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Research Article

A radiographic analysis of the use of banana-shaped articulating interbody spacers in lumbar spine fusion: Retrospective design

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ABSTRACT

Introduction: The minimally invasive transforaminal lumbar interbody fusion (MIS TLIF) procedure gains access to the disc space while avoiding major structures such as the great vessels anteriorly, spinal cord posteriorly, and lumbosacral plexus bilaterally. MIS TLIF procedures may be limited in capacity for the implanting of large interbody spacers due to the relatively small access window of Kambin's triangle. The current study examines patients treated with an articulating expandable interbody spacer designed to address the limitations of the MIS TLIF procedure.

Methods: This study is a retrospective chart review of clinical and radiographic data from 46 patients at a single site. Radiographs were measured to determine preoperative and postoperative disc height, neuroforaminal height, intervertebral angle and lumbar lordosis.

Results: Anterior disc height increased significantly from 10.0 ± 3.4 mm at preoperative to 14.1 ± 2.3 mm at 3-month follow-up. Posterior disc height increased significantly ($p < 0.001$) from 5.7 ± 2.2 mm to 7.8 ± 2.3 mm at 3-month follow-up. Lumbar lordosis increased significantly ($p = 0.013$) from $51.2 \pm 16.1^{\circ}$ at preoperative to $56.8 \pm 14.9^{\circ}$ at 3-month follow-up.

Conclusions: The results of the current study support the use of articulating expandable interbody spacers through an MIS TLIF approach for lordosis correction. The anteriorly placed interbody spacer allowed for increased lordosis within the segment and through the lumbar region of the spine. Further prospective studies are needed to better establish the benefits of this interbody design.

1. Introduction

The transforaminal lumbar interbody fusion (TLIF) approach may protect a patient from serious complications by avoiding the great vessels anteriorly, the spinal cord posteriorly, and the nerves of the lumbar plexus laterally. Minimally invasive transforaminal lumbar interbody fusion (MIS TLIF) follows the same angle of approach but is performed through ports or a retractor while avoiding the most sensitive structures [1,2]. Traditional TLIF interbody spacers are positioned across the center of the vertebral body; however a biomechanical research study [3] found that this is the least stable region of the body. It was shown that the anterior and posterior margins of the endplate are stiffer than the central region, and with this information, the authors of the study suggested that implants designed to be placed on these peripheral regions can prevent subsidence [3]. Articulating crescent-shaped interbody implants have been designed to be placed anteriorly on the apophyseal ring through a TLIF approach.

Larger implants, both in terms of footprint and height, may improve stability of the segment and allow for indirect decompression, which may help reduce of compressive neuroforaminal symptoms. However, larger implants risk damage to the exiting nerve roots and/or require wider muscle distraction. In addition, access through the facet dictates the initial size of the interbody spacer that can be implanted [2], making areas such as L5–S1 particularly difficult to size correctly. Kaito et al. found that patients suffering from adjacent segment disease had more average distraction of the disc space during fusion, suggesting that overdistraction may lead to subsidence or adjacent disc disease [4]. Continuously expandable interbody spacers address each of these concerns by allowing insertion of the spacer through the limited space created for the TLIF approach, expanding *in situ*, and achieving optimal height, thereby avoiding overdistraction.

