

Static versus Expandable Interbody Spacers: Preliminary 1-Year Clinical and Radiographic Results

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ABSTRACT

Background

To compare the clinical and radiographic outcomes of static versus expandable interbody spacers following minimally invasive Lateral Lumbar Interbody Fusion (LLIF).

Methods

Sixty-four patients were included in this study: 32 who underwent LLIF with a static spacer, and 32 with an expandable spacer. Supplemental transpedicular posterior fixation was used in all cases. These patients were followed for 12 months post-operative. Clinical and radiographic outcomes were assessed using patients' self-reported forms and radiographs.

Results

Patient age, sex, operative time, blood loss, and length of hospital stay were similar between the static and expandable spacer groups ($p > 0.05$). Mean visual analog scale, Oswestry Disability Index, and RAND-36 Item Health Survey scores improved significantly from preoperative to 12-month follow-up in both groups ($p < 0.05$). Intervertebral disc and neuroforaminal heights increased significantly within each group from preoperative to 12-month follow-up ($p < 0.01$), but were not different between groups ($p > 0.05$). Segmental lordosis increased significantly in the expandable group ($14.0^\circ \pm 7.9^\circ$ preoperatively to $16.4^\circ \pm 8.8^\circ$ at 12 months) ($p = 0.01$) but did not increase significantly in the static group ($p = 0.40$). Spacer subsidence was reported in 32.4% of static and 9.8% of expandable interbody spacer levels ($p < 0.01$).

Conclusion

LLIF using expandable interbody spacers resulted in clinical outcomes similar to those of static spacers; however, the expandable group experienced a significantly greater increase in segmental lordosis and a significantly lower subsidence rate than the static group.

Introduction

The early development of interbody fusion spacers for spinal arthrodesis was first described by Bagby. Technological advancements have seen the development of a variety of interbody spacers over time, ranging from

material used (mesh, titanium, polyetheretherketone, etc.) to insertion methods (open versus minimally invasive) and finally, the ability to expand the spacers insitu. Interbody spacers are designed to provide immediate stability to the operated segment while arthrodesis occurs, correct mechanical deformation, and provide an optimized fusion environment [1-3]. Interbody spacers also aim to increase the neuroforaminal space, restore disc height, and restore lordosis throughout the segment [2]. To date, most clinical studies on interbody fusion have focused on static spacers, which are considered to be the gold standard for the treatment of patients with spinal pathologies. While the use of static spacers has yielded favorable clinical outcomes, iatrogenic endplate damage due to excessive spacer trialing and forceful impaction may lead to complications including spacer migration, subsidence, retropulsion, breakage, and pseudoarthrosis [4-8]. Expandable interbody spacers were designed to address the issues encountered with the use of static spacers. Expandable spacers are inserted at a minimized profile and expanded in situ, offering a more optimized fit between vertebral endplates, controlled height restoration, decreased impaction during insertion, and less trialing in comparison to static spacers. While the number of published clinical studies on the utility of expandable spacers is limited, these publications document excellent patient-reported clinical outcomes, restoration of intervertebral disc height, and high rates of intervertebral fusion [9-12]. To the authors' knowledge, there is only one clinical study to date that examines radiographic outcomes between static and expandable interbody spacers [13]. Due to the scarcity of published data examining outcomes between the two spacers, this study was initiated to investigate and compare the clinical and radiographic outcomes of static versus expandable interbody spacers for minimally invasive Lateral Lumbar Interbody Fusion (LLIF).

Materials and Methods

1. Patient population

This prospective study included a total of 64 patients. Thirty-two patients (41 operative levels) underwent LLIF

with a static interbody spacer (TRANSCONTINENTAL[®], Globus Medical Inc., Audubon, PA), and 32 patients (42 operative levels) with an expandable interbody spacer (RISE[®]-L, Globus Medical, Inc.). All patients demonstrated objective evidence of degenerative disc disease at one or two contiguous level(s) between L2 and S1, with up to grade 1 spondylolisthesis and the absence of previous surgical intervention at the index level(s). All procedures included supplemental posterior fixation, and all patients reached 12-month follow-up. The participating institution received Institutional Review Board approval.

