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Technical notes & surgical techniques

Laterally placed expandable interbody spacers improve radiographic and clinical outcomes: A 1-year follow-up study

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A B S T R A C T

Introduction: A common surgical option for the treatment of degenerative disc disease is minimally invasive lateral lumbar interbody fusion (MIS LLIF). This approach has been shown to minimize blood loss and soft tissue dissection when compared to open posterior lumbar interbody fusion. Expandable lateral interbody spacers are designed to maximize segmental lordosis, which is essential for sagittal balance correction. This study describes the clinical and radiographic outcomes of patients treated with expandable interbody spacers for MIS LLIF.

Methods: A retrospective, single surgeon, clinical and radiographic study was performed on 37 consecutive patients who underwent MIS LLIF at 1–2 contiguous level(s) using expandable spacers. Radiographic and clinical functional outcomes were collected and compared at preoperative and postoperative time points up to 12 months. Parametric and nonparametric tests were used when appropriate with p value < 0.05 being significant (SPSS® v20.0.0 software for Windows (IBM Corp., Armonk, New York, USA) software was used to analyze data statistically).

Results: Thirty-seven consecutive patients were evaluated with an average age of 60 ± 12.0 years, and 37.8% were female. Mean Visual Analog Scale (VAS) for leg and back pain decreased significantly by a mean of 6.7 ± 1.3 points from preoperative to 12 months ($p < 0.001$). Oswestry Disability Index (ODI) scores significantly decreased by a mean of 63.2 ± 13.2 points ($p < 0.001$). Lumbar lordosis improved by a mean of 2.3 ± 8.8° at 12 months postoperative (P = 0.112). There were 46 spinal levels, with 39.1% (18/46) at L4–L5 and 37.0% (17/46) at L3–L4. Anterior, middle, and posterior disc height significantly increased from preoperative to 12 months with a mean of 4.9 ± 3.5 mm, 4.2 ± 3.8 mm, and 2.2 ± 2.4 mm, respectively ($p < 0.001$). Mean neuroforaminal height increased by 3.4 ± 3.7 mm at 12 months ($p < 0.001$). Segmental lordosis improved by 3.7 ± 2.9° from preoperative to 12 months. There was 100% fusion at all levels, with no cases of radiolucency and 1 case of subsidence at 12 months. There were no reported implant-related complications, with 0% pseudoarthrosis. Estimated blood loss at both 1-level (1L) and 2-level (2L) was < 50 cc. Mean operative time was 57.6 ± 15.3 min for 1 L fusions and 93.6 ± 14.0 min for 2 L fusions. Mean fluoroscopic times were 23.0 ± 10.9 sec for 1 L fusions and 32.4 ± 23.4 sec for 2 L fusions. Length of hospital stay was 3.8 ± 1.6 days for 1 L fusions and 4.2 ± 2.2 days for 2 L fusions.

Conclusion: Significant increases in disc height, neuroforaminal height, segmental lordosis, and indirect decompression were achieved and maintained up to 1-year follow-up from baseline. Functional clinical outcomes were significantly improved for patients who underwent MIS LLIF using expandable interbody spacers based on decreased VAS pain scores and ODI scores at 1-year follow-up. The use of expandable spacers was shown to be safe, durable and effective for the studied patients.

Abbreviations: MIS, Minimally Invasive Surgery; LLIF, Lateral Lumbar Interbody Fusion; VAS, Visual Analog Scale; ODI, Oswestry Disability Index; 1 L, 1 level; 2 L, 2 level; DDD, Degenerative Disc Disease; PLIF, Posterior Lumbar Interbody Fusion; TLIF, Transforaminal Lumbar Interbody Fusion; ALIF, Anterior Lumbar Interbody Fusion; LLIF, Lateral Lumbar Interbody Fusion; ASD, Adjacent Segment Disease; BSF, Brantigan, Steffee, and Fraser; ADH, Anterior Disc Height; PDH, Posterior Disc Height; AP, Anteroposterior; SD, Standard Deviation; MDH, Middle Disc Height; NFH, Neuroforaminal Height

