

Expandable Titanium Interbody Spacer via Lateral Approach Improves Radiographic and Clinical Outcomes: A 2-Year Follow-up Study

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Abstract

Introduction: Severe degenerative disc diseases necessitate surgical management with large interbody spacers to regain disc space. Static interbody spacers are the standard of care for minimally invasive lateral lumbar interbody fusion (MIS LLIF). However, using large static interbody spacers requires aggressive endplate preparation prior to implant insertion, which may lead to subsidence and compromised stability. This study describes the clinical and radiographic outcomes of patients treated with expandable interbody spacers following MIS LLIF.

Materials and Methods: This is a single-surgeon, retrospective Institutional Review Board-exempt chart review on 22 consecutive patients who underwent MIS LLIF at 1–2 contiguous level(s) using expandable interbody spacers. Radiographic and clinical functional outcomes were collected and compared at preoperative and postoperative time points up to 24 months. Statistical results were significant if $p < 0.05$.

Results: Twenty-two consecutive patients were evaluated—average age, 57.6 ± 11.0 years; 45.5% were female. Visual Analog Scale (VAS) back and leg pain scores decreased significantly by an average of 7.1 ± 1.2 points at 24 months ($p < 0.001$). Oswestry Disability Index (ODI) scores significantly decreased by a mean of 67.1 ± 10.0 points at 24 months ($p < 0.001$). Lumbar lordosis improved by a mean of $1.8 \pm 8.0^\circ$ at 24 months. Among the 28 spinal levels, 42.9% were at L3–L4 and 39.3% at L4–L5. Anterior, middle, and posterior disc height significantly increased at 24 months by averages of 4.7 ± 3.6 , 4.0 ± 3.9 , and 1.9 ± 2.4 mm, respectively ($p < 0.001$). Neuroforaminal height significantly increased at 24 months by a mean of 2.6 ± 3.7 mm ($p < 0.001$). Segmental lordosis significantly improved by $2.5 \pm 2.0^\circ$ at 24 months ($p < 0.001$). There was 100% fusion at all levels, with no cases of radiolucency. One incidence of subsidence (1/28, 3.6%) was reported at 24 months. There were no reported implant-related complications, with 0% pseudoarthrosis and no secondary procedures.

Conclusion: This study showed positive clinical and radiographic outcomes for patients who underwent MIS LLIF with expandable interbody spacers. Sagittal correction and indirect decompression were achieved and maintained up to 24-month follow-up from baseline, based on increased disc height, neuroforaminal height, and segmental lordosis. Functional clinical outcomes significantly improved based on decreased VAS pain and ODI scores at 24 months. The use of lateral expandable spacers was shown to be safe, durable, and effective for the studied patient population.

Keywords: Lumbar lordosis; Spinal stenosis; Neurogenic claudication; Spinal fusion

Introduction

Lumbar interbody fusion is a surgical procedure used to relieve pain and restore quality of life in the aging population with degenerative disc disease (DDD). Restoration and maintenance of spinopelvic parameters after spine surgery is commonly associated with improved outcomes [1-10]. Various lumbar interbody fusion techniques have been described including anterior lumbar interbody fusion (ALIF), posterior lumbar interbody fusion (PLIF), transforaminal lumbar interbody fusion (TLIF), oblique lumbar interbody fusion (OLIF), and lateral lumbar interbody fusion (LLIF). These techniques have their own advantages and potential complications, as determined by anatomic obstacles and graft placement [11].

Minimally invasive surgical (MIS) approaches have gained popularity due to multiple advantages including reduced blood loss, minimal tissue disruption, shorter operative time, and reduced recovery time [12-15]. Moreover, minimally invasive lateral lumbar interbody fusion (MIS LLIF) has gained popularity since it was first introduced by Ozgur [16], because it allows for these advantages of MIS in addition to effective interbody stabilization, optimal disc space preparation, and placement of large interbody spacers [13,17-21]. These benefits may lead to disc height restoration, adequate neuroforaminal height and indirect decompression, and durable sagittal correction, which are essential to surgery success [1,2,20-24].

