Assessment of radiographic and clinical outcomes of an articulating expandable interbody cage in minimally invasive transforaminal lumbar interbody fusion for spondylolisthesis

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OBJECTIVE The inability to significantly improve sagittal parameters has been a limitation of minimally invasive surgery for transforaminal lumbar interbody fusion (MIS TLIF). Traditional cages have a limited capacity to restore lordosis. This study evaluates the use of a crescent-shaped articulating expandable cage (Altera) for MIS TLIF.

METHODS This is a retrospective review of 1- and 2-level MIS TLIF. Radiographic outcomes included differences in segmental and lumbar lordosis, disc height, evidence of fusion, and any endplate violations. Clinical outcomes included the numeric rating scale for leg and back pain and the Oswestry Disability Index (ODI) for low-back pain.

RESULTS Thirty-nine patients underwent single-level MIS TLIF, and 5 underwent 2-level MIS TLIF. The mean age was 63.1 years, with 64% women. On average, spondylolisthesis was corrected by 4.3 mm (preoperative = 6.69 mm, postoperative = 2.39 mm, p < 0.001), the segmental angle was improved by 4.94° (preoperative = 5.63°, postoperative = 10.58°, p < 0.001), and segmental height increased by 3.1 mm (preoperative = 5.09 mm, postoperative = 8.19 mm, p < 0.001). At 90 days after surgery the authors observed the following: a smaller postoperative sagittal vertical axis was associated with larger changes in back pain at 90 days (r = -0.558, p = 0.013); a larger decrease in spondylolisthesis was associated with greater improvements in ODI and back pain scores (r = -0.425, p = 0.043, and r = -0.43, p = 0.031, respectively); and a larger decrease in pelvic tilt (PT) was associated with greater improvements in back pain (r = -0.548, p = 0.043). For the 1-year PROs, the relationship between the change in PT and changes in ODI and numeric rating scale back pain were significant (r = 0.612, p = 0.009, and r = -0.803, p = 0.001, respectively) with larger decreases in PT associated with larger improvements in ODI and back pain. Overall for this study there was a 96% fusion rate.

Fourteen patients were noted to have endplate violation on intraoperative fluoroscopy during placement of the cage. Only 3 of these had progression of their subsidence, with an overall subsidence rate of 6% (3 of 49) visible on postoperative CT.

CONCLUSIONS The use of this expandable, articulating, lordotic, or hyperlordotic interbody cage for MIS TLIF provides a significant restoration of segmental height and segmental lordosis, with associated improvements in sagittal balance parameters. Patients treated with this technique had acceptable levels of fusion and significant reductions in pain and disability.

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KEY WORDS spondylolisthesis; minimally invasive; TLIF; transforaminal lumbar interbody fusion; lordotic cage

ABBREVIATIONS EBL = estimated blood loss; LL = lumbar lordosis; MIS = minimally invasive surgery; NRS = numeric rating scale; ODI = Oswestry Disability Index; OR = operating room; PI = pelvic incidence; PRO = patient-reported outcome; PT = pelvic tilt; SVA = sagittal vertical axis; TLIF = transforaminal lumbar interbody fusion.

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Spondylolisthesis is a common indication for spine surgery, with clinical evidence that fusion is an effective treatment for this pathology. Transforaminal lumbar interbody fusion (TLIF) has been shown to be an effective surgical procedure for spondylolisthesis and there is growing interest in whether minimally invasive surgery for TLIF (MIS TLIF) can provide the same benefits. Although MIS TLIF is associated with a significant learning curve, increased use of fluoroscopy, and risk of nerve injury, its benefits over open TLIF include decreased operating time, decreased intraoperative blood loss, decreased hospital stay, improved cost-effectiveness, faster return to work, and decreased pain.

One controversy with MIS TLIF is the ability to provide adequate reduction of spondylolisthesis and correction of radiographic parameters, or even whether such changes are necessary. With a growing body of evidence emphasizing the finding that the restoration of spinopelvic parameters after spine surgery is associated with improved outcomes, there has been interest in applying these principles to MIS TLIF as well. Current product limitations, which include cage footprint size, fixed height of interbody cage, and nonlordotic shape of the implant, have limited the surgeon’s armamentarium to achieve these goals by providing inadequate anterior column height restoration through the access corridors of both open and MIS TLIF.

