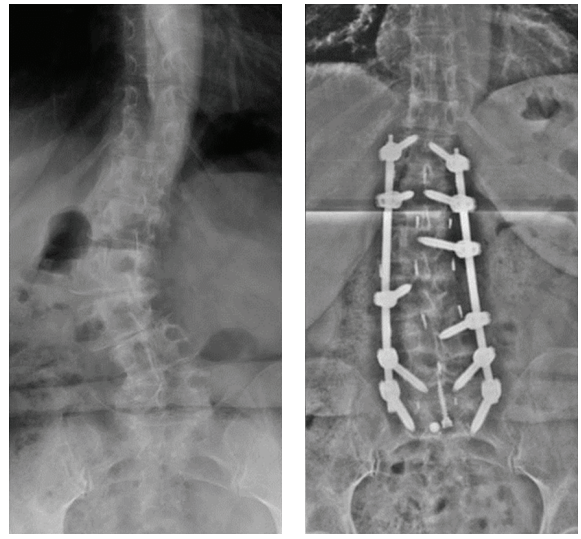
2.3. Surgical Technique. Interbody fusion was completed using the XLIF technique (NuVasive, Inc., San Diego, CA) as described by Ozgur et al. [10]. Laterally placed interbody spacers were supplemented with Osteocel Plus allograft cellular bone matrix (NuVasive, Inc., San Diego, CA). Lateral approaches were made from the concave side. Posterior instrumentation involved percutaneous placement of transpedicular screws and rods (SpheRx, DBR, NuVasive, Inc., San Diego, CA) (Figure 1). A total of 127 levels from T10 to L5 (average of 4.2 levels; range 1–7 levels) were treated using XLIF. In addition to XLIF, traditional anterior interbody fusion (ALIF) was used in 11 patients who required an L5-S1 fusion. Typically, all required procedures were performed during a single operative session. However, in patients requiring ALIF, the ALIF and instrumentation portions of the case were performed two days after the XLIF portion.

2.4. Clinical Outcome Scores. Validated clinical outcome scores were obtained on all patients preoperatively and at most recent followup. Outcome scores included the Oswestry Disability Index (ODI), short form-12 (SF-12) and visual analog pain score (VAS) for back and leg pain. Complications were recorded as any deviation from a normal postoperative course.

2.5. Statistical Analysis. Frequency statistics were used to characterize patient demographics and treatment variables. Clinical outcome scores were evaluated with paired t-tests using SPSS v. 19.0 (SPSS IBM, Inc. Chicago, IL). Statistical significance was defined as $P < 0.05$.

Table 1: Characteristics of thirty patients treated with XLIF.

Age (years)	65.9 (53–76)
Sex	11 men; 19 women
BMI	28.8 (19–38)
Deformity	18 apex-left; 12 apex-right
Cobb Angle	20.2° (10.1°–42.0°)



(a) (b)

Figure 1: Preoperative (a) and postoperative (b) anteroposterior radiographs of the lumbar spine in a patient treated with XLIF with percutaneous pedicle screws and rods.

3. Results

3.1. Clinical Outcome Scores. The study group demonstrated a significant improvement in multiple clinical outcomes scores from preoperative to most recent followup (Table 2). The average ODI decreased from 24.8 to 19.0, a significant improvement ($P < 0.001$). The average SF-12 mental and physical component scores improved, although the change was not significant. The average VAS back pain score decreased from 6.8 to 4.6, a significant improvement ($P < 0.001$). The average VAS leg pain score decreased from 5.4 to 2.8, a significant improvement ($P < 0.001$).

3.2. Postoperative Complications. Of the thirty patients who underwent surgery, eight (26.6%) were noted to experience complications. Two patients had lateral wound breakdown which was healed via secondary intention. One patient had a pedicle fracture at T12. This patient was asymptomatic and did not require additional intervention. One patient developed a symptomatic nonunion at L1-L2. This patient returned to the operating room 13 months after his initial procedure for revision fusion and extension of hardware. One patient developed a hernia at his lateral incision and underwent an elective hernia repair by a general surgeon several months after his initial procedure. One patient had uncontrolled atrial fibrillation after the XLIF stage of her

Table 2: Clinical outcomes in thirty patients treated with XLIF.

	Preoperative	Postoperative	*P* value
ODI	24.8	19.0	<0.001*
SF-12M	62.8	64.2	0.20
SF-12P	28.6	32.3	0.07
VAS Back	6.8	4.6	<0.001*
VAS Leg	5.4	2.8	<0.001*

*Statistically significant.

reconstruction. As a result, the posterior instrumentation stage was delayed until six weeks after the XLIF stage.

Two patients had iatrogenic rupture of the anterior longitudinal ligament (ALL). Rupture of the ALL is often considered a technical deviation during XLIF. However, for the purposes of this paper, it was recorded as a complication. In one of the patients, the ALL rupture occurred at L4-L5. To address this, an anterior plate was placed across L4-5 during the planned ALIF portion of the case. In the second patient, the ALL rupture was at L3-L4. To provide additional stability, a lateral plate was placed during the XLIF exposure. Both of these patients went on to an uncomplicated fusion, which was confirmed with thin-cut computed tomography one year after surgery.

It is also notable that a substantial portion of patients reported anterior thigh pain/numbness after surgery. However, the authors did not consider this a "complication" given that it is expected to occur in a sizable percentage of patients undergoing the transpsoas approach. If the patient's symptoms persisted beyond the immediate postoperative period, it was recorded as a complication. However, in the studied population, all reported anterior thigh pain and numbness had resolved by 4 weeks.

4. Discussion

Historically, scoliosis correction has involved a combined anterior/posterior approach or a posterior-only approach. Though these techniques have been demonstrated to improve clinical outcomes, they are also associated with a high complication rate [24, 25]. Specifically, the anterior approach is associated with bowel injuries, ileus, vascular injury, and retrograde ejaculation [26–28]. Posterior approaches necessitate exposure of the dura and nerve roots, placing them at greater risk for injury. A recent large study by Pateder et al. [29] revealed a complication rate of up to 45% for traditional scoliosis surgery.

Recent studies have indicated that surgical morbidity may be reduced with the use of less invasive techniques such as XLIF. A multicenter study by Isaacs et al. [11] involving a separate patient population more than the study herein demonstrated that the perioperative morbidity of XLIF in the treatment of adult degenerative scoliosis compares favorably to more invasive techniques. A study by Youssef et al. [12] demonstrated fewer complications and quicker recoveries in patients with lumbar degenerative disease treated with XLIF.

