Driving *Value and Outcomes* in the Treatment of Lumbar Spinal Stenosis

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Disclosure

The intent of this webinar is to encourage discussion between healthcare professionals who are familiar with the Ambulatory Surgery Center environment, and discuss how the coflex® device’s PMA approved indications for use were based on rigorous FDA IDE study parameters.

Because of patient variables and surgeon techniques that naturally occur and can deviate from the norm in the care of patients, Paradigm Spine, LLC can not infer or imply a guarantee of performance and results when using the coflex® Interlaminar Stabilization™ device.

All Sunshine Laws, where applicable, will apply. All content is for educational and discussion purposes only and is not considered to represent training certification.

Please contact Medical Affairs at Paradigm Spine, LLC at 212-583-9700 ext 2195 for questions.
THANK YOU
Becker’s and Dr. Chappuis
Defining Value

- Value Based Purchasing
- Quantity to Quality
- The Value Proposition
- Sharing Value with all Stakeholders
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.

\[
\text{Value} = \frac{\text{Effectiveness}}{\text{Cost}}
\]
From Quantity to Quality
The Value Proposition
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
The coflex® Opportunity

• Defines Value Through Evidence-Based Medicine
• Level One Evidence
• Prospective Comparative Effectiveness Data
• Driving Down Costs and improving QUALYS
• Securing the Intended Clinical Effect Now
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).
coflex® IDE Clinical Trial Overview

- **Multi-Center, Randomized, Prospective, Controlled Study**
  - Investigational Device: Decompression + Stabilization w/ coflex®
  - Control: Laminectomy w/ Pedicle Screw Fixation
  - Medtronic CD Horizon or DePuy Expedium & Autologous Posterolateral Fusion

- **2 Patient Populations:**
  - Spinal Stenosis with Low Back Pain (without Spondylolisthesis)
  - Degenerative Spondylolisthesis (up to Grade 1)

- **Enrollment**
  - 384 patients, 40 roll in, 344 randomized 2:1 investigational to control
  - 21 Investigational Sites Throughout US

- **coflex® Clinical PMA Submitted To FDA In March 2011**
  - 1st Module (Mechanical Testing), 2nd Module (QSR/GMP), & 3rd Module (Clinical)

**PMA Approval October, 2012**

- Extensive Labeling Claims Can be Made
- Mechanism of Action Can be Demonstrated
- Economic Data for CMS

*Landmark 1st Of A Kind Study!*
coflex® Study Design

- Significant Clinical, Radiographic & Health Economic Data
- **1st Comparative Effectiveness Study in Spinal Stenosis**
  - Multiple Settings of Care: Hospital In-Patient; Hospital Out-Patient; ASC
  - Collected & Analyzed Costs, Charges, Hospital & Physician Payments
- **Primary Endpoint - Composite Clinical Success (CCS) Criterion**
  - Improvement of at least 15 points in the Oswestry Low Back Pain Disability Index (ODI) at 24 months compared to baseline
  - No reoperations, revisions, removals, or supplemental fixation
  - No major device-related complications, including but not limited to permanent new or increasing sensory or motor deficit at 24 months
  - **No lumbar epidural steroid injection at any post-operative time point**
- Rigorous Statistical Analysis Plan
Clinical Composite Success Rate

- An improvement of at least 15 points 24 months post OP
- No revision, removal or supplement fixation
- No lumbar epidural steroid injection
- No device related complications
## Composite Clinical Success Outcomes

<table>
<thead>
<tr>
<th></th>
<th>coflex®</th>
<th>Fusion Control</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Subjects at Baseline</strong></td>
<td>215</td>
<td>107</td>
</tr>
<tr>
<td><strong>Subjects at Baseline</strong></td>
<td>215</td>
<td>107</td>
</tr>
<tr>
<td><strong>coflex®</strong></td>
<td>66.2%</td>
<td>Fusion</td>
</tr>
<tr>
<td><strong>Fusion Control</strong></td>
<td>57.7%</td>
<td></td>
</tr>
<tr>
<td><strong>Total of 135 coflex® subjects achieved CCS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total of 60 fusion subjects achieved CCS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Lost to Follow-Up</strong></td>
<td>11</td>
<td>3</td>
</tr>
<tr>
<td><strong>Re-Op Failures</strong></td>
<td>23</td>
<td>8**</td>
</tr>
<tr>
<td><strong>Injections</strong></td>
<td>19</td>
<td>10</td>
</tr>
<tr>
<td><strong>Sensory/Motor Deficits</strong></td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td><strong>ODI Failures</strong></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.
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)