It is hypothesized that tools utilizing fewer instrument passes *in situ*

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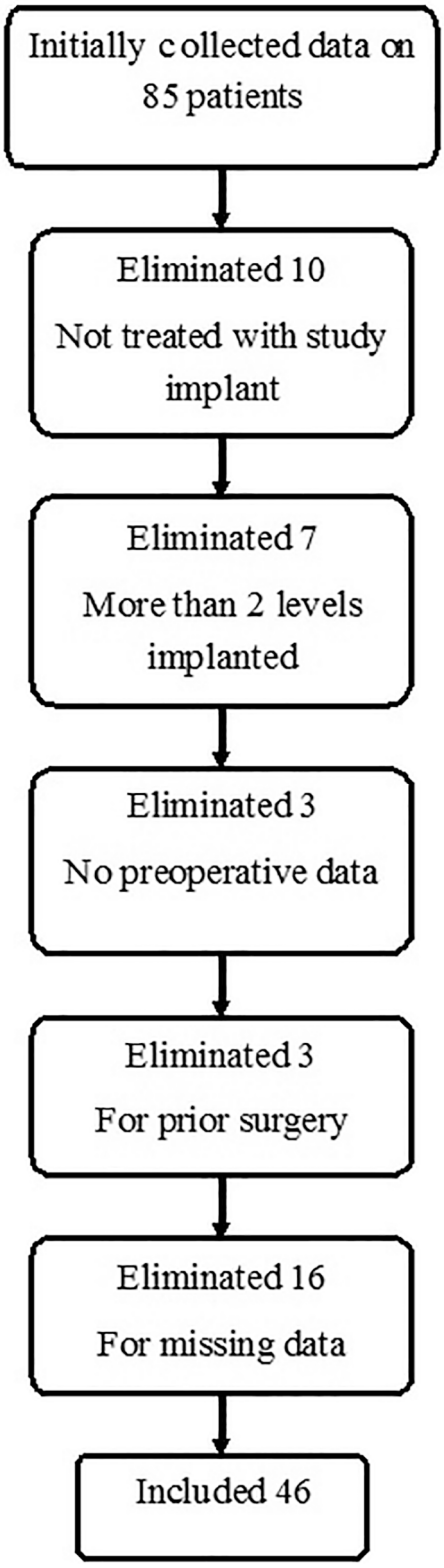

Fig. 1. Description of reason for patient exclusion.

may also help decrease blood loss and muscular retraction time. Minimally invasive techniques were shown to lead to shorter hospital stays and greater reduction of pain and disability in a meta analysis of 21 studies [5]. The instruments used to insert the studied device include an integrated implant holder. This holder allows the surgeon to implant the spacer and expand it without passing additional instruments through the incision.

2. Methods

This study was an IRB exempt retrospective chart review of subjects from a single site having underwent transforaminal interbody fusion performed by one surgeon with the use of an articulating expandable titanium interbody spacer. Inclusion criteria required that the surgery was performed for the treatment of low back pain and/or radiculopathy. Patients treated at more than 2 levels were excluded, or if data could not be collected for preoperative and/or 3 month follow-up appointments. Out of 85 patients initially screened, a total of 46 patients met the inclusion/exclusion criteria, exclusion breakdown in Fig. 1.

2.1. Surgical technique

Patients included in this study underwent implantation of the interbody spacer through a transforaminal surgical approach. Access to the disc space was obtained by resecting the facet joint of the indicated level. A thorough discectomy was performed to make appropriate space for the interbody spacer. The interbody spacer was then passed through the safe area of Kambin's triangle and placed within the disc space. Once within the disc space, the articulating implant mechanism was unlocked, and by guiding the inserter, the implant was pivoted such that it lay across the disc space on the anterior edge of the apophyseal ring.

2.2. Device description

The devices studied (ALTERA® spacers) are expandable lumbar interbody fusion devices, primarily made from titanium alloy, that are intended for use in skeletally mature patients with degenerative disc disease at 1 or 2 contiguous levels of the lumbosacral spine (Fig. 2).

2.3. Outcome assessment

Patient radiographs were measured using Surgimap v2.2.15.1 software for Windows (Nemaris Inc, New York City, New York). Disc height was measured at two locations. Anterior height was measured from the most anterior edge of the superior endplate to the anterior edge of the inferior endplate. Similarly, posterior disc height was measured from the posterior edges of the endplates. Segmental lordosis, lumbar lordosis, and intervertebral angle were measured. Patient demographic data including height, weight, and body mass index were collected. A subsidence assessment was performed by identifying those surgical levels which had an anterior disc height loss of greater than 2 mm between 6-week and 3-month follow-up. Those identified levels were then reviewed for evidence of endplate violation indicative of subsidence [6]. Fusion was assessed at 3-month follow-up by comparing segmental lordosis between flexion and extension radiographs. A difference in segmental lordosis of less than $\pm 5^{\circ}$ was considered fused [7].

