Motion Preserving MIS Stabilization for Stenosis Surgery
Expanding Your ASC Practice
Hallett Mathews, MD, MBA
Becker’s ASC Conference June 12, 2014
Disclosure

Licensed (VA), Board Certified Orthopedic Spinal Surgeon

Boarded until 2019, twice recertified

Former Medtronic VP and Chief Medical Officer 2007 to 2011

Former President of MCRA (Musculoskeletal Clinical Regulatory Advisors) 2011 to 2012

Currently Executive Vice President and Chief Medical Officer Of Paradigm Spine, LLC headquartered in New York City, NY
Our Challenge….let’s break this down, for lumbar spinal stenosis, can we use……

• Minimally Invasive Surgery – how did we get here?
• Decompression – what does this mean?
• Stabilization – possible in an ASC setting?
• Motion Preservation – is this possible?
• All in an ASC setting?
• Is there a value statement here?
Minimally Invasive Surgery circa 1955 - present

• Really started with an approach and a diagnostic dilemma
• Lindbloom, 1956 described discography
• Craig, 1956 described the posterolateral approach for tumor biopsy
• Fisher, 1961 described chemonucleolysis using chymopapain
• Hijikata, 1974 described arthroscopic assisted discectomy
• Onik, 1983 Automated Percutaneous Lumbar Discectomy
• Kambin, Leu 1988 discussed the biportal approach posterolaterally
• Mathews, 1990 described foraminal approach and percutaneous subcutaneous pedicle fixation for percutaneous fusion
Minimally Invasive Era was Launched
………Primarily Fusion

• Laparoscopic Lumbar Fusion- Mathews, *Spine* 1995
• Thoracoscopic Discectomy and Fusion – Regan, Rosenthal, Picetti 1996
• Retroperitoneal Transpsoatic Fusion – Michelson 1996
• Infuse – PMA approval 2002 opened the field

• *Limitations of access were solved with biologics? Could we fix bad carpentry?*
Motion Preservation Era

- Charite – 1985 Karin Butner Janz
- Prestige, later Bryan cervical TDA – 1994 in Bristol, England
- Prodisc – early 1990s in France with T Marnay
- Numerous others *countered the fusion driven previous 2 decades* when they were approved in the US
- Cervical TDA is a realistic ASC procedure? – can relieve stenosis
- Lumbar TDA could be an ASC procedure? with the appropriate setup
- Implant costs and payer coverage requirements are challenging
What About Lumbar Stenosis Patients?

• Can patients undergo surgical decompression in the ASC setting?  
  YES

• Microsurgical decompression using open MIS approach can decompress stenosis with direct and limited visualization (Traditional).  
  MILD, Boxano, others with newer techniques
Can Stenosis Patients Undergo Stabilization in an ASC Setting?

- **Sure** – X–Stop (MDT), Superion (Vertiflex) (PMA pending), DIAM (MDT) (PMA pending), others
Can Lumbar Stenosis Patients Receive Open MIS Surgical Decompression and Stabilization in the ASC Setting?

• X-Stop – not on label, **not performed with open decompression**

• DIAM – not approved and labeling will **not be with open decompression**

• Vertiflex – not approved and **not to be used with open decompression**

• Percutaneous fusion of facets and TP after decompression using MIS technique- **approved**

• coflex® - **approved for open surgical decompression and stabilization for stenosis patients L 1 to L 5 , one or two levels**
Can Motion Preserving MIS stabilization Occur after Open Surgical Decompression for Lumbar Stenosis?

- Historically – fusion? **Not motion preserving**
- Lumbar Disc Replacements – **not indicated for facet arthropathy, stenosis**
- X-Stop – **not indicated for open decompression, not motion preserving**
- DIAM, Vertiflex – not indicated for open decompression, extension block

- **coflex®** - only approved interlaminar, motion preserving stabilization to be performed after open surgical decompression of moderate to severe spinal stenosis with up to grade 1 spondylolisthesis, L 1 to L 5 - **ASC compatible**
What is coflex®?

• First invented 1992, implanted in 1994
• Acquired 2005 by Paradigm Spine, LLC after 10 yr follow-up for patients
• FDA PMA protocol approval 2006 for a level 1 prospective RCT including *decompression and pedicle screw stabilization (fusion)* as a control, and *decompression with coflex®* as the investigational group with 2:1 investigational to control
• PMA approved October 2012
• *a priori* studied comparative effectiveness, adjacent level disease, point of service (ASC setting)
The Importance Of The *coflex*® Difference, Compared To Fusion

- Stabilizes while preserving motion at the treated level
- Preserves physiological kinematics at the adjacent level
- Protects decompression procedure
- Allows for faster pain relief (at 6 weeks)

- Increased hypermobility in the adjacent segment
- Increased rate of adjacent segment surgery at 2 yrs
- More invasive & time consuming procedure
- Increased revision & reoperation rates at 2 yrs
- Significant complications when it goes wrong…
Evidence Based Medicine:

Evolved from clinical epidemiology

A discipline promoted by the creation of the Journal of Clinical Epidemiology 1988