2. Surgical technique

Patients were placed in the lateral decubitus position. A laterally centered oblique incision was made over the involved disc segment. Blunt dissection was performed through the retroperitoneal fat and psoas muscle to access the disc space, and retractors were used. An annulotomy was performed, disc material was removed, and the endplates were decorticated. Sequential trials were used to gradually distract the disc space. An appropriate-size lateral spacer was then selected, packed with appropriate bone graft, and placed within the disc space. If an expandable spacer was used, it was expanded to the desired height and back-filled with additional bone graft. Once positioning of the spacer was verified, the retractor was removed (Figures 1 and 2). The expandable interbody spacer used in this study is manufactured from titanium alloy with an internal component made from radiolucent polymer. This spacer was inserted at a contracted height and expanded in situ once correctly positioned within the intervertebral space (Figure 3). The static interbody spacer is manufactured from radiolucent polymer with titanium alloy or tantalum markers, and included a self-distracting leading edge for implant insertion (Figure 4). Both spacers were available in various heights and geometric options to fit the anatomical needs of a variety of patients.

3. Outcome measures

Demographic and perioperative data such as patient age, sex, operative time, blood loss, and length of hospital stay were recorded. Self-reported patient

questionnaires, including the Visual Analog Scale (VAS), Oswestry Disability Index (ODI), and RAND36-Item Health Survey (RAND-36) scores, were collected preoperatively, and postoperatively at 6 weeks and 3, 6, and 12 months. Radiographic outcomes including intervertebral disc height, neuroforaminal height, and segmental lordosis were evaluated preoperatively and postoperatively at all time points. Intervertebral disc height was measured on lateral x-rays from the center of the operative superior endplate to a corresponding point on the inferior endplate. 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 the superior endplate of the cephalad vertebral body to the inferior endplate of the caudal vertebral body. The incidence of implant subsidence was also recorded and defined as a reduction of intervertebral disc height greater than 2mm in comparison to six-week postoperative measurements.

4. Statistical analysis

Statistical analysis was performed using SPSS® v20.0.0 software for Windows (IBM Corp., Armonk, New York, USA). Descriptive statistics are reported as mean and standard deviation, ratio, or frequency and percentage where applicable. Changes from preoperative to postoperative time intervals were assessed using the Wilcoxon signed-rank test for ordinal variables, or a paired sample t-test for interval variables. The Wilcoxon Mann-Whitney test for ordinal variables and the independent samples t-test for interval variables were used for comparison between groups. Furthermore, a Chi-square test was performed to assess differences in categorical variables between groups. Statistical significance was indicated at $P < 0.05$.

Results

A total of 64 patients, treated between May 2014 and February 2016, were enrolled in this study at a single site. The mean spacer height used in the static group was 11mm with either 6° or 10° of lordosis; mean initial spacer height used in the expandable group was 8mm, expanding up to a maximum of 15mm, with 6° of

