



Static versus Expandable Interbody Spacers: Final 2-Year Clinical and Radiographic Results

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Abstract

Background: Lateral Lumbar Interbody Fusion (LLIF) procedures using large interbody static spacers may require excessive trialing and forceful impaction, leading to iatrogenic endplate disruption, excessive neural retraction, and implant subsidence. The *in situ* expansion capability offered by expandable interbody spacers facilitates insertion to help reduce endplate damage and optimize endplate contact.

Objective: This study reported radiographic and clinical outcomes of static and expandable interbody spacers following LLIF.

Methods: This study included 64 patients with degenerative disc disease who underwent LLIF at 1 to 2 contiguous level(s) using a polyether-ether-ketone static or titanium expandable intervertebral spacer. Half (32) of the patients were treated with static spacers, and half (32) with expandable spacers. All spacers were supplemented by posterior screw and rod stabilization.

Results: Mean VAS pain and ODI, and RAND 36 scores improved significantly ($p < 0.05$) at 24-month follow-up. Patients treated with expandable implants were found to have significantly lower scores for VAS back and leg pain and ODI at 24-month follow-up compared to static implants. Intervertebral disc height increased significantly ($p < 0.05$) from baseline for expandable and static groups at each follow-up through 24 months. At 12-month follow-up the static group had significantly higher subsidence rates. No new subsidence cases developed between 12-month and 24-month follow-up.

Conclusion: In this cohort, clinical use of expandable interbody spacers resulted in better outcomes through 24-month follow-up compared to static interbody spacers, with the expandable group showing significantly greater improvements in pain and disability than the static group at 24 months.

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Introduction

Lumbar interbody fusion has been shown to result in superior pain relief and greater stability than nonoperative treatment over time [1,2]. Approaches to the spine anteriorly, posteriorly, and transforaminal are each associated with their own complications profiles [3]. Lateral Lumbar Interbody Fusion (LLIF) was developed as a technique to address a number of potential complications and difficulties inherent to other surgical approaches to the disc space [4]. A lateral approach allows for a large interbody spacer to be placed across the most structurally stable region of the vertebral body [5].

Expandable interbody spacers have been developed to reduce impaction force and optimize intervertebral fixation and maintenance of sagittal correction until fusion occurs [6]. The merging of these surgical approach and implant developments have produced an expandable interbody spacer that can be implanted through a lateral transpoas approach.

This 24-month follow-up study is a continuation of a previous 12-month study report [7] comparing the clinical and radiographic outcomes of static versus expandable interbody spacers for minimally invasive LLIF.

Material and Methods

Patient population

The current report describes outcomes of 64 patients previously described in a 12-month follow-up study [7]. This nonrandomized, prospective study consists of data collected on patients who

Table 1: Clinical outcomes data for static and expandable cohorts.

	Static						Expandable					
	Preop			24 months			Preop			24 months		
	n	\bar{X}	s	n	\bar{X}	s	n	\bar{X}	s	n	\bar{X}	s
VAS Back	31	7.4	1.8	22	1.3	1.7	29	6.7	2.2	16	1.3	1.7
VAS Leg	31	6.9	2.6	22	4.1	3.6	30	6.3	2.6	16	1.6	2.4
ODI	32	50.5	19.2	21	31.1	20	31	41.6	14.1	14	13.8	14.2
MCS	27	42.1	22.8	23	56.5	23.8	32	48.2	21.8	17	72.6	24.4
PCS	26	26.1	15.1	24	46.1	25	32	32.5	12.6	17	57.5	24.7

have undergone LLIF. Inclusion criteria comprised a diagnosis of Degenerative Disc Disease (DDD) with up to grade 1 spondylolisthesis at two consecutive levels between L2 and L5 without any prior surgical intervention at the intended level. Patients were either instrumented with a static polyether-ether-ketone interbody spacer (TRANSCONTINENTAL[®], Globus Medical, Inc., Audubon, PA), or an expandable titanium interbody spacer (RISE-L[®], Globus Medical, Inc.) (Figure 1). All patients received supplemental posterior fixation using pedicle screws and rods. Institutional review board approval was acquired prior to data collection, and all patients completed informed consent prior to enrollment in the study.

