Clinical Study Summary

The expandable transforaminal lumbar interbody fusion – Two years follow-up

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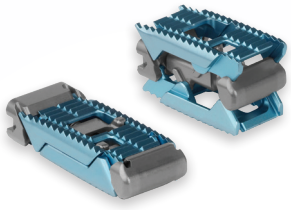
J Craniovertebr Junction Spine 9(1): 50–55, 2018

CALIBER®
Expandable TLIF Spacer



RISE®
Expandable TLIF Spacer

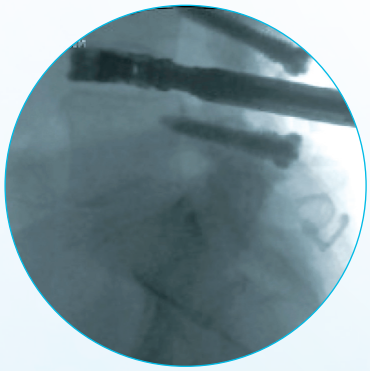
ALTERA®
Articulating Expandable TLIF Spacer

Objective: To determine if an expandable transforaminal lumbar interbody fusion (TLIF) spacer achieved satisfactory clinical outcomes while allowing for safe placement, improvement, and maintenance of foraminal and disc dimensions at 24 months post-surgery with low risk of spacer migration, subsidence, and nerve injury.

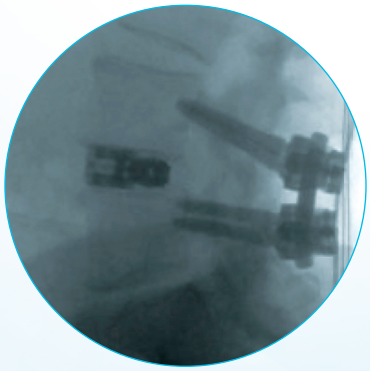
Method: A retrospective review of 54 patients (62 levels) with MIS or midline TLIF using Globus Medical CALIBER®, RISE®, or ALTERA® expandable interbody devices over a 24 month period.

Clinical outcomes were measured using the Oswestry Disability Index and Visual Analog Scale (10 point) back and leg pain scores. Radiological assessment was performed using standing lateral X-rays.

ALTERA®

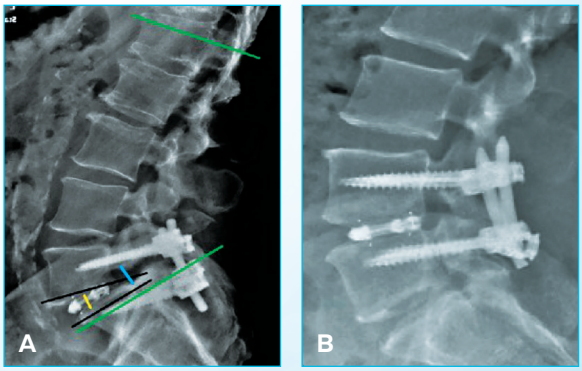


Insertion



Lordosis restoration

CALIBER®



(A) Variable angles and neural dimensions: Blue line= disc height; Yellow line= focal and global Cobb angle, **(B)** Follow-up X-ray

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Results:

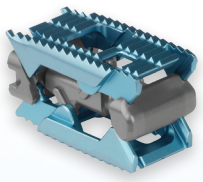
- Disc height increased from 8.3 to 13.3mm, neuroforaminal height from 17 to 19mm, focal Cobb angle from 5.5° to 7.3°, and global Cobb angle from 40.9° to 45.4°. These results were durable up to 24 months ($P<0.001$)
- The fusion rate was 93% at 12 months and 100% at 24 months postoperative, respectively
- Mean ODI score decreased from 61.4 to 38.3, mean back pain VAS from 7.7 to 4.6, and mean leg pain VAS from 7.8 to 3.7, postoperatively at 24 months.
- No instances of spacer migration or subsidence or intra/postoperative neurological complications.

Radiographic outcomes at two years

	Mean Disc height (mm)	Mean Neuroforaminal height (mm)	Mean Focal Cobb angle (°)	Mean Global Cobb angle (°)
Preoperative	8.3 (3.0)	17.0 (3.4)	5.5 (4.3)	40.9 (15.7)
Postoperative (24 months)	13.3 (2.6)	19.0 (2.7)	7.3 (3.3)	45.4 (16.0)
	$P<0.001^{\S}$	$P=0.001^{\S}$	$P=0.001^{\S}$	$P=0.001^{\S}$

CONCLUSION

Preliminary results from this 54 patient study suggest that the use of an expandable interbody spacer achieves satisfactory outcomes by improving and maintaining foraminal dimensions and disc height with minimal complications.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GMSS34
09.18 Rev A