Wrote:" Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.”
US Preventive Services Task Force (USPSTF)
Systems to stratify evidence by quality have been developed, such as this one by the U.S. Preventive Services Task Force for ranking evidence about the effectiveness of treatments or screening:[29]
Level I: Evidence obtained from at least one properly designed randomized controlled trial.
Level II-1: Evidence obtained from well-designed controlled trials without randomization.
Level II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
Level II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled trials might also be regarded as this type of evidence.
Level III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.
Level 1 Clinical Data & Hierarchy of Evidence

**Level 1 Clinical Data:** Defined as clinical evidence obtained from a properly designed, randomized, controlled clinical trial representing outcomes that have met an extensive set of quality criteria intended to minimize bias. *Level 1 clinical data is generally accepted as the most reliable evidence of whether a treatment is effective.*

**Level 2 Clinical Data:** Defined as clinical evidence derived from a non-randomized controlled trial comprised of a prospective (pre-planned) clinical study, with pre-determined eligibility criteria and outcomes measures.

**Level 3 Clinical Data:** Defined as clinical evidence derived from observational studies with controls, and includes retrospective, interrupted time series, case control studies, cohort studies with controls, and health services research that includes adjustment for likely confounding variables.

**Level 4 Clinical Data:** Defined as clinical evidence derived from observational studies without controls (e.g. cohort studies without controls, case series without controls, and case studies without controls).
Study Design. Prospective, randomized, multicenter, Food and Drug Administration Investigational Device Exemption trial.

Objective. To evaluate the safety and efficacy of Coflex interlaminar stabilization compared with posterior spinal fusion in the treatment of 1- and 2-level spinal stenosis and degenerative spondylolisthesis.

Summary of Background Data. Long-term untoward sequelae of lumbar fusion for stenosis and degenerative spondylolisthesis have led to the search for motion-preserving, less-invasive alternatives.

Methods. Three hundred twenty-two patients (215 Coflex and 107 fusions) from 21 sites in the United States were enrolled between 2006 and 2010. Subjects were randomized to receive laminectomy and Coflex interlaminar stabilization or laminectomy and posterolateral spinal fusion with spinal instrumentation in a 2:1 ratio. Overall device success required a 15-point reduction in Oswestry Disability Index, no reoperations, no major device-related complications, and no postoperative epidural injections.

Results. Patient follow-up at minimum 2 years was 95.3% and 97.2% in the Coflex and fusion control groups, respectively. Patients taking Coflex experienced significantly shorter operative times (P < 0.0001), blood loss (P < 0.0001), and length of stay (P < 0.0001). There was a trend toward greater improvement in mean Oswestry Disability Index scores in the Coflex cohort (P = 0.075).

Both groups demonstrated significant improvement from baseline in all visual analog scale back and leg parameters. Patients taking Coflex experienced greater improvement in Short Form 12 physical health outcomes (P = 0.050) and equivalent mental health outcomes. Coflex subjects demonstrated significant improvement in all Zurich Claudication Questionnaire outcomes measures compared with fusion (symptom severity [P = 0.023]; physical function [P = 0.008]; satisfaction [P = 0.006]). Based on the Food and Drug Administration composite for overall success, 66.2% of Coflex and 57.7% of fusions succeeded (P = 0.999), thus demonstrating noninferiority. The overall adverse event rate was similar between the groups, but Coflex had a higher reoperation rate (10.7% vs. 7.5%; P = 0.426). At 2 years, fusions exhibited increased angulation (P = 0.002) and a trend toward increased translation (P = 0.063) at the superior adjacent level, whereas Coflex maintained normal operative and adjacent level motion.

Conclusion. Coflex interlaminar stabilization is a safe and efficacious alternative, with certain advantages compared with lumbar spinal fusion in the treatment of spinal stenosis and low-grade spondylolisthesis.

Key words: Coflex interlaminar stabilization, spinal fusion, spinal stenosis, degenerative spondylolisthesis.

Level of Evidence: 1

Spine 2013;38:1529–1539

The recent Spine Patient Outcomes Research Trial (SPORT) studies and others have demonstrated clear superiority of laminectomy compared with conservative care at 4 years, and have confirmed the use and cost-effectiveness of this most commonly performed spinal procedure in the spinal stenosis population.1-4
Clinical Composite Success Rate

- ODI Score
  - An improvement of at least 15 points 24 months post OP

- Surgery
  - No revision, removal or supplement fixation

- Epidural
  - No lumbar epidural steroid injection

- Device
  - No device related complications
# Composite Clinical Success Outcomes

<table>
<thead>
<tr>
<th>Subjects at Baseline</th>
<th>coflex®</th>
<th>Fusion Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Lost to Follow-Up</td>
<td>11</td>
<td>3</td>
</tr>
<tr>
<td>- Re-Op Failures</td>
<td>23</td>
<td>8**</td>
</tr>
<tr>
<td>- Injections</td>
<td>19</td>
<td>10</td>
</tr>
<tr>
<td>- Sensory/Motor Deficits</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>- ODI Failures</td>
<td>17</td>
<td>20*</td>
</tr>
</tbody>
</table>

*More conversions to fusion in coflex cohort more ODI failures in fusion cohort

**Two more fusion re-ops occurred which were not CCS failures due to the surgery happening at adjacent levels vs. at the level of the implant.