Besides decreased morbidity, there may also be biological benefits to XLIF and other lateral access surgery. With ALIF, PLIF, or TLIF, there is a mandatory breach of both the annulus and a longitudinal ligament. However, XLIF allows for preservation of the anterior and posterior longitudinal ligaments, conserving stability at treated levels. Additionally, XLIF allows for placement of a wide cage that rests on strong peripheral bone, potentially reducing the risk of cage subsidence [30].

Due to these potential benefits, lateral access surgery has rapidly increased in popularity. As more surgeons adopt the technique, the indications for lateral access surgery have broadened to include scoliosis surgery. However, more data is needed regarding the clinical outcomes of scoliosis patients treated with XLIF and other lateral access surgery. Specifically, there are few studies in the literature looking at the clinical outcomes of patients with adult degenerative scoliosis treated with lateral access techniques [30–35].

The study herein reports a single surgeon's experience with thirty consecutive patients treated with XLIF. A comprehensive panel of validated outcome measurements (ODI, VAS pain scores, and SF-12) were used to evaluate outcomes and clinical efficacy. Surgery led to improvement in multiple parameters, including a statistically significant improvement in ODI, VAS back pain, and VAS leg pain scores. The improvement in these outcomes supports the efficacy of XLIF in the treatment of adult degenerative scoliosis and adds to a growing body of literature supporting the effectiveness of XLIF in the treatment of scoliosis surgery. Furthermore, despite the advanced age of this study population (average age 65.9 years), the complication rate was low (26.6%) when compared to traditional approaches [29]. With the exception of two patients requiring additional surgery (one revision fusion, one elective hernia repair), the complications were minor and resolved without further intervention. In comparison, a recent study by Daubs et al. [24] using traditional approaches with a comparable population (average age 67 years) reported a complication rate of 37% with a major complication rate of 20%.

This study had several notable limitations. The most significant is a lack of a comparison group of conventional posterior or anterior/posterior approach patients. In addition, the followup period is modest, and long-term studies are needed. Nevertheless, this study supports the efficacy of XLIF in the treatment of adult degenerative scoliosis using a panel of validated clinical outcome scores with relatively large series of patients.

5. Conclusions

The goal of this study was to evaluate the role of XLIF in the treatment of adult degenerative scoliosis. In a series of thirty patients, significant clinical improvement was noted in multiple-validated outcome measurements. This series adds to a growing body of data supporting the efficacy of XLIF in the treatment of adult degenerative scoliosis. Though not without complications, XLIF was associated with less major complications and a lower overall complication rate than

traditional approaches. In order to further clarify the role of XLIF in scoliosis surgery, long-term and comparative studies are needed.

Conflict of Interests

A. M. Caputo, K. W. Michael, T. M. Chapman Jr., G. M. Massey, and C. R. Howes declared no conflict of interests. R. E. Isaacs has an ongoing financial relationship with Nuvasive, Inc. C. R. Brown has an ongoing financial relationship with Nuvasive, Inc.

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Research Article

Lateral Surgical Approach to Lumbar Intervertebral Discs in an Ovine Model

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The sheep is becoming increasingly used as a large animal model for preclinical spine surgery studies. Access to the ovine lumbar intervertebral discs has traditionally been via an anterior or anterolateral approach, which requires larger wound incisions and, at times, significant abdominal retraction. We present a new minimally invasive operative technique for a far-lateral approach to the ovine lumbar spine that allows for smaller incisions, excellent visualisation of intervertebral discs, and minimal abdominal retraction and is well tolerated by animals with minimal morbidity.

1. Introduction

The sheep spine shares many similarities, both anatomically and biochemically, to the human spine, making it increasingly popular as a large animal model for preclinical spine surgery studies [1–3]. The ovine spine has been used as a model for disc degeneration [4–9], to test novel implant devices [10–12], and as a preclinical model for biological therapies such as stem cell treatments or administration of growth factors [13–16].

Posterior approaches to the lumbar intervertebral discs, commonly used in human surgery, are difficult in the sheep due to the presence of the spinal cord within the lumbar spinal canal and ossification of the posterior longitudinal ligament (PLL). For this reason, the ovine lumbar intervertebral discs have traditionally been accessed via an anterior or anterolateral approach [5, 17]. This retroperitoneal or transperitoneal approach carries risks that include bowel and great vessel injury, neural injury, and hernia formation. The procedure also requires a large abdominal incision with greater retraction of abdominal viscera, which can be harmful to the animal.

We describe here a new minimally invasive lateral approach to the sheep lumbar spine, which affords easy access to the lumbar intervertebral discs and is well tolerated by the animals. The technique allows for a small focused incision, which is away from dependent abdominal areas, decreasing the risk of postoperative hernia and abdominal and wound complications. A similar minimally invasive extreme lateral approach has gained popularity in humans, using a transmuscular (transpsoas) route with neuromonitoring guidance [18–20]. However, in the ovine lateral approach described herein, the psoas muscle can be easily retracted without the requirement for neural monitoring. This new surgical technique provides an alternative to traditional anterior and anterolateral approaches to the sheep lumbar spine.

2. Methods

This procedure has been undertaken in 95 two-year-old East Friesian/Merino Cross wethers (weight range 55–90 kilograms) to perform lumbar annular disc injury in order

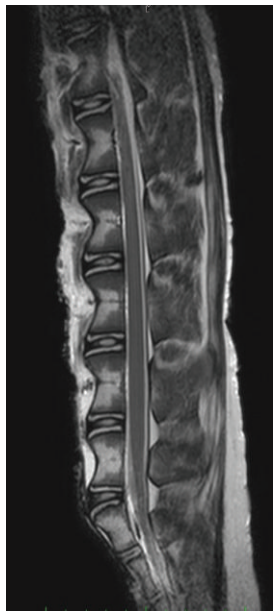


Figure 1: 3T sagittal T2-weighted MRI of ovine lumbar spine demonstrating concave elongated vertebral bodies, intervertebral discs, and the persistence of the spinal cord into the sacral region.