Patient reported visual analog scale back and leg pain scores were collected from preoperative and 6 months postoperative records. Patients were monitored for a number of intraoperative and post operative complications. Intraoperative complications monitored for included durotomy, hardware placement failure (pedicle breach; endplate violation), neurologic injury, vascular injury, MI, aspiration event, death, CVA, blindness. Postoperative complications monitored for included MI, pneumonia, death, CVA, blindness, UTI, wound infection (superficial and/or deep), loss of fixation, worsening or return of neurologic symptoms, new spinal pathology requiring intervention.

Data analysis was performed using SPSS v20.0.0 software for Windows (IBM Corp., Armonk, New York). Paired samples *t*-tests were used to compare within-subject changes between follow-up for radiographic outcomes. The increase in anterior disc height, and the increase in intervertebral angle, from preoperative to 3-month follow-up was calculated for each patient and a Pearson correlation test was

Fig. 2. ALTERA® expandable interbody spacer contracted (left) and expanded (right).

Table 1
Radiographic measurements in millimeters. (Ante) anterior (DH) disc height, (Post) posterior, (NH) neuroforaminal height, (LL) lumbar lordosis.

	Preoperative		6 wk		3 mo		6 mo	
	$\bar{X}$	s	$\bar{X}$	s	$\bar{X}$	s	$\bar{X}$	s
AnteDH	9.95	3.39	14.17	2.28	14.07	2.58	14.18	2.46
PostDH	5.73	2.19	7.75	2.52	7.81	2.29	7.79	2.89
NH	19.59	4.68	20.60	4.85	20.65	5.35	20.30	5.06

performed. Significance was defined as $p < 0.05$ for statistical tests.

3. Results

Patients' average age at surgery was 57 years (range 34 to 82). There were 23 females and 23 male patients. Average height was 5 feet 7 in., average weight was 188 (±33) pounds and average BMI was 28.6 (±5.2). Twenty-three patients had 2 level surgery and 23 patients had a single level surgery for a total of 67 surgical levels. Average operative time was 118 (±32) minutes, average blood loss was 201.7 (±115.2) cc and fluoroscopic time averaged 1.1 (±0.5) minutes. There were no intra-operative complications.

Average anterior and posterior disc height increased significantly ($p < 0.001$ at all postoperative time-points) from preoperative height at each postoperative follow-up. Anterior disc height increased 42.41% on average, and posterior disc height increased 35.25% on average at 6-week follow-up. Neuroforaminal height increased from preoperative by 1 mm on average (1.01 at 6 weeks and 1.06 at 3 months), however this difference was not significant ($p = 0.112$ at 6 weeks and $p = 0.053$ at 3 months). Average radiographic height measurement values with

