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Research Article

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Expandable Interbody Spacers Implanted Through a Lateral Approach: A Multicenter Observational Study at Two Years

Dan S Cohen[1], Richard Frisch[2], Joseph O'Brien[3], William Tally[4], Thomas K Lee[5] and Torrey Shirk[6]*

Abstract

Introduction: Evidence surrounding use of expandable interbody devices during lateral lumbar interbody fusion (LLIF) has been sparse. While all LLIF devices purport to offer advantages such as avoidance of great vessels anteriorly and the spinal cord posteriorly, sufficient consensus among data for expandable devices is lacking, particularly among multiple surgeons who may have varied surgical correction goals with these devices.

Objective: This study sought to describe outcomes of patients treated with expandable interbody spacers implanted through an LLIF approach.

Methods: The current study's patients were consecutively enrolled/treated with one of two expandable interbody spacer designs by five surgeons at five sites, using a conventional transpsoas approach. Visual Analog Scale (VAS) back/leg pain scores, Oswestry Disability Index (ODI), and plain film radiographs were collected. Patients completed self-reported outcomes preoperatively and at 6, 12 weeks, 6, 12, and 24 months postoperative.

Results: A total of 79 patients were enrolled across five study sites. Average age at time of surgery was 63 years (Range 33–81). Average VAS lower back pain scores decreased significantly ($p<0.001$) from 6.7 (± 2.3) preoperatively to 2.9 (± 3.3) at 12 months and 2.9 (± 3.3) at 24 months. Average VAS leg pain scores decreased significantly ($p<0.001$) from 5.6 (± 2.8) preoperatively to 2.3 (± 2.6) at 12 months and 2.5 (± 2.9) at 24 months. Average ODI scores decreased significantly ($p<0.001$) from 45.9 (± 15.7) preoperatively to 25.0 (± 23.3) at 12 months and 26.2 (± 23.3) at 24 months. Disc height increased significantly ($p<0.001$) from 7.7 (± 2.6) preoperatively to 12.1 (± 2.8) at 12 months and 11.5 (± 2.4) at 24 months. There was no significant difference ($p=0.091$) in disc height between 12 and 24 months, suggesting a maintenance of disc height during this period.

Conclusions: This multicenter, multi-surgeon study of two expandable lumbar interbody spacer designs demonstrates positive clinical and radiographic outcomes at 2 years.

Introduction

The lateral approach to the disc space for lumbar interbody fusion is relatively new but has become a well-established practice for many spine surgeons [1-3]. Its benefits include the lower risk to vital anatomy, specifically the great vessels anteriorly, and avoidance of the thecal sac and posterior neurological structures, particularly useful in the case of prior laminectomy [4]. The lateral approach also allows for maintenance of important structural anatomy, specifically the anterior and posterior longitudinal ligaments and the facets. Laterally placed implants benefit from placement across the apophyseal ring of the vertebral body, and larger implant footprints, which impart more structural stability than grafts placed on a localized central endplate [5]. Lastly, direct visualization of a prominent amount of disc space is possible, with extensive endplate preparation, all completed with the typical advantages of minimally invasive techniques including reduced blood loss, length of stay, infection rate, and destruction/denervation of posterior stabilizers [1,6-8].

Expandable interbody spacers are also a relatively new innovation that have become established in spine surgery [9-11]. The design of expandable interbody spacers provides a number of benefits in surgery. The lower initial height of an expandable interbody spacer while the implant is collapsed enables it to avoid constraints imposed by the patient's anatomy. This may be particularly useful in patients with severely collapsed disc spaces. Further, when compared to equivalent final-height static implants, an expandable interbody spacer requires less impaction force into the disc space [12]. Once placed within the disc space, expandable interbody spacers can be expanded to a height comparable with static spacers. *In situ* expansion may also allow for greater height, as the expansion is not limited by the initial reduced height of the disc space [13]. Finally, continuous expansion allows for variable final heights rather than being constrained by discrete implant height increments in most static interbody spacer product lines.

While a number of studies have documented expandable devices, which are used through a posterior or TLIF approach [9-11,14,15], few studies have examined the longitudinal performance of these implants through the retroperitoneal transpsoas approach. Due to surgeon preference and training, an unbiased controlled study between expandable and static techniques is not possible, yet the currently available literature on single-cohort expandable LLIFs has been limited to single institutions. The purpose of this study is to combine multi-site user experiences with two expandable LLIF configurations and assess the clinical and radiographic outcomes.

Methods

Device Descriptions

Two interbody spacers of different designs were used in this study. The CALIBER®-L (Globus Medical, Inc., Audubon, PA) interbody spacer, a first-generation expandable spacer consists of a titanium body and polyether ether ketone endplates. The RISE®-L interbody spacer (Globus Medical, Inc.), a second-generation expandable spacer, consists of a titanium body and titanium endplates. Both interbody spacers are similarly indicated for use in patients with degenerative disc disease at one or two contiguous levels of the lumbosacral

***Corresponding author:** Torrey Shirk, Musculoskeletal Education and Research Center (MERC), A Division of Globus Medical, Inc., 2560 General Armistead Avenue, Audubon, PA 19403, USA, Tel:6109301800; E-mail: tshirk@globusmedical.com

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spine, and these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Supplemental fixation is required.