Total of 135 coflex® subjects achieved CCS

Total of 60 fusion subjects achieved CCS

- coflex®: 66.2%
- Fusion: 57.7%
Accomplishments

- 384 Study Surgeries
- More than 55,000 CRF pages
- Greater than 375,000 Clinical Data Points
- 12,188 Radiographs
- 463 Monitoring Visits
- 11 FDA Inspections
  (9 Sites, 1 CRO, and 1 Sponsor Audit)
ROM at Level of Implant (Degrees)

- Pre-Op: Value = 0.286
- Month 24: Value = 0.000

*Not evaluated for Fusion

coflex® maintains Index Level Motion at 24 Months
ROM Above Level of Implant (Degrees)

*Not evaluated for Fusion

coflex® protects adjacent Segments from excessive Motion at 24 Months
Foraminal Height – X-Ray Analysis (mm)

coflex® maintains foraminal Height at 24 Months

Now proven at 4 years!

17.6 at 36 months
17.4 at 48 months
24 month CT post-foraminotomy and maintenance of foraminal height

Pre-op CT

Month 24 CT

15-205
Can low-grade spondylolisthesis be effectively treated by either coflex interlaminar stabilization or laminectomy and posterior spinal fusion? Two-year clinical and radiographic results from the randomized, prospective, multicenter US investigational device exemption trial

Clinical article

Reginald Davis, M.D., 1  Joshua D. Auerbach, M.D., 2 Hyun Bae, M.D., 3 and Thomas Errico, M.D. 4

1 Greater Baltimore Neurosurgical Associates, Baltimore, Maryland; 2 Department of Orthopaedics, Bronx-Lebanon Hospital Center, Albert Einstein College of Medicine, Bronx, New York; 3 The Spine Institute, Santa Monica, California; and 4 Department of Orthopaedic Surgery, Hospital for Joint Diseases, NYU Langone Medical Center, New York, New York

Object: Posterolateral spinal fusion (PSF) has long been the standard of care for degenerative spondylolisthesis, but less invasive, motion-preserving alternatives have been proposed to reduce the complications associated with fusion while still providing neural decompression and stabilization. The object of the current study is to evaluate the safety and efficacy of coflex Interlaminar Stabilization compared with PSF to treat low-grade spondylolisthesis with spinal stenosis.

Methods: This is a prospective, randomized, multicenter FDA investigational device exemption (IDE) trial comparing coflex Interlaminar Stabilization with laminectomy and PSF. A total of 322 patients from 21 sites in the US were enrolled between 2006 and 2008 for the IDE trial. The current study evaluated only the subset of patients from this overall cohort with Grade I spondylolisthesis (9% in the coflex group and 51% in the fusion group). Subjects were randomized 2:1 to receive decompression and coflex interlaminar stabilization or decompression and posterolateral spinal fusion with spinal instrumentation. Data collected included perioperative outcomes, Oswestry Disability Index (ODI), back and worse leg visual analog scale (VAS) scores, 12-item Short Form Health Survey, Zurich Claudication Questionnaire (ZCQ), and radiographic outcomes at a minimum of 2 years. The FDA criteria for overall device success required the following to be met: 10-point reduction in ODI, no reoperations, no major device-related complications, and no postoperative epidural injections.

Results: At a minimum of 2 years, patient follow-up was 94.0% and 94.1% in the coflex and fusion control groups, respectively. There were no group differences at baseline for any demographic, clinical, or radiographic parameter. The average age was 63 years in the coflex cohort and 65 years in the fusion cohort. Coflex subjects experienced significantly shorter operative times (p < 0.0001), less estimated blood loss (p = 0.0001), and shorter length of stay (p < 0.0001) than fusion controls. Both groups experienced significant improvements from baseline at 2 years in ODI, VAS back, VAS leg, and ZCQ, with no significant group differences. With the exception of significantly greater ZCQ satisfaction with coflex at 2 years. FDA overall success was achieved in 62.8% of coflex subjects (59 of 94) and 52.5% of fusion controls (30 of 57) (p = 1.000). The reoperation rate was higher in the coflex cohort (44 [14.1%] of 310) compared with fusion (1 [0.9%] of 110, p = 0.18), although this difference was not statistically significant. Fusion was associated with significantly greater angulation and translation at the superior and inferior adjacent levels compared with baseline, while coflex showed no significant radiographic changes at the operative or index levels.

Conclusions: Low-grade spondylolisthesis was effectively stabilized by coflex and led to similar clinical outcomes, with improved perioperative outcomes, compared with PSF at 2 years. Reoperation rates, however, were higher in the coflex cohort. Patients in the fusion cohort experienced significantly increased superior and inferior level angulation and translation, while those in the coflex cohort experienced no significant adjacent or index level radiographic changes from baseline. Coflex Interlaminar Stabilization is a less invasive, safe, and equally efficacious clinical solution to PSF to treat low-grade spondylolisthesis, and it appears to reduce stresses at the adjacent levels. Clinical trial registration no.: NCT00534235 (ClinicalTrials.gov).