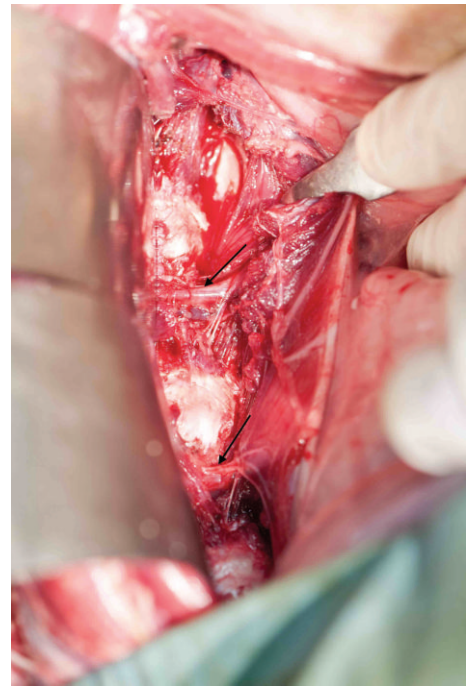


Figure 2: Intraoperative photo demonstrating radicular vessels at two levels (arrows) running horizontally across vertebral bodies 1 cm below intervertebral discs.

to elicit disc degeneration ($n = 86$), perform discectomy procedures ($n = 9$), and implant stem cells for novel therapies ($n = 86$). In 72 of these animals, the procedure has been performed bilaterally from the left side to illicit disc degeneration, and then three months later from the contralateral right side to inject regenerative stem cells. This approach has allowed access from L1 to L6. In the course of our experiments, animals are typically monitored for at least six months following surgery, prior to postmortem.

3. Surgical Anatomy

The sheep characteristically has six lumbar vertebrae although seven may be apparent with the presence of transitional lumbosacral anatomy. Vertebral body to intervertebral disc height ratio in adult sheep is greater than that in humans vertebral body heights commonly exceed 40 mm (mean 42.49, SD 2.36) whilst disc heights are usually only 4-5 mm (mean 4.48, SD 0.66). The discs and endplates appear as bulbous convex expansions in between concave elongated vertebral bodies (Figure 1). The sheep transverse processes are larger than in the human, are easily palpable, and are visible in the flank region, serving as useful landmarks when performing surgery.

Radicular veins and arteries can be found running approximately 1 cm below the inferior endplates across the vertebral bodies and are variable in size and number (Figure 2). When torn, bleeding can be profuse but is controlled with bipolar diathermy. Muscular insertions into the lower lumbar vertebral bodies are usually thick and tendinous, whilst those higher in the lumbar spine are thin and easily divided. This lateral surgical approach can be performed, without limitation, from the right or left sides.

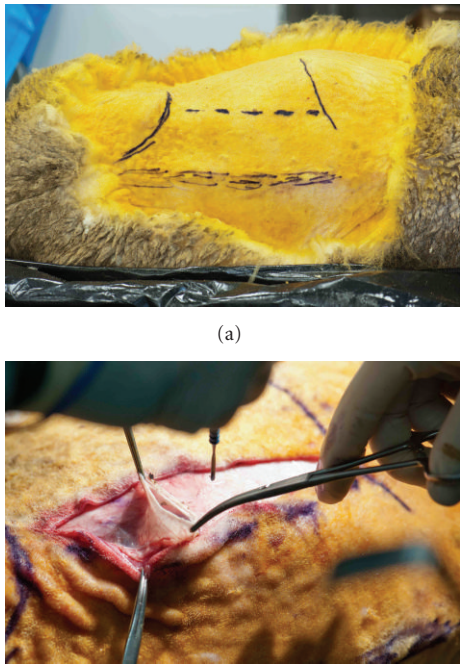
The spinal cord continues into the sacral region in the sheep, and one must be aware of this when passing instruments through the disc space so as not to cause cord injury. From our observations, the PLL is often ossified, or at least partially calcified, and serves as a protective barrier in this situation.

4. Surgical Technique

4.1. Preparation. All surgical and experimental procedures were approved by the Monash Medical Centre Animal Ethics Committee as conforming to the Australian code of practice for the care and use of animals for scientific purposes 7th Edition, 2004.

Sheep are fasted for 24 hours in order to prevent abdominal distension and aspiration of rumen fluids during surgery. Animals are sedated with intravenous medetomidine hydrochloride (Domitor—0.015–0.02 mg/kg), to facilitate transport to the operating theatre, followed by intravenous injection of thiopentone (10–13 mg/kg) for anaesthetic induction. An endotracheal tube is inserted and anaesthesia maintained by isofluorane (2-3% in oxygen) inhalation. All animals receive perioperative intravenous antibiotic (amoxicillin 1 g IV). We do not use muscle relaxation.

Once anaesthetised, the sheep is placed on the operating table in the lateral position. The lateral abdomen (flank) and spine is shaved and prepared with chlorhexidine and alcoholic-iodide antiseptic wash followed by sterile draping. Local anaesthetic (bupivicaine 0.5%) is subcutaneously



(a)

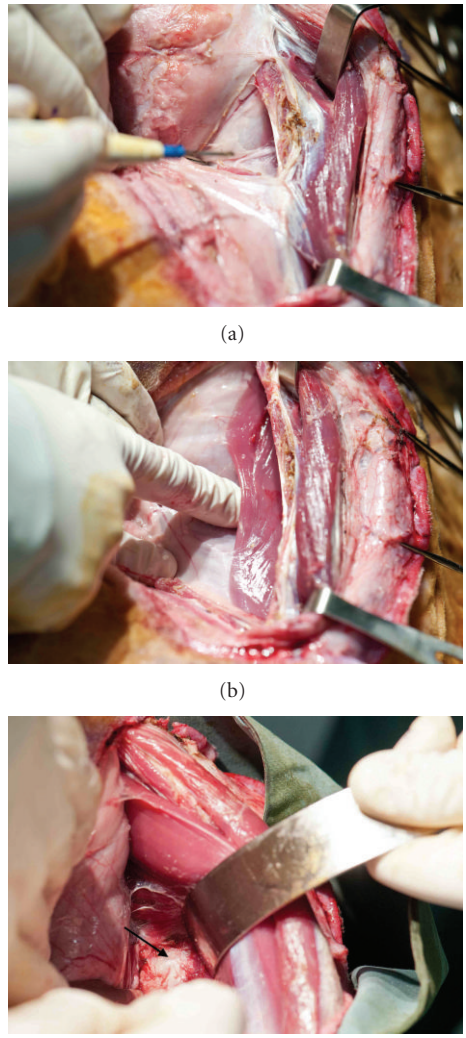
(b)

Figure 3: (a) Preoperative photo of sheep in right lateral position demonstrating lumbar spinous processes (lower dashed line), left lumbar transverse processes (upper dashed line), iliac crest (left), and costal margin (right). (b) Longitudinal incision made parallel to and 1 cm anterior to transverse processes. Lateral aspect of abdominal wall fascia and musculature partially opened.

injected around the incision site. Strict sterile precautions are maintained at all times.