lordosis. Patient age, sex, number of levels treated, operative time, blood loss, and length of hospital stay were similar between the static and expandable spacer groups ($p > 0.05$) (Table 1). Surgery was most common at L4-L5 among one-level patients and at L2-L4 among two-level patients. Mean VAS back pain scores in the static group improved significantly from 7.4 ± 1.8 preoperatively to 2.2 ± 2.6 at 12months postoperatively, and also in the expandable group from 6.7 ± 2.2 to 2.1 ± 2.6 ($p < 0.01$) (Figure 5). Similarly, mean VAS leg pain scores in the static group improved significantly from 6.9 ± 2.6 preoperatively to 2.1 ± 2.5 at 12months postoperatively, and also in the expandable group from 6.3 ± 2.6 to 1.9 ± 2.4 ($p < 0.01$) (Figure 6). ODI scores improved significantly from 50.5 ± 19.2 preoperatively to 20.6 ± 19.7 at 12months postoperatively in the static group, and from 41.6 ± 14.1 to 19.0 ± 15.7 in the expandable group ($p < 0.01$) (Figure 7). Finally, RAND-36 physical component summary scores improved significantly from 26.1 ± 15.1 preoperatively to 58.4 ± 26.8 at 12months postoperatively in the static group, and from 32.5 ± 12.6 to 70.0 ± 22.9 in the expandable group ($p < 0.01$) (Figure 8); mental component summary scores also improved significantly from 42.1 ± 22.8 preoperatively to 65.2 ± 26.1 at 12months postoperatively in the static group, and from 48.2 ± 21.7 to 71.1 ± 24.2 in the expandable group ($p < 0.01$) (Figure 8). Pre- and postoperative VAS, ODI, and RAND-36 scores across time intervals showed no significant differences between groups, except for postoperative VAS leg pain at 3 months ($p = 0.04$) and the preoperative RAND-36 physical component score ($p = 0.01$) in both groups. Intervertebral disc and neuroforaminal heights increased significantly for each group from the preoperative time interval to as early as 6weeks postoperative, and increases were maintained through 12-month follow-up (Tables 2 and 3). Intervertebral disc height was statistically different between the static and expandable groups preoperatively (8.8 ± 2.8 mm versus 7.1 ± 2.2 mm, $P < 0.01$), but at no other time interval. Similarly, neuroforaminal height was statistically greater in the

static versus the expandable group preoperatively ($20.1 \pm 4.1\text{mm}$ versus $18.0 \pm 4.2\text{mm}$, $P=0.02$) as well as at 12months ($22.3 \pm 3.8\text{mm}$ versus $20.4 \pm 4.6\text{mm}$, $P=0.04$). Segmental lordosis (Table 4) increased significantly from preoperative to 12months postoperative in the expandable group ($p=0.01$), but did not increase significantly in the static group ($p=0.40$). Spacer subsidence was significantly greater in the static group (32.4%) in comparison to the expandable group (9.8%) ($p=0.01$) (Table 5). All cases of spacer subsidence were asymptomatic and none required revision surgery. No other implant-related complications were reported.

Table 1: Demographic and Operative Data

	Static Group (n=32)	Expandable Group (n=32)	P-value
Age, years*	66.3 ± 8.9	67.7 ± 10.0	0.55
Sex, M:F	10:22	14:18	0.32
Number of Levels			0.78
1 Level	23 (71.9%)	22 (68.8%)	
2 Levels	9 (28.1%)	10 (31.2%)	
Operative Time, min*	70.4 ± 38.1	77.7 ± 45.7	0.49
Blood Loss, cc*	52.3 ± 85.9	45.8 ± 54.1	0.72
Hospital Stay, days*	2.2 ± 1.4	2.3 ± 1.2	0.78

Note: *Mean \pm standard deviation

Table 2: Disc Height (mm)

	Static Group	Expandable Group	P-Value
Preoperative	8.8 ± 2.8	7.1 ± 2.2	0.00
6 weeks	13.4 ± 2.4	13.1 ± 2.7	0.65
3 months	12.9 ± 2.7	12.6 ± 3.0	0.70
6 months	12.9 ± 2.6	11.8 ± 2.7	0.72
12 months	12.6 ± 2.9	12.5 ± 2.7	0.90
P-Value (preoperative to 12 months)	0.00	0.00	

Values are mean \pm SD

Table 3: Neuroformainal Height (mm)

	Static Group	Expandable Group	P-Value
Preoperative	20.1 ± 4.1	18.0 ± 4.2	0.02
6 weeks	22.6 ± 4.1	21.8 ± 4.6	0.40
3 months	22.4 ± 3.8	21.0 ± 3.9	0.11
6 months	21.9 ± 4.1	21.5 ± 3.6	0.60
12 months	22.3 ± 3.8	20.4 ± 4.6	0.04
P-Value (preoperative to 12 months)	0.00	0.02	

Values are mean \pm SD

Table 4: Segmental Lordosis (degrees)

	Static Group	Expandable Group	P-Value
Preoperative	14.9 ± 8.5	14.0 ± 7.9	0.60
6 weeks	15.1 ± 8.1	15.8 ± 8.3	0.70
3 months	14.8 ± 8.6	15.5 ± 8.8	0.74
6 months	14.8 ± 8.2	15.7 ± 8.6	0.63
12 months	14.2 ± 8.5	16.4 ± 8.8	0.26
P-Value (preoperative to 12 months)	0.40	0.01	