Patient Follow-up at Two Years

coflex®
95.3%
Fusion
97.2%
Decompression and Coflex Interlaminar Stabilization Compared With Decompression and Instrumented Spinal Fusion for Spinal Stenosis and Low-Grade Degenerative Spondylolisthesis

Two-Year Results From the Prospective, Randomized, Multicenter, Food and Drug Administration Investigational Device Exemption Trial

Reginald J. Davis, MD,* Thomas J. Erico, MD,† Hyun Bae, MD,‡ and Joshua D. Auerbach, MD⁻

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 postero-lateral 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 = 0.001), 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 analogue 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 experienced 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, 65.2% 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
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

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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 1 spondylolisthesis (99 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 (2011), back and 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: 15-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 94.9% 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 82.3% of coflex subjects (56 of 68) and 62.5% of fusion controls (30 of 48) (p = 0.004). The reoperation rate was higher in the coflex cohort (14.1% of 99) compared with fusion (3.9% of 51; 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).

Abbreviations used in this paper: AE = adverse event; BMP = bone morphogenic protein; CCS = composite clinical success; CEC = Clinical Events Committee; IDE = investigational device exemption; ODI = Oswestry Disability Index; PSF = posterolateral spinal fusion; SF-12 = 12-item Short Form Health Survey; SPORT OS = Spine Patient Outcomes Research Trial for degenerative spondylolisthesis; VAS = visual analog scale; ZCQ = Zurich Claudication Questionnaire.

This article contains images that are displayed in color online but in black-and-white in the print edition.
Commentary & Perspective

In the Eye of the Beholder


Jeffery L. Stambough, MD, MBA

Abouchou et al. should be congratulated on the publication of their paper on mitigating bias in the reporting of adverse events in spine surgery. This paper provides an excellent discussion of the challenges in accurately capturing the true burden of adverse events in spine surgery. The authors propose a comprehensive methodology that emphasizes the need for greater transparency in the reporting of adverse events and the development of standardized reporting systems. This approach is critical in ensuring that the true burden of adverse events is accurately captured and that appropriate corrective actions are taken to improve patient safety.

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## coflex® vs. Fusion Cost Savings (Inpatient Setting)

<table>
<thead>
<tr>
<th>Metrics</th>
<th>Medicare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case Volume (Scaler)</td>
<td>1</td>
</tr>
<tr>
<td>Fusion Inpatient Payment</td>
<td>$23,326.53^1</td>
</tr>
<tr>
<td>coflex® Inpatient Payment</td>
<td>$10,929.33^1</td>
</tr>
<tr>
<td>Fusion Reoperation Rate 1 Year</td>
<td>4.73%^2</td>
</tr>
<tr>
<td>coflex® Reoperation Rate 1 Year</td>
<td>3.40%^3</td>
</tr>
<tr>
<td>Fusion Reoperation Rate 2 Year</td>
<td>12.23%^2</td>
</tr>
<tr>
<td>coflex® Reoperation Rate 2 Year</td>
<td>6.00%^3</td>
</tr>
<tr>
<td><strong>Costs Including Reoperation</strong></td>
<td></td>
</tr>
<tr>
<td>1 Year Cost Fusion (Inpatient)</td>
<td>$24,429.87</td>
</tr>
<tr>
<td>1 Year Cost coflex® (Inpatient)</td>
<td>$11,300.93</td>
</tr>
<tr>
<td>2 Year Cost Fusion (Inpatient)</td>
<td>$26,179.36</td>
</tr>
<tr>
<td>2 Year Cost coflex® (Inpatient)</td>
<td>$11,585.09</td>
</tr>
<tr>
<td><strong>Savings After Payment</strong></td>
<td></td>
</tr>
<tr>
<td>1 Year Savings</td>
<td>$13,128.95</td>
</tr>
<tr>
<td>2 Year Savings</td>
<td>$14,594.27</td>
</tr>
</tbody>
</table>

*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®
Comparative Cost-Effectiveness of coflex® Interlaminar Stabilization Versus Instrumented Posterolateral Lumbar Fusion for Treatment of Lumbar Spinal Stenosis and Spondylolisthesis

**Introduction:** Comparative clinical and health insurance perspective cost evaluation was conducted to assess the cost-effectiveness of a non-instrumented, non-fusion, interlaminar lumbar stabilization device (coflex®) compared to instrumented posterolateral lumbar fusion (PF) for the treatment of lumbar spinal stenosis (LSS) with and without spondylolisthesis. 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. The study investigated the clinical and health insurance perspectives of treatment with coflex® (non-fusion) compared to PF for the treatment of LSS with and without spondylolisthesis.