However, several expandable lordotic interbody cages now exist for use in TLIF. One current cage on the market incorporates a crescent shape with articulation and expansion in a lordotic configuration (Altera, Globus Medical), and allows for placement via a transfemoral trajectory (Fig. 1). It is specifically designed to be articulated and positioned horizontally across the anterior column and then expanded to achieve greater height while maintaining a low entry profile (Fig. 2). The cage itself also has a built-in lordotic configuration, again contributing to further lordosis. Of note, the cage material used is primarily titanium alloy. The purpose of this study was to assess the efficacy of this cage in a clinical setting. We hypothesized that this cage design allows for improved restoration of intradiscal height and improved segmental lordosis, while allowing for correction of spondylolisthesis. An additional hypothesis was that patient-reported outcomes (PROs) would be consistent with those of other series published in the literature.

**Methods**

**Patient Population**

This study was approved by the Henry Ford Hospital Institutional Review Board. This is a retrospective cohort study using prospectively collected data. In a query of all lumbar interbody fusion cases performed using the Globus Altera cage between November 2014 and December 2016, 58 patients with 98 levels of intervention were identified, with cases ranging from 1 to 4 levels of interbody fusion. For this investigation, our analysis was limited to 1- and 2-level interventions, totaling 44 patients. One patient with a single-level intervention was excluded because their indication for surgery was discitis.

**Clinical and Radiographic Assessment**

Patient demographic data included patient age, sex, and body mass index, and the American Society of Anesthesiologists grade was also collected. Surgical data included number of levels operated on, operating room (OR) time, and estimated blood loss (EBL). For all patients, routine clinical follow-up was done at 6 weeks, 3 months, 6 months, 1 year, and 2 years after surgery. The 36-inch lateral standing films were obtained preoperatively, 3 months, 6 months, 1 year, and 2 years after surgery. The CT scans were performed at 6 months and 1 year to assess for bony fusion. The PROs were collected preoperatively, 3 months, 1 year, and 2 years after surgery. Primary outcomes included both clinical and radiographic outcome measures. Clinical outcome measures consisted of PROs, and included the Oswestry Disability Index (ODI) for low-back pain and the numeric rating scale (NRS) for low-back and leg pain.

Radiographic analysis included full-length, free-standing anteroposterior and lateral 36-inch spine radiographs as well as CT scans. Standing films were analyzed for sagittal parameters in a standardized fashion by using validated software (Surgimap). Primary radiographic outcome measures included pelvic incidence (PI), pelvic tilt (PT), lumbar lordosis (LL), PI-LL mismatch, and sagittal vertical axis (SVA). In addition, measurements of the disc height at the posterior vertebral body, segmental angle, and sagittal angle and of the amount of listhesis (measured by the offset of posterior vertebral body wall in millimeters) were also collected. Postoperative CT scanning was done to assess for bony fusion, with any evidence of bridging bone in the interbody space (either around or through

**FIG. 1.** Photographs of the Altera cage—this is a 31-mm length × 10-mm width, 15° lordotic cage expanded to 13 mm. **A:** Top-down view illustrates graft window and cage footprint. **B:** Front view of the cage shows the expansion mechanism. **C:** Lateral view illustrates the lordotic angle built into the cage.
the cage), and/or bridging of the facets being considered a bony fusion. Subsidence was measured using both CT scans and radiographs.

**Description of Surgical Technique**

All operations were performed by the senior author (V.C.). The patient is placed prone by using a Jackson frame (Mizuho) with a horizontal chest pad as well as hip and thigh pads. Two 25-mm paramedian incisions are made 4 cm (or wider, depending on patient’s body habitus) off the midline. Using fluoroscopy guidance, a Jamshidi needle is used to cannulate the pedicle, and a K-wire is left in place. Depending on the laterality of the symptoms, the approach for the TLIF is made from one side, and an incision is made in the lumbosacral fascia. A Cobb elevator is used to dissect the muscle attachments off the facet complex. Sequential tissue dilators are docked onto the facet with a medial trajectory, and an expandable retractor with blades of appropriate depth is inserted over the dilator and secured to a rigid arm (MARS 3VL, Globus Medical).

