

Clinical Evaluation of TruFUSE® Lumbar Facet Fusion System

Joseph C. Maroon MD; Jeffrey Bost; Darren LePere BS; Stephanie Bost BS; Louis Williams BS; Matt El-Kadi MD Department of Neurosurgery, University of Pittsburgh Medical Center

Introduction

The TruFUSE® lumbar facet fusion system is a unique allograft milled bone dowel used to fuse facet joints. We evaluated subjects undergoing TruFUSE® fusion for stable grade I spondylolisthesis and stenosis comparing operative time, length of stay, blood loss and outcome to a similar literature-based cohort of patients undergoing pedicle screw fusion (PSF).

Methods

From 2009 to 2011, 41 subjects (17M, 24F, ave. age 69.5 yr) underwent TruFUSE® facet fusion along with transverse process bone fusion and laminectomy. Length of stay, operative time, blood loss and outcomes were compared to eight literature-based cohort that analyzed similar parameters following pedicle screw fusion.

Picture 1



Single side facet fusion with TruFUSE(R)dyed blue



Placement of spacula into the facet joint.

Results

The 41 subjects' mean operative time for laminectomy, transverse process fusion and TruFUSE® facet fusion was 106 min, with a mean blood loss of 145 cc, and a mean hospital stay of 1.7 days (77% one day). A follow-up at avg. six months, 33 (80%) subjects reported subjective outcomes of "excellent" or "somewhat improved," four (10%) "unchanged," and four (10%) "worse." Flexion and extension radiographs showed 39 of the 41 patients had spinal stability at an average six months post-op and all had signs of early fusion. TruFUSE® subjects had significantly (p<0.0001) shorter surgeries (106 min compared to the literature data range of 185 - 240 min); significantly (p<0.0001) shorter hospitalization (1.7 days compared to 4 - 19 days). Mean estimated blood loss (EBL) was significantly lower (p<0.001) (145 cc compared to 321 cc and 1,082 cc range for PSF). Subjective outcome and radiographic stability were comparable between groups.

Conclusions

This comparison using the TruFUSE® lumbar facet fusion system demonstrates improvements in length of stay, surgical blood loss, and operative time in our selected patient population compared to several published lumbar pedicle screw fusion systems outcomes. There could be economic benefits also.

Learning Objectives

1. Understand common reasons for lumbar facet fusion.

2. Learn about a unique minimally traumatic facet fusion system.

3. Learn the advances of facet fusion verse PSF with stable lumbar spondylolisthesis.

References

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Degenerative Spondylolisthesis: Does fusion method influence outcome? Four-year results of the spine patient outcomes research trial.
Spine.2009;24:2351-60. Picture 3



Placement of drill guide into the facet joint.



Close up view of TruFUSE(R) inserted into a facet joint