Expandable interbody spacers have recently been designed to allow for controlled restoration of disc height, diminished impaction forces and reduced iatrogenic distraction during insertion that would otherwise be required for the use of static interbody spacers [25]. Clinical outcome studies are needed to determine the safety and efficacy of any new technology such as this one. The goal of this study is to evaluate the radiographic and clinical outcomes over a 2-year follow-up of patients who underwent MIS LLIF using expandable interbody spacers.

Materials and Methods

Patient population

This is a single surgeon, retrospective, Institutional Review Board-exempt evaluation. Included patients presented with DDD at one or two contiguous levels from L1 to L5 with or without Grade 1

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spondylolisthesis and were treated with MIS LLIF surgery using an expandable interbody spacer (RISE[®]-L, Globus Medical, Inc. Audubon, PA, USA) with posterior instrumentation (Figures 1 and 2) from August 2016 to January 2017. Patients were excluded from the analysis if they were under 18 years of age or greater than 80 years of age; underwent more than 2-level surgery; had a previous fusion attempted at the operative level; diagnosed with a condition that would interfere with bony fusion/healing; had a history of alcohol and/or drug abuse; or smoked more than 1 pack per day. All patients were required to quit smoking 2-3 weeks prior to surgery with negative nicotine test. The most common diagnosis of these patients was degenerative spondylolisthesis and spinal stenosis with neurogenic claudication. Clinical and radiologic outcomes were assessed from a prospectively collected database using patient self-assessment forms and radiographic records.

Surgical technique

While under general anesthesia, patients were placed in the lateral decubitus position and secured to a radiolucent table with adhesive tape, with the break positioned at the greater trochanter and the iliac crest above the break. Under fluoroscopic guidance, an oblique incision was made at the symptomatic disc segment. Blunt dissection was performed under direct visualization through subcutaneous tissue, external and internal oblique muscles, and transversus abdominis. Retroperitoneal fat was mobilized anteriorly, revealing the underlying psoas muscle. The psoas muscle was palpated, and X-rays confirmed the level and location of the spinal marker. Blunt dissection was performed anteriorly to or at the very anterior part of the psoas muscle down to the operative intervertebral disc level. Neuromonitoring stimulation did not show any nerve conduction abnormalities (lumbar plexus).

Autogenous bone graft was harvested from the bone marrow aspiration. After fluoroscopic confirmation of the appropriate level, a minimally invasive retractor was docked, dilated at the segment, and secured to the table-mounted arm. An annulotomy was then performed, followed by a discectomy. Under fluoroscopic imaging, adequate endplate preparation was completed, and trial spacers were placed to allow for gradual distraction of the disc space. An appropriately sized expandable interbody spacer was selected, packed with autogenous bone graft, and implanted in the disc space. The spacer was then expanded to the desired height, determined by tactile feel, and backfilled with autogenous bone graft.



Figure 1: Oblique view of continuously expandable interbody spacer in (A) Minimized and (B) Expanded forms (RISE[®]-L, Globus Medical, Inc.).