**Methods:** The clinical and health insurance perspectives were analyzed from a societal perspective. Cost estimates were based on Medicare claims, using the Medicare Common Classification System (CMS) 2010 coding system. Treatment patterns over 5 years were estimated using a microsimulation model, with costs and utilities estimated from a Markov model.

**Results:** The clinical and health insurance perspectives were estimated using a Markov model. The model compared the long-term cost and effectiveness of treatment with coflex® and PF. The health insurance perspective found that treatment with coflex® resulted in lower costs and better health outcomes compared to PF. The clinical perspective also found that treatment with coflex® resulted in lower costs and better health outcomes compared to PF.

**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®.

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**Accepted Journal of ClinicoEconomics and Outcomes Research March, 2014**
The Role of Stabilization

Pre 2012 Post Decompression for Stenosis

- **Fusion stabilization** for back pain and or instability
- **No motion preservation** device approved
- **Intended clinical effect** may be a year away for fusion

Post Oct 2012 PMA Approval coflex®

- **Interlaminar stabilization** post open direct microsurgical decompression for moderate to severe spinal stenosis
- **Maintains motion and foraminal height**
- **Does not alter adjacent level kinematics**
- **Immediate intended clinical effect**
Why is this important?

- Cost of Care and Spinal Fusion
- Increasing Incidence of Fusion for Low Back Pain after Decompression
- Every 8 Seconds US citizen turns 65 yo; Spinal Stenosis Incidence Increasing
- Increasing Incidence of Fusion for Low Back Pain After Decompression
- Payer Push Back – Where is the EBM for the Increased Cost?
- Readmission Data from Medicare
- Spinal fusions serve as case study for debate over when certain surgeries are necessary

- 465,000 fusions in the US in 2011
Macro Trends In Treatment of Spinal Stenosis

- **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)

- **Payors Are Pushing Back On Fusion!**
  - Payors 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.
Lumbar Spinal Stenosis Epidemiology

Epidemiology

- 8 - 11% Incidence of LSS in the U.S.\(^1\)
- LSS is the most common reason for spine surgery in people over 50\(^2\)
- Costs billions of dollars each year in its diagnosis, treatment, and lost work hours\(^3\)

A Significant Market Opportunity

U.S. Market For Spinal Stenosis Patients (2012-2020)

CAGR = 9%

1.2M Patients (1)

2.4M Patients (1)

Readmission Rates After Decompression Surgery in Patients With Lumbar Spinal Stenosis Among Medicare Beneficiaries

Urvij Modhia, MBBS, MD,* Steven Takemoto, PhD,* Mary Jo Braid-Forbes, MPH,† Michael Weber, MD,* and Sigurd H. Berven, MD*

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Figure 1. Flow chart illustrating patient selection steps for this study.
What is the Perfect Patient?

- Conservative Care
- Previous Treatments, ESIs
- Patient Expectations
- Patient Selection
- The First Patient – Images and Goals
The *coflex®* Interlaminar Technology is an interlaminar stabilization device indicated for use in one or two level lumbar stenosis from L1-L5 in skeletally mature patients with at least moderate impairment in function, who experience relief in flexion from their symptoms of leg/buttocks/groin pain, with or without back pain, and who have undergone at least 6 months of non-operative treatment. The *coflex®* is intended to be implanted midline between adjacent lamina of 1 or 2 contiguous lumbar motion segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s).
## Market Opportunity

<table>
<thead>
<tr>
<th>Condition</th>
<th>Estimated Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leg Pain</td>
<td>~600,000 Patients</td>
</tr>
<tr>
<td>Back Pain</td>
<td>~286,000* Patients</td>
</tr>
<tr>
<td>Instability</td>
<td>~261,000* Patients</td>
</tr>
<tr>
<td></td>
<td>~106,000* Patients</td>
</tr>
</tbody>
</table>

