coflex® Strategic Presentation
Stenosis….past and present

What, Where, Why, How, and Evidence

Paradigm Spine, LLC

David S. Raskas, MD

David S. Raskas, MD
Board Certified Orthopedic Surgeon
Specializing in Spine

"I have enjoyed being a spinal surgeon as I have always enjoyed doing technically demanding things. Each patient I see has unique needs and every step of the treatment process – from initial diagnosis and treatment planning to surgery and rehabilitation – is very interesting and rewarding to me. Helping patients return to their highest level of function is both a daily goal and a lasting commitment of mine. That is a process I focus on through a minimally invasive approach to spinal surgery. Minimally invasive surgery will lead to the safest and fastest recovery. Most patients can be treated and go home in less than 24 hours."

Overview – Stenosis…Past and Present, Goals for Today -

- **Spectrum of Degenerative Lumbar Pathology**
  - Spinal Stenosis
  - Degenerative spondylolisthesis
- **Matching procedures with pathology**
- **Defining Value in Management of Spinal Disorders**
- **Evidence-based approach to assessment of new technologies**

Spectrum of Spinal Disorders

- ***Neural Compromise***
  - ***Intervertebral disc herniation***
  - ***Spinal Stenosis***
  - ***Degenerative Spondylolisthesis***
- Instability
- Deformity
- Tumor
- Infection
- Axial back pain

SPORT Study

Spinal Stenosis

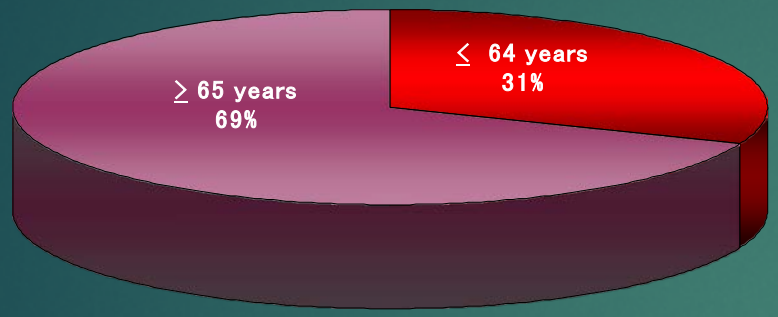
- Narrowing of the spinal canal with compromise of the space available for the neural elements

Symptoms

- Neurogenic (pseudo-) claudication
  - DeJerine (1911)
  - Aching leg pain or heaviness with ambulation, upright posture
  - Relieved by leaning forward, sitting
  - Going up hills easier than down hills