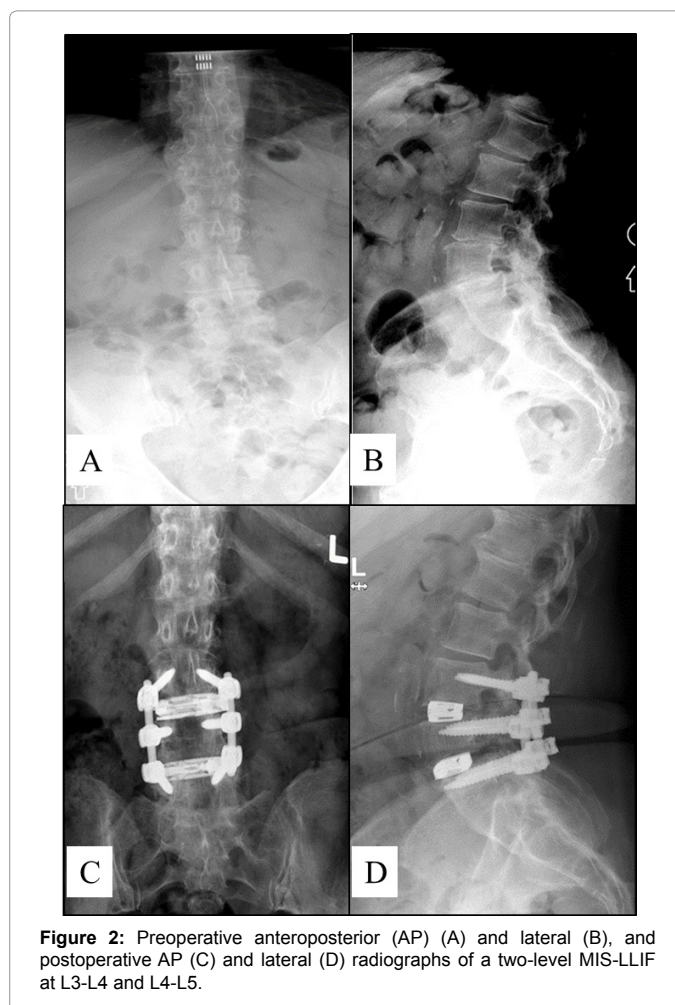


Figure 2: Preoperative anteroposterior (AP) (A) and lateral (B), and postoperative AP (C) and lateral (D) radiographs of a two-level MIS-LLIF at L3-L4 and L4-L5.

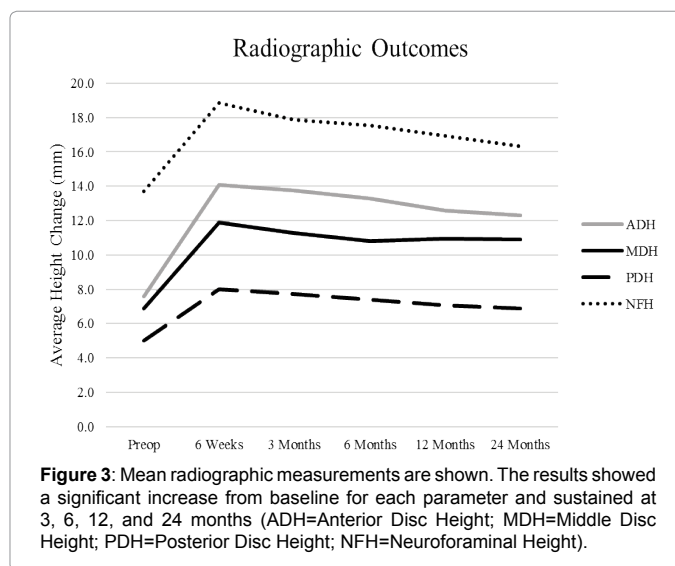


Figure 3: Mean radiographic measurements are shown. The results showed a significant increase from baseline for each parameter and sustained at 3, 6, 12, and 24 months (ADH=Anterior Disc Height; MDH=Middle Disc Height; PDH=Posterior Disc Height; NFH=Neuroforaminal Height).

The titanium alloy expandable interbody spacer used in this study was inserted at a contracted height and expanded *in situ* once correctly positioned within the intervertebral space, offering continuous expansion for optimal endplate-to-endplate contact.

Posterior decompression was performed in cases of severe spinal

stenosis with neurological deficit or in cases where LLIF procedure did not increase preoperative disc height by more than double. Pedicle screws and rods were used for supplemental fixation. Locking caps were set once the rods were in their proper position. Intraoperative fluoroscopy images were taken of the final construct. Surgical incisions were cleaned and closed in the standard fashion.

