

CLINICAL STUDY SUMMARY

Two-Year Clinical and Radiographic Outcomes of Expandable Interbody Spacers Following Minimally Invasive Transforaminal Lumbar Interbody Fusion: A Prospective Study

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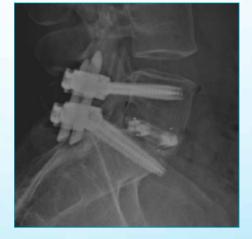
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OBJECTIVE: The aim of this study was to evaluate the clinical and radiographic outcomes of patients who underwent minimally invasive transforaminal lumbar interbody fusion (MIS TLIF) with the CALIBER® expandable TLIF spacer.

METHOD: Forty patients from four institutions who underwent MIS TLIF using the CALIBER® expandable TLIF spacer were followed for 24 months. Visual Analog Scale (VAS), Oswestry Disability Index (ODI), disc height, foraminal height, segmental and lumbar lordosis, and fusion were assessed.

Lateral Radiographs







Pre-operative

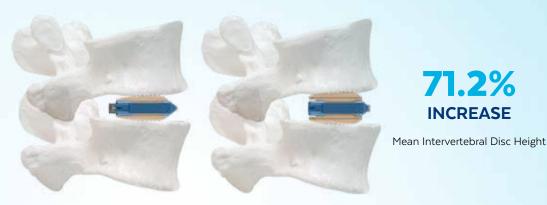
24 months post-operative



Radiographic outcomes demonstrated the following improvements at 24 months:

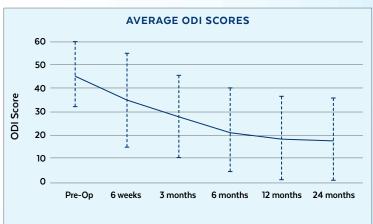
12.1% INCREASE

Mean Neuroforaminal Height



- Mean intervertebral disc height increased significantly from 7.3 \pm 2.6mm to 12.5 \pm 1.2mm (P < .001).
- Foraminal height increased significantly from 17.3 \pm 4.3mm to 19.4 \pm 4.2mm (P < .001).
- Mean lower back, left leg, and right leg pain VAS scores decreased significantly by 59.1%, 72.4%, and 73.1%, respectively.
- ODI scores also decreased significantly by 59.7%.
- · No cases of spacer migration, breakage, or subsidence were reported.





CONCLUSION: In this study, intraoperative insertion, impaction, number of passes through the neural structures, and fit were better with a CALIBER® expandable TLIF spacer than a static spacer. Significant improvements in disc and foraminal height restoration with immediate and progressive pain relief were reported. There were no neurologic injuries or spacer-related complications at 24 months.



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