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1. Introduction

Degenerative lumbar disc disease (DDD) is a progressive irreversible condition linked to aging and a contributing factor for low back pain. DDD can lead to the loss of disc height and lordosis, resulting in significant disability manifested by radiculopathy, myelopathy, spinal stenosis, degenerative spondylolisthesis and herniations [1]. When conservative treatments fail, lumbar spinal fusion with interbody spacers is an effective treatment option [2]. The goal of spinal arthrodesis is to restore alignment and stabilize the spine until fusion occurs. There are a variety of approaches for lumbar interbody fusion [posterior (PLIF), transforaminal (TLIF), oblique (OLIF), anterior (ALIF) and (LLIF)], all having several anatomical trajectories and potential trade-offs determined by the extent of resection of local supportive structures and graft size [3].

Minimally invasive lateral lumbar interbody fusion (MIS LLIF) has gained popularity due to its muscle-sparing dissection, decreased soft tissue retraction, shorter operative time, and reduced postoperative pain [4,5]. LLIF permits the use of large intervertebral spacers and preserves primary segmental stabilizing structures [6]. This transpsoas approach indirectly decompresses neural elements through direct visualization of the intervertebral disc space in preparation for placement of an intervertebral spacer [7]. Crucial to this approach is achieving adequate disc height, neuroforaminal height, and indirect decompression, along with segmental and lumbar lordosis, through the use of an optimally sized interbody device. Maintaining correction until fusion occurs is paramount to achieving better patient outcomes.

Historically, static interbody spacers have been used as a lumbar interbody device to achieve sagittal correction. Larger implants are placed to allow for indirect decompression and optimal sagittal correction [8]. However, static interbody spacers have been associated with higher rates of subsidence leading to loss of disc height and lordosis which may compromise stability [9–13].

These concerns can be addressed through the use of a continuously expandable lateral interbody spacer for spinal fusion to restore disc height, neuroforaminal height, and lordosis thereby providing indirect decompression and maximizing patient outcomes [14,15]. For any new technology, clinical outcome studies are needed to determine safety and efficacy. This study aims to determine the radiographic and clinical outcomes of patients who underwent MIS LLIF using expandable spacers.

2. Materials and Methods

2.1. Patient population

This retrospective clinical study with IRB approval, included 37 consecutive patients and 46 operative levels with a diagnosis of DDD at one or two contiguous levels from L1 to L5 with or without Grade 1 spondylolisthesis. All patients underwent a MIS LLIF surgery using an expandable interbody spacer (RISE®-L, Globus Medical, Inc. Audubon, PA, USA) with posterior instrumentation (Fig. 1) from August 2016 to January 2017. There were no deformity cases, thus LLIF was used for sagittal correction. Patients were included if they were 18 years of age up until 80 years. Patients were excluded if they underwent more than a 2-level surgery, had previous fusion at the operative level, a diagnosis with a condition that would interfere with bony fusion/healing, a history of alcohol and/or drug abuse, and if they smoked more than 1 pack per day. All patients were required to quit smoking 2–3 weeks prior to surgery with negative nicotine test. Degenerative spondylolisthesis and spinal stenosis with neurogenic claudication were the most common diagnosis for this patient population. Data were collected preoperatively and postoperatively at 6 weeks, 3, 6, and 12 months. Patient self-assessment forms and radiographic records were used to assess clinical and radiologic outcomes.

Fig. 1. Oblique view of a continuously expandable interbody spacer in minimized (A) and expanded (B) forms (RISE L, Globus Medical, Inc. Audubon, PA USA).

2.2. Surgical technique

While under general anesthesia, patients were placed in the lateral decubitus position and secured with adhesive tape, to a radiolucent table with the break positioned at the greater trochanter with 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. The retroperitoneal fat was mobilized anteriorly, exposing 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 was done in the initial step and whenever retractors were relocated. Neuromonitoring did not show any nerve conduction abnormalities (lumbar plexus) or signal changes. After confirmation of the appropriate level via fluoroscopy, 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 expandable interbody spacer of appropriate size was selected, packed with autograft, and implanted at the middle or slightly anteriorly middle of the disc space (Fig. 2). The spacer was then expanded to the desired height and back-filled with autograft (Fig. 3).