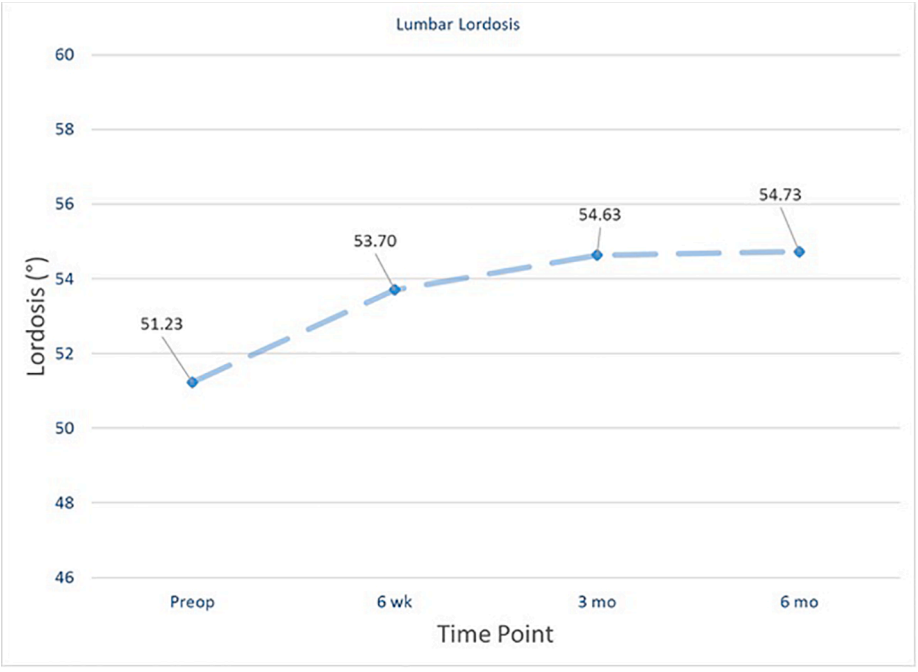

Fig. 3. Lumbar lordosis in degrees over time.

Table 2
Radiographic angular measurements in degrees. (IVA) intervertebral angle, (SL) segmental lordosis, (LL) lumbar lordosis.

	Preoperative		6 wk		3 mo		6 mo	
	$\bar{X}$	s	$\bar{X}$	s	$\bar{X}$	s	$\bar{X}$	s
IVA	7.66	4.65	9.78	5.18	9.17	4.95	10.22	5.09
SL	19.30	7.72	19.83	7.53	20.91	7.39	19.53	7.31
LL	51.23	16.12	53.70	14.70	54.63	16.26	54.73	14.27

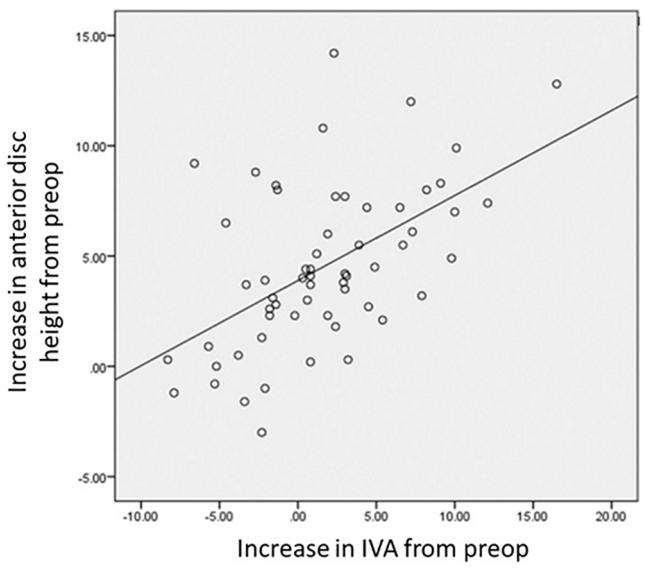

Fig. 4. Scatter plot of increase from preoperative values of anterior disc height and intervertebral angle. Trend line depicts that an increase in anterior disc height was correlated with an increase in intervertebral angle.

Table 3
VAS back and leg pain scores.

VAS Scores	Preoperative		6-month		12-month	
	Mean	Std. Dev	Mean	Std. Dev	Mean	Std. Dev
Back pain	8.07	1.11	3.57	1.55	1.93	1.14
Leg pain	8.13	1.22	2.57	1.43	1.20	1.13

standard deviations are listed in Table 1.

At 6-week follow-up, IVA increased significantly ($p = 0.008$) by 2.12°and maintained a significant ($p = 0.018$) difference from preoperative at 3-month follow-up. Segmental lordosis was not significantly increased ($p = 0.224$) at 6-week follow-up, but the difference reached significance ($p = 0.012$) at 3-month follow-up. Lumbar lordosis (Fig. 3) increased significantly ($p = 0.018$) by an average 2.47°at 6-week follow-up, and remained significantly increased from preoperative at 3-month ($p < 0.001$) and 6-month ($p < 0.001$) follow-up. Radiographic angular measurements are listed in Table 2.

