

Interspinous Process Fixation versus Pedicle Screw Fixation in Circumferential Arthrodesis: Outcomes from a Prospective Randomized Multi-Center Trial

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Introduction

Interspinous process fixation (ISPF) has received increased consideration as a minimally disruptive adjunct to circumferential spinal arthrodesis; however, it is still unclear whether ISPF can support long-term healing outcomes similar to those supported by pedicle screw fixation (PSF). The objective of this study was to prospectively compare the outcomes of subjects receiving anterior (ALIF) or lateral (LLIF) interbody fusion with adjunctive ISPF or PSF.

Learning Objectives

By the conclusion of this session, participants should be able to discuss/identify...

1) Outcome trends achieved with adjunctive ISPF in circumferential fusion

2) Patient demographics/pathologies for which ISPF may be advantageous

3) Similarities and differences between outcomes achieved with adjunctive ISPF or PSF

Methods

All subjects received single-level interbody fusion (ALIF or LLIF) with supplemental ISPF (n=66) or PSF (n=37) for the treatment of degenerative disc disease and/or spondylolisthesis. The randomization ratio was 2:1, ISPF to PSF subjects. The PSF approach (MIS/open; uni/bilateral) and interbody approach (ALIF or LLIF) were per investigator institutional standardof-care. Perioperative outcomes, patient reported outcomes, and fusion outcomes were collected through 24mo. Analysis was performed using a linear mixed model (p<0.05).



Results

No statistically significant differences were observed between cohorts with respect to change in patient reported outcome scores (ODI, SF-36, ZCQ, and NRS/VAS) from baseline to 1.5, 3, 6, 12, or 24months. Mean ODI score improvement at 12mos/24mos was 26.5/23.3 and 23.2/23.1 for ISPF and PSF subjects, respectively. The difference in ODI improvement of +3.3pts at 12mos exceeded the established non-inferiority margin of 10pts. Radiographic fusion success was (score of BSF-3) ISPF – 94.9% and PSF – 85.0%, respectively.



Conclusions

ISPF subjects demonstrated clinically advantageous trends across all follow-up metrics, achieving significant reduction in all patient reported outcomes and exhibiting quality bone formation in both the anterior and posterior aspects.