4.2. Lateral Approach to the Lumbar Intervertebral Discs. Landmarks used for the incision are easily palpable; these are the iliac crest, lumbar transverse processes and the costo-vertebral angle (Figure 3(a)). A longitudinal incision parallel and 1cm anterior to the transverse processes is made (Figure 3(b)). The length and exact location of the incision is guided by the desired disc level to be reached. A 10cm incision will facilitate access to 3-4 levels, with incisions extending to the iliac crest facilitating access to the lower lumber spine, whilst those extending to the costo-vertebral angle allow access to the upper lumbar and lower thoracic spines. Disc levels from T12/L1 to L5/L6 can be accessed using this approach. Smaller focused incisions can be used to access single-disc levels.

Following sharp incision, the subcutaneous tissue is divided using monopolar diathermy. The lateral aspect of the abdominal wall musculature is also divided and, here, represents only a fatty fascial layer. The key to entering the retroperitoneal space, with minimal disruption to the peritoneum and its contents, is to longitudinally divide the thoracolumbar fascia at its attachment to the transverse processes (Figure 4(a)). With the thoracolumbar fascia divided, the quadratus lumborum and psoas muscles become visible. Traversing neurovascular bundles supplying the



(a)

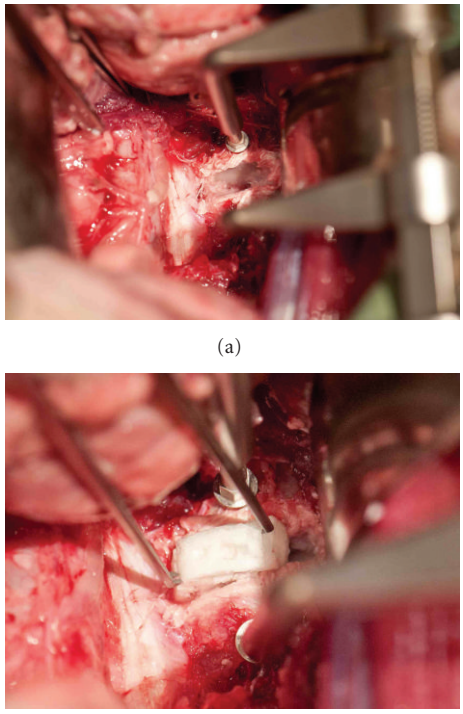
(b)

(c)

Figure 4: (a) Division of thoracolumbar fascia at its attachment to the transverse processes allows entry into retroperitoneal space. Erector spinae muscle is retracted laterally. (b) With the thoracolumbar fascia divided the psoas muscle becomes visible. The peritoneum can be carefully separated from the posterior abdominal wall musculature with blunt dissection. (c) Psoas muscle retracted laterally and abdomen retracted medially revealing the intervertebral disc (arrow).

abdominal wall may be seen and attempts should be made to preserve these, although division does not appear to cause adverse effects. Now digital blunt dissection facilitates easy separation of the peritoneum from the posterior abdominal wall musculature and allows identification of the anterolateral aspect of the vertebral bodies and intervertebral discs (Figure 4(b)).

We do not routinely suture small breaches in the fragile peritoneum or attempt to visualise the aorta and inferior vena cava, which can be palpated medially. As suggested by Baramki et al. [17], a Hohmann retractor with the tip positioned on the contralateral vertebral body is the best instrument to retract the abdominal contents and great



(a)

(b)

Figure 5: (a) Intraoperative photograph demonstrating intervertebral space following total discectomy. Distraction pins have been inserted into adjacent vertebral bodies to facilitate discectomy procedure. (b) Insertion of a mesenchymal progenitor cell-seeded polycaprolactone biological disc into the intervertebral space via lateral approach.

vessels. The psoas and quadratus lumborum muscles are easily retracted posterolaterally, by the assistant, using a Diva retractor, further exposing the intervertebral discs (Figure 4(c)).

The intervertebral bodies appear a long concave depressions, whilst the intervening intervertebral discs are convex swellings, which are easily palpated. By positioning retractors immediately over the discs, disruption of lumbar segmental arteries and veins, which are located approximately 1 cm caudal to the inferior endplate, can be avoided. If bleeding from these segmental vessels occurs, bipolar cautery affords simple haemostasis. Surgical loupe magnification with headlight illumination facilitates identification and preservation of exiting vessels and nerves.

At this stage, the exact disc level can be confirmed with lateral X-ray. Using the far-lateral approach described, the entire ipsilateral half of the intervertebral discs can be identified. Rotating the operating table away from the surgeon will open the view to the anterior portion of the disc. From our experience, muscular attachments over the disc can be easily swept aside using blunt dissection for levels L3/4 and above. For levels L4/5 and below, thicker tendinous muscular attachments require sharp division, using bipolar diathermy and scissors in order to expose the disc. Disc levels from T12/L1 to L5/6 can be easily reached using this lateral approach. The L6/S1 disc is difficult to access due to obstruction by the iliac crest.

Once the desired procedure has been performed on the disc (s) (Figures 5(a) and 5(b)), and haemostasis is achieved, the wound is irrigated with Ringers' solution and a layered closure undertaken, using 2–0 Vicryl to the lateral abdominal wall tissues and continuous subcutaneous suture to the skin. Minimal blood loss occurs throughout this procedure, which, in our hands, is estimated to be approximately 10ml per animal. The entire procedure can be performed in less than one hour with minimal postoperative discomfort to the animal.

4.3. Postoperative Management. We routinely use a transdermal fentanyl patch (Durogesic 75 mcg/hr) positioned in the inguinal region for postoperative analgesia. Further analgesia using buprenorphine (300 mcg IV) can be administered, but is seldom required. As soon as each sheep breathes spontaneously, following cessation of isofluorane anaesthesia, it is extubated and then transferred to a holding cage where it is given food when fully alert and standing. Medetomidine hydrochloride is reversed with atipamezole (Antisedan 0.06 mg/kg–0.08 mg/kg). The sheep is observed for approximately one hour following surgery, after which it can be returned to its holding pen with other animals. No significant problems with postoperative mobility or pain have been encountered; even when complete disc removal procedures are performed.

5. Discussion

Lateral approaches to the human lumbar spine, such as the XLIF (extreme lateral lnterbody fusion) procedure, have gained popularity as a minimally invasive approach to the lumbar intervertebral discs. In the human lateral approach, a retroperitoneal transpsoas route is employed and requires real-time neuromonitoring to ensure safe passage through the psoas without damage to the lumbar plexus [19]. Postoperative motor nerve injury related to the approach is reported at 0.7 to 3.4%, whilst sensory symptoms occur in 1.6 to 10.3% [19, 21–23]. Many of these neural deficits are transient, however, neural injury remains a concern with this procedure.