Outcome measures

Demographic and perioperative data were recorded. Operative times and fluoroscopy times were collected during the LLIF. Patient self-assessment questionnaires, such as the Visual Analog Scale (VAS) for back and leg pain and Oswestry Disability Index (ODI) were evaluated preoperatively and at 6 weeks, 3, 6, 12, and 24 months postoperatively. Radiographic parameters, including disc height, neuroforaminal height, segmental lordosis, and lumbar lordosis were assessed at 6 weeks, 3, 6, 12, and 24 months. Intervertebral fusion, radiolucency, adjacent segment disease (ASD), pseudoarthrosis, implant subsidence, breakage and expulsion were reported at 24 month follow-up.

Radiographic measurements were completed by a trained researcher and verified by an orthopaedic surgeon. Disc heights were measured from superior endplate to inferior endplate at the anterior, middle and posterior portions of the disc space in the lateral plane. Neuroforaminal height was measured as the distance from the inferior pedicle wall of the level above to the superior pedicle wall of the level below. Segmental lordosis was defined as the angle between the inferior endplate of the caudal vertebral body and the superior endplate of the cephalad vertebral body. Lumbar lordosis was measured from the endplate of S1 to the superior endplate of L1. Fusion was evaluated on radiographic images using the Brantigan, Steffee, and Fraser (BSF) radiographic classification [26] (Table 1). According to this classification, BSF-1 is radiographic pseudoarthrosis, BSF-2 is radiographical locked pseudoarthrosis, and BSF-3 is radiographical fusion (Table 1). Subsidence was defined as a measured reduction in disc height greater than 2mm compared to 6-week disc height. ASD was assessed clinically and in correlation with radiographic studies.

Statistical analysis

Statistical analysis was performed with SPSS® Statistics software (SPSS® v22, IBM Corp., Armonk, NY, USA). Frequency analyses and paired sampled *t*-tests were used to calculate changes in ordinal and interval variables from preoperative to each postoperative follow-up time. Statistical significance was set at *p*<0.05.

Results

Patient demographic and operative data

Twenty-two consecutive patients (28 operative levels) underwent MIS LLIF surgery using an expandable interbody spacer with posterior instrumentation. The average age of the 22 patients was 57.6 ± 11.0 years and 45.5% (10/22) of the population was female (Table 2). There were 28 spinal fusion levels, with 17.9% (5/28) at L2-L3, 42.9% (12/28) at L3-L4, and 39.3% (11/28) at L4-L5. Of the 22 patients, 73% (16/22) were one-level procedures and 27% (6/22) were two-level fusions. Mean operative times were 59.9 ± 16.5 min for one-level fusions and 85.8 ± 6.3 min for two-level fusions. Mean fluoroscopic times were 20.4 ± 8.4 sec for one-level fusions and 24.0 ± 17.0 sec for two-level fusions. Lengths of hospital stays were 4.0 ± 1.5 days for one-level fusions and 4.0 ± 1.4 days for two-level fusions. Mean estimated blood loss was 17.9 ± 5.0 cc and 24.2 ± 7.4 cc for one-level and two-level fusions, respectively (Table 3).

Clinical outcomes

Patients reported improvements in pain and disability. Mean VAS scores for back or leg pain significantly improved from baseline by 4.0 ± 1.2 points at 6 weeks, 5.1 ± 1.1 points at 3 months, 5.6 ± 1.6 points at 6 months, 6.4 ± 1.5 points at 12 months, and 7.1 ± 1.2 points at 24 months (all *p*<0.001). ODI scores decreased significantly by an average of 37.1 ± 11.5 points at 6 weeks, 46.7 ± 10.8 points at 3 months, 55.2 ± 13.3 points at 6 months, 61.3 ± 15.3 points at 12 months, and 67.1 ± 0.0 points at 24 months (all *p*<0.001) (average scores are listed in Table 4).