Surgical Technique

Despite their differing designs, surgical techniques for interbody spacer placement were essentially identical for the two implants. Patients undergoing lateral lumbar interbody fusion (LLIF) were placed in the lateral decubitus position and secured to the table with surgical tape. Using fluoroscopy, the incision site was marked on the skin at the involved disc segment and the incision was made. Using blunt dissection, access to the disc space was obtained through the retroperitoneal fat and psoas muscle. A retractor was placed and secured. An annulotomy was performed and the endplates were decorticated to expose bleeding bone. Trials were used to determine the appropriate implant size. The implant was inserted into the disc space, and its positioning was confirmed using fluoroscopy. The implant was then subsequently expanded using the integrated inserter/expansion mechanism. Implant height was then confirmed using fluoroscopy. Once the implant was correctly placed, the surgeon removed the implant inserter and closed up the incision in the normal fashion. Pedicle screws and rods were then placed through a posterior approach, either on the same day or in a next-day procedure, depending on surgeon preference.

Data Collection

The current analysis was performed on data collected by five surgeons at five locations. Institutional Review Board approval was obtained before data collection and prospective enrollment. Patients were enrolled consecutively and preoperative data were collected at time of enrollment. Intraoperative data were collected at time of surgery, and length of stay was collected at discharge. Postoperative data were collected at 6 and 12 weeks, 6, 12, and 24 months. patients completed self-reported outcomes including the Visual Analog Scale (VAS) for back and leg pain, and the Oswestry Disability Index (ODI) at preoperative and postoperative time points. ODI scores are presented as percentages, out of 100. Plain film radiographs were collected preoperatively and at each postoperative follow-up time point. Disc height, neuroforaminal height, and segmental lordosis were measured from plain film radiographs.

Statistical Analysis

Statistical analysis was performed using SPSS® v20.0.0 software for Windows (IBM Corp., Armonk, NY). Means of age, operative time, length of hospital stay, and estimated blood loss were determined. Type of implant and operative levels were calculated as frequencies. Patient-reported outcomes, including VAS and ODI, and radiographic outcomes over time were compared using paired sample t-tests. Statistical significance was defined as a $p<0.05$.

Results

A total of 79 patients were enrolled across five study sites. Average patient age at time of surgery was 63 years (range 33–81). Average length of stay was 2.25 days. Average operative time was 92.7 minutes, and average estimated blood loss was 57.0 cc. Twenty-seven of the 79 patients were treated with CALIBER®-L interbody spacers, and 52 were treated with RISE®-L spacers. The majority of patients were treated at the L4–L5 level (Table 1) and 21 patients were treated at two operative levels, for a total of 100 operative levels.

Table 1: Operative Level.

	Frequency
L1–L2	3
L2–L3	13
L3–L4	40
L4–L5	44

Table 2: Patient-reported outcomes *denotes significant difference from preoperative.

	Preop	6-week	12 week	6-month	12-month	24-month
VAS Back	6.8 ± 2.3	2.8 ± 2.6*	2.9 ± 3.0*	2.3 ± 2.4*	2.9 ± 3.3*	2.9 ± 3.3*
VAS Leg	5.6 ± 2.8	2.4 ± 2.7*	2.1 ± 2.6*	1.6 ± 2.2*	2.3 ± 2.6*	2.5 ± 2.9*
ODI (%)	45.9 ± 15.7	33.8 ± 21.3*	27.9 ± 22.3*	19.4 ± 19.1*	25.0 ± 23.3*	26.2 ± 23.3*

Table 3: Radiographic measurements *denotes significant difference from preoperative.

	Preop	6-week	12 week	6-month	12-month	24-month
DH (mm)	7.7 ± 2.6	12.6 ± 2.5*	12.4 ± 2.7*	11.9 ± 2.6*	12.1 ± 2.8*	11.5 ± 2.4*
NF (mm)	19.7 ± 4.3	22.7 ± 4.3*	22.3 ± 4.0*	22.1 ± 3.7*	21.3 ± 4.6*	23.0 ± 3.8*
SL (°)	14.4 ± 7.7	16.1 ± 7.45*	15.8 ± 8.0	15.7 ± 7.5*	15.8 ± 7.7	14.8 ± 6.8

Patient-reported outcomes are listed in Table 2. Average VAS back pain scores decreased significantly by 3.9 at 24-month follow-up.Average VAS Leg pain scores decreased significantly by 3.1 at 24 months. Average ODI scores decreased significantly by 19.7% at 24 months. All improvements in patient-reported outcome scores were determined to be significant.

Radiographic measurement outcomes are listed in Table 3. Average disc height increased significantly by 3.7 mm at 24- month follow-up. All increases in disc height were determined to be significant. Average neuroforaminal height increased by 3.4 millimeters at 24-month follow-up. All increases in neuroforaminal height were determined to be significant. Average segmental lordosis remained stable with an average increase of 0.4 degrees at 24-month follow-up.