© Rauschning

Lumbar Spinal Stenosis Epidemiology



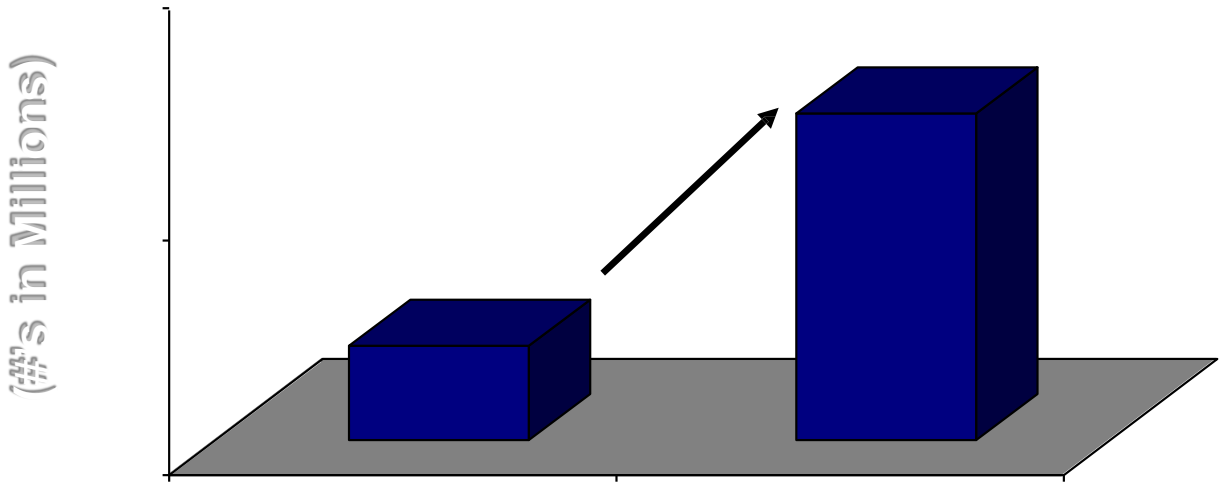
Source: Verispan, 2004

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]**

1. Murphy et al, BMC musculoskeletal Disorders, 2006, Jennis et al, Spine 2000.
2. Murphy et al, BMC musculoskeletal Disorders, Szpalski, European Spine Journal, 2003
3. Knowledge Enterprises, Inc.

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



Stenosis Is Largest Single-Growing Patient Demographic In Spine![1]

(1) Nick Shamie, MD, orthopedic spine surgeon at UCLA Medical Center of Los Angeles and a spokesman for the American Academy of Orthopedic Surgeons cited in: The Wall Street Journal (Business), Feb 15, 2011.

LUMBAR STENOSIS CARE PLAN

- **Cons care, PT**
- **ESIs**

Progression

Mechanical LBP ?

- **Direct surgical decompression - *Laminectomy***
- **Indirect decompression**

- Stabilization - **Fusion**
- Motion preserving stabilization – **coflex®**

Costs and Outcomes

Determining Value in Spine Care: Epidural Steroid Injections as an Example

Wong, David *Spineline* Jan/Feb 2014

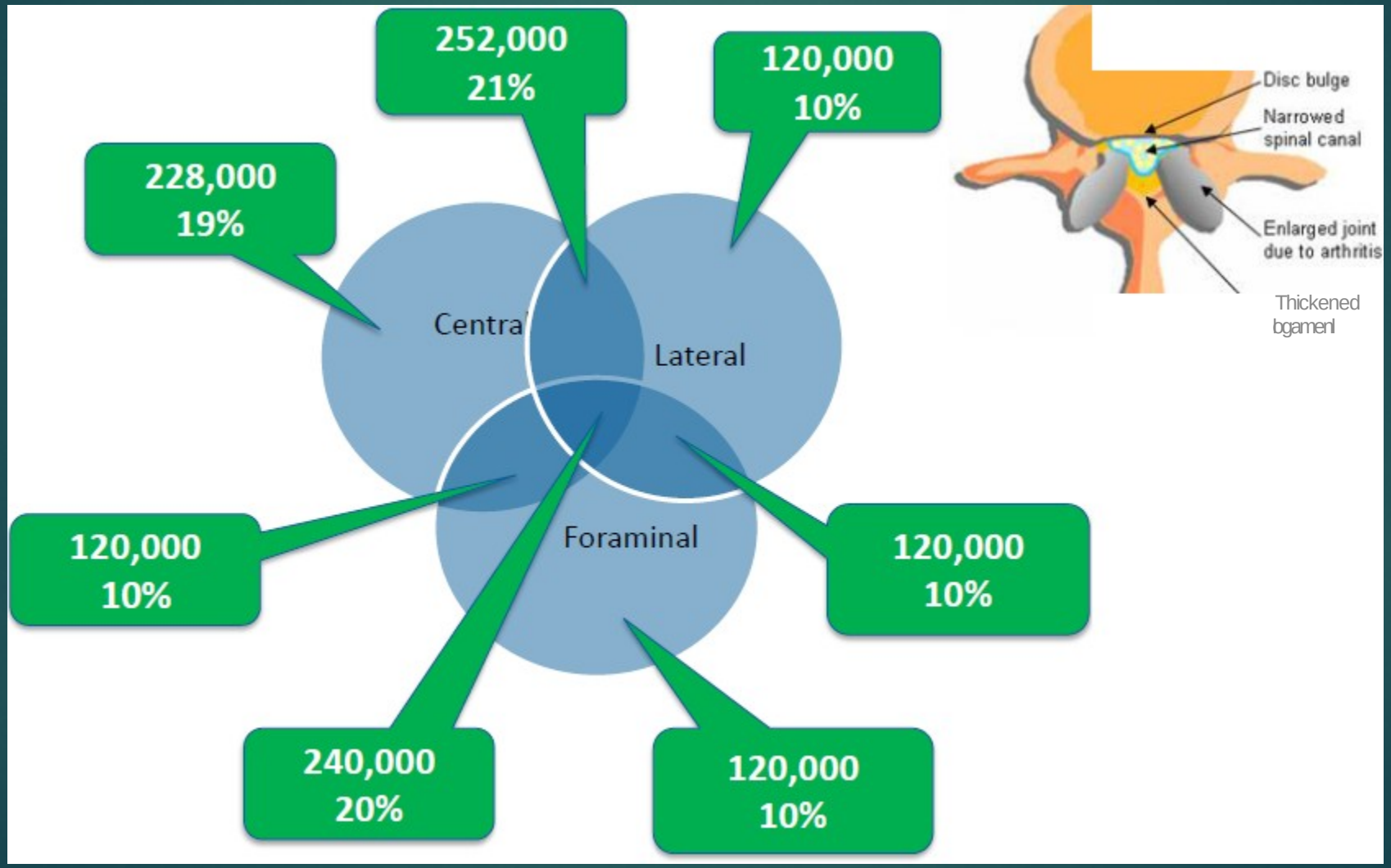
- ESIs are rarely performed in the UK, whereas in 2011, 2.3 M in US Medicare patients alone!
- Using Comparative Effectiveness Research (CER), what is a positive outcome and thus a valuable outcome
- Then, short term vs long term relief? Level 1 evidence
- Value, Cost /QALY at one year was $570,000
- NICE requires <$50,000 Cost/QALY for reimbursement in UK NHS
- For CER research, only RCTs can be used for meta-analysis

