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A Novel Lateral Titanium Expandable Interbody Spacer with Integrated Plate Restores Anterior and Posterior Disc Height and Intervertebral Lordosis

Robert L Brady[1*], Jessica R Riggleman[2], Amber L Edsall[2] and Charles G Ledonio[2]

[1]*Coastal Orthopedics, 761 Main Avenue Suite 115, Norwalk, Connecticut, USA*
[2]*Musculoskeletal Education and Research Center (MERC), A Division of Globus Medical, Inc., 2560 General Armistead Avenue, Audubon, Pennsylvania, USA*

Abstract

Background: Expandable integrated titanium interbody spacers have been introduced in recent years for use in minimally invasive lateral lumbar interbody fusion (MIS LLIF) procedures. These devices offer *in situ* expansion that enables them to conform to intervertebral anatomy with potentially less endplate disruption and greater indirect decompression. This study describes the radiographic outcomes in patients who underwent MIS LLIF using titanium expandable interbody spacers with an integrated plate.

Method: This is a single-surgeon, retrospective, Institutional Review Board-exempt chart review conducted from June 2015 to December 2017 on consecutive patients diagnosed with spondylolisthesis who underwent MIS LLIF at 1–2 contiguous level(s) using a lateral integrated titanium expandable interbody spacer. Radiographic outcomes were collected and compared from preoperative to postoperative at 2 and 6 weeks, 3, 6, 9, and 12 month follow-ups. Statistical results were significant when $P<0.05$.

Results: Seventeen consecutive patients were evaluated with an average age of 69.2 ± 7.9 years (range: 51–82 years), and 58.8% were female. Mean anterior disc height significantly improved from baseline by 68.3% (7.7 ± 4.5 mm), 58.4% (6.9 ± 5.0 mm), 59.4% (7.0 ± 4.6 mm), 56.4% (6.1 ± 5.0 mm), 52.5% (5.7 ± 4.8 mm), and 51.5% (4.2 ± 4.0 mm) at 2 and 6 weeks, 3, 6, 9, and 12, months, respectively ($P<0.001$). Mean posterior disc height significantly improved from baseline by 78.0% (4.9 ± 2.9 mm), 67.8% (4.3 ± 2.9 mm), 66.1% (4.3 ± 2.9 mm), 69.5% (4.3 ± 3.0 mm), 57.6% (3.8 ± 2.7 mm), and 61.0% (3.2 ± 2.5 mm) at 2 and 6 weeks, 3, 6, 9, and 12, months, respectively ($P<0.001$). Segmental and lumbar lordosis remained consistent at all postoperative time points ($P>0.05$).

Conclusion: This study showed significant positive radiographic outcomes for patients who underwent MIS LLIF using novel integrated titanium expandable interbody spacers, based on significant post-operative changes in intervertebral lordosis and anterior and posterior disc height observed through 12-month follow-up.

Keywords: Expandable; Fusion; LLIF; Minimally invasive

Introduction

Conservative treatment is the standard of care for initial management of low back pain and leg pain caused by degenerative disc disease with or without spondylolisthesis. When non-operative treatment fails, lumbar interbody fusion using several approaches and techniques utilizing a variety of interbody spacers is considered. Hallmarks of a successful lumbar spinal fusion include restoration of disc height and lordosis, maintenance of sagittal alignment, and a stable fixation to promote arthrodesis. Common techniques for lumbar interbody fusion include posterior lumbar interbody fusion (PLIF) or transforaminal lumbar interbody fusion (TLIF), and anterior lumbar interbody fusion (ALIF). Conversely, pseudarthrosis, graft dislodgement, and neurologic injury are complications that have been reported with posterior approaches [1,2]. In addition, open posterior approaches can result in spinal muscular atrophy and dysfunction, and failed back syndrome [3]. Consequently, anterior lumbar interbody fusion has also been associated with vascular injury, somatic neurologic injury, deep venous thrombosis, sexual dysfunction, ureteral injury, bowel injury, lumbar sympathetic dysfunction, and hernias [4-6].

Maintenance of sagittal alignment until fusion occurs has been shown to improve patient outcomes [7-12]. Therefore, a stable construct is important for spinal fixation. Interbody devices with integrated plates have been biomechanically shown to be more stable than non-integrated interbody spacers, especially with supplemental posterior fixation using pedicle screws and rods [13-15].