Values are mean \pm SD

Table 5: Subsidence

	Static Group	Expandable Group	P-Value
12 months	12/37 (32.4%)	4/41 (9.8%)	0.01

Discussion

Since the advent of the first interbody fusion spacer for lumbar arthrodesis, a large number of interbody spacers have continued to evolve and become available on the market. The goal of interbody fusion is to provide immediate stability to the operated segment while arthrodesis occurs. Static interbody spacers have historically been used in conjunction with anterior, posterior, transforaminal, and lateral lumbar interbody fusion procedures, and have produced favorable clinical outcomes [14-18]. However, complications such as subsidence and migration have been reported [4-8]. Expandable interbody spacers have been designed to mitigate the challenges associated with the use of static spacers. Clinical studies comparing outcomes between static and expandable interbody spacers are scarce; the authors therefore sought to compare clinical and radiographic outcomes between static and expandable spacers following lateral lumbar interbody fusion. While clinical outcomes were similar, there were differences observed in segmental lordosis and subsidence rates between the groups. Segmental lordosis increased significantly from the preoperative time interval to 12-month follow-up in the expandable group, but not in the static group, despite all spacers implanted having either 6 or 10 degrees of lordosis. One possible explanation for this observed difference may be the amount of trialing that a static spacer requires in comparison to an expandable spacer. Due to the repeated trialing necessary for a static spacer, iatrogenic endplate damage may occur [19], which may limit the amount of

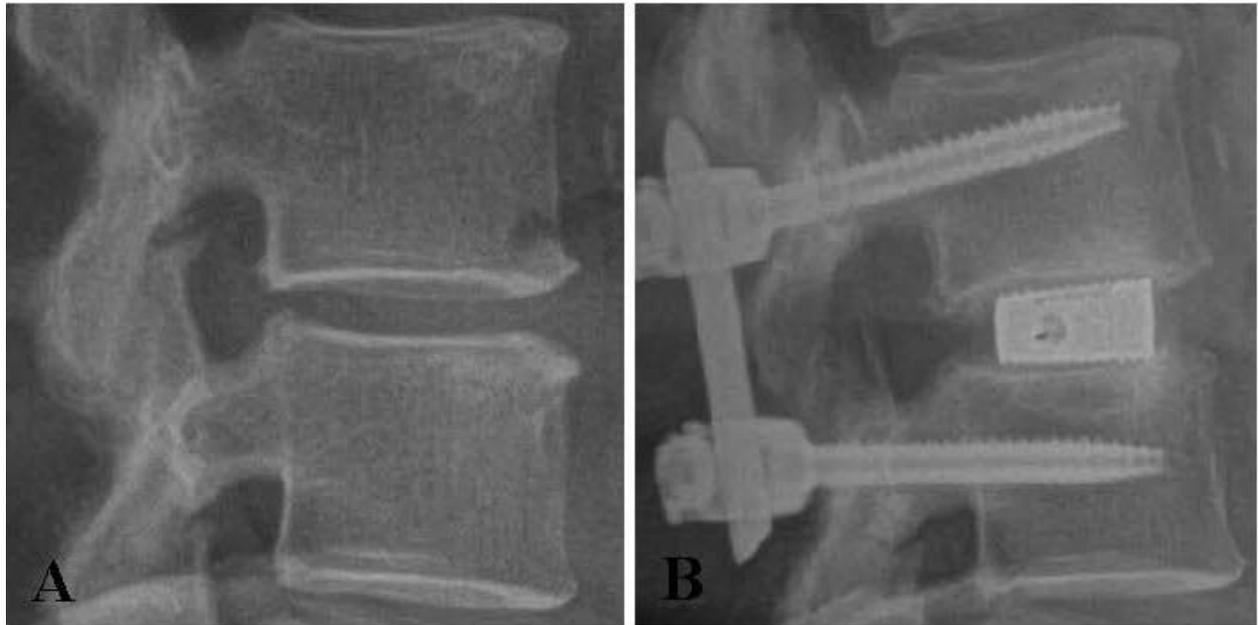


Figure 1: Representative (A) preoperative and (B) 12-month postoperative lateral plain film radiographic images of a 64-year-old female who underwent LLIF with an expandable interbody spacer at L4-L5.