An analysis of collected radiographs determined that, of the 100 surgical levels studied, 4 were subsided. The patients with subsided levels were asymptomatic and no revision surgeries were needed to address the subsidence. There was one instance of adjacent segment disease, with screw lucency, which was treated with a revision LLIF and replacement screws and rods. A second revision for back pain included a decompression and screw removal. A third patient was treated with medication for low back and anterior thigh pain. This resulted in a total of 7 documented complications for a complication rate of 8.86%.

Discussion

Insufficient data exist to show the value of expandable technology in the LLIF approach. While the value of LLIF itself has been corroborated by numerous studies including those on economic/hospital costs [6,16,17], the advantages of minimally invasive surgery [18,19,16], fusion rate [20,21], and complication profiles [3,22-24], there have been no reports on a multi-site cohort treated exclusively with expandable technology. This study is a first step in collecting data in terms of patient-reported outcomes.

The radiographic results of the current study are comparable to other studies of lateral approaches using static spacers (Table 4). Patients in this study had an average disc height increase of 49%, while Sato et al. [25] reported a 61% increase, Kono et al. [26] reported a 22% increase, and Lee et al. [27] reported 46% and 52% anterior and

Table 4: Comparative studies.

	DH	NH
current	49%	16%
Sato 2015	61%	16% & 18%
Lee 2014	46% & 52%	35%
Kono 2018	22%	-

posterior disc height increases, respectively. Lateral approaches to the disc space have been shown to provide indirect decompression through increasing neuroforaminal height in surgically treated patients. Sato et al. reported 18% and 16% increases in left and right foraminal height, respectively, and Lee et al reported a 35% increase in foraminal height. The current study shows similar increases in neuroforaminal height after lateral lumbar interbody fusion, increasing from 19.7 ± 4.3 mm to 23.0 ± 3.8 mm at 24 months, a 16% increase. These increases were maintained through 2-year follow-up, demonstrating the stability of the implant and construct.

Comparable studies on expandable interbody spacers have been published recently. Massie et al. [10] investigated an expandable interbody placed from a transforaminal approach. In that study, ODI scores were reduced from preoperative by an average 32.5 (± 20.4) points at 24-month follow-up, back pain scores were reduced to an average 5.1 (± 4.2), and leg pain was reduced to an average 4.4 (± 3.6). Boktor et al. [11] found disability score improvements of an average of 23.1, and pain scores were reduced to an average of 4.7 (± 2.7) at 24-month follow-up. Li et al. [28] reported on clinical outcomes of the titanium interbody in the current study. Disability scores were reduced by an average 67.1 (± 10) points, and back pain scores were reduced to an average 1.0 (± 0.8). Results of the current study are comparable to these reports from the literature. Average VAS back pain scores decreased significantly by 3.9, VAS leg pain scores decreased significantly by 3.1, and ODI scores decreased significantly by 19.7% at 24 months.

Conclusions

In this cohort, disability and pain scores significantly reduced postoperatively, and these reductions were maintained through 24-month follow-up. Similarly, disc and neuroforaminal height also increased significantly through 24-month follow-up. Overall, expandable interbody spacers demonstrated positive clinical and radiographic outcomes at 24 months. This study adds to the growing body of research on the clinical impact on patients of expandable interbody spacers used in LLIF, and demonstrates that expandable interbody spacers used in a lateral approach led to outcomes that are comparable to published results for other lateral and expandable interbody spacers.

Conflicts of Interest

DSC reports consulting and royalty agreements with Globus Medical, Inc. (GMI). RF reports consulting, royalty, research support agreements with GMI. JO is a consultant with GMI, Stryker, Seaspine, Medtronic, and RTI Surgical; receives royalties from GMI, Stryker, Seaspine, RTI Surgical, and Nuvasive; and reports stock ownership/options with RTI Surgical and 4 Web. WT reports grants and research support from GMI. TKL receives research support from GMI. TS is a salaried employee of GMI.

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Author Affiliations

Top

[1]*South Florida Spine Institute at Mount Sinai Medical Center, 4308 Alton Rd, Miami Beach, FL 33140, USA*

[2]*Southeastern Spine Institute, 1106 Chuck Dawley Blvd., Mount Pleasant, SC, USA*

[3]*OrthoBethesda Orthopedic Maryland, 10215 Fernwood Road, Physician Suite 506 #210, Bethesda, Maryland 20817, USA*

[4]*Athens Orthopedic Clinic, 1765 Old West Broad Street, Building 2, Suite 200, Athens GA 30606, USA*

[5]*Spinemore Surgical Associates, P.C., 12152 Tesson Ferry Rd, Saint Louis, MO, 63128, USA*

[6]*Musculoskeletal Education and Research Center (MERC), A Division of Globus Medical, Inc., 2560 General Armistead Avenue, Audubon, PA 19403, USA*