Clinical and radiographic evaluation of a novel interlaminar fusion implant (coflex-F) system to augment lumbar interbody fusion

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IMAST 2011
Copenhagen, Denmark
**Disclosures**

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18th International Meeting  
on Advanced Spine Techniques  
Authors Disclosure Information

- a. Grants/Research Support  
- b. Consultant  
- c. Stock/Shareholder  
- d. Speakers’ Bureau  
- e. Other Financial Support
Introduction

Interbody fusion remains the gold standard treatment for a variety of lumbar degenerative disorders (ALIF, ALIF/PSF, Lateral IF/PSF, TLIF, PLIF):

Limitations of pedicle screw instrumentation

- Time
- Potentially morbid approach (open)
- Radiation to surgeon/patient
- Risk to neurologic structures
- Cranial facet joint violations with MIS screw insertion
- 50% violation → ASD??
- Learning curve

Beck, *Eur Spine J*, 2009
Radiation Exposure

• 2006 Survey of SRS membership:
  – Among male SRS surgeon members, there is a 25-fold higher incidence of thyroid cancer than expected, and a higher overall cancer rate.

• Potentially increased with MIS
Alternatives to Pedicle Screws

- Stand-alone anterior constructs
- Cage + anterior plate
- Translaminar screw
- Spinous Process Devices

Interlaminar Fixation

- MIS-compatible
- Minimize radiation exposure
- Minimal soft-tissue damage
- Avoid cranial facet joints
- Avoid proximity to neural structures
- Support from strong laminar bone, not spinous processes
  - Laminar bone 2-5x stronger than spinous process
    (Trautwein, *Spine J*, 2010)
Introduction

• Ample biomechanical data has shown similar performance profile of interspinous process device with bilateral pedicle screws in cadaveric models
  – Karahalios, JNS, 2010
  – Wang JC, JNS, 2006

• Paucity of clinical and radiographic outcomes data on the efficacy of Interlaminar/Interspinous Process Devices to promote interbody fusion

Hypothesis

Interlaminar stabilization provides sufficient stability to promote anterior interbody fusion in vivo
Purpose

- The current study aims to report the clinical and radiographic data from a multicenter European trial in which the coflex-F™ interlaminar fusion device was used to stabilize lumbar interbody fusion for a variety of degenerative lumbar conditions.

- Prospective, non-randomized
- Post-Market surveillance study
- 6 surgeons
- ALIF, PLIF and TLIF cages
- End point 6-24 months
- No use of BMP included

- n=68, implants=76
- Average height: 169 cm
- Average weight: 82 kg
- Average age: 60 years
Methods
A total of 90 subjects were enrolled and have been followed up radiographically ranging from 6-24 months post-operatively.

A board-certified, independent musculoskeletal radiologist performed radiographic assessments

1. evidence of bridging bone
2. $<3$mm translational motion
3. $<5$ degrees of angular motion, and
4. fusion success (i.e. lack of detectable motion)
Patient Demographics

- Indications (more than one possible)

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<thead>
<tr>
<th>Diagnosis</th>
<th>Count</th>
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<tr>
<td>DDD</td>
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<tr>
<td>Grade I spondylolisthesis and/or equivalent retrolisthesis</td>
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<tr>
<td>HNP</td>
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<td>Angular or translatory instability</td>
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<td>Degenerative Scoliosis</td>
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Results: Radiographic$^1$

- Bridging bone was present in 96.3% (78/81)
- 100% of patients (65/65) had <3mm translational motion
- 100% (65/65) had <5 degree of angular motion

The fusion rate, using established radiographic criteria, was $95.2\%$ (59/62)

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$^1$Of the 90 patients enrolled in the study:
81 patients (90%) had radiographic data that permitted assessment of fusion status.
65 patients had flexion-extension films, and
62 patients had all radiographic measures available for review.
## Results: Clinical

### VAS-Back

<table>
<thead>
<tr>
<th></th>
<th>Pre-op</th>
<th>6 wks</th>
<th>3 months</th>
<th>6 months</th>
<th>12 months</th>
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<tr>
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<td><strong>Mean</strong></td>
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### ODI

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### VAS Right Leg

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<tr>
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### VAS Left Leg

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Results: Safety

• No adverse events relating directly to the coflex-F™ device were reported by the treating surgeons.

• One SAE relating to the surgical procedure was reported on a wound problem.

• Another SAE was reported on subsidence of the interbody cage with progression of spondylolisthesis.

• One confirmed spinous process fracture. The total incidence of confirmed spinous process fractures was $1/90 = 1.1\%$. 
Conclusions

- Posterior stabilization to augment lumbar interbody fusion was achieved in 95.2%.
- Clinical outcomes were comparable to other published series in the literature.
- Allows for soft-tissue sparing, reduced blood loss, reduced surgical time, improved safety profile, protection of cranial facet joints, and avoids radiation exposure to surgeon and patient.
- Attractive alternative to pedicle screw instrumentation to augment lumbar interbody fusion.