RISE®-L is a vertically expanding LLIF devise manufactured from titanium alloy, designed to maximize indirect decompression, provide a large graft space for optimal fusion and minimize impaction forces. The device is inserted at a contracted height and expanded up to 7 mm *in situ* once correctly positioned within the intervertebral space, offering continuous expansion for optimal endplate-to-endplate contact. The footprint options include ;18 and 22 mm widths, 5 lengths (40–60 mm, in 5 mm increments), 7–17 mm height (height range dependent on lordosis), and in parallel or 2 lordotic profiles (6° and 10°). The 18 mm width was the most commonly used width in this study at 90% vs the 22 mm. Fluoroscopy and the tactile feel of the implant in the disc space, determined appropriate expansion. The overall height was determined through the 3Nm torque safety feature using the Lateral Torque-Limiting Driver by counting the number of revolutions of the driver

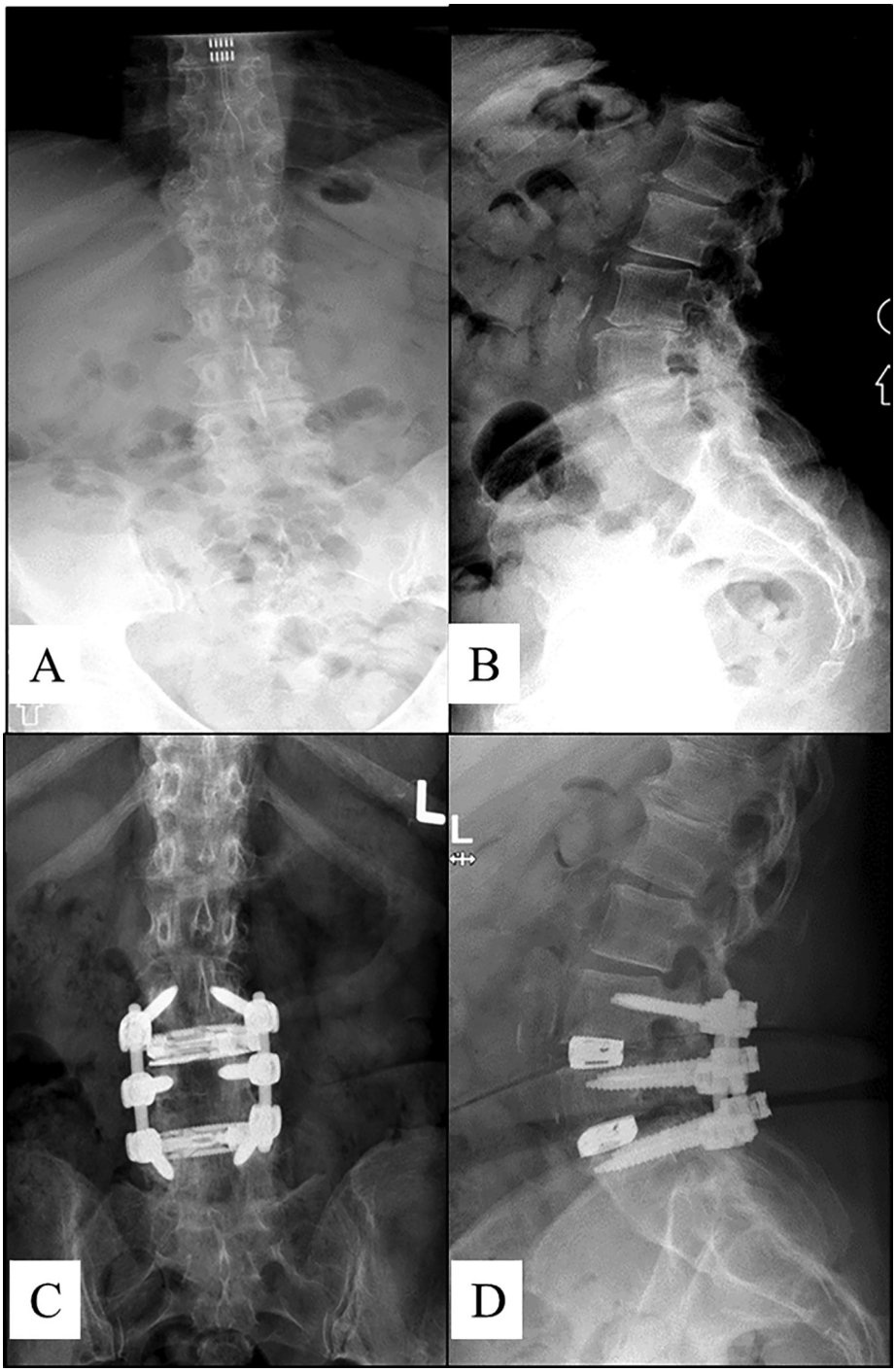

Fig. 2. Preoperative anteroposterior (AP) (A) and lateral (B) radiographs and postoperative AP (C) and lateral (D) of a 2 L MIS-LLIF at L3/L4 and L4/L5.

(one revolution is 0.5 mm of expansion).

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, posterior decompression was performed. 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.

Three doses (depends on weight, 1–2 g) of antibiotics was administered (preoperative, intraoperative, and postoperative) for prophylaxis.

2.3. Outcome measures