(http://thejns.org/login0.317112013.4.SPINEI2636)

KEY WORDS • degenerative spondylolisthesis • coflex • fusion • spinal stenosis

1 J Neurosurg: Spine 1 May 3/,2013

S

ince the classic article from Herkowitz and Kurz4 in 1991 in which fusion significantly outperformed decompression alone in a prospective, randomized controlled trial, lumbar spinal fusion has been the standard

This article contains some figures that are displayed in color online but in black-and-white in the print edition.
Mitigating Adverse Event Reporting Bias in Spine Surgery

Joshi D, Aubuchon MD, Antim M, Atkinson, PhD, Moinuddin M, Michael C, Corley, MD, Alia D, Murra-Becker, MD, Peter H, Wang, MD, and Greg Morgan, MD, MA. 


Background: Almost all studies in the lower extremity and spine literature have raised concerns about the ability to report adverse events from randomized spinal surgery studies. To address this, a clinical trial design was conducted. This study (ClinicalTrials.gov Identifier: NCT01878527) conducted an investigation with the aim of assessing the impact of adverse event reporting in a randomized controlled trial of a novel device, used in the treatment of adolescent idiopathic scoliosis. 

Methods: The study was a noninferiority, single-centre, randomised controlled trial of the novel device and control. The primary objective was to compare the adverse event rates between the two groups. An independent data monitoring committee was responsible for the safety of the patients. 

Results: A total of 100 patients were enrolled, 50 in each group. The mean follow-up was 12 months. The incidence of adverse events was similar between the two groups. The incidence of adverse events was lower in the experimental group compared to the control group. The adverse events were arranged into categories according to the nature of the event and the potential for harm. 

Conclusions: The present study demonstrates that the novel device is safe and effective. The incidence of adverse events was low, thus reducing the risk of harm. The results of this study provide evidence for the safety and efficacy of this novel device in the treatment of adolescent idiopathic scoliosis.
Role of Coflex as an Adjunct to Decompression for Symptomatic Lumbar Spinal Stenosis

Naresh Kumar,1 Siddarth M Shah,2 Yau Hong Ng,2 Vinodh Kumar Pannierselvam,2 Sudeep DasDe,2 and Liang Shen3
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2Department of Orthopaedic Surgery, National University Hospital, Singapore, Singapore.

3Biostatistics Unit, Yong Loo Lin School of Medicine, National University of Singapore, Singapore, Singapore
Prospective cohort study.

Purpose

To assess whether additional implantation of Coflex following spinal decompression provided better clinical outcomes compared to decompression alone for symptomatic lumbar spinal stenosis (LSS) and to determine whether improvement in clinical outcomes correlated with changes in the radiological indices studied.

Overview of Literature

Literature on benefits of additional Coflex implantation compared to decompression alone for symptomatic LSS is limited.

Methods

Patients with symptomatic LSS who met the study criteria were offered spinal decompression with Coflex implantation. Those patients who accepted Coflex implantation were placed in the Coflex group (n=22); while those opting for decompression alone, were placed in the comparison group (n=24). Clinical outcomes were assessed preoperatively, six-months, one-year and two-years postoperatively, using the Oswestry disability index, 100 mm visual analogue scale (VAS)-back pain and VAS-leg pain, and short form-36 (SF-36). Radiological indices (disc height, foraminal height and sagittal angle) were assessed preoperatively, six months, one year, and two years postoperatively.
Results

Both groups showed statistically significant (p<0.001) improvement in all the clinical outcome indicators at all points in time as compared to the preoperative status. However, improvement in the Coflex group was significantly greater (p<0.001) than the comparison group. Changes in the radiological indices did not correlate significantly with the improvement in clinical outcome indicators.

Conclusions

Additional Coflex implantation after spinal decompression in symptomatic LSS offers better clinical outcomes than decompression alone in the short-term. Changes in radiological indices do not correlate with the improvements in clinical outcomes after surgery for symptomatic LSS.
Clinical comparison between coflex and X-Stop\(^1\) ZCQ outcomes at month 24

Reginald Davis, MD

\(^1\)XStop data based on:
A Multicenter, Prospective, Randomized Trial Evaluating the X STOP Interspinous Process Decompression System for the Treatment of Neurogenic Intermittent Claudication. Two-Year Follow-Up Results
James F. Zucherman, MD,* Ken Y. Hsu, MD,* Charles A. Hartjen, MD,† Thomas F. Mehalic, MD,‡ Dante A. Implicito, MD,§§
Michael J. Martin, MD,¶ Donald R. Johnson II, MD, Grant A. Skidmore, MD,¶¶ Paul P. Vessa, MD,‖ James W. Dwyer, MD,‖‖
Stephen T. Puccio, MD,¶¶¶¶ Joseph C. Caufden MD,¶¶ and Richard M. Ozuna, MD
### ZCQ Outcomes of coflex (and v fusion) v x-stop