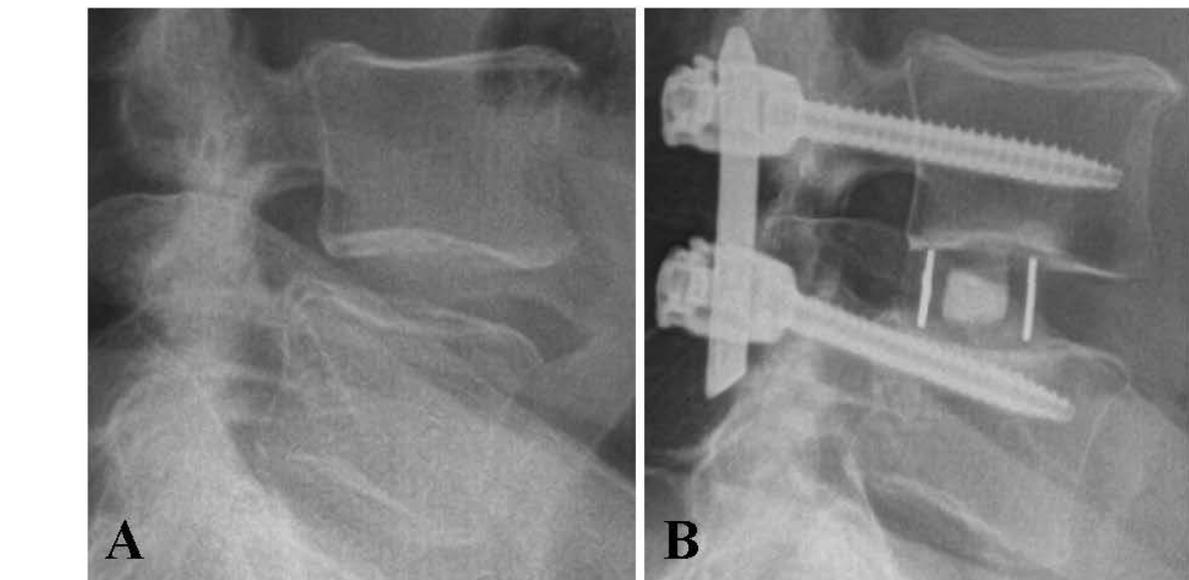


Figure 2: Representative (A) preoperative and (B) 12-month postoperative lateral plain film radiographic images of a 67-year-old female who underwent LLIF with a static interbody spacer at L3-L4.

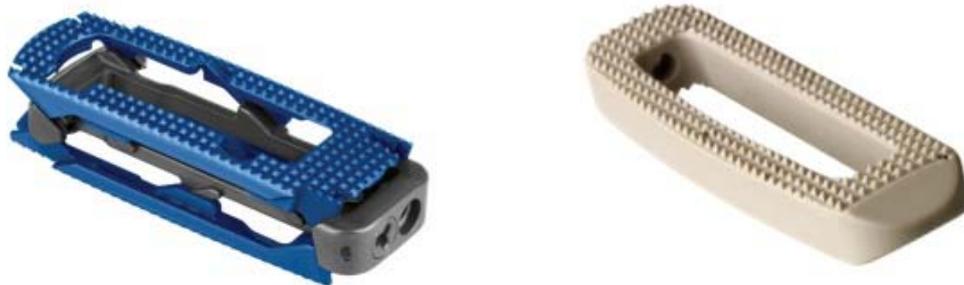


Figure 3: Representative (A) Oblique view of the expandable interbody spacer (RISE®-L) used in the current study. The implant is shown in its expanded state. And (B) Oblique view of the static interbody spacer (TransContinental®).