Measuring Cost, Quality & Satisfaction: The Transparency Factor

	Value Cost per 1yr QALY-gained	Cost 1-yr Direct Healthcare	Cost 1-yr Indirect	Quality Surgical Morbidity	Satisfaction NASS Satisf. Index*	Occupation Mean Return to Work
Lumbar Laminectomy for *Lumbar Stenosis*	$33,700	$14,264	$10,452	5.6%	73%	10 wks
ACDF for *Cervical Radiculopathy*	$42,320	$23,444	$6,322	4%	88%	4 wks
Lumbar Laminectomy & Fusion for *Spondylolisthesis*	$42,854	$25,251	$11,584	4.4%	76%	8.0 wks
Revision ACDF for *Adjacent Segment Disease*	$58,396	$25,391	$7,225	7.5%	75%	5 wks
Revision Lumbar Fusion for *Recurrent Stenosis*	$58,846	$30,808	$12,879	15%	65%	16.0 wks
Revision Lumbar Fusion for *Pseudoarthrosis*	$59,945	$28,751	$18,623	12%	53%	20.0 wks
Revision Lumbar Fusion for *Adjacent Segment Disease*	$62,955	$28,239	$19,607	2%	77%	8.0 wks
Medical Management for *Lumbar Disc Herniation*	$87,327	$8,427	$384	----	28%	----
Medical Management for *Lumbar Stenosis*	$95,500	$8,992	$358	----	30%	----
Medical Management for *Lumbar Spondylolisthesis*	$146,033	$9,191	$351	----	23%	----