Expandable integrated titanium interbody spacers have been introduced in recent years for minimally invasive lateral lumbar interbody fusion (MIS LLIF) procedures. These devices offer *in situ* expansion that enables them to conform to intervertebral anatomy with potentially less endplate disruption and greater indirect decompression. Their integrated plates and screws provide additional stability. Such innovations in MIS LLIF require radiographic outcomes to determine efficacy. This study describes the radiographic outcomes in patients who underwent MIS LLIF using titanium expandable interbody spacers with an integrated plate.

Research Methodology

This is a single-surgeon, retrospective, Institutional Review Board-exempt chart review study on consecutive patients diagnosed with spondylolisthesis who underwent MIS LLIF at 1–2 contiguous level(s) using a lateral integrated titanium expandable interbody spacer (ELSA®; Globus Medical Inc.; Audubon, PA, USA) (Figures 1 and 2). Radiographic outcomes were collected and compared from preoperative to postoperative at 2 and 6 weeks, 3, 6, 9, and 12 month follow-ups. Statistical results were significant when $P<0.05$.

***Corresponding author:** Robert L. Brady, Coastal Orthopaedics, P.C. of OrthoConnecticut Norwalk, *Connecticut, USA*, Tel: (203)845-2200; E-mail: bbradymd@yahoo.com

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Surgical technique

After the induction of general anesthesia, patients were placed in the lateral decubitus position and secured to the operating table with adhesive medical tape. Under fluoroscopic guidance, an oblique incision was made at the operative disc segment. Blunt dissection was performed under direct visualization through the retroperitoneal space. Retroperitoneal fat was mobilized anteriorly, exposing the underlying psoas muscle. The psoas muscle was palpated, and blunt dissection was performed down to the operative intervertebral disc level. 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, the endplates were prepared.

Figure 1: Integrated expandable titanium interbody spacer.

An expandable trial was used to allow for gradual distraction of the disc space. An expandable interbody spacer of appropriate size was selected, packed with autograft, and implanted laterally across the disc space. The screw holes were prepared with an angled awl and integrated screws were inserted. The spacer was then expanded to the desired height and backfilled with autograft (Figure 3). The integrated screws were final tightened. The expandable interbody spacer used in this study is manufactured from titanium alloy. The device is inserted at a contracted height and expanded *in situ* once correctly positioned within the intervertebral space. Pedicle screws and rods were used for supplemental posterior fixation. Locking caps were set once the rods were in their proper position. Intraoperative fluoroscopy images were taken to verify the screw and rod position. Surgical incisions were cleaned and closed in the standard fashion.

Quantitative measurements

Radiographic lumbosacral parameters were measured on upright lateral radiographs using imaging software (Surgimap®; Globus Medical, Inc., Audubon, PA) (Figure 4). Measurements included disc height, intervertebral angle, segmental lordosis, and lumbar lordosis. Disc height was defined as the distance between the inferior and superior endplates at the anterior and posterior portions of the vertebral body. Intervertebral angle was measured between the anterior inferior endplate of one vertebra and the anterior superior endplate of the successive vertebra. Segmental lordosis was measured as the Cobb angle of the superior endplate of the level below the LLIF and the inferior endplate of the level above the LLIF. Lumbar lordosis was measured as the angle between the superior endplate