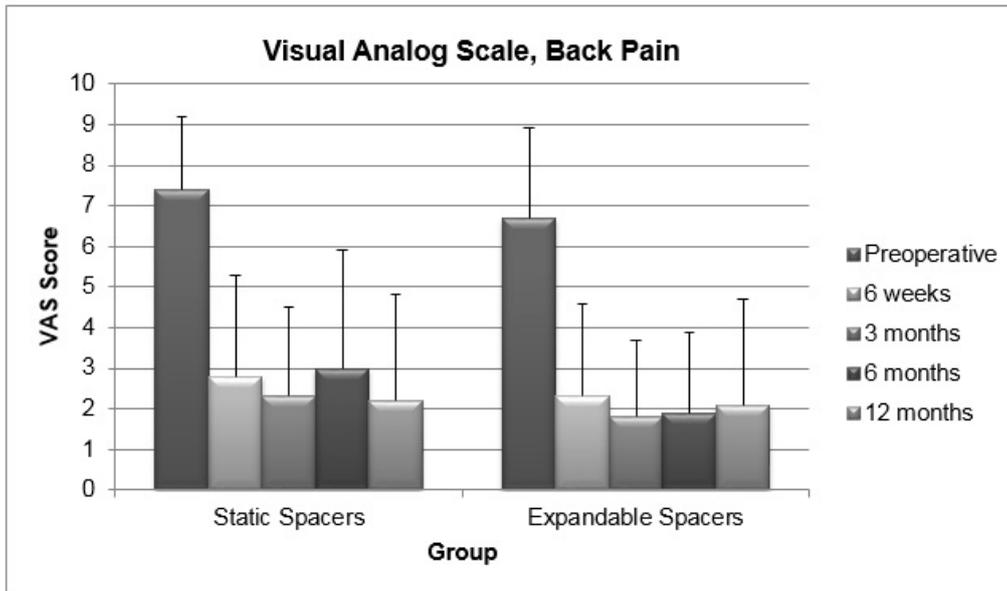


Figure 4: VAS back pain scores for static versus expandable groups from preoperative to 12-month postoperative assessment (bar height indicates mean value and error bars \pm one standard deviation).

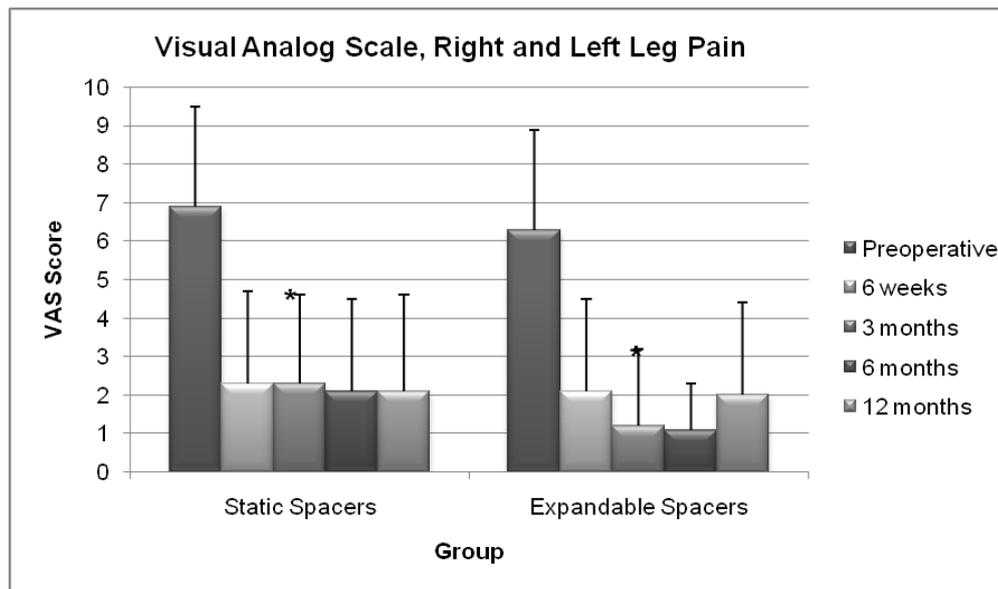


Figure 5: VAS leg pain scores for static versus expandable groups from preoperative to 12-month postoperative assessment (bar height indicates mean value and error bars \pm one standard deviation).