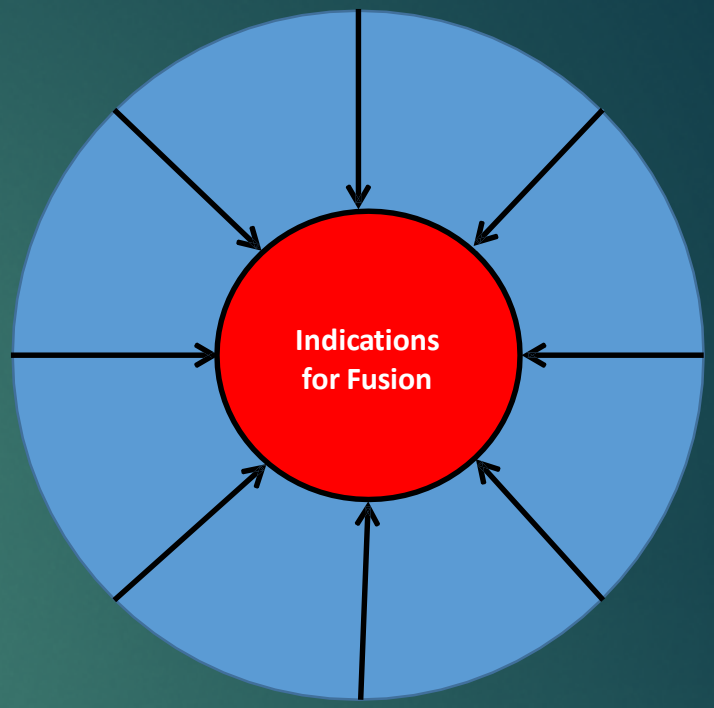
** percent patients reporting satisfaction with their outcome*

1.2M US Patients seeking treatment for LSS



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.

Perioperative outcomes, complications, and costs associated with lumbar spinal fusion in older patients with spinal stenosis and spondylolisthesis

Kevin L. Ong, PhD, PE[1], Edmund Lau, MS[2], Jordana Schmier, MA[3], Jorge A Ochoa, PhD, PE[2],

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Key words: spine fusion, stenosis, spondylolisthesis, lumbar spine

Running title: Spine fusion for stenosis and spondylolisthesis

Ong, Lau, Schmier, Ochoa 2014
Perioperative Outcomes, Complications, and Costs……

•Conclusions: Over half of the PSF-treated patients in this study had LSS alone, and 32% of stenosis-only patients underwent fusion, suggesting that factors other than spondylolisthesis play a significant role in the decision to recommend spinal fusion in this elderly population. One in 4 elderly fusion patients being treated for LSS or spondylolisthesis underwent reoperation on the spine within 2 years, and nearly 1 in 2 was readmitted for a surgery-related complication. These data highlight several areas where improvements may be made in the effective delivery and cost of surgical care for patients with spinal stenosis and spondylolisthesis.

Accepted JNS May 2014

1 What is coflex® ?

Paradigm Spine, LLC: The coflex®Facts

1. **Disruptive Technology Platform - coflex® Interlaminar Family of Products**
   - ***>100,000 implantations w/ > 15 Years Clinical & Commercial History***
   - World class clinical results
   - ***3 prospective randomized multi-center studies, level one evidence in print***
   - ***Uniquely differentiated mechanism of action compared to interspinous devices***

2. **Not a "Me-Too" Product**

Built Minimally Invasive, Differentiated Platform 9 Years Ago

coflex® Interlaminar Implant Overview

- **Technology Description**: coflex® is an Interlaminar Functionally Dynamic Implant Designed to Impart a Stabilization Effect at the Operative Level(s)

- **Surgical Technique**: 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).**

- **Mechanism of Action**: Permits Maintenance or Improvement in Foraminal Height, & Produces a Stabilizing Effect in the Lumbar Spine

- **FDA Approval**: October 17, 2012

The coflex® Interlaminar Technology is the First and Only Non-Fusion, Minimally Invasive, Motion Preserving Device that Stabilizes Spinal Stenosis Patients after Decompression Due to its Unique Interlaminar Design.

Controls Rotation - Aids in preventing Expulsion, controls Rotation

Single-Piece Implant - Excellent Fatigue Strength, No Wear Debris

Biocompatible - Titanium Alloy

Contact Surface - to minimize Expulsion

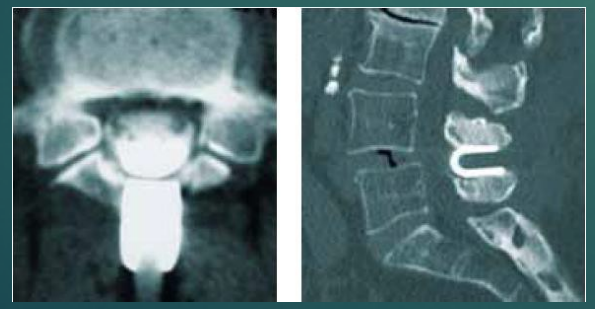
2 Part Functional Design

Interlaminar Stabilization

- Unique coflex® design allows for deep insertion post surgical decompression
- Apex of "U" permanently maintains foraminal height and volume
- Offloads facets and posterior annulus