We have successfully performed the lateral approach described above in the sheep lumbar spine without complication in 95 animals, totalling 175 lumbar surgeries, as part of studies investigating stem cell mediated disc regeneration. To our knowledge, neural complications related to lumbosacral plexus injury have not occurred. Unlike in the human approach, which is transpsoas and requires neuromonitoring, the sheep psoas can be retracted without the requirement for neuromonitoring, with no apparent harm to the animals.

We have not encountered any postoperative infections. We believe this is a result of extensive skin preparation prior to surgery with wide wool clipping and multiple antiseptic washes using chlorhexidine and alcoholic iodine. Blood loss has been minimal and there have been no anaesthetic

complications or postoperative pain management concerns with this technique. We have not experienced any clinically apparent neural or great vessel injury, and postoperative hernia or wound dehiscence has not occurred to date. Our technique of not repairing peritoneal breaches has not led to clinically apparent bowel herniation or obstruction.

6. Conclusions

This minimally invasive lateral approach to the anterior sheep lumbar spine affords easy access to the intervertebral discs from L1 to L6 and can be performed safely without significant morbidity to the animals. The procedure allows for good visualisation and surgical access to the intervertebral discs. This procedure provides an alternative to anterior approaches, which require larger incisions and greater abdominal retraction.

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Clinical Study

The Effect of the Retroperitoneal Transpsoas Minimally Invasive Lateral Interbody Fusion on Segmental and Regional Lumbar Lordosis

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Background. The minimally invasive lateral interbody fusion (MIS LIF) in the lumbar spine can correct coronal Cobb angles, but the effect on sagittal plane correction is unclear. *Methods*. A retrospective review of thirty-five patients with lumbar degenerative disease who underwent MIS LIF without supplemental posterior instrumentation was undertaken to study the radiographic effect on the restoration of segmental and regional lumbar lordosis using the Cobb angles on pre- and postoperative radiographs. Mean disc height changes were also measured. *Results*. The mean follow-up period was 13.3 months. Fifty total levels were fused with a mean of 1.42 levels fused per patient. Mean segmental Cobb angle increased from 11.10° to 13.61° ($P < 0.001$) or 22.6%. L2-3 had the greatest proportional increase in segmental lordosis. Mean regional Cobb angle increased from 52.47° to 53.45° ($P = 0.392$). Mean disc height increased from 6.50 mm to 10.04 mm ($P < 0.001$) or 54.5%. *Conclusions*. The MIS LIF improves segmental lordosis and disc height in the lumbar spine but not regional lumbar lordosis. Anterior longitudinal ligament sectioning and/or the addition of a more lordotic implant may be necessary in cases where significant increases in regional lumbar lordosis are desired.

1. Introduction

Minimally invasive spine surgery is an alternative to traditional open operations for the treatment of degenerative spine disease. Advantages include less major complications, less blood loss, less wound infections, earlier patient mobilization, and shorter hospital stays [1–7].

Minimally invasive lateral interbody fusion (MIS LIF), such as, with Extreme Lateral Interbody Fusion (XLIF; NuVasive, San Diego, CA, USA) or Direct Lateral Interbody Fusion (DLIF; Medtronic, Minneapolis, MN, USA), has been used to treat degenerative spine disease, including degenerative scoliosis [4–8]. In the lumbar spine, a retroperitoneal transpsoas approach is taken. Using this technique, coronal Cobb angles can be improved [5–7, 9]. The effects of sagittal Cobb angles, such as, with lumbar lordosis (LL) and the overall global sagittal balance have not been as well established, however [9, 10]. This is an important topic since a positive global sagittal imbalance is most closely linked to a decreased quality of life, health status outcomes, and function [11]. Sagittal imbalance can lead to higher energy requirements to stand and ambulate, leading to early fatigue, intolerance to standing, and walking with compensation through other joints.

The aim of this study is to evaluate the effect of the XLIF technique in the lumbar spine on the restoration of segmental and regional LL in patients with degenerative spine disease. An additional study focus will be to evaluate the effect on segmental disc heights in the sagittal plane.

2. Materials and Methods

This is an IRB-approved, retrospective review of a prospectively collected database. Thirty-five consecutive patients with available preoperative and postoperative radiographs for analysis were included in this study (Table 1). The mean age at the time of surgery was 61.3 years. All patients had

Table 1: Demographics.

Parameter	Value
Total number of patients	35
Mean age at time of surgery (years)	61.3 (33–79)
Male : female ratio	11 : 24
Mean follow-up period (months)	13.3
Total number of levels fused	50
Levels fused per patient	1.42

evidence of lumbar degenerative disease (spondylosis, adult degenerative scoliosis, or adjacent segment failure).

To be included, patients had to have undergone MIS LIF with placement of a 10° lordotic, PEEK interbody cage at any level from L1-2–L4-5 without any supplemental posterior instrumentation. Specifically, only patients who underwent stand-alone interbody fusions, patients who had interbody fusions supplemented only with a lateral plate, or patients who underwent interbody fusion where only the caudal level was instrumented from a previous operation (pedicle screws, facet screws, or interspinous process spacers) were measured for sagittal segmental and regional Cobb angles as well as disc heights.

Surgical indications included segmental instability for the target disc with combined minimal canal stenosis, degenerative disc disease, disc herniation, and adjacent segment failure.

The XLIF procedure was performed as previously described [8]. Patients are positioned in a lateral decubitus position, typically with the side giving the best clearance of the ipsilateral iliac crest or the concave side of any scoliotic curve up. A small incision is made, and a muscle splitting technique is used to gain access to the retroperitoneal space and facilitate localization of the correct disc space under fluoroscopic guidance.

A discectomy is performed, endplates prepared, and a 10° lordotic, PEEK cage (CoRoent XL, NuVasive, San Diego, CA, USA) of either 50, 55, or 60 mm in length, 18 or 22 mm in width, and 8 to 10 mm in height was implanted. All cages were filled with allograft [0.7–1.4 mg of recombinant human bone morphogenetic protein-2 (rhBMP-2)(INFUSE, Medtronic, Minneapolis, MN, USA) mixed with hydroxyapatite and tricalcium phosphate (Formagraft, NuVasive, San Diego, CA, USA) per level] or 5 cc of cadaveric cancellous bone mixed with mesenchymal stem cells (Osteocel, NuVasive, San Diego, CA). Implants were centered just posterior to half of the disc space. The ALL and PLL were left intact.