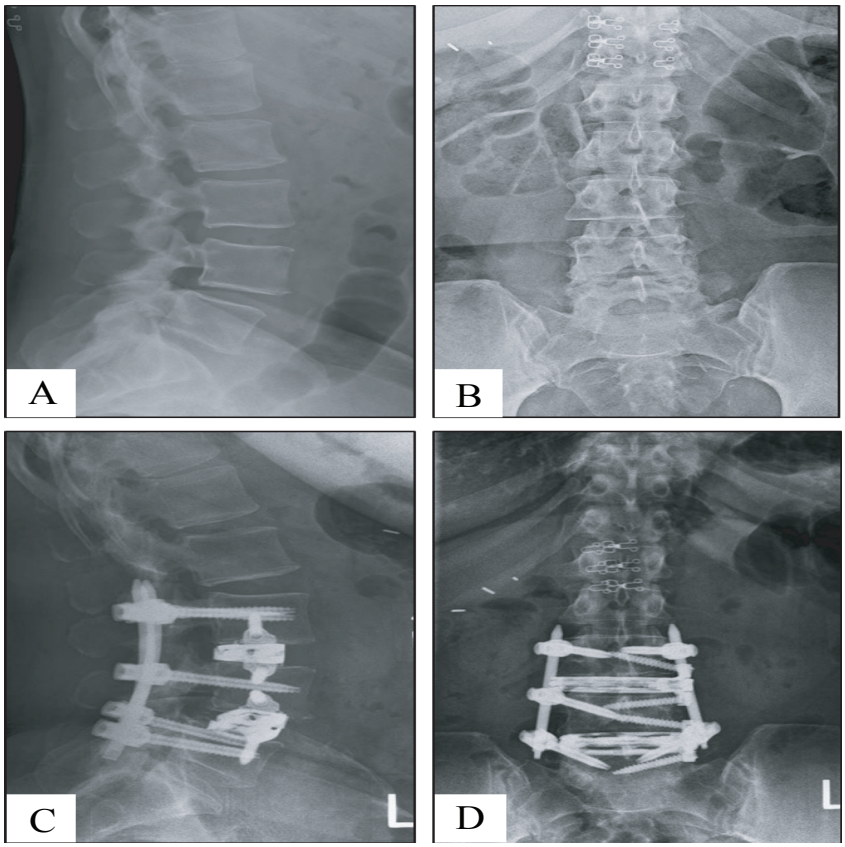

Figure 2: Pre-operative lateral (A) and antero-posterior (B) radiographs and postoperative lateral (C) and antero-posterior (D) radiographs of a two-level MIS LLIF using an adjustable lordotic expandable interbody spacer at L3–L4 and L4–L5.

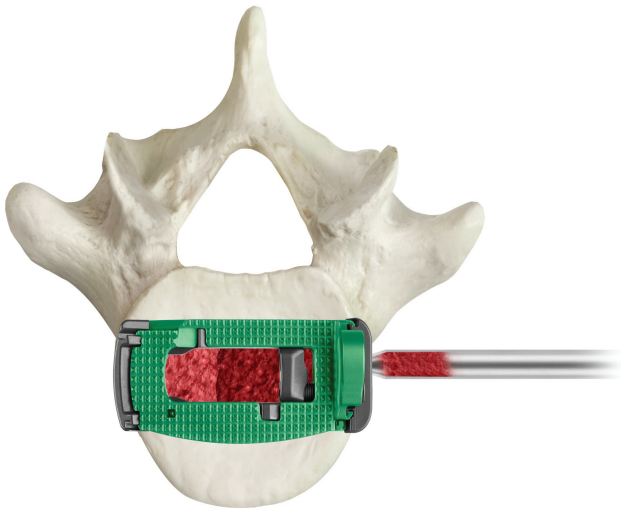

Figure 3: Additional bone graft material packed into the graft chamber of the implant after expansion.

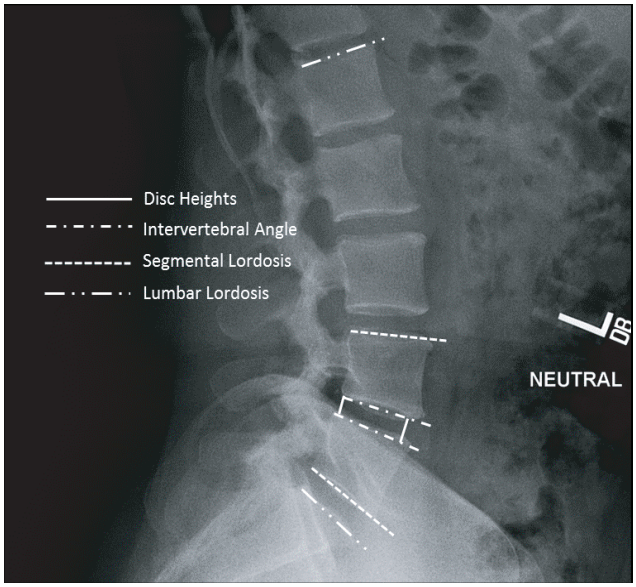

Figure 4: Standing lateral lumbar spine radiograph with superimposed lines displaying the measurements evaluated in this study. Measurements included disc heights, intervertebral angle, segmental lordosis, and lumbar lordosis.

of L1 and the superior endplate of S1. Subsidence was measured as the mean difference between 2 week and 12 month anterior disc heights and posterior disc heights. A difference of 3 mm is an indication of subsidence.