Motion Preservation

- coflex® is compressible in extension
- Axial force shock absorption
- Mantains sagittal balance and lordosis
- Maintains physiological adjacent segment kinematics



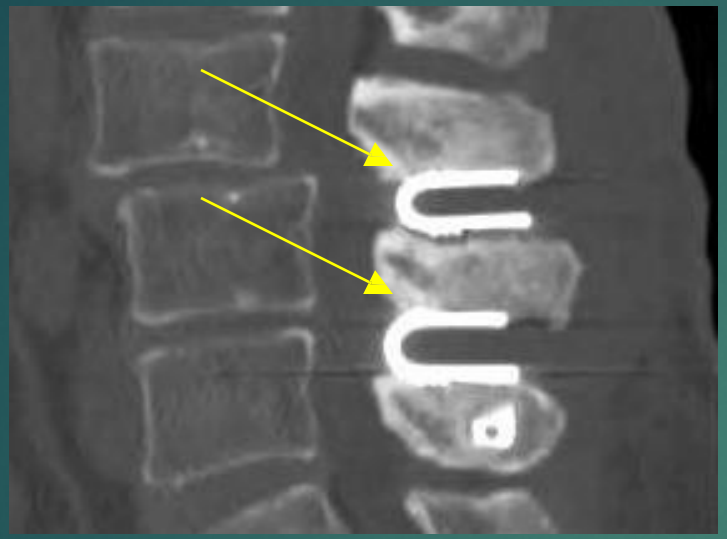
coflex® Overview: Robust Interlaminar Stabilization

coflex® Mechanism of Action

- The Apex of the U is the closest to the center-of-rotation
  - More physiological motion = better quality of motion
- Laminar is 2-5x stronger than spinous process
  - Reduces subsidence & erosion risk
- Parallel distraction of posterior disc & facets
- Maintains normal motion at index & adjacent levels
- Maintenance of foraminal height & volume
- Allows for direct decompression
- Higher surface contact with bony anatomy
- Allows for "Neutral Stabilization" of the segment

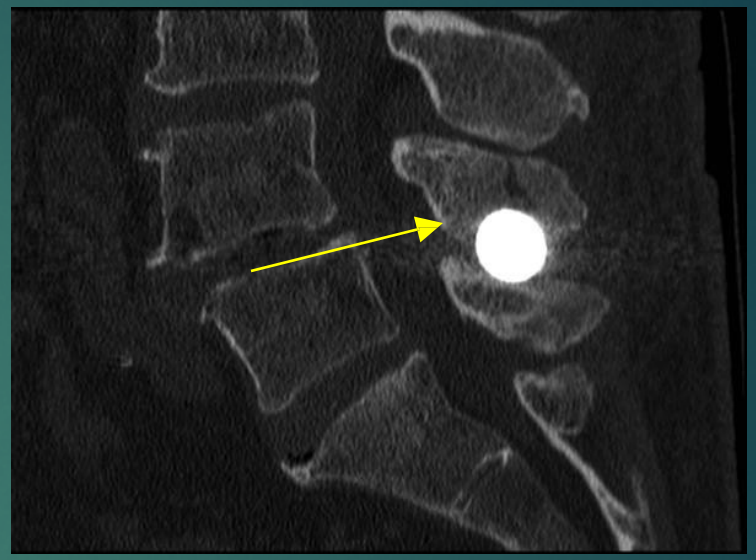
2 Confusion about coflex®

Surgical Procedures & Load Distribution



- coflex® Surgery Involves Direct Decompression
  - Inserted in Neutral Position
  - Load Sharing on Laminar bone (2-5x Stronger) & Spinous Process
  - Wings Act as Splint on Spinous Process
    - Despite Fracture, Decompression Maintained
    - Wings Do Not Cover Location of Maximum Stress