The rest of the TLIF is performed using an intraoperative microscope. Using a high-speed burr, a total facetectomy and a hemilaminectomy is performed to expose the dura mater and traversing nerve root. The disc is incised sharply, and disc material is removed using a combination of pituitary rongeur, disc shavers, and curettes (Fig. 3A). Graft materials are inserted into the disc space, and then the interbody cage is packed with grafting material and hammered into the disc space. Using fluoroscopy, the cage is inserted until its tip reaches the anterior anulus (Fig. 3B). The articulation mechanism is then released, and the cage is rotated into as lateral an orientation as possible (Fig. 3C). The cage is then expanded up to the appropriate height, which is torque limited, and confirmed on intraoperative fluoroscopy (Fig. 3D). Additional graft material is then further filled into the expanded interbody spacer with the aid of a special funnel. More graft is then packed behind the spacer until level with the posterior wall of the vertebral body. The microscope and retractor are then removed. On the contralateral side, a small stab incision in the lumbosacral fascia is performed, and soft-tissue dilators are then passed around the K-wires bilaterally. Pedicle screws are then placed over the K-wire bilaterally. On the TLIF side a rod is placed down the extended screw tabs through the preexisting fascial incision. On the contralateral side, our preference is to pass the rod under the fascia through the extended screw tabs without cutting the fascia between the screws. Locking screws are then placed, and the extended tabs are broken off the screw heads (Fig. 3E).

**Statistical Analysis**

Descriptive statistics of means, SDs, frequencies, and percentages were computed for the demographic and surgical information. Wilcoxon 2-sample tests were done to
compare groups of patients for EBL and OR time. For the radiographic measures, means and SEs were computed using methods that take into account the correlation within a patient with a 2-level procedure. Paired t-tests were used to compare pre- and postoperative measures for lordosis, PI-LL mismatch, SVA, and change in listhesis (in single-level patients only), as well as changes from baseline to 90 days and 1 year for PROs. For pre- to postoperative changes in segmental angles and segmental height, methods similar to paired t-tests that take into account multilevel procedures were done. Spearman correlation coefficients were computed to assess the relationships (associations) between pre- and postoperative changes in radiographic measures and changes in PROs. For the patients with 2-level procedures, the maximum pre- to postoperative change over the 2 levels was used in this correlation analysis. All testing was done at the 0.05 testing level. We used SAS version 9.4 to perform all statistical analyses.

Results

General Findings

There were 44 patients included in this study, with 39 (89%) having a single-level procedure and 5 having 2-level procedures. The mean age for all patients was 63.1 years (range 26–85 years), 64% were female, and 89% were Caucasian. All of the 39 single-level interventions were performed for spondylolisthesis. In the 5 patients treated with multilevel operations, 2 of the 10 total levels had spondylolisthesis. Three (7%) cases were isthmic, whereas the remainder were degenerative. The median OR time for the single-level procedures was 139 minutes, and for the 2-level procedures it was 250 minutes (p = 0.003). For the single-level procedures there appeared to be a learning curve, with the first 10 procedures having a median OR time of 182 minutes and the remaining procedures having a median OR time of 135 minutes (p < 0.001). The mean EBL was 58.3 ml for the single-level procedures and 115 ml for the 2-level procedures (p = 0.027). Among the single-level procedures, there was a trend toward decreased blood loss over time; for the first 10 procedures the mean EBL was 75.5 ml (SD 32.5 ml) and for the remaining procedures the mean EBL was 52.3 ml (SD 37.3 ml; p = 0.057). More demographic and surgical information can be found in Table 1. Of the 44 patients, 16 (36%) had been followed for at least 2 years, 22 (50%) for at least 1 year, and 6 (14%) for almost 1 year at the time of this report. The median follow-up for all patients was 1.5 years.