Radiographic outcomes

Lumbar lordosis increased by an average of 4.1 ± 8.2° at 6 weeks, 4.0 ± 7.1° at 3 months, 2.8 ± 8.3° at 6 months, 2.4 ± 8.7° at 12 months, and 1.8 ± 8.0° at 24-month follow-up. Segmental lordosis was maintained for 24 months postoperative as well, increasing significantly by 2.5 ± 2.0°, (*p*<0.001). At 24 months postoperative, anterior, middle, and posterior disc heights had significantly improved from baseline by averages of 4.7 ± 3.6, 4.0 ± 3.9, and 1.9 ± 2.4mm respectively (all *p*<0.001) (Figure 3, Table 5). Additionally, neuroforaminal height increased 2.6 ± 3.7 mm from preoperative to 24-month follow-up (*p*<0.005). All operative levels were considered radiographically fused (BSF-3) [26], and there were no cases of radiolucency at 24-month follow-up.

Implant-related observations

There were no reported implant-related complications, with no incidence of pseudoarthrosis and no occurrence of implant breakage or expulsion at any operative level. There were no secondary surgical

BSF-1: Radiographical Pseudoarthrosis is indicated by collapse of the construct, loss of disc height, vertebral slip, broken screws, displacement of the carbon cage, significant resorption of the bone graft, or lucency visible around the periphery of the graft or cage.
BSF-2: Radiographical Lock Pseudoarthrosis is indicated by lucency visible in the middle of the cages with solid bone growing into the cage from each vertebral endplate.
BSF-3: Radiographical Fusion: Bone bridges at least half of the fusion area with at least the density originally achieved at surgery. Radiographical fusion through one cage (half of the fusion area) is considered to be mechanically solid fusion even if there is lucency on the opposite side.

Table 1: Classification of interbody fusion success [26].

Parameters	Overall
Number of Patients	22
Sex	
Female, n (%)	10 (45.5%)
Male, n (%)	12 (54.5%)
Age, average ± SD (range)	58 ± 11.0 (34–77)

Table 2: Baseline characteristics.

Parameters	Overall
Type of Surgery, n(%)	
One-level	16 (72.7%)
Two-level	6 (27.3%)
Levels Instrumented, n(%)	
L2–L3	5 (17.9%)
L3–L4	12 (42.9%)
L4–L5	11 (39.2%)
Mean Estimated Blood Loss	
One-level	<50cc
Two-level	<50cc
Operative Time, average ± SD	
One-level	59.9 ± 16.5
Two-level	85.8 ± 6.3
Fluoroscopic Time, average ± SD	
One-level	20.4 ± 8.4
Two-level	24.0 ± 17.0
Length of Hospital Stay, average ± SD	
One-level	4.0 ± 1.5
Two-level	4.0 ± 1.4

Table 3: MIS LLIF fusion procedure characteristics.

Parameter	Baseline	6 Weeks	3 Months	6 Months	12 Months	24 Months
VAS	8.2 ± 0.7	4.2 ± 1.1*	3.1 ± 1.0*	2.5 ± 1.4*	1.8 ± 1.3*	1.0 ± 0.8*
ODI	77.6 ± 7.3	40.5 ± 11.9*	30.9 ± 10.4*	22.5 ± 12.4*	16.4 ± 13.2*	10.5 ± 6.9*

**p*<0.05 compared to baseline. Average ± SD is reported.

Table 4: VAS back and leg pain and ODI average scores.

Parameters	Baseline	6 Weeks	3 Months	6 Months	12 Months	24 Months
Anterior Disc Height	7.6 ± 3.6	14.1 ± 2.6*	13.8 ± 2.3*	13.3 ± 2.4*	12.6 ± 2.5*	12.3 ± 2.3*
Middle Disc Height	6.9 ± 3.6	11.9 ± 2.4*	11.3 ± 2.1*	10.8 ± 2.3*	10.9 ± 2.0*	10.9 ± 2.1*
Posterior Disc Height	5.0 ± 2.2	8.0 ± 1.6*	7.7 ± 1.3*	7.4 ± 1.5*	7.1 ± 1.4*	6.9 ± 1.2*
Neuroforaminal Height	13.7 ± 3.1	18.9 ± 2.9*	17.9 ± 3.5*	17.6 ± 3.0*	16.9 ± 3.4*	16.3 ± 2.8*
Segmental Lordosis	4.7 ± 2.5	8.4 ± 2.6*	8.0 ± 2.7*	7.9 ± 2.8*	7.6 ± 3.0*	7.2 ± 2.5*
Lumbar Lordosis	41.2 ± 8.4	45.3 ± 5.8*	45.3 ± 4.9*	44.0 ± 5.7	43.6 ± 7.2	43.0 ± 6.4

**p*<0.05 compared to baseline. Average ± SD is reported.

Table 5: Average radiographic parameters.

procedures required at the index or adjacent levels reported. There was only 1 case of subsidence and 4 cases of ASD reported. However, there was no revision surgery up to the 24-months follow up.