### Patient Profile

<table>
<thead>
<tr>
<th>Condition</th>
<th>Symptomatology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leg Pain</td>
<td>Intermittent neurogenic claudication</td>
</tr>
<tr>
<td></td>
<td>Intermittent neurogenic claudication</td>
</tr>
<tr>
<td></td>
<td>Mild to moderate stenosis</td>
</tr>
<tr>
<td>Back Pain</td>
<td>Intermittent neurogenic claudication</td>
</tr>
<tr>
<td></td>
<td>Intermittent neurogenic claudication</td>
</tr>
<tr>
<td></td>
<td>Significant back pain (&gt; leg pain)</td>
</tr>
<tr>
<td>Instability</td>
<td>Insignificant back pain</td>
</tr>
<tr>
<td></td>
<td>Insignificant back pain</td>
</tr>
<tr>
<td></td>
<td>No instability</td>
</tr>
<tr>
<td></td>
<td>Significant back pain (&gt; leg pain)</td>
</tr>
<tr>
<td></td>
<td>Up to Grade I spondylolisthesis (stable)</td>
</tr>
<tr>
<td></td>
<td>Degenerative lumbar scoliosis ≥ 25° Cobb Angle</td>
</tr>
<tr>
<td></td>
<td>Dominant back pain</td>
</tr>
<tr>
<td></td>
<td>Unstable spondylolisthesis &gt; Grade I</td>
</tr>
<tr>
<td></td>
<td>Degenerative lumbar scoliosis &gt; 25° Cobb Angle</td>
</tr>
<tr>
<td></td>
<td>Unstable intrinsic spondylolisthesis</td>
</tr>
</tbody>
</table>

### Treatment

<table>
<thead>
<tr>
<th>Condition</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leg Pain</td>
<td>Decompression</td>
</tr>
<tr>
<td></td>
<td>Decompression</td>
</tr>
<tr>
<td></td>
<td>Decompression + corpectomy</td>
</tr>
<tr>
<td>Back Pain</td>
<td>Decompression</td>
</tr>
<tr>
<td></td>
<td>Decompression + fusion</td>
</tr>
<tr>
<td>Instability</td>
<td>Decompression</td>
</tr>
</tbody>
</table>

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*Approximate numbers.
Pre-Op MRI
Incision and Localization
Lateral Fluro Intraop and AP X-Ray
Case Study
Patient Pre-Op

- 68 y/o 5’1” 125 lbs
- Can not walk, pain to calves, left greater than right
- VAS 7 avg. 10 worst
- RA, hypertension, cataracts
- humira, methotrexate
Pre-Op MRI
Post-Op Films

12mm coflex® device
Case Study
Patient Pre-Op

- 50 y/o female
- Complaining of lower back pain and bilateral radiculopathy
- Pain radiates into the left hip and is aggravated by standing and walking, alleviated by rest
- Failed conservative therapy
- No previous spinal surgery
• Severe spinal canal stenosis is noted at L4-5

• There appears to be a Synovial cyst at L4-5 resulting in severe spinal stenosis

• Multilevel degenerative disc disease is also noted
Post-Op Films
Post-Op Films
Case Study

Patient Pre-Op

- 74 year old gentleman with no co-morbidities
- 2 year history of bilateral buttock pain that increases with walking and severely limits his activities
- Failed PT and ESIs
- Mild mechanical LBP
Sagittal and Axial MRI
No movement on Flex/Ext
Post-Op Film
Case Study

Patient Pre-Op

- 46M mechanical low back pain and right leg pain
Post-Op Films

1.4°
3.8°
2.1°
The coflex® Set Up

- Preop Education and Informed Consent
- Preop Planning and OR Set Up
- OR Management
- Post Op PACU Protocols
- First 6 Weeks
Value in the Patient Circle of Care

- Patient Value
- Payer Value
- Facility Value
- Employer Value
- Family Value
- Society Value
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!

*Compared to fusion

Proven Clinical Outcomes
**The coflex® Solution**

**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

- 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.

- Patients that were satisfied with outcome at 2 years:
  - Fusion: 84%
  - coflex*: 91%
  - 7% increase

- Improvement of at least 15 points in ODI:
  - Fusion: 90%
  - coflex*: 96%
  - 6% increase
The Value Proposition

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
It is all about your time!

You
- Reduced OR time
- Reduced risk, simple and elegant treatment option

Patient
- Faster recovery
- Back to work quicker

Payor
- Fewer reoperations; back to work quicker

Facility
- Earlier discharge
- Outpatient option

It is all about your time!
Thank You Dr. Chappuis!

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