Demographic and perioperative data were recorded. Patient self-assessment questionnaires, such as the VAS for back and leg pain and ODI were evaluated preoperatively and at 6 weeks, 3, 6, and 12 months postoperatively. Radiographic parameters (Fig. 4), including disc height, neuroforaminal height, segmental lordosis, lumbar lordosis, intervertebral fusion, radiolucency, adjacent segment disease (ASD), pseudoarthrosis, implant subsidence, breakage and expulsion were assessed. ASD was assessed clinically and in correlation with radiographic studies.

Two observers assessed fusion with an agreed consensus using

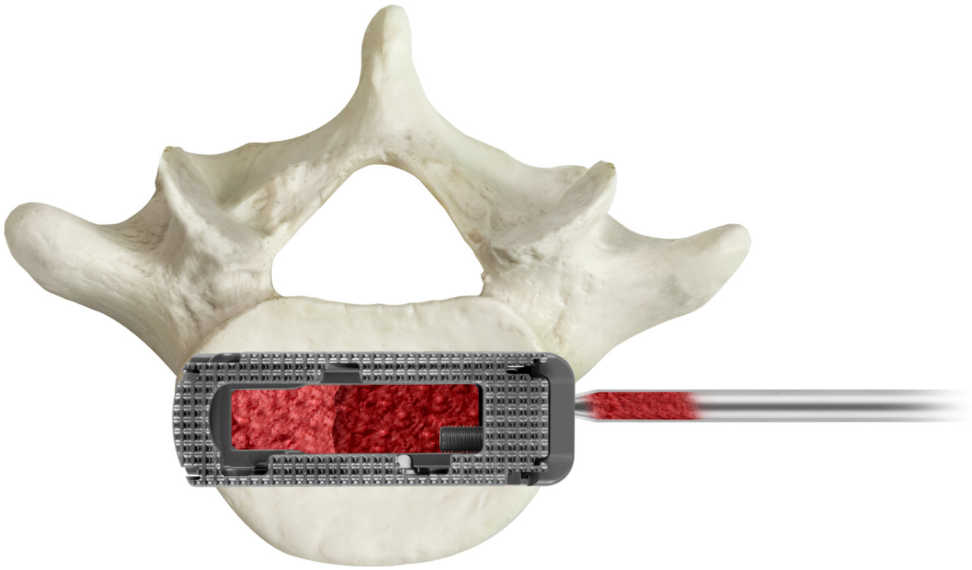

Fig. 3. Illustration of backfilling capability: Additional bone graft may be packed into the graft chamber of the implant after expansion and around implant if desired.

flexion/extension x-rays at one-year follow-up and used Fogel et al. as a reference for grading [16] via the Brantigan, Steffee, and Fraser (BSF) radiographic classification [16]. According to this classification, BSF-1 is radiographic pseudoarthrosis, BSF-2 is radiographical lock pseudoarthrosis, and BSF-3 is radiographical fusion (Table 1). Radiographic measurements were completed by a trained researcher and verified by an orthopaedic surgeon. Subsidence was defined as a measured reduction in disc height greater than 3 mm compared to disc height at 6 weeks postoperatively [17,18]. ASD was assessed clinically and in correlation with radiographic studies. Disc heights were measured at the anterior, middle and posterior portions of the endplates immediately above and below the referenced index levels on 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 measured from inferior endplate of the caudal vertebral body to the superior endplate of the cephalad vertebral body. Lumbar lordosis was measured from the endplate of S1 to the superior endplate of L1.