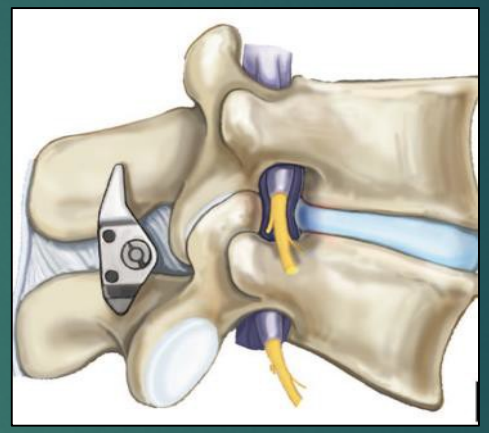
Spinous Process Fracture in X-STOP



- X-Stop Indirect Decompression
  - Inserted in Over-Distracted Position
  - Highly Loaded, Point Contact
  - No Physical Attachment to Spinous Process
    - Once Fractured, Loss of Tension & Indirect Decompression
    - Wings Cover Location of Maximum Stress (X-ray Visualization Difficult)

coflex® Interlaminar Stabilization versus Interspinous Distraction

Different Mechanisms of Action & Different Patients



coflex® Surgery Involves Direct Decompression & Stabilization

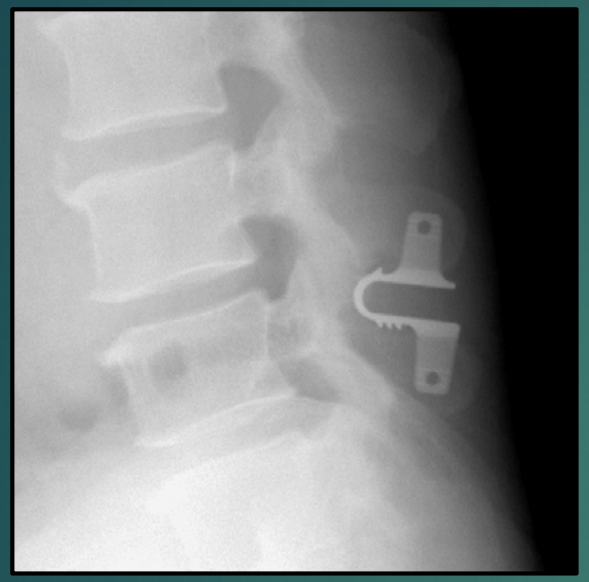
- Moderate-Severe Stenosis
- Direct Neurologic Decompression
- Load Sharing on Laminar bone (2-5x Stronger than spinous process) & Spinous Process
- Maintains Foraminal Height & Stabilizes F/E & Translation
- Functional Load Bearing device

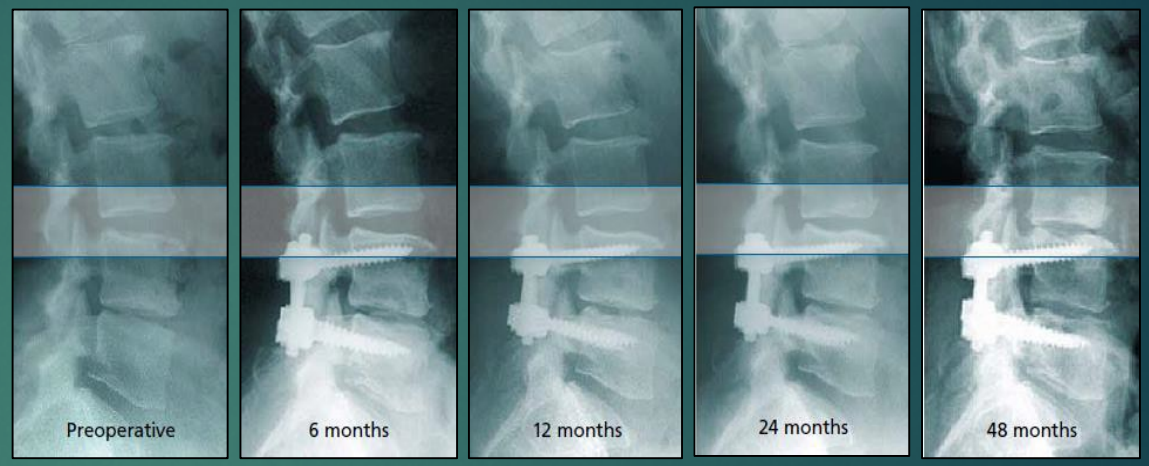
Interspinous Indirect Decompression (X-STOP)