A 2-screw fixation (one rostral and one caudal) titanium lateral plate (XLP, NuVasive, San Diego, CA, USA) was used in all but one patient (Figure 1). Appropriate positioning and size were fluoroscopically confirmed. The rostral and caudal screw entry points were centered to clear each corresponding endplate as well as the ipsilateral segmental artery. Screws were placed parallel to the endplates, and bicortical purchase was obtained. The plate was then seated over the screw heads, and the lock nuts were secured.

Preoperative and postoperative upright anterior-posterior and lateral lumbar spine radiographs were obtained in all patients. The most recent postoperative radiographs from routine 6- and 12-week, 6-, 12-, 18-, and 24-month follow-up appointments were used for comparison.

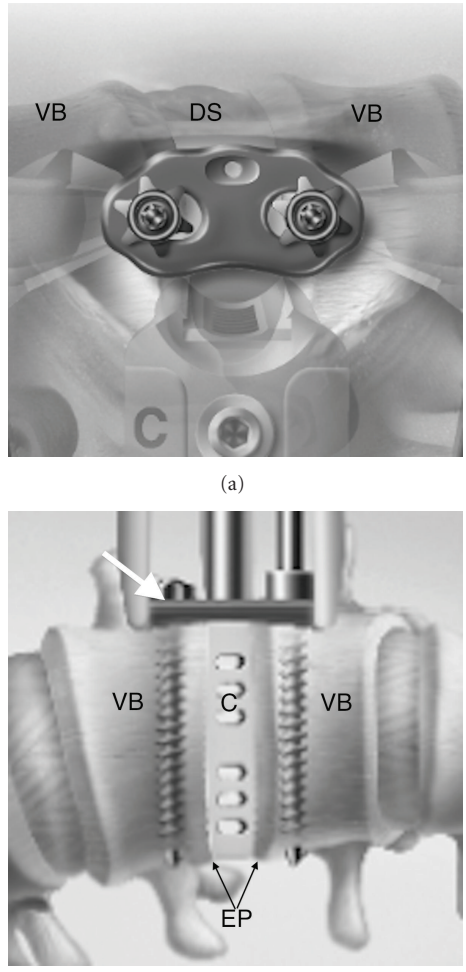

Figure 1: XLP lateral plate. (a) Lateral view. Notice the plate spans across the disc space (DS) and is secured down to the vertebral bodies (VB) with lock nuts. (b) AP view. Lateral plate (white arrow) is seated on two bicortical screws, which are parallel to the adjacent endplates (EP). A cage (C) is depicted in the disc space. (Images used with permission of NuVasive, Inc., San Diego, CA, USA).

Lordosis measurements were made on lateral radiographs. The Cobb method was used for segmental and regional LL measurements (Figure 2), [12, 13] All measurements were obtained digitally using Centricity 3.0 workstations (GE Healthcare). Segmental Cobb angles were measured using the superior endplate of the rostral vertebral body and inferior endplate of the caudal vertebral body. By using this method, measurements of the true angle can be obtained as opposed to a measurement of what may represent the lordosis of the cage. The mean disc height was taken as the mean of the anterior and posterior disc heights.

All measurements were collected and organized using an excel spreadsheet (Microsoft, Redmond, WA, USA). Of the total, a hypolordosis subgroup (preoperative regional Cobb angle of <42°) and a normolordosis group (preoperative

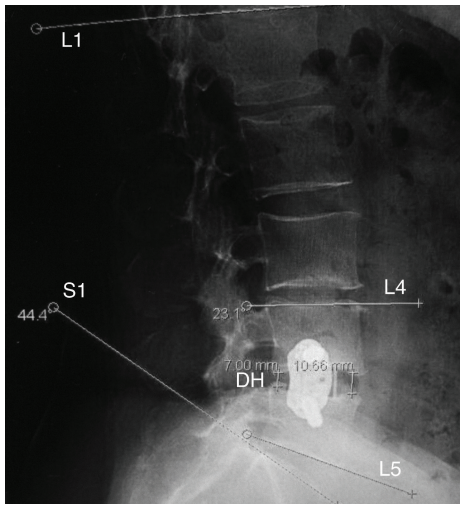

Figure 2: Representative lordosis and disc height measurements. Regional Cobb angles are based on the superior endplate of L1 and the superior endplate of S1 to measure regional lumbar lordosis. Segmental Cobb angles are based on the superior endplate of the rostral vertebral body and the inferior endplate of the caudal vertebral body (L4 and L5 in this example). Disc heights are calculated using the average between the anterior and posterior disc heights.

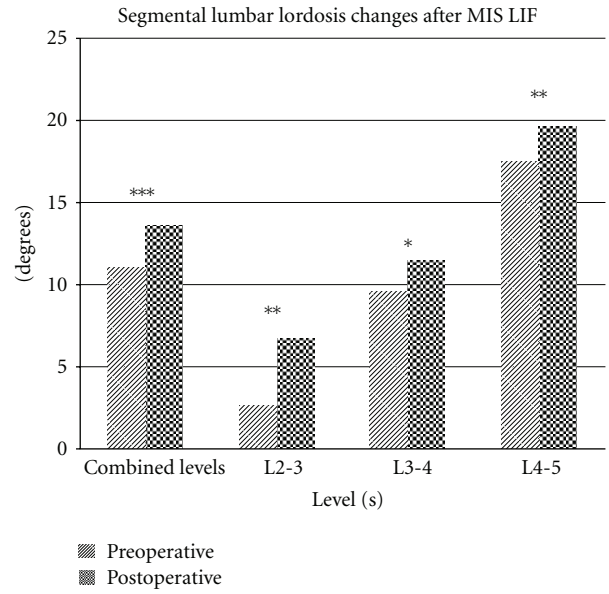

Figure 3: Segmental lumbar lordosis changes after MIS LIF. Statistically significant increases were observed at each measured level as well as in aggregate. (* = $P < 0.05$,** = $P < 0.01$,*** = $P < 0.001$).

regional Cobb angle of ≥42°) were then analyzed for the above endpoints. Statistical analysis was carried out with IBM SPSS 19.0 using the paired t-test and nonparametric Wilcoxon Signed Ranks test.

3. Results

Thirty-five patients were included, of which 7 were hypolordotic and 28 were normolordotic based on preoperative lateral radiographs. The mean follow-up period was 13.3 months. Fifty total levels were fused giving a mean of 1.42 levels fused per patient.

The mean segmental Cobb angle increased from 11.10° ± 9.29 to 13.61° ± 8.46 ($P < 0.001$) (Figure 3). The mean regional Cobb angle increased from 52.47° ± 10.55 to 53.45° ± 11.90 ($P = 0.392$) (Figure 4). The mean disc height increased from 6.50 mm ± 2.51 to 10.04 mm ± 2.75 ($P < 0.001$) (Figure 5).