Increases in anterior disc height and intervertebral angle were tested for correlation and were found to be significantly ($p < 0.001$) correlated with a coefficient of 0.536. The values are graphed and the trend line is shown in Fig. 4. Similar comparisons were made with posterior disc height and neuroforaminal height increases, and these were found to not be significantly correlated ($p = 0.508$ and $p = 0.459$ respectively) with intervertebral angle. A comparison of 6-week to 3-month follow-up radiographs determined 6 patients with anterior disc height loss of greater than 2 mm. Of these patients, 1 patient was determined to have evidence of endplate violation on radiographs resulting in a subsidence rate of 1.49% (1/67). The fusion assessment determined that, of those patients with available flexion extension radiographs, 56 of 63 levels had within ±5° difference, a 88.8% fusion rate.

VAS back pain scores (Table 3) decreased significantly ($p < 0.001$) from preoperative values at 6 postoperative. Similarly, VAS leg pain scores also decreased significantly ($p < 0.001$) from preoperative values at 6 months postoperative (Fig. 4). The study patients did not experience any intraoperative or postoperative complications (Fig. 5).

4. Discussion

The restoration of a natural sagittal alignment has become the focus of lumbar fusion surgery in recent years. Patients suffering from low back pain have been found to have less lumbar lordosis than healthy persons [8,9]. Increases in lumbar lordosis have been correlated with improvements in clinical outcomes [10,11].

The current study describes the use of an articulating implant placed anteriorly across the apophyseal ring of the vertebral body. It is theorized that anterior TLIF placement allows for more lumbar lordosis correction. A study of the placement of lateral implants found that more anteriorly placed interbody spacers had on average more lordosis correction [12]. An implant placed in a similar location on the vertebral body from a posterior approach is expected to have a similar effect on lordosis. The current study found that lumbar lordosis significantly

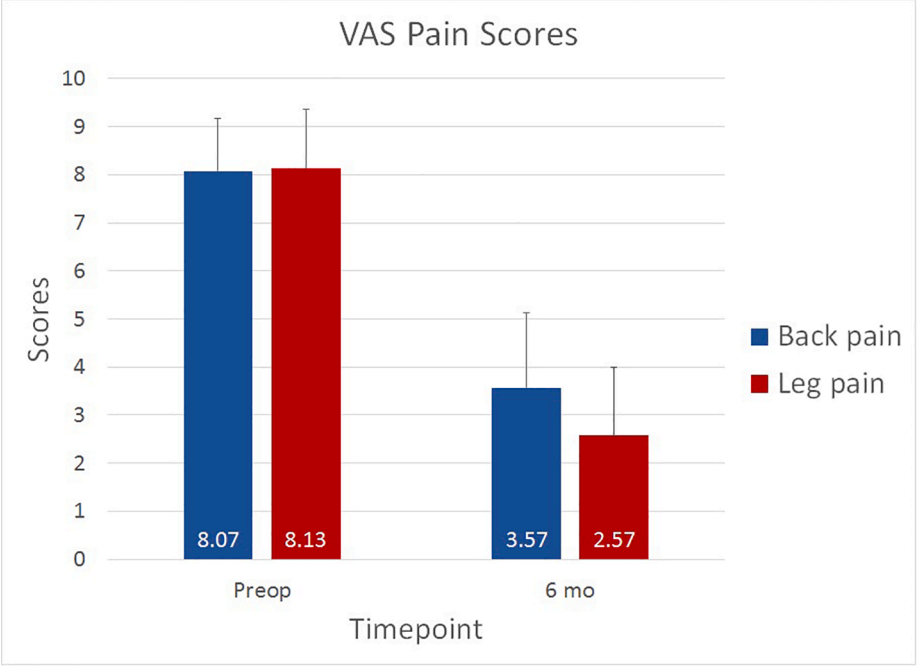

Fig. 5. Visual analog scale (VAS) back pain scores.