- Mild-Moderate Stenosis
- Indirect Neurologic Decompression via interspinous distraction
- Inserted in Distracted Position
- Extension block

Motion Preserving, Dynamic Implant

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…**

3 coflex Clinical Overview

The Different Types Of FDA Regulatory Submissions

1. Premarket Notification (510(k))

- Demonstrates Device is Substantially Equivalent to a Legally Marketed Device
  - Example: Pedicle Screws, Trauma Plates, Metal/Poly Hips

2. Premarket Approval (PMA)

- FDA Process of Scientific & Regulatory Review to Evaluate Safety & Effectiveness of Class III Devices
  - Example: Total Disc Replacement, BMPs

3. Investigational Device Exemption (IDE)

- Allows Investigational Device to be Used in Clin. Study
- Collect Safety & Effectiveness Data
- Required to Support a PMAAppl. or 510(k) Submission

Understanding Evidence-Based Medicine

	DEVICE	COMPANY	INDICATION	APPROVAL YEAR
1.	COFLEX (Interlaminar)	PARADIGM SPINE	Spinal Stenosis	2012
2.	PCM (Cervical Disc)	NUVASIVE	Cervical DDD	2012
3.	SECURE-C (Cervical Disc)	GLOBUS	Cervical DDD	2012
4.	BRYAN (Cervical Disc)	MEDTRONIC SOFAMOR DANEK	Cervical DDD	2009
5.	PRODISC-C (Cervical Disc)	SYNTHES	Cervical DDD	2007
6.	PRESTIGE (Cervical Disc)	MEDTRONIC SOFAMOR DANEK	Cervical DDD	2007
7.	PRODISC–L (Lumbar Disc)	SYNTHES	Lumbar DDD	2006
8.	X STOP (Interspinous)	MEDTRONIC SOFAMOR DANEK	Spinal Stenosis	2005
9.	CHARITE ARTIFICIAL DISC (Lumbar Disc)	DEPUY (J&J)	Lumbar DDD	2004
10.	AFFINITY (Cervical Cage)	MEDTRONIC SOFAMOR DANEK	Cervical DDD	2002
11.	INFUSE w/ LT CAGE (Lumbar Cage)	MEDTRONIC SOFAMOR DANEK	Lumbar DDD	2002
12.	(BAK-C) (Cervical Cage)	ZIMMER / SULZER SPINE-TECH	Cervical DDD	2001
13.	BRANTIGAN (Lumbar Cage))	DEPUY (J&J)	Lumbar DDD	1999
14.	INTER FIX (Lumbar Cage)	SOFAMOR DANEK (MEDTRONIC)	Lumbar DDD	1999
15.	BAK (Lumbar Cage)	SPINE-TECH (ZIMMER)	Lumbar DDD	1996
16.	RAY TFC (Lumbar Cage)	US SURGICAL (STRYKER)	Lumbar DDD	1996