Discussion

The results from this cohort showed positive radiographic and clinical outcomes for the use of expandable interbody spacers with a MIS-LLIF approach. At 24 months, MIS LLIF with expandable interbody spacers significantly maintained disc height and segmental lordosis by 58% and 53%, respectively. Additionally, VAS back and leg pain scores and ODI scores improved by 88% and 87%, respectively, at 24 months.

There was a consistent increase in disc height and segmental lordosis found in this study compared to results of static interbody spacers reported in the literature. In 2012, Le et al. [27] reported a 22.6% increase in segmental lordosis and a 54.5% increase in disc height in 35 patients with MIS-LLIF. In a prospective observational study of 52 patients who underwent standalone lateral interbody fusion, Marchi et al. [28] reported increases in disc height and segmental lordosis at 24 months by 55% and 62%, respectively. Furthermore, Lee et al. [21] found a 75% improvement in disc height and a 12% improvement in segmental lordosis at 6 months.

In this study, improvements in VAS pain and ODI scores were better than those reported in the literature. Multiple studies [20-23,29-34] in the literature demonstrate improvements in VAS back and leg pain scores and ODI scores after an LLIF procedure. Youssef et al. [34] completed a retrospective literature review of 14 original lateral approach publications and found 84 patients who had undergone an LLIF from 2004 to 2010. Average VAS and ODI scores significantly improved from baseline to 12 months by 77% and 56%, respectively. In a prospective analysis by Rodgers et al. [33] 600 patients reported improvement in VAS scores by an average of 65%. In 2015, Malham et al. [20] found significant decrease in VAS and ODI scores from baseline to 12 months by 49% and 42%, respectively. Kotwal et al. [32] conducted a study on 118 patients with 24-month follow-up after LLIF surgery, and reported a significant 53% improvement in VAS scores and a 43% improvement in ODI scores.

Subsidence of interbody fusion devices can lead to revision surgery. In this study, there was only one case of subsidence out of 22 patients (4.5%), but it did not require revision surgery. Tempel et al. [35] reported an 11.4% subsidence rate in 34 out of 297 patients who underwent LLIF; of the 34 cases, 18 (6.1%) required revision.

Other studies reported higher subsidence rates. Marchi et al. [28]

reported subsidence in 9 out of 52 cases (17%), with 7 out of 52 cases (13%) needing revision surgery. In a separate study by Castro et al. [29], 10 out of 35 patients (29%) experienced subsidence, and 3 out of 35 patients (9%) needed further surgical intervention. Static spacers were used in each of these studies, which could explain the higher subsidence rate. To this point, an expandable *versus* static spacer analysis by Frisch et al. [36] found a significantly higher subsidence rate in the static spacer group (16%) compared to the expandable group (0%). Expandable spacers are designed to optimize endplate-to-endplate fit, and these results suggest that expandable spacers may help reduce the risk of subsidence.

Conclusion and Limitations

As with any study, the current evaluation has limitations; these include a small sample size and a single-surgeon analysis. However, the long follow-up and consistency with the literature may offset these issues with respect to the scope of the conclusions drawn. Further follow-up and corroboration of these results from other institutions may confirm the benefits of expandable devices in conjunction with the MIS LLIF procedure.

This study evaluated the safety and efficacy of an expandable interbody spacer used during an LLIF procedure. Improvements were achieved in both radiographic and clinical outcomes, and were maintained through 24-month follow-up. The use of expandable spacers was shown to be safe, durable, and effective in the patients studied.

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