**Clinically significant improvements at month 24**

<table>
<thead>
<tr>
<th></th>
<th>coflex® (total n=215)</th>
<th>Fusion (total n=107)</th>
<th>X STOP (total n=100)</th>
<th>p-value coflex® vs fusion</th>
<th>p-value fusion vs X STOP</th>
<th>p-value X STOP vs coflex®</th>
</tr>
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<tbody>
<tr>
<td><strong>Symptom Severity</strong></td>
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<tr>
<td></td>
<td>142/161 (88.2%)</td>
<td>67/86 (77.9%)</td>
<td>56/93 (60.2%)</td>
<td>0.041</td>
<td>&lt;0.00001</td>
<td>0.01</td>
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<td><strong>Physical Function</strong></td>
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<tr>
<td></td>
<td>138/161 (85.7%)</td>
<td>63/86 (73.3%)</td>
<td>53/93 (57.0%)</td>
<td>0.025</td>
<td>&lt;0.0001</td>
<td>0.02</td>
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<td><strong>Patient Satisfaction</strong></td>
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<td></td>
<td>152/162 (93.8%)</td>
<td>69/86 (80.2%)</td>
<td>68/93 (73.1%)</td>
<td>0.039</td>
<td>&lt;0.0001</td>
<td>0.26</td>
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<td><strong>Overall Success</strong></td>
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<tr>
<td></td>
<td>126/161 (78.3%)</td>
<td>58/86 (67.4%)</td>
<td>45/93 (48.4%)</td>
<td>0.367</td>
<td>&lt;0.001</td>
<td>&lt;0.01</td>
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*Defined as a decrease of at least 0.5 points*
The Influence of Preoperative Back Pain on the Outcome of Lumbar Decompression Surgery

Frank S. Kleinstück, MD, Dieter Grob, MD, Friederike Lattig, MD, Viktor Bartanusz, MD, Francois Porchet, MD, Dezsö Jeszenszky, MD, David O’Riordan, BSc, and Anne F. Mannion, PhD

Study Design. Prospective study with 12-month follow-up.

Objective. To examine how the relative severity of low back pain (LBP) to leg/buttock pain (LP) influences the outcome of decompression surgery for spinal stenosis.

Summary of Background Data. Decompression surgery is a common treatment for lumbar spinal canal stenosis, with generally good outcomes. However, concomitant LBP at presentation can make it difficult to decide Decompression surgery in the lumbar spine is one of the most common procedures for spinal canal stenosis, and outcomes are generally good,¹ but there is certainly room for improvement.²⁻⁴ With an increasing number of elderly patients seeking an active lifestyle, and limitations in the conservative management of the disease, surgery is becoming more widely accepted. Many studies have looked at independent predictors of surgical outcome with varying results. However, the relationship between preoperative pain characteristics and surgical outcome has not been adequately investigated in this population.
Methods. The Spine Society of Europe Spine Tango system was used to acquire the data from 221 patients. Inclusion criteria were lumbar degenerative spinal stenosis, first-time surgery, maximum 3 affected levels, and decompression as the only procedure. Before and 12 months after surgery, patients completed the multidimensional Core Outcome Measures Index (COMI; includes 0–10 LP and LBP scales); at 12 months, global outcome was rated on a Likert-scale and dichotomized into “good” and “poor” groups.

Results. There was a low but significant positive correlation between baseline LP-minus-LBP scores and both improvement in the multidimensional COMI score after 12 months ($r = 0.21, P = 0.003$) and the score on the 12-month global outcome scale ($r = 0.19, P = 0.007$). In the good outcome group, mean baseline LP was 2.3 (±3.7) points higher than LBP; in the poor group, the corresponding value was 0.8 (±3.4) ($P = 0.01$ between groups). In multivariate regression analyses (controlling for age, gender, comorbidity), baseline LBP intensity was the most significant predictor of the 12-month COMI score, and preoperative LP-minus-LBP score of the global outcome (each $P < 0.05$).

Conclusion. Overall, greater back pain relative to LP at baseline was associated with a significantly worse outcome after decompression. This finding seems intuitive, but has rarely been quantified in the many predictor studies conducted to date. Consideration of relative LBP and LP scores may assist in clinical decision-making and in establishing realistic patient expectations.

Key words: spinal stenosis, decompression surgery, registry, back pain, leg/buttock pain. Spine 2009;34: 1198–1203
coflex® for back pain

Only patients with significant back pain (>50mm on a 100mm VAS pain scale) were enrolled into the coflex® IDE study.

*In the immediate post-op phase, coflex® relieves back pain by offloading the facets.*

- Longer term, this serves to stabilize the degenerative process
- In the coflex® study, VAS Back Pain Scores showed a **70%** improvement at two years
- The SPORT® study showed a **32.5%** improvement in the Low Back Pain Bothersome Index at two years (in those subjects who received surgical treatment)*.
- coflex® **70%** vs decompression only **32.5%** improvement
- **Confirms the need for facet stabilization to improve back pain!!!**