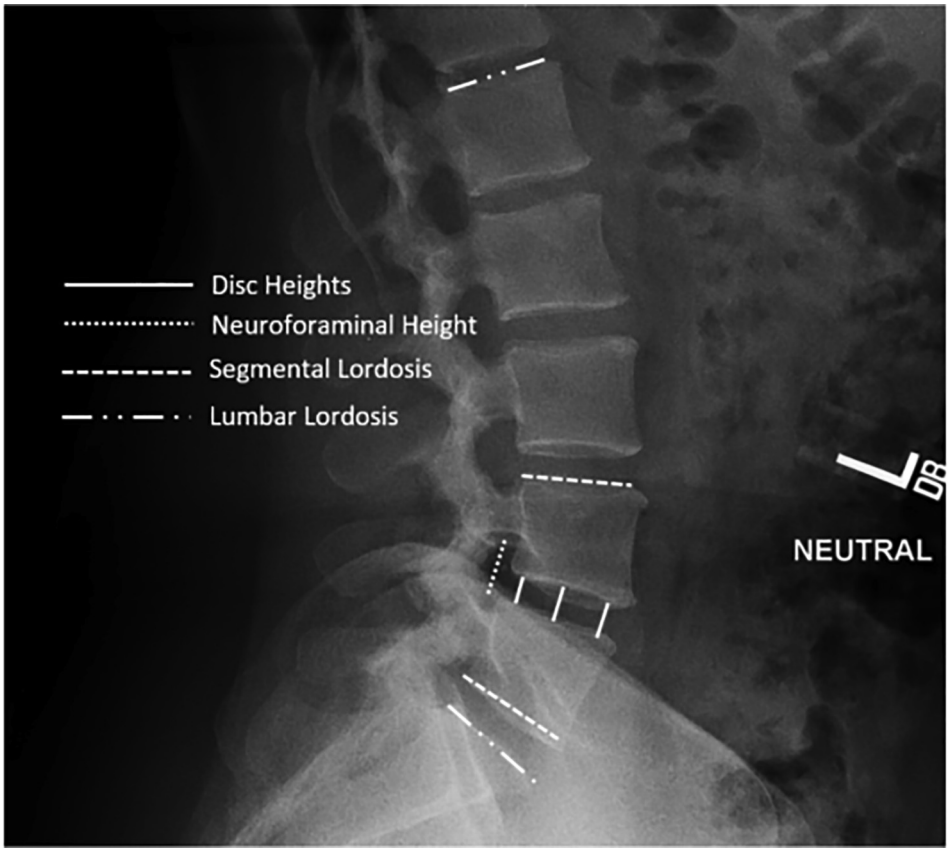

Fig. 4. Standing lateral lumbar spine radiograph with superimposed lines demonstrating the measurements assessed in this study: disc heights (anterior, middle, posterior), neuroforaminal height, segmental lordosis, and lumbar lordosis.

Table 1
Classification of interbody fusion success: Brantigan, Steffee, Fraser [16] (BSF).

BSF-1: *Radiographical Pseudarthrosis* is indicated by a collapse of the construct, loss of disc height, vertebral slip, broken screws, displacement of the carbon cage, or significant resorption of the bone graft, or lucency visible around the periphery of the graft or cage.
BSF-2: *Radiographical Lock Pseudarthrosis* 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.

2.4. Statistical analysis

Statistical analysis was performed with SPSS® v20.0.0 software for Windows (IBM Corp., Armonk, New York, 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 $p < 0.05$.