Surgical technique

This technique was previously described in a paper by the same lead author [7]. A direct lateral retroperitoneal transpsoas approach was used to visualize the intervertebral disc space. An annulotomy was performed, and the appropriate spacer size was determined through trialing of the disc space. An interbody spacer packed with bone graft was inserted. If an expandable interbody spacer was used, it was inserted at a contracted height and was expanded *in situ* in accordance with surgeon discretion. Both static and expandable interbody spacers were available in various heights and geometric options to fit the anatomical needs of the patient.

Outcome measures

Data including patient reported pain and functional outcomes, radiographic imaging, and patient demographics were collected prospectively. Specifically, patient age, sex, operative time, blood loss, and length of hospital stay were included as demographic data. Patient-reported outcomes included Visual Analog Scale (VAS) back and leg pain, Oswestry Disability Index (ODI), and RAND 36-item Health Survey (RAND36) scores, and these were collected at preoperative, 6-week, and 3-, 6-, 12-, and 24-month follow-up. Anterior-posterior and lateral radiographs were collected at the same time points. Radiographs were collectively assessed by two orthopedic spine surgeons and a consensus was reached on fusion status, as defined by the presence of bridging bone and fusion mass on anterior-posterior and lateral views. Using plain film radiographs, disc height, neuroforaminal height, and segmental lordosis were measured. Disc height was measured using lateral images, from the center of the endplate of the superior vertebra, perpendicularly to the endplate of the inferior level. Neuroforaminal height was measured from the inferior pedicle wall of the cephalad level to the superior pedicle wall of the caudal level. Segmental lordosis was measured by the superior endplate of the superior vertebra, and the inferior endplate of the inferior vertebra of the segment. Implant subsidence was determined by consensus of two spinal surgeons, and was defined as endplate violation leading to at least 2 mm of disc height loss.

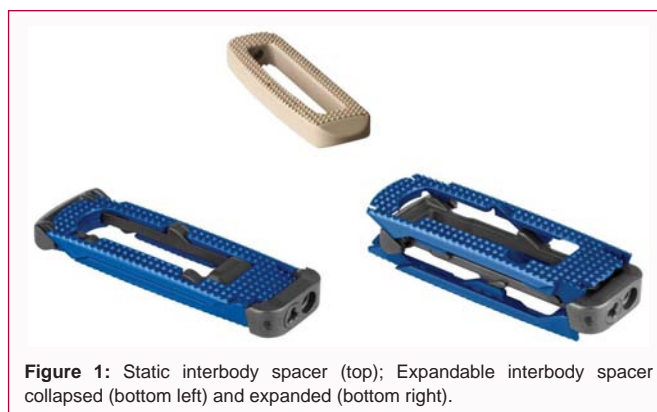


Figure 1: Static interbody spacer (top); Expandable interbody spacer collapsed (bottom left) and expanded (bottom right).

Statistical analysis

Paired sample t-tests were used to compare patient outcomes including VAS, ODI, RAND 36 scores, and radiographic outcomes over time. Demographic data were reported as mean and standard deviation, or frequency or percentage for categorical data. Statistical analysis was performed using SPSS[®] v20.0.0 software for Windows (IBM Corp., Armonk, NY). And independent sample t-test was used to compare quantitative data between study groups. Statistical significance was defined as a $p < 0.05$.

Results

The average age of all patients was 67.1 (± 9.4) years. Women made up 62.5% of the patients in this study. At the 24-month follow-up time point, 64.6% (42/64) of patients returned, though not all patients completed all measures (Table 1). No significant differences were observed between the static and expandable groups in operative time, with an average of 70.4 (± 38.1) minutes for surgeries using static interbody spacers and 77.7 (± 45.7) minutes for surgeries using expandable interbody spacers. Average estimated blood loss was 52.3 (± 85.9) cc and 45.8 (± 54.1) cc, respectively. Length of hospital stay averaged 2.2 (± 1.4) days and 2.3 (± 1.2) days, respectively. No significant difference ($p < 0.05$) was observed between groups for either blood loss or length of stay.