The proportional increase in mean segmental Cobb angle was 22.6% for all levels. Proportional gains in segmental Cobb angles progressively declined with more caudal lumbar segments, with 157.8%, 13.9%, and 8.7% increases for L2-3, L3-4, and L4-5, respectively.

The proportional increase in mean preoperative disc heights was 54.5% for all levels. A proportional increase in mean preoperative disc heights of 58.6%, 44.7%, and 61.0% was observed for L2-3, L3-4, and L4-5, respectively.

For the hypolordotic subgroup, the mean segmental Cobb angle increased from 2.38° ± 8.61 to 5.90° ± 7.06 ($P = 0.051$). The mean regional Cobb angle increased from 37.74° ± 2.74 to 39.39° ± 10.53 ($P = 0.636$). The mean preoperative disc height increased from 6.45 mm ± 2.76 to 9.82 mm ± 3.25 ($P < 0.043$).

For the normolordotic subgroup, the mean segmental Cobb angle increased from 13.02° ± 8.37 to 15.30° ± 7.84 ($P < 0.001$). The mean regional Cobb angle increased from 56.40° ± 8.21 to 57.34° ± 9.52 ($P = 0.498$). The mean preoperative disc height increased from 6.51 mm ± 2.49 to 10.08 mm ± 2.68 ($P < 0.001$).

4. Discussion

The MIS LIF via the retroperitoneal transpsoas lumbar interbody fusion is an alternative to traditional open anterior-only, posterior-only, or circumferential operations [8]. Though the most common complications associated with this procedure include transient ipsilateral thigh numbness and iliopsoas weakness, in general, major complications are lower, there tends to be less blood loss, less wound infections, patients mobilize earlier, and hospital stays are shorter [1–7]. Clinical outcomes data are also promising as reported by Mundis et al. [10], where they demonstrated improved radiographic parameters as well as improved clinical results with a lower complication profile compared to traditional open approaches.

Traditional open operations, such as, anterior lumbar interbody fusion (ALIF), posterior lumbar interbody fusion (PLIF), and transforaminal lumbar interbody fusion (TLIF) have led to the development of this technique. Briefly, advantages of the ALIF include a large interbody graft for disc space reexpansion, restoration of LL, and elimination of discogenic pain [14]. In addition, posterior facet joint complexes and tension bands remain intact. However, an access surgeon may be needed, and complications can include a risk of vascular injury and also rare iatrogenic retrograde ejaculation in males postoperatively. The TLIF[15, 16] was developed as a

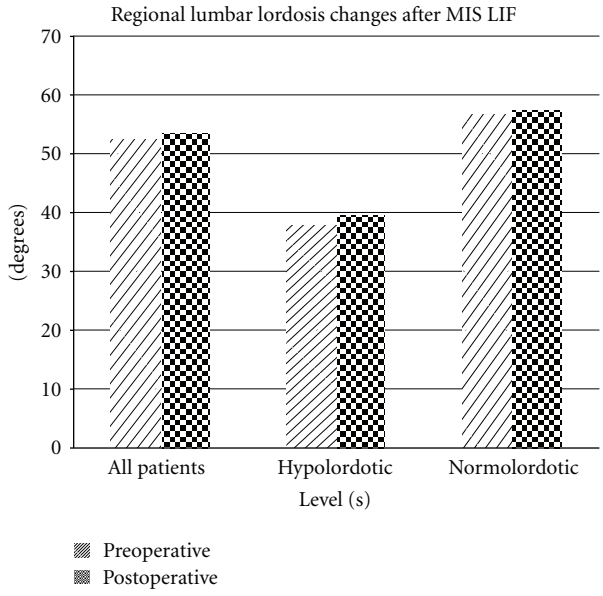

Figure 4: : Regional lumbar lordosis changes after MIS LIF. No statistically significant increases were observed.

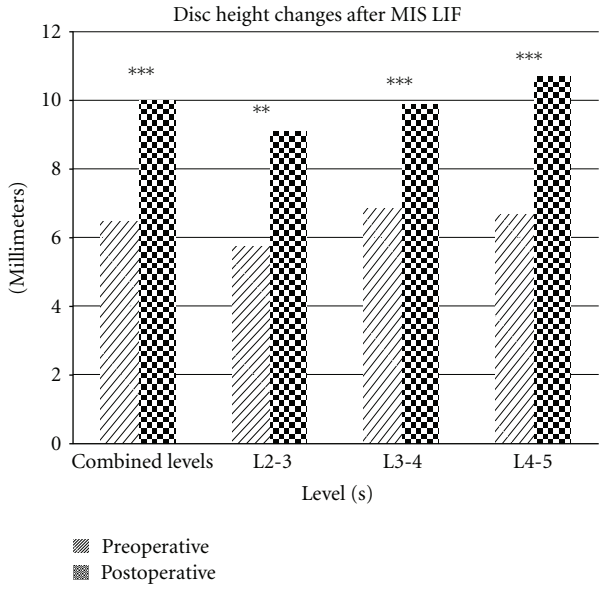

Figure 5: Disc height changes after MIS LIF. Statistically significant increases were observed at each measured level as well as in aggregate. ($* = P < 0.05$,$** = P < 0.01$,$*** = P < 0.001$).

modification of the PLIF [17] to decrease the degree of nerve root and thecal sac manipulation, and it allows for interbody fusion, concurrent posterior segmental instrumentation, and circumferential fusion. Potential restoration of LL is gained by shortening of the posterior aspect of the spine by applying compressive forces to the segmental pedicle screws. It can be performed either in an open or minimally invasive manner. The graft size is typically smaller than that of the ALIF, however.

Hsieh et al. [18] compared the postoperative radiographic changes of disc height, foraminal height, local (segmental) disc angle, and LL for ALIF and TLIF. Though both involve placement of an interbody graft and subsequently an increase in disc height, ALIF was found to be superior to TLIF in its capacity to restore foraminal height (18.5% increase versus 0.4% decrease), local disc angle (8.3° increase versus 0.1° decrease), and LL (6.2° increase versus 2.1° decrease).

The MIS LIF via the retroperitoneal transpsoas approach shares the advantages of these two traditional approaches since large interbody cages can be placed to provide indirect decompression as in ALIF, and the operation can be done through a small incision in a minimally disruptive approach as in TLIF.

This technique is also an appealing option for potential restoration of coronal and sagittal balance in spinal deformity due to the large, lordotic interbody cages, and the potential for less complications, given that traditional open posterior surgery for deformity has a 25% to 80% risk of postoperative complications including excessive blood loss, infection, neurologic injury, and medical complications [2, 3].