* Surgical versus Nonsurgical Therapy for Lumbar Spinal Stenosis
James N. Weinstein, D.O., M.S., Tor D. Tosteson, Sc.D., Jon D. Lurie, M.D., M.S., Anna N.A. Tosteson, Sc.D., Emily Blood, M.S., Brett Hanscom, M.S., Harry Herkowitz, M.D., Frank Cammisa, M.D., Todd Albert, M.D., Scott D. Boden, M.D., Alan Hilibrand, M.D., Harley Goldberg, D.O., Sigurd Berven, M.D., and Howard An, M.D., for the SPORT Investigators*
coflex® in the ASC

- 72 yo female with 2 year history of neurogenic pseudoclaudication
- Conservative care failed, modified activities
- Failed numerous ESIs
- Healthy, active and wants to continue ADLs
- Thin, healthy, ASA 1
Case: 46M mechanical right leg and low back pain
European EBM and Additional Research

- Dutch PMA
- German PMA
- US Post Approval Study
- US Observational Study
Interspinous process device versus standard conventional surgical decompression for lumbar spinal stenosis: randomized controlled trial

OPEN ACCESS

Wouter A Moojen neurosurgery resident and epidemiologist 1 2, Mark P Arts neurosurgeon 2, Wilco C H Jacobs epidemiologist 1, Erik W van Zwet statistician 3, M Elske van den Akker-van Marle health economist 4, Bart W Koes epidemiologist 5, Carmen L A M Vleggeert-Lankamp neurosurgeon 1, Wilco C Peul neurosurgeon and epidemiologist 1 2, for the Leiden-The Hague Spine Intervention Prognostic Study Group (SIPS)

1Department of Neurosurgery, Leiden University Medical Center, Leiden, Netherlands; 2Department of Neurosurgery, Medical Center Haaglanden, The Hague, Netherlands; 3Department of Medical Statistics
Surgical Management of Spinal Stenosis: A Prospective Randomized (Level 1) Comparison of Decompression with or without interlaminar stabilization; an interim analysis comparing clinical and functional outcomes

Authors: Prof. Dr. med. Michael Rauschmann, Dr. med. D. Adelt, PD Dr. med. J. Franke, Greg Maislin, MS, MA, Dr. med. S. Schmidt, Dr. med. Steffen Sola

Background: The management of spinal stenosis (SS) is characterized by significant variability in surgical strategies. Changes in leg and back pain, function, and reoperations have been reported with wide variation. This interim analysis of a prospective randomized study, show interesting results.

Purpose: To compare outcomes in patients treated for SS with decompression alone (“D”) vs. with decompression and interlaminar stabilization (“D+IS”)

Results: 19.4% D+IS subjects experienced a TF (17 reops & 2 epidurals) compared to 30.4% D (16 reops & 15 epidurals). D+IS pts had significantly less m24 narcotic use compared to D pts (11.1% vs 25.8%, p=0.044). 41 D+IS and 45 D pts had no-TF and thus had a m24 evaluation. Superiority of D+IS in terms of CCS (no TF with ODI success) was observed in 54.7% (35/64) vs 38.9% (28/72) (p=0.065). When m24 narcotic use is added, 50.0% D+IS vs 33.3% D achieve CCS (p=0.049). A CCS of no TF with a mean VAS leg pain improvement of >=20mm was achieved in 51.6% vs 37.5%. When narcotic use is added to this endpoint, 59.4% D+IS vs 37.5% D (p=0.011) achieve success. For VAS Back pain among the non-TFs, 71.1% D+IS vs 78.1% D had improvement >=20 mm. For a CCS defined as no TF with VAS back pain mean improvement of >=20mm and no m24 narcotics, 46.9% D+IS vs 37.5% D achieved success. For functional treadmill outcomes among non-TFs, 82.5% (33/40) D+IS vs 66.7% (22/33) D had improvement in max walking distance >= 8 min, or to the point of walking for 15 min on. When CCS was defined by no TF and walking success, 55.9% (33/59) D+IS vs 34.4% D (21/64) (p=0.016) achieved CCS; with narcotic use added, 52.5% D+IS vs 31.2% D (p=0.017) had success.

Conclusion: Decompression with interlaminar stabilization resulted in measurably and significantly better functional outcomes, lower treatment failure rates, and less use of oral narcotic pain medications compared with decompression alone.
Value in Spine

Have we, ….. or can we ever do this analysis?
The Value Proposition for Spine - Difficulties

- Increasing commoditization of spinal devices
- Lack of EBM for PEEK cervical cages (AETNA, Humana)
- Leads to precert challenges that challenge indications
- Where are the value statements for spine?
- Without value supports, price and reimbursement erode
- Leading to a structural collapse for devices, procedures, facilities
From Quantity to Quality
Cost-Based vs. Value-Based Healthcare Reform

To achieve sustainability of current U.S. healthcare system, **Value-based purchasing** is being adopted by most stakeholders in medicine.

\[
\text{Value} = \frac{\text{Effectiveness}}{\text{Cost}}
\]
Treatment Costs Could Influence Doctor’s Advise, Andrew Pollack, *NYT*, Friday, April 16, 2016

- Dr Lowell Schnipper Am Soc Clin Onc suggest docs “should be and are stewards of the larger society”
- ACC and AHA announced they would begin to use cost data to rate the value of treatments in their joint clinical practice guidelines
- $50,000 per QALY rated as high value
- Dr Steven Pearson from NIH discussed this as “an important shift in the way doctors in America are talking about cost and value.”
Determining Value in Spine Care: Epidural Steroid Injections as an Example

Wong, David  
*SpineLine*, Jan/Feb 2014

• ESIs are rarely performed in the UK, whereas in 2011, 2.3 M in US Medicare patients alone!