Radiographic and Clinical Outcome Measures

Significant improvement in the degree of spondylolisthesis and segmental height and angle were noted. On average, spondylolisthesis was corrected by 4.3 mm (preoperative 6.69 mm, postoperative 2.39 mm, p < 0.001), segmental angle was improved by 4.94° (preoperative 5.63°, postoperative 10.58°, p < 0.001), and segmental height increased by 3.1 mm (preoperative 5.09 mm, postoperative 8.19 mm, p < 0.001). The differences between pre- and postoperative measurements of lordosis, PI-LL mismatch, SVA, and PT were not significant (Table 2).

Of the 44 patients, 24 (54%) had PROs measured at
Of the 38 patients with at least 1 year since surgery, 23 (61%) of them had PROs measured at baseline and 1 year. For all 3 PROs (i.e., ODI, back pain, leg pain), there was a significant improvement observed when we compared baseline to 90-day outcomes ($p < 0.001$). The ODI decreased by 15.3 points ($p < 0.001$) at 90 days compared with baseline and was decreased by 15.7 points ($p = 0.001$) at 1 year compared with baseline. Back pain and leg pain also declined significantly, and this improvement was sustained at 1 year. The ODI and back and leg pain scores were still lower at 2 years, but these findings were not statistically significant given the small number of patients with baseline and 2-year PROs (Table 3).

### Associations of Changes in Radiographic Measures and Changes in PRO

The relationship between the postoperative SVA and change in back pain was significant ($r = -0.558$, $p = 0.013$), with a smaller postoperative SVA associated with larger changes in back pain at 90 days. In addition, a larger decrease in spondylolisthesis was associated with larger changes (improvements) in ODI and back pain scores ($r = -0.425$, $p = 0.043$, and $r = -0.43$, $p = 0.031$, respectively). Also, a larger decrease in PT was associated with a larger change (improvement) in back pain scores ($r = -0.548$, $p = 0.043$). None of the other correlation coefficients were significant for the 90-day outcomes. For the 1-year PROs, the relationship between the change in PT and the changes in ODI and NRS back pain were significant ($r = 0.612$, $p = 0.009$, and $r = -0.803$, $p = 0.001$, respectively) with larger decreases in PT associated with larger improvements in ODI and back pain. None of the other correlation coefficients were significant for the 1-year outcomes.

### TABLE 2. Preoperative and postoperative radiographic measures in 44 patients with spondylolisthesis

| Radiographic Measures | No. of Pts | Mean ± SE | p Value* |
|-----------------------|------------|-----------|----------|
| Spondylolisthesis in mm (1-level ops only) | | | |
| Preop | 39 | 6.69 ± 0.63 | | |
| Postop | 39 | 2.39 ± 0.40 | | |
| Postop − preop | 39 | −4.30 ± 0.62 | <0.001 |
| LL | | | |
| Preop | 35 | 47.37 ± 2.32 | | |
| Postop | 40 | 50.55 ± 1.95 | | |
| Postop − preop | 33 | 2.48 ± 1.49 | 0.104 |
| PI-LL mismatch | | | |
| Preop | 38 | 0.50 ± 2.54 | | |
| Postop | 38 | −2.45 ± 3.58 | | |
| Postop − preop | 36 | −1.28 ± 2.27 | 0.576 |
| Segmental angle | | | |
| Preop | 49 | 5.63 ± 0.70 | | |
| Postop | 49 | 10.58 ± 0.54 | | |
| Postop − preop | 49 | 4.94 ± 0.76 | <0.001 |
| Segmental height | | | |
| Preop | 49 | 5.09 ± 0.28 | | |
| Postop | 49 | 8.19 ± 0.31 | | |
| Postop − preop | 49 | 3.10 ± 0.29 | <0.001 |
| SVA | | | |
| Preop | 33 | 3.64 ± 0.62 | | |
| Postop | 38 | 3.51 ± 0.65 | | |
| Postop − preop | 28 | −0.48 ± 0.45 | 0.299 |
| PT | | | |
| Preop | 35 | 16.23 ± 1.78 | | |
| Postop | 37 | 15.54 ± 1.34 | | |
| Postop − preop | 29 | −0.10 ± 1.33 | 0.938 |

Variations in number of patients reflect some inconsistency of compliance in collecting PRO data.