Statistical analysis

The statistical analysis was performed using IBM® SPSS® Version 25 (IBM® Corp.; Armonk, NY, USA). Descriptive statistics are presented as frequencies and percentages. Radiographic measurements are presented as means and standard deviations. Statistical significance was shown at P<0.05.

Results

Patient demographics

A total of 17 consecutive patients underwent MIS LLIF from June 2015 to December 2017 and were implanted with an expandable integrated lateral interbody spacer with posterior fixation. The patients were 58.8% (10/17) female and 41.2% (7/17) male with an average age of 69.2 ± 7.9 years (range: 51–82 years). The average body mass index was 29.6 ± 9 kg/m^2. The average Charlson Comorbidity Index was 3.9 ± 1.5 points (Table 1).

Surgical data

Of the 17 patients, 52.9% (9/17) underwent one-level and 47.1% (8/17) underwent two-level MIS LLIF, for a total of 25 spinal levels treated. Of the 25 levels, 60.0% (15/25) were treated at L4–L5, and 40.0% (10/25) at L3–L4 (Table 2).

Radiographic parameters

Mean anterior disc height significantly improved from baseline by 68.3% (7.7 ± 4.5 mm), 58.4% (6.9 ± 5.0 mm), 59.4% (7.0 ± 4.6 mm), 56.4% (6.1 ± 5.0 mm), 52.5% (5.7 ± 4.8 mm), and 51.5% (4.2 ± 4.0 mm) at 2 and 6 weeks, 3, 6, 9, and 12, months, respectively (P<0.001) (Figure 5).

Mean posterior disc height significantly improved from baseline by 78.0% (4.9 ± 2.9 mm), 67.8% (4.3 ± 2.9 mm), 66.1% (4.3 ± 2.9 mm), 69.5% (4.3 ± 3.0 mm), 57.6% (3.8 ± 2.7 mm), and 61.0% (3.2 ± 2.5 mm) at 2 and 6 weeks, 3, 6, 9, and 12, months, respectively (P<0.001) (Figure 6).

Mean intervertebral angle significantly improved from baseline by 46.3% (9.8 ± 4.8 mm), 34.3% (9.0 ± 3.9 mm), and 41.8% (9.5 ± 4.1 mm) at 2 and 6 weeks, and 3 months, respectively (P<0.05). For intervertebral angle, the mean improvement from baseline to 6, 12, and 24 months was not significant (P>0.05). Segmental and lumbar lordosis remained consistent at all postoperative time points (P>0.05) (Table 3).

Parameters	Overall
Number of patients	17
Sex	**n (%)**
Female	10 (58.8%)
Male	7 (41.2%)
Age, mean (SD, range)	69.2 (7.9) (51–82)
CCI, mean (SD, range)	3.9 (1.5) (1–7)

Table 1: Baseline characteristics.

Parameters	Overall
Type of Surgery	**n (%)**
One-level	9 (52.9%)
Two-level	8 (47.1%)
Levels Treated	**n (%)**
L3–L4	10 (40.0%)
L4–L5	15 (60.0%)

Table 2: MIS LLIF surgical data.

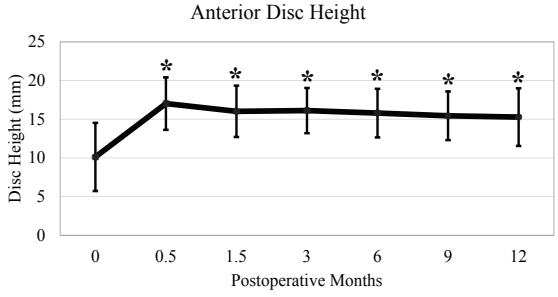

Figure 5: Mean anterior disc height measurements are shown. The results showed a significant increase from baseline and sustained at 0.5, 1.5, 3, 6, 9, and 12 months. *P<0.001 compared to baseline.

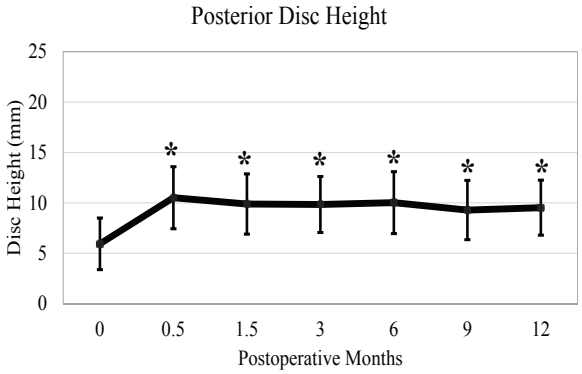

Figure 6: Mean posterior disc height measurements are shown. The results showed a significant increase from baseline and sustained at 0.5, 1.5, 3, 6, 9, and 12 months. *P<0.001 compared to baseline.