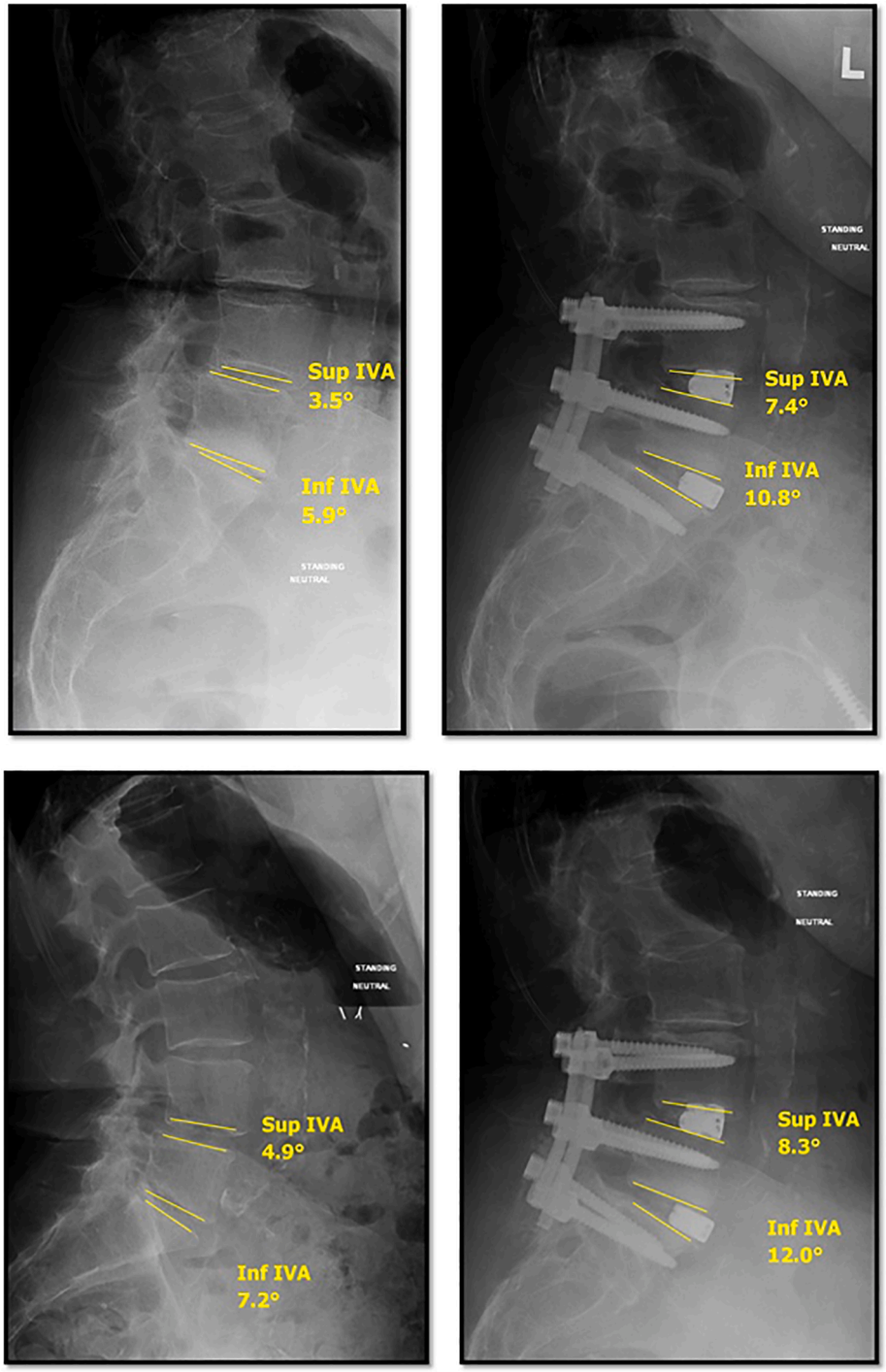

Fig. 6. Lateral lumbar radiographs demonstrating increased intervertebral angle in a patient treated with two articulating TLIF interbody spacers.

increased by 6 weeks postoperatively and remained significantly increased through 6 months follow-up (Fig. 6). Increases in anterior disc height, where the implant was placed, were also correlated with increased intervertebral angle at 3-month follow-up. Posterior disc height and neuroforaminal height increases were not correlated with intervertebral angle. This suggests that greater anterior disc height restoration allows for more correction in the sagittal plane (Fig. 7), though a causal relationship cannot be established in this retrospective design.