* p values were calculated from paired t-tests by using methods for comparing pre- to postoperative measurements.

### TABLE 3. Patient-reported outcomes in individuals with spondylolisthesis

| PRO | Follow-Up Time | No. of Pts | Mean ± SD | p Value* |
|-----|----------------|------------|-----------|----------|
| ODI | Baseline | 29 | 39.2 ± 13.2 | | |
| 90 days | 30 | 27.5 ± 20.7 | | |
| Change from baseline to 90 days | 24 | 15.3 ± 18.4 | <0.001 |
| 1 yr | 34 | 27.4 ± 19.0 | | |
| Change from baseline to 1 yr | 23 | 15.7 ± 20.1 | 0.001 |
| 2 yrs | 11 | 32.5 ± 20.4 | | |
| Change from baseline to 2 yrs | 6 | 9.8 ± 15.7 | 0.186 |
| Back pain | Baseline | 27 | 6.7 ± 2.4 | | |
| 90 days | 31 | 3.3 ± 3.0 | | |
| Change from baseline to 90 days | 24 | 3.7 ± 3.3 | <0.001 |
| 1 yr | 32 | 4.5 ± 3.9 | | |
| Change from baseline to 1 yr | 20 | 3.3 ± 4.6 | 0.004 |
| 2 yrs | 12 | 5.1 ± 4.2 | | |
| Change from baseline to 2 yrs | 6 | 3.2 ± 4.2 | 0.125 |
| Leg pain | Baseline | 27 | 6.9 ± 2.6 | | |
| 90 days | 31 | 3.7 ± 3.8 | | |
| Change from baseline to 90 days | 24 | 3.7 ± 3.4 | <0.001 |
| 1 yr | 32 | 4.3 ± 3.2 | | |
| Change from baseline to 1 yr | 20 | 3.8 ± 3.3 | <0.001 |
| 2 yrs | 11 | 4.4 ± 3.6 | | |
| Change from baseline to 2 yrs | 6 | 4.0 ± 4.1 | 0.064 |

Variations in number of patients reflect some inconsistency of compliance in collecting PRO data.

* p values were calculated from paired t-tests.
Intradiscal height without significant subsidence, and improvement in the segmental lordosis.

Key Results

The use of this lordotic cage illustrates the potential for significant segmental correction within the sagittal plane, with a mean improvement of 4.94° of lordosis at a mean follow-up of 1.5 years. By way of historical comparison with traditional MIS TLIF, other studies have demonstrated 2°–3° of segmental correction in the sagittal plane.15,21,23,48 In comparison with other forms of sagittal correction, historically MIS TLIF has shown only modest improvements in segmental lordotic angle. Additionally, the increase in segmental lordotic restoration in this study compares favorably to a weighted average increase of 3.9° published in a review by Uribe et al.43 Despite these positive findings, it is important to note that the question whether improvement in LL translates into actual improved clinical outcomes for treatment of spondylolisthesis has not been reliably answered in the literature.31 The same can also be said for height restoration, which was also improved in this study, but is unproven regarding clinical efficacy.

For sagittal alignment parameters, given that the vast majority of patients only had 1-level pathology, we did not expect to observe a tremendous degree of sagittal imbalance preoperatively. Therefore, we did not expect to dramatically alter the overall sagittal balance postoperatively. Our study does demonstrate short-term improvements in back pain correlated with improving SVA at 90 days, as well as an association with decreasing PT and improvements in ODI and back pain at 1 year, consistent with what has been previously reported.3,18,25,34,41 Although sagittal parameters are more commonly associated with preoperative planning and outcomes in deformity surgery, our results do show that even in 1- and 2-level lumbar fusion surgery, maintenance of sagittal balance parameters can correlate with better clinical outcome.