Parameters	Baseline	2 Weeks	6 Weeks	3 Months	6 Months	9 Months	12 Months
Anterior Disc Height (mm)	10.1 (4.4)	17.0 (3.4)*	16.0 (3.3)*	16.1 (2.9)*	15.8 (3.1)*	15.4 (3.2)*	15.3 (3.7)*
Posterior Disc Height (mm)	5.9 (2.6)	10.5 (3.1)*	9.9 (3.0)*	9.8 (2.8)*	10.0 (3.1)*	9.3 (2.9)*	9.5 (2.7)*
Intervertebral Angle (°)	6.7 (4.6)	9.8 (4.8)*	9.0 (3.9)*	9.5 (4.1)*	8.9 (4.3)	9.3 (3.9)	8.9 (3.6)
Segmental Lordosis (°)	17.7 (7.7)	16.9 (9.0)	16.4 (8.3)	16.9 (8.0)	16.9 (8.5)	16.9 (8.5)	15.9 (8.0)
Lumbar Lordosis (°)	48.6 (13.2)	51.0 (9.9)	51.3 (10.6)	50.7 (11.6)	51.6 (11.6)	53.4 (12.7)	54.4 (11.6)
*P<0.05 compared to baseline. Mean (SD).							

Table 3: Radiographic parameters.

Subsidence

The mean difference in ADH from 2 weeks to 12 months is 2.2 ± 2.0 mm. The mean difference in posterior disc height from 2 weeks to 12 months is 1.0 ± 1.4 mm. There was no subsidence reported by 12 month follow-up.

Complications

There were no implant-related complications reported. One iatrogenic L4–L5 non-displaced vertebral fracture was reported at 2 weeks post-operative. No reoperations were needed, and fracture has healed as of the completion of this manuscript.

Discussion

Long-term biomechanical and radiographic outcomes are essential to demonstrate the effectiveness of integrated expandable lateral lumbar interbody spacers in restoring and maintaining disc height and indirect decompression. The benefits of plates and screws include improved biomechanical fixation and higher fusion rates [16]. Recent biomechanical studies have shown that integrated interbody spacers provide more stability in 3 degrees of range of motion: flexion and extension, lateral bending, and axial rotation. Supplemental posterior pedicle screw and rod fixation provided the most stability in range of motion testing. Kornblum et al. [17] reported superior biomechanical stability of integrated lateral lumbar interbody spacers compared to non-integrated spacers. Lateral lumbar interbody spacers with bilateral pedicle screw fixation are the most stable in lateral bending and axial rotation [17]. Louie et al., [18] reported on 25 patients who underwent LLIF with stand-alone interbody spacers for adjacent segment disease following previous lumbar fusion. Functional and radiographic outcomes significantly improved and were maintained up to 18-month follow-up. Clinically, the use of integrated lateral lumbar interbody spacers with posterior supplemental fixation provided similar immediate and durable stability up to 12-month follow-up.

In the current study, indirect decompression is evident given the significant improvement in anterior and posterior disc height. In a recent study, Scherman et al. has shown that increased disc height at 12-month follow-up may lead to good clinical outcomes [19].

Study Limitations

Although this is a single-surgeon, single-site retrospective study without comparison to a cohort, the results are consistent with findings from the literature. According to Obremskey et al. [20], a well-executed orthopaedic study of this nature includes a patient population where a standard treatment protocol is used, a follow-up rate of >80%, and follow-up of patients at specified time-intervals, all of which this study has met. This study forms the foundation for future studies with a higher level of evidence. Comparative studies with larger sample sizes and longer follow-ups are needed to determine effectiveness versus traditional treatment. Further long-term studies with patient reported outcome measures are needed to determine the safety and durability of this technique.

Conclusion

This study showed significant positive radiographic outcomes for patients who underwent MIS LLIF using novel integrated titanium expandable interbody spacers based on significant postoperative changes in intervertebral lordosis and anterior and posterior disc height observed through 12-month follow-up. Segmental and lumbar lordosis was sustained, maintaining sagittal alignment. No subsidence was reported.

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