3. Results

3.1. Patient demographic and operative data

From August 2016 to November 2017, 37 consecutive patients with an average age of 60.3 ± 12.0 years were included, and 37.8% (14/37) were female (Table 2). There were 46 spinal fusion levels, with 39% (18/46) at L4-L5 and 37% (17/46) at L3-L4. Of the 37 patients, 76% (28/37) were 1 L procedures and 24% (9/37) were 2 L fusion. Mean operative time was 57.8 ± 15.3 min for 1 L fusions and 93.6 ± 14.0 min for 2 L fusions. Mean fluoroscopic times were 23.0 ± 10.9 sec for 1 L fusions and 32.4 ± 23.4 sec for 2 L fusions. Length of hospital stay was 3.8 ± 1.6 days for 1 L fusions and 4.2 ± 2.2 days for 2 L fusions. Mean estimated blood loss for 1 L fusions was 21.7 ± 12.3 cc and for 2 L fusions 23.9 ± 6.5 cc. Minimal minor perioperative complications were reported; with 10–15% thigh numbness which resolved on their own at 2–6 weeks postoperatively and a 10% ileus complication rate, which resolved a few days after surgery. There were no reported cases of infection due to MIS approach.

Table 2
Patient demographics and operative data.

Rise-L spacers	
n (%) or mean ± SD	
Total no. patients	37
Gender	
Male	23 (62.2%)
Female	14 (37.8%)
Age, years	60.3 ± 12.0
Operative levels	
L1-L2	1 (2.2%)
L2-L3	10 (21.7%)
L3-L4	17 (37.0%)
L4-L5	18 (39.1%)
Number of levels	
1	28 (75.7%)
2	9 (24.3%)
Operative time 1-level (minutes)	57.6 ± 15.3
Operative time 2-level (minutes)	93.6 ± 14.0
Estimated blood loss 1-level (cc)	21.7 ± 12.3
Estimated blood loss 2-level (cc)	23.9 ± 6.5
Length of hospital stay 1-level(days)	3.8 ± 1.6
Length of hospital stay 2-level (days)	4.2 ± 2.2
Fluoroscopy Time 1-level (seconds)	23.0 ± 10.9
Fluoroscopy Time 2-level (seconds)	32.4 ± 23.4

SD, standard deviation.

Additionally, no cases of vascular, bowel, or plexus injuries were reported.

3.2. Clinical outcomes

Patients reported improvements in pain and disability. Mean VAS scores for back or leg pain decreased significantly from preoperative to 12 months by 6.7 ± 1.3 points ($p < 0.001$). ODI scores decreased significantly by an average of 63.2 ± 13.2 points ($p < 0.001$) (Table 3).

3.3. Radiographic outcomes

Lumbar lordosis improved by an average of 2.3 ± 8.8° (high standard deviation due to variance in each patient's preoperative lordosis) from preoperative to 12 months ($p = 0.112$) as well as segmental lordosis by 3.7 ± 2.9° at 12-month follow-up ($p < 0.001$) (Table 3). Anterior, middle and posterior disc height significantly increased at 12 months postoperatively with a mean of 4.9 ± 3.5 mm, 4.2 ± 3.8 mm, and 2.2 ± 2.4 mm, respectively ($p < 0.001$) (Table 4). Mean neuroforaminal height increased by 3.4 ± 3.7 mm from preoperative to 12 months ($p < 0.001$) (Fig. 5). All operative levels were considered radiographically fused (BSF-3) [16], and there were no cases of radiolucency at 12-month follow-up.

3.4. Implant-related observations

There were no reported implant-related complications, with no evidence of pseudoarthrosis (at 12-months postoperatively) and no occurrence of implant breakage or expulsion at any operative level. There was 100% fusion and no secondary surgical procedures required at the index or adjacent levels reported. There was only 1 (1/46, 2.2%) case of subsidence and 3 cases of suspected ASD reported. However, there was no revision surgery through 12-month follow-up.