Mean VAS lower back (Figure 2) and leg (Figure 3) pain and ODI scores (Figure 4) improved significantly ($p < 0.05$) from preoperative scores through 24-month follow-up. Patients treated with expandable implants were found to have significantly ($p < 0.05$) lower scores for VAS back pain (Table 1). A significant difference ($p < 0.05$) in mean VAS leg pain scores between treatment groups was observed. Average ODI scores at 24-month follow-up were significantly lower ($p < 0.05$) for patients treated with expandable implants compared to those treated with static implants. Patients treated with expandable interbody spacers had significantly improved self-reported clinical

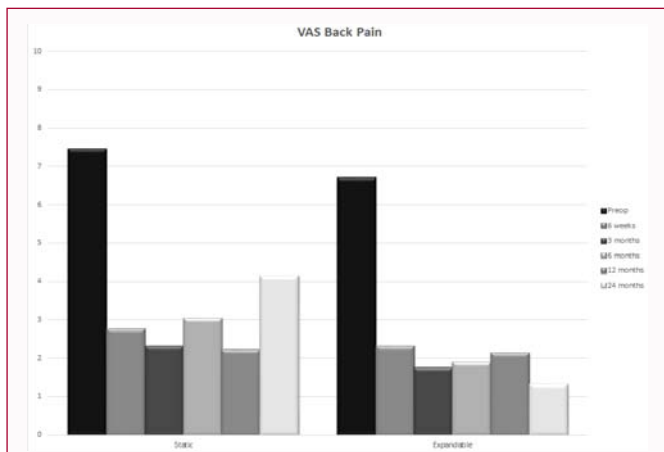


Figure 2: VAS back pain average scores over time for static and expandable treatment groups. Visual Analog Scale (VAS).

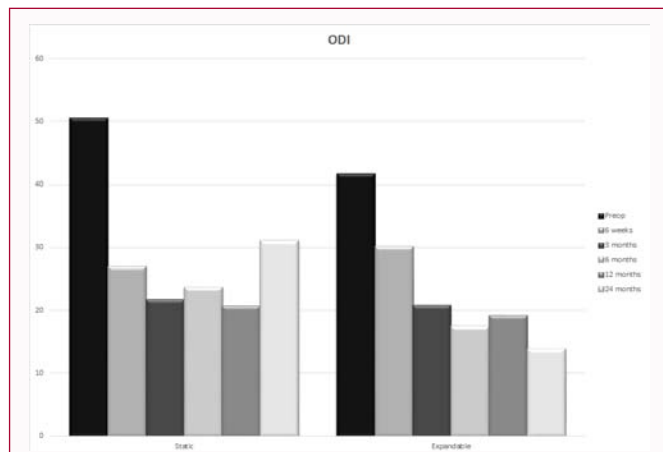


Figure 4: ODI average scores over time for static and expandable treatment groups. Oswestry Disability Index (ODI).

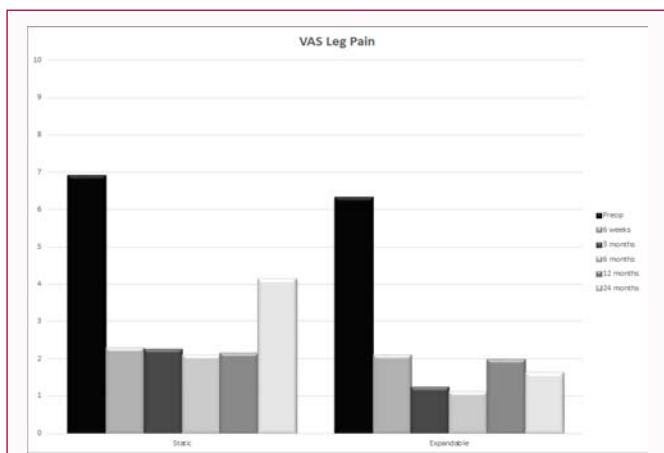


Figure 3: VAS leg pain average scores over time for static and expandable treatment groups. Visual Analog Scale (VAS).

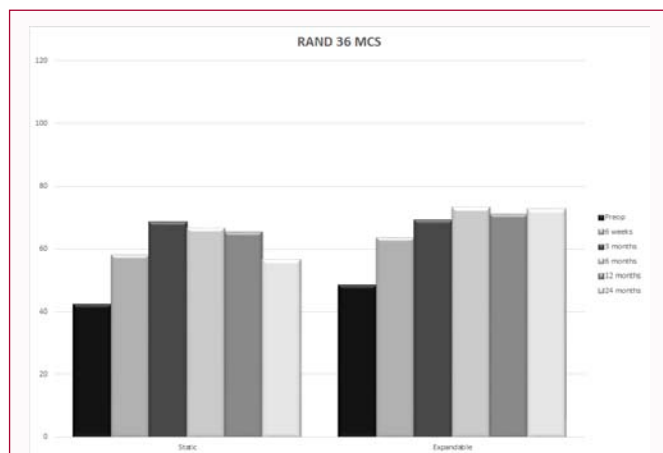


Figure 5: RAND 36 MCS average scores over time for static and expandable treatment groups. Mental Component Summary (MCS).

outcomes compared to those treated with static interbody spacers. Both groups’ mean self-reported clinical outcomes significantly improved from baseline to 24-month follow-up.