The implant studied in the current paper includes the added feature of *in situ* expansion, which allows for greater disc height restoration. The external dimensions of an interbody spacer implanted with a TLIF technique may be restricted by the patient's anatomy. *In situ* expansion allows for the interbody device to be inserted at a reduced height, with less trialing and impaction, and expanded to the target disc height. The current study shows significantly improved anterior and posterior disc heights at each postoperative follow-up.

Similar results have been achieved with the same implant by other authors. Hawasli et al. [13] found significant increases in disc height and segmental lordosis in a study of 44 patients through 7 months. Massie et al. [14] studied 44 patients retrospectively and found significant increases in segmental height and angle, as well as significant decreases in back and leg pain at 1-year follow-up. Tassemeier et al. [15] compared the same implant to an obliquely placed expandable TLIF implant and

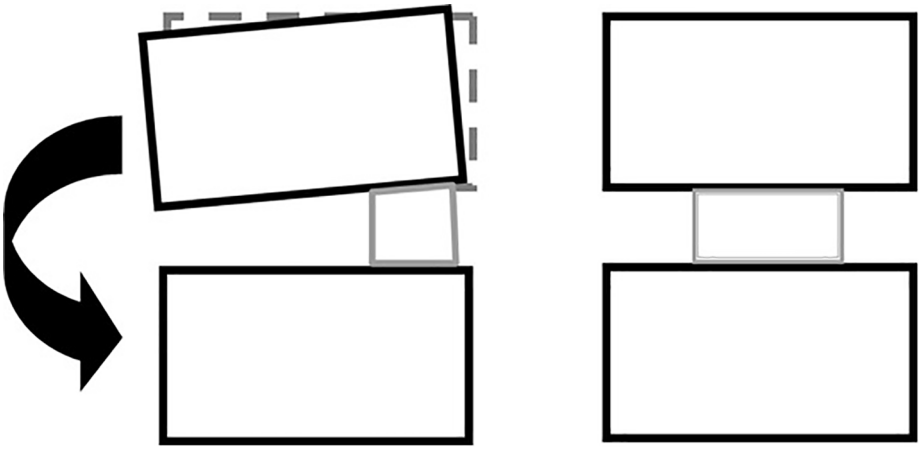

Fig. 7. (Left) Anterior placement may allow for greater sagittal correction than (Right) traditional obliquely placed interbody spacers.

found greater disc height restoration from the articulating implant than the obliquely placed implant. Segmental angle was measured and was found to have increased by an average of 6.3° in this study.

The limitations of this study include its retrospective nature and the small sample size. Forty of the original 85 patients were not included in the analysis due to not meeting the inclusion criteria or for unavailable data. This may have had unknown impacts on the generalizability of the study. Further prospective studies are needed to collect more data on patients treated with articulating expandable interbody fusion spacers.

5. Conclusion

The use of articulating expandable interbody spacers in TLIF procedures may improve sagittal balance parameters, intervertebral disc height, and pain scores. Further prospective studies are needed to better establish the corrective capabilities of this implant.

CRediT authorship contribution statement

Anthony Russo: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Validation, Visualization, Writing - original draft, Writing - review & editing, Writing - review & editing. **Katelyn Stetzner:** Data curation, Project administration. **Torrey Shirk:** Formal analysis, Visualization, Writing - original draft, Writing - review & editing.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Anthony Russo MD declares the following relationships: Consultant, royalties and research support from Globus Medical; consultant and research support from Orthofix; consultant for Surgentec. Katelyn Stetzner received research support from Globus Medical. Torrey Shirk is a salaried employee of Globus Medical.

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