

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

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Disclosures

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Authors Disclosure
Information**

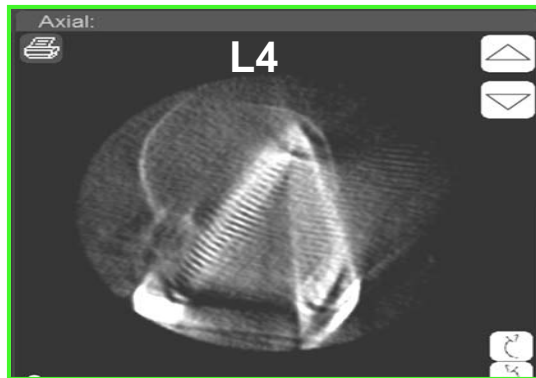
- a. Grants/Research Support
- b. Consultant
- c. Stock/Shareholder
- d. Speakers' Bureau
- e. Other Financial Support

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

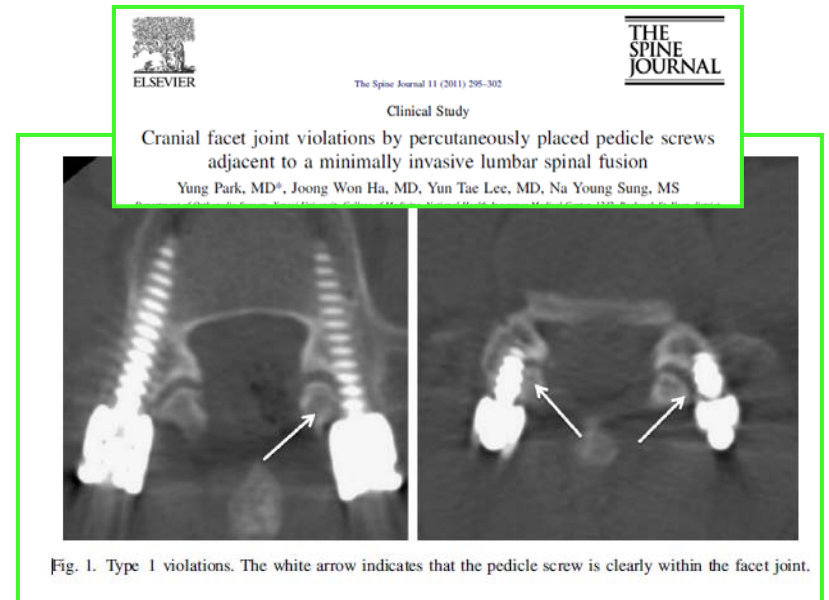


Fig. 1. Type 1 violations. The white arrow indicates that the pedicle screw is clearly within the facet joint.

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.
 - Wagner TA, Lai SM, Asher MA. SRS Surgeon Members' Risk for Throid Cancer: Is it Increased? *Proceedings of the 41st Annual Meeting of the Scoliosis Research Society* , 73. 2006.
- 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

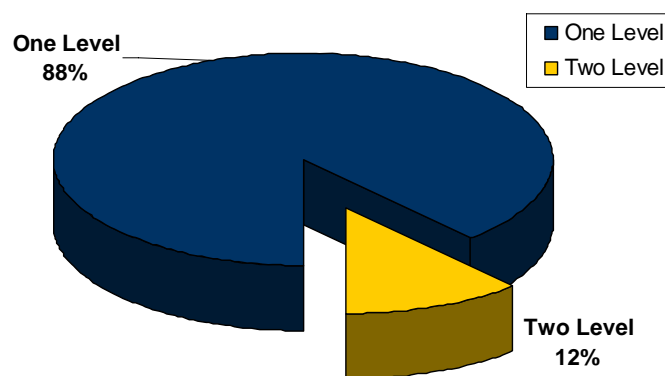
- Ample biomechanical data has shown similar performance profile of interspinous process device with bilateral pedicle screws in cadaveric models
 - Karahalios, JNS, 2010
 - Wang JC, JNS, 2006
- Paucity of clinical and radiographic outcomes data on the efficacy of Interlaminar/Interspinous Process Devices 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



Radiographic Data

Methods

A total of 90 subjects were enrolled and have been followed up radiographically ranging from 6-24 months post-operatively.

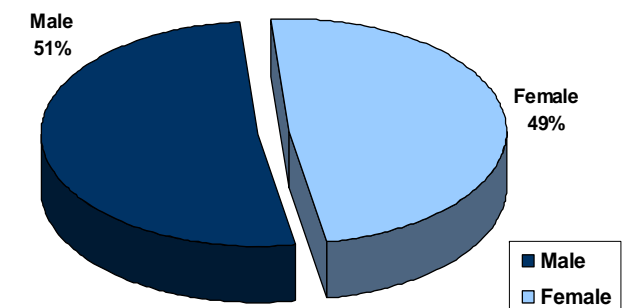
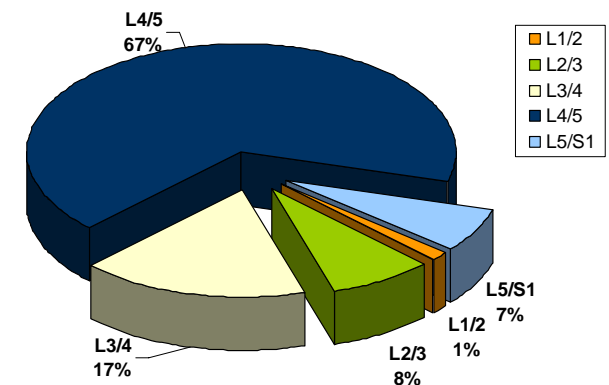
A board-certified, independent musculoskeletal radiologist performed radiographic assessments

1. evidence of bridging bone
2. <3mm 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)

DDD	54
Grade I spondylolisthesis and/or equivalent retrolisthesis	41
HNP	19
Angular or translatory instability	14
Spinal Stenosis	6
Degenerative Scoliosis	1



Results: Radiographic¹

- 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)

Results: Clinical

VAS-Back

	Pre-op	6 wks	3 months	6 months	12 months
N	63	17	46	54	45
Mean	7.1	4.5	3.1	2.8	2.6

ODI

	Pre-op	6 wks	3 months	6 months	12 months
N	64	17	47	53	44
Mean	53.3	36.7	30.1	28.8	23.9

VAS Right Leg

	Pre-op	6 wks	3 months	6 months	12 months
N	63	16	47	52	44
Mean	3.7	1.5	1.6	1.3	1.1

VAS Left Leg

	Pre-op	6 wks	3 months	6 months	12 months
N	63	16	46	54	44
Mean	4.3	2.8	1.5	1.7	1.3

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