The static interbody group had an average Mental Component Summary (MCS) score of 56.5 (± 23.8) compared to the expandable interbody group which had an average MCS score of 72.6 (± 24.4) (Figure 5). The static interbody group had an average physical component summary (PCS) score of 46.1 (± 24.9) compared to expandable interbody group which had an average PCS score of 57.5 (± 24.7) (Figure 6). Patients in the expandable group had a significantly higher MCS score, although PCS scores were not significantly different (p=0.156) at 24-month follow-up.

Intervertebral disc height increased significantly (p<0.05) from baseline for both expandable and static groups at each follow-up through 24 months. At 12-month follow-up, the static group had significantly higher subsidence rates. No new cases of subsidence developed between 12- and 24-month follow-up.

Discussion

Long-term follow-up comparing static and expandable interbody spacers is needed to determine their effectiveness and advantages in improving patient outcomes. This study provides evidence that patients treated with expandable interbody spacers have significantly lower pain scores and lower disability scores than those treated with

static spacers. Compared with a previous report on the same cohort of patients at 12-month follow-up, these clinical outcomes are shown to be durable through 24-month follow-up.

Similar results were reported by Massie et al. [8] using an expandable interbody spacer, as patient ODI scores were reduced from baseline to 32.5 ± 20.4 at 24-month follow-up. In the same study, back pain was reduced to an average score of 5.1 ± 4.2, and leg pain was reduced to 4.4 ± 3.6. These results are comparable to the current study, in that they show a significant reduction of symptoms through the use of expandable interbody spacers. A study by Ozgur et al. [9] reported outcomes similar to those reported in this study on patients treated with static implants. Patients treated with expandable implants in the current study improved to a greater degree than those treated with static spacers at 24-month follow-up.

A comprehensive review of the literature by Joseph et al. [10] in 2015 found a subsidence rate of 10.84% in 1,900 patients. Within this review, prior studies reported subsidence rates varying from 0.3% to 77% [11,12]. The current study reports a subsidence rate of 3 out of 28 expandable implants, or 10.7%, compared to 6 out of 26 static implants, or 23.1% of levels. No new instances of subsidence were observed between 12- and 24-month follow-up.

The limitations of this study include a small number of patients and loss to follow-up of patients in both arms of the study at 2 years.

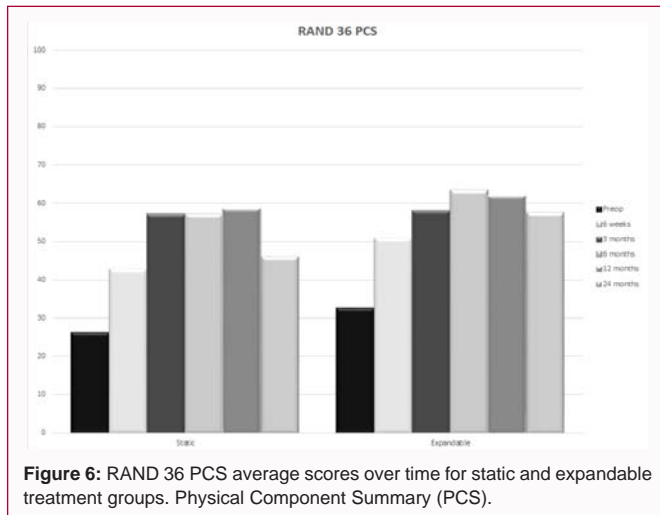


Figure 6: RAND 36 PCS average scores over time for static and expandable treatment groups. Physical Component Summary (PCS).

However, the final number of patients did not impact the ability to perform statistical analysis to determine significance. This study was not randomized, but patients were enrolled consecutively and data were prospectively collected, strengthening the conclusions.

Conclusion

Patients who underwent LLIF using expandable interbody spacers had significantly lower VAS back and leg pain scores, lower ODI disability scores, and lower subsidence rates than patients treated with static interbody spacers. Results were maintained at 24-month follow-up from a 12-month follow-up report.

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