*Indicates statistical difference between groups at the indicated time interval ($p < 0.05$).

lordosis gained at the operated segment. Expandable spacers require less trialing and therefore endplate integrity may be better preserved, which may result in the desired lordosis. Posterior fixation provides the stability to help maintain lordosis over time. The current study's findings are consistent with other studies [20,21], that report a greater increase in segmental lordosis with expandable spacers when compared to static spacers. However, Yee et al. [13] found that irrespective of

spacer type, patients experienced similar increases in segmental lordosis.

Conclusion

This study found a significantly greater rate of subsidence in the static group in comparison to the expandable group. Subsidence of an interbody spacer is a clinical concern due to an increased risk of recurrence of symptoms, loss of disc height and indirect

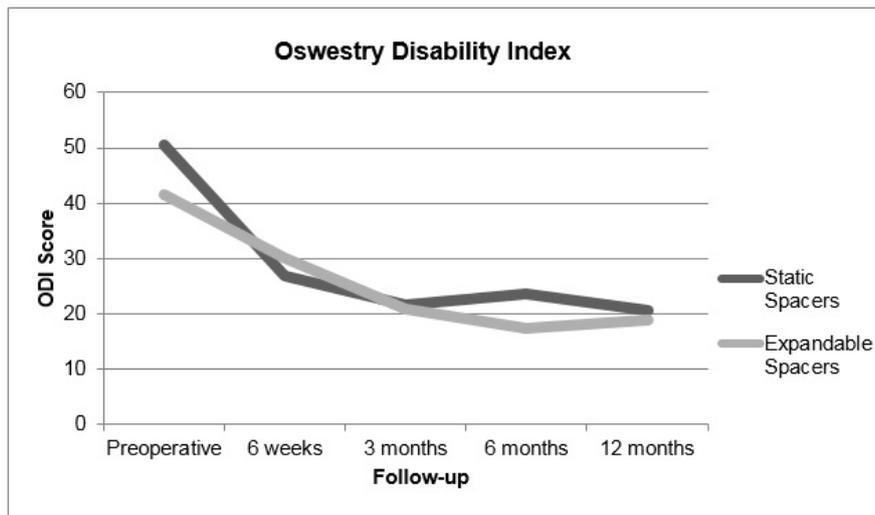


Figure 6: ODI scores for both patient groups from preoperative through 12-month postoperative assessment.

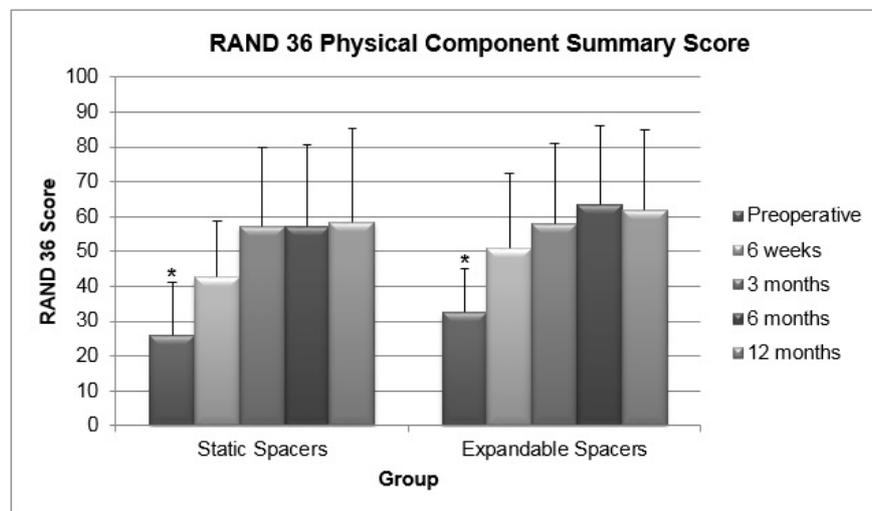


Figure 7: RAND-36 Physical Component Scores for static versus expandable groups from preoperative to 12-month postoperative assessment (bar height indicates mean value and error bars \pm one standard deviation). *Indicates statistical difference between groups at the indicated time interval ($p < 0.05$).