4. Discussion

Degenerative disc disease with loss of lordosis and disc height is the most common condition for debilitating back pain frequently associated with referred and radicular leg pain [19]. The goal of MIS LLIF is to restore and maintain disc height and lordosis to correct sagittal alignment with minimal complications associated with ALIF, PLIF, and TLIF procedures [4,7,20–22]. Restoring sagittal alignment is critical to achieving excellent short and long-term outcomes [20,23]. Expandable interbody spacers with built-in lordosis allow for insertion at a low profile, as well as expansion *in situ* to restore disc height and segmental lordosis [24]. In this study, mean VAS pain scores decreased significantly from baseline at 12 months postoperatively by 81.7% (6.7 ± 1.3points) and ODI scores significantly decreased by 81.7% (63.2 ± 13.2 points) ($p < 0.001$). The observed clinical outcomes demonstrated that expandable interbody spacers are effective at improving the average pain and disability scores by two to five times the MCID, at 1-year follow-up [25,26]. Optimal disc height, neuroforaminal height and segmental lordosis were achieved and maintained, with a 62.3% increase in middle disc height, 25.0% increase in neuroforaminal height and a 73.1% increase in segmental lordosis from preoperative to final follow-up. These significant radiographic improvements demonstrated that expandable interbody spacers when used with a lateral lumbar interbody fusion are durable up to 12 months' follow-up. The radiographic and clinical results in the current study are comparable to other studies that used expandable interbody spacers [15]. Boktor et al. included 54 patients using the MIS TLIF approach with 24 month follow-up, also reported low complication rates, short hospital stay, and significant restoration and maintenance of disc height, neuroforaminal height, and segmental lordosis [27]. Implant subsidence was observed in only 1 of the 46 operative levels. Other studies have shown similar

Table 3
Pain, disability, and lordosis outcomes.

Outcomes	Preoperative	6 Weeks	3 Months	6 Months	12 Months	P value*
VAS Back and Leg Pain (mean ± SD)	8.2 ± 0.70	4.3 ± 1.2	2.8 ± 1.1	2.4 ± 1.3	1.5 ± 1.1	< 0.001
ODI (mean ± SD)	77.5 ± 7.3	44.1 ± 13.2	31.1 ± 10.5	22.9 ± 11.5	14.2 ± 11.0	< 0.001
Global Lumbar Lordosis (mean ± SD)(degrees)	41.2 ± 8.2	46.4 ± 6.6	45.4 ± 5.8	43.8 ± 5.7	43.6 ± 6.6	0.112
Segmental Lordosis (mean ± SD) (degrees)	5.2 ± 2.9	10.1 ± 3.8	9.7 ± 3.8	9.5 ± 3.7	9.0 ± 3.5	< 0.001

*Preoperative values compared with 12-month values. VAS, visual analog scale; ODI, Oswestry Disability Index; SD, standard deviation.

Table 4
Mean changes of disc height and neuroforaminal height from baseline.

Parameter	Mean height change ± SD	P value
ADH6wks	6.8 ± 4.4	< 0.05
ADH3mos	5.9 ± 3.2	< 0.05
ADH6mos	5.4 ± 3.5	< 0.05
ADH12mos	4.9 ± 3.5	< 0.05
MDH6wks	5.8 ± 5.0	< 0.05
MDH3mos	4.8 ± 3.5	< 0.05
MDH6mos	4.4 ± 3.8	< 0.05
MDH12mos	4.2 ± 3.8	< 0.05
PDH6wks	3.4 ± 2.7	< 0.05
PDH3mos	2.9 ± 2.0	< 0.05
PDH6mos	2.6 ± 2.1	< 0.05
PDH12mos	2.2 ± 2.4	< 0.05
NFH6wks	5.4 ± 3.8	< 0.05
NFH3mos	3.9 ± 3.7	< 0.05
NFH6mos	3.8 ± 3.4	< 0.05
NFH12mos	3.4 ± 3.7	< 0.05

ADH – anterior disc height, MDH – middle disc height, PDH – posterior disc height, NFH – neuroforaminal height; wks – weeks, mos – months.

subsidence results. Frisch et al. [28] reported that implant subsidence was significantly higher in the static spacer group (16%) compared to the expandable spacer group (0%). A systematic review on subsidence after LLIF, conducted by Macki et al. [29] reported a 10.3% subsidence rate (n = 141/1362 patients, 14 articles) and a reoperation rate for subsidence of 2.7% (n = 41/1470 patients, 16 articles) when various sized static polymeric spacers were used.