• Using Comparative Effectiveness Research (CER), what is a positive outcome and thus a valuable outcome

• Then, short term vs long term relief? Level 1 evidence

• Value, Cost /QALY at one year was $570,000

• NICE requires <$50,000 Cost/QALY for reimbursement in UK NHS

• For CER research, only RCTs can be used for meta-analysis
SPINE SAFETY ALERT
Information for Healthcare Professionals:
Epidural Corticosteroid Injection: Drug Safety Communication - Risk of Rare but Serious Neurologic Problems
Including methylprednisolone, hydrocortisone, triamcinolone, betamethasone, and dexamethasone

SOURCE: FDA MedWatch

ISSUE: FDA is warning that injection of corticosteroids into the epidural space of the spine may result in rare but serious adverse events, including loss of vision, stroke, paralysis, and death. The injections are given to treat neck and back pain, and radiating pain in the arms and legs. The effectiveness and safety of epidural administration of corticosteroids have not been established, and FDA has not approved corticosteroids for this use.

FDA is requiring the addition of a Warning to the drug labels of injectable corticosteroids to describe these risks.

BACKGROUND: To raise awareness of the risks of epidural corticosteroid injections in the medical community, FDA's Safe Use Initiative convened a panel of experts, including pain management experts to help define the techniques for such injections which would reduce preventable harm. The expert panel's recommendations will be released when they are finalized. FDA will convene an Advisory Committee meeting of external experts in late 2014 to discuss the benefits and risks of epidural corticosteroid injections and to determine if further FDA actions are needed.

RECOMMENDATION: Patients should discuss the benefits and risks of epidural corticosteroid injections with their health care professionals, along with the benefits and risks associated with other possible treatments.

See the Drug Safety Communication for a Data Summary and additional information for both patients and healthcare professionals.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch safety alert, including a link to the FDA Drug Safety Communications, by clicking here.

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of government and other resources for patient safety-related notices that may be useful to our members. Information from these notices is also archived on the NASS website at https://www.spine.org/Pages/ResearchClinicalCare/PatientSafety/SpineSafetyAlerts.aspx. This information is provided as a service for information and education only.
Spinal fusions serve as case study for debate over when certain surgeries are necessary

Washington Post Business
10/28/2013

465,000 fusions in the US in 2011
Hospital Costs At An All Time High

- Top 3 surgical procedures by cost*:

  ✓ # 1 - Spinal Fusion ($11.3B)
  ✓ # 2 - Balloon Angioplasty ($11.0B)
  ✓ # 3 - Total Knee Replacement ($10.4B)

Payers Are Pushing Back On Fusion!

- Payers routinely require pre-authorizations for fusion
- Surgeon increasingly engaged in “justification” of procedure

  ✓ Burden of evidence needed to support rationale for surgery

Fusion Procedure Outcomes Under Close Scrutiny

- The readmission rate for spine fusion is 24.3% at 2 yrs*
- Reoperation rate for spine fusion is 15.5% at 2 yrs*
- Still no real consensus as to best way to treat these patients (no data)

* U.S. Centers for Disease Control and Prevention (CDC) 2011 data.
1.2M US Patients seeking treatment for LSS

- Central: 252,000 (21%)
- Lateral: 120,000 (10%)
- Foraminal: 228,000 (19%)
- Foraminal: 120,000 (10%)
- Foraminal: 120,000 (10%)
- Foraminal: 240,000 (20%)

Diagram showing types of LSS conditions and the number of patients suffering from each type.
coflex® Is Cost Effective!

- Each coflex® procedure frees up ~2 hours of OR time!
  - 55 less minutes of operative time
  - 30-45 less minutes of set-up time
  - 30-45 less minutes of breakdown time

- That’s a $3,600 savings @ $30 min. For OR time cost!
**coflex® Delivers Better Treatment & Greater Value At Lower Cost!**

**Faster Symptom Relief** - At 6 weeks, coflex® patients showed early relief of their spinal stenosis symptoms compared to fusion patients (90% vs. 77%, measured by ZCQ).

**Lasting Symptom Relief** - At 2 years, coflex® patients showed lasting relief of their spinal stenosis symptoms compared to fusion patients (88% vs. 78%, measured by ZCQ).

**Patient Satisfaction** - At 2 years, coflex® patients were satisfied with their outcome compared to fusion patients (94% vs. 87%).

**Shorter Operating Time** - coflex® surgeries were 36% faster compared to fusion surgeries (98 minutes vs. 153 minutes).

**Shorter Hospital Stay** - coflex® patients spent 40% less time in the hospital compared to fusion patients (1.9 days vs. 3.2 days).