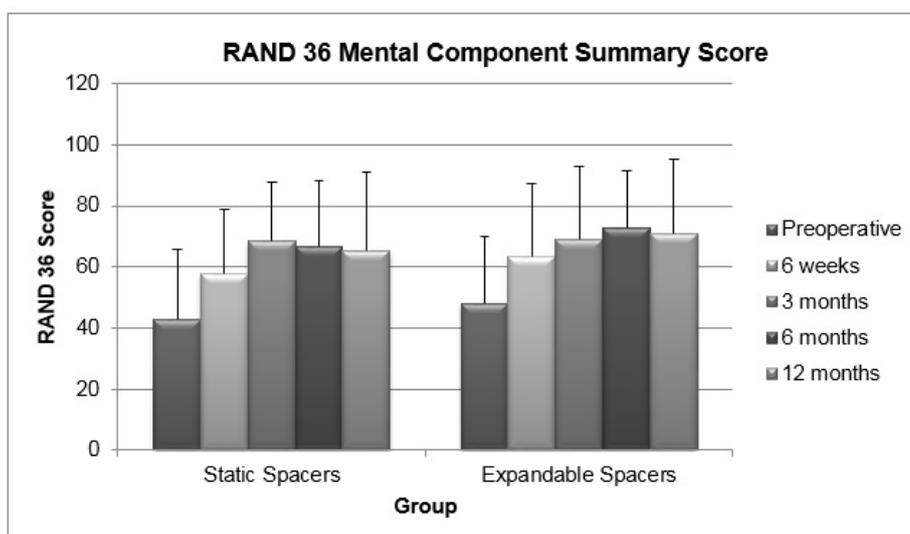


Figure 8: RAND-36 Mental Component Score for static versus expandable groups from preoperative to 12-month postoperative assessment (bar height indicates mean value and error bars \pm one standard deviation).

neural decompression, the need for revision surgery, and pseudoarthrosis [19,22,23]. Risk factors believed to be associated with spacer subsidence include use of a narrow spacer, over-distraction of the intervertebral space, and lack of supplemental fixation [9,23-25]. Most researchers, however, agree that the preservation of endplate integrity is key to preventing subsidence. During discectomy, care should be taken to adequately prepare the endplates [26]; however, iatrogenic endplate damage can occur when a static spacer is impacted into the disc space, which may lead to subsidence. In contrast, an expandable spacer only requires a single trial and implant, which reduces the possibility of endplate damage during implant insertion. While the rate of subsidence was significantly greater in the static group in comparison to the expandable group in this study (32.4% vs 9.8%), all cases were asymptomatic and none required revision surgery. Follow-up will continue through the 24-month time interval for continued evaluation of patient outcomes. One limitation of this study was the absence of Computed Tomography (CT) scans for the assessment of fusion. Because no patient required revision surgery at the index level(s) and CT scans are not routinely performed as part of the follow-up plan, CT scans were not obtained for the patients in this study. Another limitation of this study was the short-term (12-month) follow-up period. However, this study is part of a larger 24-month follow-up prospective study, and new findings will be reported upon completion. Although results in this study are preliminary, they suggest that the use of both static and expandable interbody spacers in LLIF lead to improvements in patient pain and disability, and an increase in disc and neuroforaminal heights. The results also suggest that expandable interbody spacers may offer important clinical advantages in terms of decreased endplate damage, which may lead to an increase and maintenance in segmental lordosis, as well as a decreased risk of subsidence.

Conflict of Interest

Dr. Frisch is a consultant for and receives royalties from Globus Medical Inc. IYL and GJ are salaried employees

of Globus Medical Inc. IYL performed statistical analysis. All authors participated in conception and design of the study, acquisition and interpretation of data, and the drafting of the article or revising it critically. All authors approved the final manuscript for submission for publication.

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