

# Clinical Evidence Summary Expandable Interbody Devices

Article	Description	Results/Summary

# **ALTERA®**

#### Massie et al. 2018

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

Neurosurg Focus 44 (1):E8, 2018

Retrospective review of 1- and 2-level MIS TLIF radiographic and clinical outcomes using ALTERA® expandable spacer

Cohorts: 39 patients (1-level) 5 patients (2-level) MIS TLIF using ALTERA® expandable spacer provided significant restoration of segmental height and lordosis, with improvement in sagittal balance parameters and significant reduction in pain and disability.

- Spondylolisthesis was corrected by 4.3mm on average (preoperative=6.69mm, postoperative=2.39mm, p<0.001)
- Segmental lordosis improved by 4.94° on average (preoperative=5.63°, postoperative=10.58°, p<0.001)</li>
- Segmental height increased by 3.1mm on average (preoperative=5.09mm, postoperative=8.19mm, p<0.001)
- · Overall fusion rate was 96%
- Favorable outcomes demonstrated with 1- and 2-level MIS TLIF

### Hawasli et al. 2017

Minimally Invasive transforaminal lumbar interbody fusion with expandable versus static interbody devices, radiographic assessment of sagittal segmental and pelvic parameters

Neurosurg Focus 43 (2):E10, 2017

Retrospective review of clinical data following MIS TLIF using the ALTERA® spacer in 44 patients (48 interbody spacers)

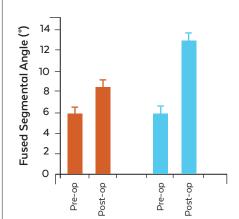
Cohorts:

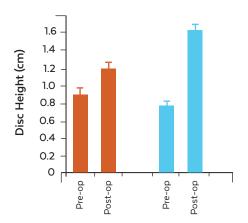
28 patients with 29 expandable spacers
16 patients with 19 static spacers

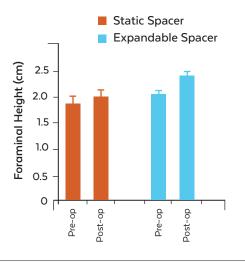
MIS TLIF with ALTERA® led to a greater and longer lasting increase in disc height, foraminal height, and index level segmental lordosis than static interbody devices, especially in patients with a collapsed disc space.

- Disc height was 32.7% greater in patients with expandable interbody devices than those with static interbody devices
- Foraminal height was 14.8% greater in patients with expandable interbody devices when compared with patients with static devices
- Segmental lordosis was 41.9% greater in patients with expandable interbody devices compared to static interbody devices
- Mean change in ODI score was 22.3 for the expandable interbody group and 13.6 for the static group

# Hawasli et al. 2017 Outcomes









# **CALIBER®**

#### Kim et al. 2016

Minimally invasive transforaminal lumbar interbody fusion using expandable technology: a clinical and radiographic analysis of 50 patients

World Neurosurg 90:228-235, 2016

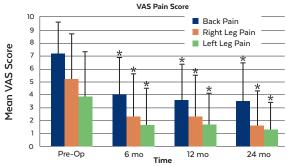
Prospective clinical data from 50 patients treated with CALIBER® expandable interbody spacer and posterior stabilization

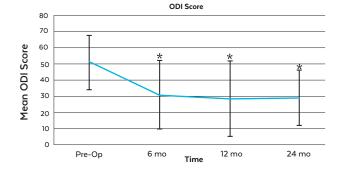
Cohorts:

38 patients (1-level) MIS TLIF 12 patients (2-level) MIS TLIF 62 operative levels CALIBER® expandable interbody spacer led to significant improvement in clinical and radiographic outcomes after MIS TLIF, including intervertebral disc height restoration and high fusion rates, with no evidence of device-related complications.

- Mean postoperative VAS back and leg pain scores and ODI scores decreased significantly at 6, 12, and 24 months compared to preoperative scores (p<0.05)</li>
- Postoperative disc height (8.3±2.7 vs. 11.3±1.9mm) increased significantly and was maintained through 24 months
- Postoperative radiographs showed no evidence of spacer migration, subsidence, or collapse
- Radiographic evidence of fusion was seen at all operative levels at 12 months (93%, 54/58) and 24 months (97%, 28/29)

#### Kim et al. 2016 Outcomes





\*Indicates statistically significant differences at P < 0.05 from the preoperative time interval

# CALIBER®-L

# Frisch et al. 2018

Clinical and radiographic analysis of expandable versus static lateral lumbar interbody fusion devices with two-year follow-up

J Spine Surg 4(1):62-71, 2018

Retrospective comparison of clinical and radiographic outcomes and device-related complications in patients treated with static and CALIBER®-L expandable spacers following LLIF

Cohorts

29 patients had LLIF with static spacer

27 patients had LLIF with CALIBER®-L expandable spacer

LLIF using CALIBER®-L expandable spacers resulted in similar clinical and radiographic outcomes when compared to static spacers, and led to a lower subsidence rate.

- Mean VAS and ODI scores improved significantly from preoperative to 24 months follow-up in both groups (p<0.05)</li>
- Preoperative intervertebral and neuroforaminal height increased significantly in both groups (p<0.01)</li>
- Evidence of radiographic fusion was observed in all operative levels in both static and expandable spacer groups by 24 months
- Implant subsidence was reported in 16.1% of static levels and none of the expandable levels (p<0.01)

#### RISE®-L

#### Frisch et al. 2017

Static versus expandable interbody spacers: preliminary 1-year clinical and radiographic results

J Clin Neurol Neurosurg Spine 1(1):113, 2017

Retrospective comparison of clinical and radiographic outcomes of expandable versus static interbody spacers following minimally invasive LLIF in 64 patients

Cohorts:

32 patients with RISE®-L expandable spacer

32 patients with static spacer

Patients in the RISE®-L expandable spacer group experienced a greater increase in segmental lordosis and a lower subsidence rate than those in the static group.

- Patients treated with RISE®-L demonstrated a 17% increase in segmental lordosis from 14°±7.9° preoperatively to 16.4°±8.8° 12 month postoperative (p=0.01)
- No significant increase in segmental lordosis was observed in the static group (p=0.40)
- Subsidence was greater in the static group (32.4%) than the expandable group (9.8%) (p<0.01)