**Less Blood Loss** - coflex® patients had less blood loss during surgery compared to fusion patients (110cc vs. 349cc).

**Stability In The Treatment Area** - At 2 years, coflex® patients retained their pre-operative range of motion (within 10%) & translation (within 5%) at the area of treatment.

**More Natural Movement At Treatment Area & Surrounding Spinal Segments** - At 2 years, coflex® patients retained their pre-operative range of motion (within 15%) at the areas below & above the treatment area, & fusion patients saw a 25-50% increase in unnatural motion at the areas below & above the treatment area.
coflex® Patients Do Better Faster = A True MIS Procedure

- Fewer coflex® patients needed narcotics 6 weeks after surgery, which was sustained through two years, compared to fusion.

- The use of the coflex® device reduced the patients' blood loss by 69% compared to fusion.

- More patients were satisfied with the coflex® procedure compared to fusion.

- Improvement of at least 15 points in ODI.
coflex® Directly Impacts Hospital Costs!

- Average LOS was reduced by 1.96 days with coflex®¹
- Average savings is $3,449 per procedure with coflex®²

¹Comparative Cost-effectiveness Analysis of Coflex® Interlaminar Stabilization versus Posterolateral Fusion for Lumbar Stenosis and Low-grade Spondylolisthesis. March 20 – 23, 2012 - Barcelona, Spain

²$1,910 is national average expenses per hospital day. Henry J. Kaiser Family Foundation, 2010
Comparative Cost-Effectiveness of coflex® Interlaminar Stabilization Versus Instrumented Posterolateral Lumbar Fusion for Treatment of Lumbar Spinal Stenosis and Spondylolisthesis

Authors:
-Jordana Kate Schmier (corresponding author), Health Sciences, Exponent Inc., Alexandria, VA USA
-Marci Halevi, Paradigm LLC, New York, NY, USA
-Greg Maislin, Biomedical Statistical Consulting, Wynnewood, PA, USA
-Kevin Ong, Biomedical Engineering, Exponent Inc., Philadelphia, PA, USA

Conclusion:
The clinical and health insurance communities each have vested interest in identifying treatment options for moderate to severe LSS with and without spondylolisthesis that are both clinically beneficial and cost-effective. This study found that over five years, treatment with coflex® resulted in important reductions in health care costs accompanied by utilities that were better than those experienced by patients treated with fusion. This finding was robust and no reasonable sensitivity analysis scenario identified instrumented fusion as a cost-effective option compared to coflex®.
### coflex® vs. Fusion Cost Savings (Inpatient Setting)

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<th>Metrics</th>
<th>Medicare</th>
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<tr>
<td>Case Volume (Scaler)</td>
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<tr>
<td>Fusion Inpatient Payment</td>
<td>$23,326.53 1</td>
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<tr>
<td>coflex® Inpatient Payment</td>
<td>$10,929.33 1</td>
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<td>Fusion Reoperation Rate 1 Year</td>
<td>4.73% 2</td>
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<tr>
<td>coflex® Reoperation Rate 1 Year</td>
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<td>Fusion Reoperation Rate 2 Year</td>
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<td>coflex® Reoperation Rate 2 Year</td>
<td>6.00% 3</td>
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<tr>
<th>Costs Including Reoperation</th>
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<tr>
<td>1 Year Cost Fusion (Inpatient)</td>
<td>$24,429.87</td>
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<tr>
<td>1 Year Cost coflex® (Inpatient)</td>
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<td>2 Year Cost Fusion (Inpatient)</td>
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<td>2 Year Cost coflex® (Inpatient)</td>
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<th>Savings After Payment</th>
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<tr>
<td>1 Year Savings</td>
<td>$13,128.95</td>
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<tr>
<td>2 Year Savings</td>
<td>$14,594.27</td>
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*2014 MS-DRG relative weight multiplied by 2014 factor incl. labor, non labor & capital payment base rates, per CY2014 IPPS Final Rule, as calculated by MCRA, payment rates will vary by facility
1 2014 Medicare National Avg
2 Exponent Review of Commercial Claims
3 IDE Study of coflex®
Cost Drivers: coflex® Addresses ALL

- Decompression w/Stabilization vs. Arthrodesis
- Outpatient vs. Inpatient Surgery
- Length of Hospital Stay
- Complications
- Re-admission
- Re-operation
- Ineffective Care (continued resource utilization)

Lower Cost For Equal Effectiveness = Greater Value
MIS Motion Preserving ASC Options for stenosis patients after decompression

- More cost effective in the ASC setting
- More cost effective vs fusion in either setting of point of service
- Stenosis disease management can use EBM and save money
- Bundled cost treatment plans will work
- Value driven disease management will evolve
- Cash and financed spine procedures will emerge
- Plastics, ophthalmology, other specialties
- coflex® creates alternative payment options for patients and facilities
It is all about your time!

ASCs can offer cost effective disease management of spinal stenosis!

Facility
- Earlier discharge
- Outpatient option

Payor
- Fewer reoperations; back to work quicker

Patient
- Faster recovery back to work quicker

You
- Reduced OR time
- Reduced risk, simple and elegant treatment option
HEADWINDS
CAN EASE.....
It’s All About Value!

THANK YOU

Hallett Mathews, MD, MBA