With regard to the reduction of spondylolisthesis and its effect on clinical outcome, our study did identify a statistically significant correlation between the two, with greater reduction of spondylolisthesis associated with larger improvements in ODI and back pain scores. Although this finding is encouraging, a recent systematic review did not find sufficient support for this in the literature.39 One of the
chief limitations noted in this review is the lack of adequate well-powered studies, warranting further investigation. Overall, our results are consistent with other studies that demonstrate clinical improvements in disability, back pain, and leg pain after MIS TLIF. Bin Abd Razak et al. demonstrated similar reductions in ODI, and NRS back and leg pain, which were durable over 5 years. Similar to Fan et al., who studied MIS TLIF with or without the use of reduction, no significant improvement in ODI or NRS back or leg pain was associated with the degree of reduction in spondylolisthesis in our patients. In this study, improvements in back disability on average surpassed the published minimum clinically important difference for ODI and demonstrated a durable reduction throughout the duration of follow-up.

Another consideration with regard to this particular implant is that historically there has been some suspicion about expandable interbody cages regarding subsidence and risk for pseudarthrosis. In addition, the cage material is of concern, given the relatively high modulus of elasticity of titanium relative to bone as compared with polyetheretherketone, which has become more widely used. Overall, our rate of fusion as verified by CT compares favorably with series in which nonexpandable cages were used, and notably none of the patients in this series have required a return to surgery for pseudarthrosis. Three of our patients demonstrated radiographic subsidence, with none of the cases being clinically significant (i.e., requiring a reoperation or resulting in recurrent symptoms). Although further long-term follow-up is necessary (5–10 years ideally), it appears that the fact that the cage is titanium does not seem to impart a significant risk of subsidence.

**Generalizability of Findings**

Our results are generalizable to MIS TLIF surgery, and revolve primarily around the use of a specific cage design. There is a recent study by Hawasli et al., which showed comparable results using the same implant. Currently, to our knowledge, there are no other cages available in the US with a similar design. Although some may advocate that fusion (and TLIF in particular, given its additional operative risks compared with laminectomy alone—which include longer OR time, greater blood loss, risks of pseudarthrosis, risks pertaining to hardware, increased length of stay, and so on) may not be indicated for the treatment of degenerative spondylolisthesis, the question whether MIS TLIF is necessary for the management of degenerative spondylolisthesis is beyond the scope of this paper. Our goal was to present clinical and radiographic outcomes for an MIS TLIF cohort for the treatment of degenerative spondylolisthesis in which this particular interbody cage is used.

**Limitations of the Study**

There are some notable limitations of our study. Our study represents a single surgeon’s experience with a relatively small sample size. In addition, our mean follow-up of 1.5 years is relatively short, and further long-term follow-up is warranted to demonstrate whether our radiographic findings remain durable. Future study will evaluate whether increased segmental correction has a protective effect on the development of adjacent-segment degeneration and the need for additional interventions. Finally, there are some inconsistencies with the collection of PRO data at different time points; most notably there were a fair number of patients who had missing baseline data, which should be noted when interpreting our clinical results.

**Conclusions**

This study demonstrates that favorable outcomes can be obtained with the use of a titanium, crescent-shaped, articulating, expandable cage in MIS TLIF for 1- and 2-level spondylolisthesis. The use of such technology does demonstrate the potential for additional segmental lordotic restoration as compared with historically published data. It remains to be seen whether these radiographic differences will translate into improved clinical outcomes in the longer term.

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**Disclosures**

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**Author Contributions**

Conception and design: Chang, Massie. Acquisition of data: Chang, Massie, Basheer, Buraimoh. Analysis and interpretation of data: Chang, Massie. Drafting the article: Chang, Massie, Zakaria. Critically revising the article: Chang, Massie, Zakaria. Reviewed submitted version of manuscript: Chang, Massie, Zakaria. Approved the final version of the manuscript on behalf of all authors: Chang. Statistical analysis: Massie, Schultz. Administrative/technical/material support: Chang. Study supervision: Chang.

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