Only 3 cases of ASD were suspected among 37 patients, however none have required revision surgery thus far. Moreover, the current study showed that lateral expandable interbody spacers significantly restored disc height (ADH = 4.9 ± 3.5 mm, PDH = 2.2 ± 2.4 mm) and segmental lordosis by 3.8 ± 2.9° at 12 months postoperative ($p < 0.001$) (Table 3). The restoration of segmental lordosis in the current study compares satisfactorily to the weighted average of 3.9° (9% increase, 23 studies) reported by Uribe et al. [30] in their literature review ($p < 0.001$). Previous studies [20,22] reported similar improvements in segmental lordosis ranging from 2.5° to 2.8°, after LLIF using 10° lordotic cages. Similarly, in the previously-mentioned 2-year follow up study by Frisch et al. [28], comparing patients treated with lateral expandable interbody spacers to those treated with static interbody spacers, disc height significantly increased by 3.5 mm in the expandable spacer group ($p < 0.001$). In another study, Sembrano et al. [31] showed statistically significant correction of disc height and segmental lordosis using lordotic static interbody spacers compared to non-lordotic interbody spacers. Acosta et al. [21] reported that segmental lordosis (but not regional lordosis or global sagittal alignment) increased in their series of 36 patients, which is consistent with the current study.

Limitations of this study included its small sample size, lack of a control group, single surgeon experience, and 12-month follow-up. A minimum 2-year follow-up is required to assess pseudoarthrosis. Nevertheless, it provides clinical evidence on the use of lateral expandable interbody spacers for lumbar interbody fusion, which is sparse in the literature. To the author's best knowledge, this is only the second study reporting clinical outcomes for expandable lordotic interbody spacers with MIS LLIF. A 24-month follow-up study is forthcoming.

5. Conclusion

Correction of disc height and segmental lordosis was achieved using lateral expandable interbody spacers, with significant positive improvements in disc height, segmental lordosis and indirect decompression. There was 100% fusion with no revision surgery. Additionally, functional outcomes were also significantly improved. The use of expandable spacers was shown to be safe, durable and

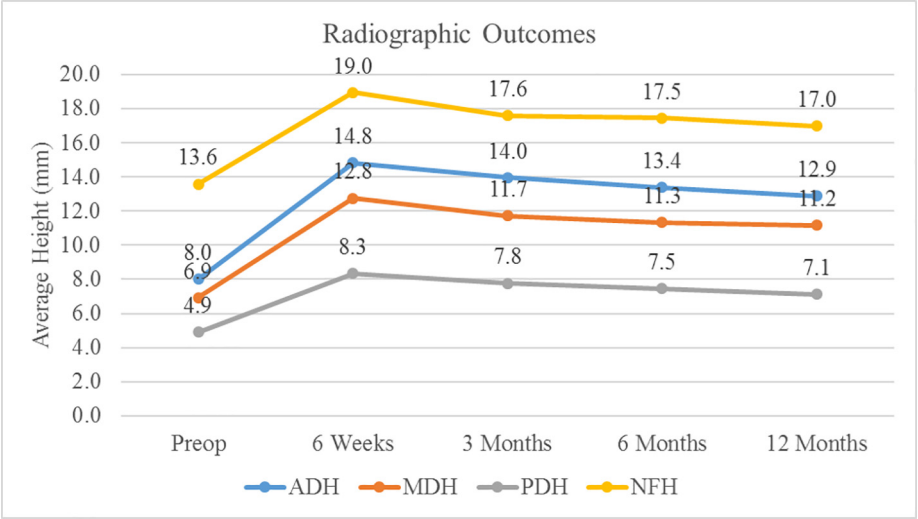

Fig. 5. Radiographic measurements from preoperative through 12-months postoperative. (ADH = anterior disc height, MDH = middle disc height, PDH = posterior disc height, NFH = neuroforaminal height). All values are averages.

effective in the studied patients.

Credit authorship contribution statement

Zheng Huang: Resources. **Yan Michael Li:** Methodology, Resources. **James Towner:** Resources. **Yan Icy Li:** Resources. **Amber Edsall:** Writing - original draft, Writing - review & editing, Conceptualization, Validation, Data curation, Visualization, Investigation. **Charles Ledonio:** Writing - review & editing, Conceptualization, Project administration.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.inat.2019.100639.

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