Expandable Technology in Minimally Invasive TLIF: A Multicenter Clinical and Radiographic Analysis of 202 Patients with Two Year Follow Up

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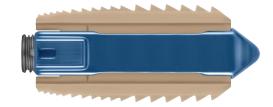
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Purpose

Static interbody cages require impaction for insertion while cages with incremental expansion allow for ease of insertion and optimized endplate contact.

This study served to document clinical and radiographic outcomes in patients who had a minimally invasive Transforaminal Lumbar Interbody Fusion (TLIF) with a device which offers controlled in-situ expansion.







Methods

A total of 202 patients comprise the basis of this retrospective analysis using an expandable interbody spacer combined with transpedicular posterior stabilization.

Clinical and radiographic records were analyzed for assessment of clinical outcomes, fusion rates, re-operations and device-related complications.

Device-related complications were defined as implant breakage, migration, subsidence, and revision surgery at the index level.

Outcome Measures

- Patient demographic data, including age, gender and symptom history.
- Intra-operative parameters including skin-to-skin operative time, estimated blood loss, fluoroscopic exposure time, duration of hospital stay and intraoperative complications.
- Patient-reported outcome measures included visual analogue scale (VAS) scores for back and leg pain and Oswestry Disability Index (ODI) scores.
- Radiographic outcomes were evaluated by review of standing AP, lateral and flexion-extension plain films.
- Peri-operative complications associated with the surgical procedure, the implantation device or both were documented.
- Outcome measures were collected pre-operatively and at 6, 12 and 24 months post-operatively.

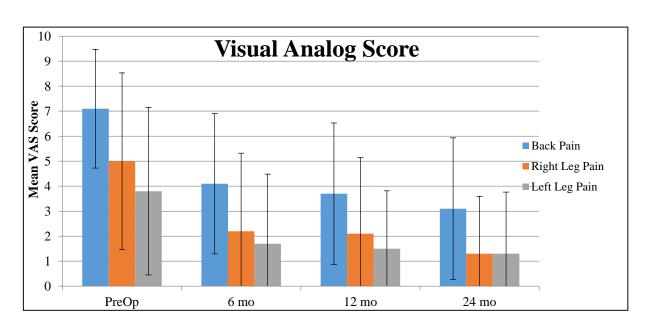
Radiographic Outcomes

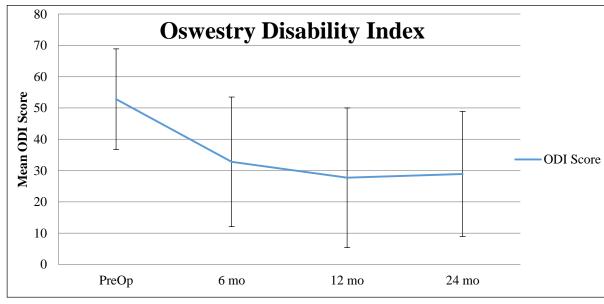
- Radiographic evaluation performed by a third party included inter-vertebral disc height, neuroforaminal height, fusion and device migration and integrity.
- Measurement of inter-vertebral disc height was based on the posterior margin of the operative disc space.
- The focal lordosis angle was measured from the superior endplate of the cephalad vertebral body and the inferior endplate of the caudad vertebral body.

 Values were reported individually by level for patients who were treated at two levels.

Results

Mean VAS and ODI scores decreased significantly from preoperative to the 24 month postoperative interval (p<0.05).

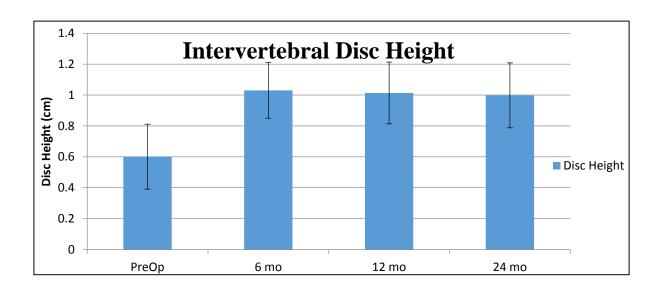




Results

Intervertebral disc heights (0.6±0.1 vs 1.1±0.2 cm) and neuroforaminal heights (1.7± 0.4 vs 2.0±0.3cm) increased significantly and were maintained throughout 24 months (p<0.05)

Radiographic Outcomes by Time (mean <u>+</u> SD)					
		Postoperative		P-value (Preoperative to 24	
	Preoperative	6 months	12 months	24 months	months)
Disc Height, cm	0.6 <u>+</u> 0.1	1.1 <u>+</u> 0.2	1.1 <u>+</u> 0.2	1.1 <u>+</u> 0.2	0.00
Neuroforaminal Height, cm	1.7 <u>+</u> 0.4	2.0 <u>+</u> 0.3	2.0 <u>+</u> 0.3	2.0 <u>+</u> 0.3	0.02
Cobb Angle, degrees	17.6 <u>+</u> 8.2	18.5 <u>+</u> 7.2	17.6 <u>+</u> 7.0	16.1 <u>+</u> 8.0	0.78

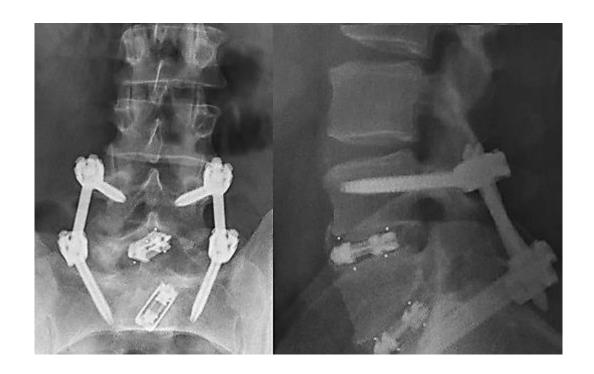


Results

- 97% of patients exhibited radiographic evidence of successful fusion by 24-month follow-up.
- There were no cases of device failure. However, asymptomatic migration or subsidence was present in 12 (5.9%) patients.
- Overall reoperation rate at the index level was 2.97% (n = 6), secondary to pedicle screw failure and pseudoarthrosis.
- No intra-operative complications were reported.

Conclusion

The use of expandable interbody cages for MIS TLIF leads to significant improvements clinical outcomes as well as radiographic outcomes in terms of intervertebral disc and neuroforaminal height restoration and fusion rates.



Disclosures

Choll W. Kim is a consultant for Globus Medical, Biomet, and K2M, and receives royalties on CALIBER® (Globus Medical).

James Lindley is a consultant for Globus Medical.

Todd M. Doerr, Phillip G. St. Louis and Ai-Min Wu have no relationships to disclose.

Ingrid Y. Luna and Gita Joshua are salaried employees of Globus Medical.

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