Of the radiographic spinopelvic parameters, a positive global sagittal imbalance, determined by the sagittal vertical axis (SVA) [19] or T1-SI [20], is most closely linked to decreased quality of life and health status outcomes. Specifically, patients with an SVA of >50 mm or a T1-SI of >0° can experience a significant decline in function [11]. These patients tend to have higher energy requirements to stand and ambulate, leading to early fatigue, intolerance to standing, and walking with compensation through other joints.

Regional LL is directly related to global sagittal alignment [10]. Multiple studies in asymptomatic adults have found the normal range of LL to be 42° to 66°.[21–26] There is clearly a wide range of what is considered normal. In addition to regional LL, segmental LL is not uniform, with the two most caudal motion segments accounting for up to 64% of LL [27–29]. Segmental lordosis progressively increases with more caudal segments, with 4°, 9°, 14°, 24°, and 24° of lordosis at L1-2, L2-3, L3-4, L4-5, and L5-S1, respectively. Overall, loss of lordosis is poorly tolerated in the lumbar spine [30, 31], and its maintenance or restoration is a critical surgical goal in order to better achieve global sagittal balance.

Acosta et al. [32] recently reported that segmental LL can be increased but not regional LL or global sagittal alignment in their series of 36 patients who underwent DLIF, of which 35 had supplemental posterior instrumentation. Their study group was heterogeneous including seven degenerative scoliosis patients. Some limitations of their study were that all but one patient had supplemental posterior instrumentation, 6° lordotic cages were used, segmental Cobb angle measurements were based on the endplates adjacent to the cage, and immediate postoperative radiographs were used for comparison.

Without similar limitations, the current study confirmed that MIS LIF can increase segmental lordosis and disc heights significantly but not regional lordosis. Only patients with degenerative lumbar spondylosis or evidence of adjacent segment failure who underwent lumbar MIS LIF using a 10° lordotic cage without any supplemental posterior

instrumentation were included. This point is particularly important since prone positioning alone can potentially increase lordosis [33, 34]. The addition of pedicle screws and a precontoured rod, particularly if in a percutaneous fashion, can then confound the picture further, since, depending on the contouring, there can be a decrease or an increase of any gained lordosis with the cage placement alone [32, 34].

A lateral plate was acceptable since biomechanical studies have demonstrated its motion restriction in lateral bending and rotation but minimal influence on flexion and extension [35, 36]. This allows for a more clear investigation of only the implant's effect on segmental and regional LL, without any confounding effect of posterior instrumentation, especially when evaluating radiographs several months to years in followup.

As opposed to the immediate postoperative radiograph, the most recent follow-up radiographs were used for comparison in this study. The use of the immediate postoperative radiograph would not allow enough time to see contributions of potential subsidence and/or collapse of the anterior support, leading to a potential overestimation of the correction gained in the long term [37].

Our segmental Cobb angles were measured using the superior endplate of rostral vertebral body and inferior endplate of caudal vertebral body as opposed to using endplates adjacent to the cage. By using this method, radiographic visualization is improved, especially with long-term followup and the addition of a lateral plate. More importantly, measurements of the true angle can be obtained as opposed to a measurement of what may actually represent the lordosis of the cage itself instead.

The findings from this study underscore the potential role that MIS LIF has in spinal deformity surgery, given its advantages as discussed above. The large, lordotic interbody cages alone appear to account for increased segmental Cobb angle and disc height based on our results. Thus, it is reasonable to expect an even more robust LL restoration and improvement with even more lordotic cages if the tension of the anterior longitudinal ligament (ALL) was electively sectioned

The greatest proportional increase in segmental LL was observed at L2-3, and this progressively decreased with lower lumbar segments. Given a constant cage lordosis and a progressively increasing physiologic segmental LL, this finding is not too surprising. Also, L1-2 and L2-3 are most amenable to correction in the coronal and sagittal planes [10], possibly because the normal lordosis is 4° and 9°, respectively.

The regional lordosis did not significantly increase when looking at the study group as a whole or when comparing hypolordotic versus normolordotic subgroups. Potential explanations for this include the maintenance of the posterior facet complex and ALL, hypertrophied facet joints in degenerative disease, and positioning of the interbody graft. However, since the most recent radiographs with a mean follow-up time of 13.3 months were used for comparison in this study, subsidence should also be included as a potential limiting factor.

The mean disc heights were significantly increased as a whole and at each segment as well. Dessicated, collapsed disc spaces are common in degenerative spine disease, and the addition of an 8 or 10 mm lordotic cage would certainly be expected to have this effect. This represents some key advantages of the MIS LIF technique in that the neural foramen is also enlarged through an indirect manner [38] with a large implant spanning the entire width of the endplate, leading to potentially less risk of subsidence [39] and subsequent maintained disc height.

As the role of MIS LIF in spinal deformity correction is further clarified through further research, it is important to keep in mind that the ultimate end goal should still be to reestablish spinopelvic harmony or the proportional relationships of one regional parameter to another as it relates to global spinopelvic alignment as spinopelvic harmony has been directly linked to a satisfactory postsurgical outcome as assessed by health-related quality of life instruments [11, 40]. Three basic radiographic targets to aim for in order to achieve spinopelvic harmony include: (1) SVA of <50 mm or T1-SI <0°, (2) pelvic tilt of <20°, and (3) LL = pelvic incidence ± 9° [11]. Attention to these three goals serves as the foundation for individual, patient-specific spinopelvic realignment in the sagittal plane, and even partial improvements of these parameters may translate to better clinical outcomes.

A limitation of this study is that an assessment of global sagittal and coronal balance was not possible in this patient population. Standing scoliosis radiographs are not routinely performed on patients without multisegmental degenerative spine disease and significant preoperative lumbar hypolordosis due to the risks from radiation exposure. Also, only 10° lordotic cages were used, and the use of a more lordotic angle and/or elective section of the ALL would potentially provide a greater degree of lordosis.

5. Conclusion

Lumbar lordosis is an important component of overall global sagittal spinopelvic alignment, and MIS LIF via a retroperitoneal transpsoas approach may play an important role in modifying LL to better attain spinopelvic harmony. Segmental lordosis is significantly increased. Even though regional lordosis is not significantly increased, it is at least maintained. Disc heights were significantly increased, which led to indirect decompression of the neural foramina. Due to the nature of the operation, however, the indirect decompression may need to be accompanied by an additional section of the ALL and/or the addition of a more lordotic interbody cage to obtain a more robust increase in regional lumbar lordosis.

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