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

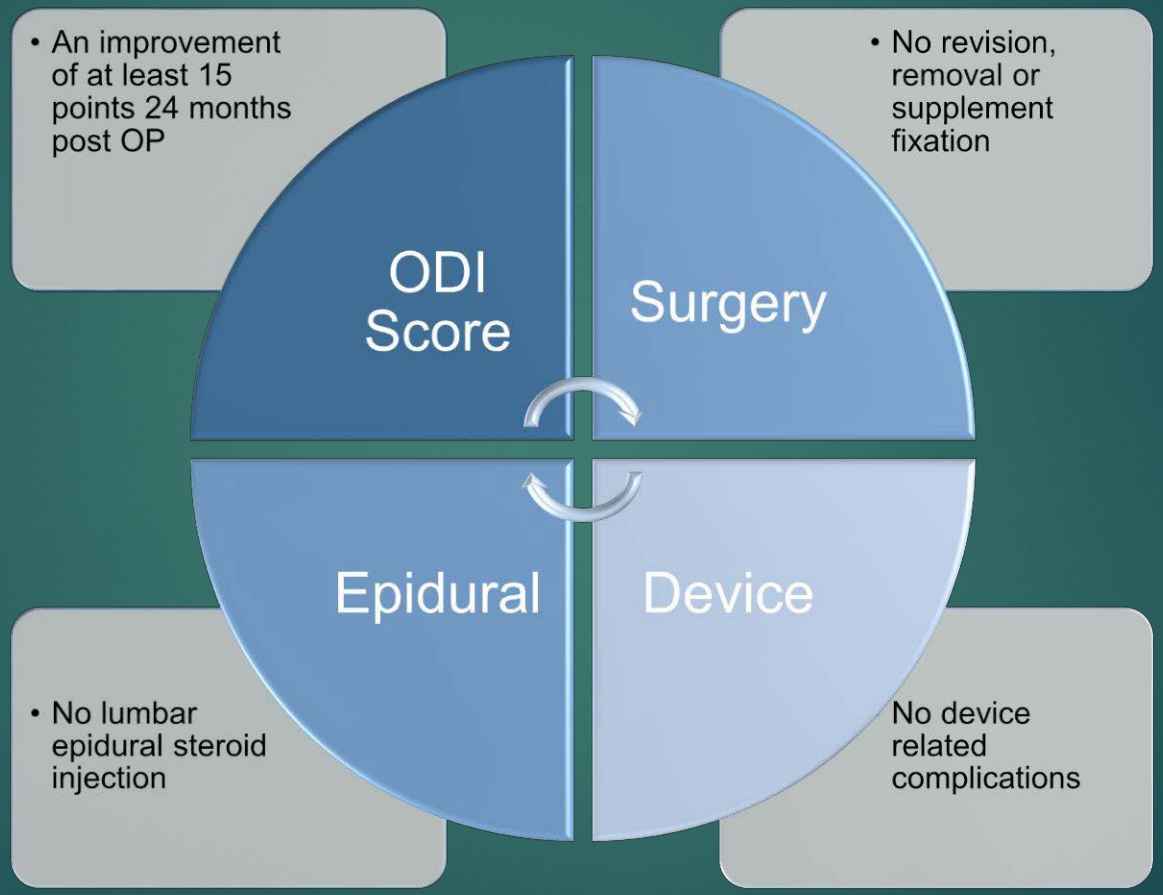
- Extensive Labeling Claims Can be Made
- Mechanism of Action Can be Demonstrated
- Economic Data for CMS

Landmark 1st Of A Kind Study!

coflex® IDE 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



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%

Composite Clinical Success Outcomes

	coflex®	Fusion Control
- Lost to Follow-Up	11	3
- Injections	19	10
- ODI Failures	17	20*

*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

coflex®
66.2%

Total of 60 fusion subjects achieved CCS

Fusion
57.7%

4

Where is the proof –EBM?

Evidence Based Medicine:

Evolved from clinical epidemiology

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

Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS (January 1996). "Evidence based medicine: what it is and what it isn't". *BMJ* **312** (7023): 71

"Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients".

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).

The Different Types Of FDA Regulatory Submissions

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3. Investigational Device Exemption (IDE)

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Year	# of 510(k)s
2012	226
2011	215
2010	161
2009	173
2008	197
2007	146
2006	118
2005	133
2004	134
2003	102
2002	106
2001	79
1996-2000	278
1991-1995	118
1986-1990	46
1981-1985	15
1976-1980	13
TOTAL	2,260

Total of 2,260[1] 510(k) Products for Spine Cleared Since 1976!!

[1]Aggregate of product codes from FDA website:

888.3050 - Spinal interlaminal fixation orthosis
888.3060 - Spinal intervertebral body fixation orthosis
888.3070 - Pedicle screw spinal system
888.3080 - Intervertebral body fusion device

Spine

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RANDOMIZED TRIAL

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. Errico, 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 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 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, 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 ($P = 0.083$) 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

From the *Greater Baltimore Neurosurgical Associates, Baltimore, MD; †Department of Orthopaedic Surgery, Hospital for Joint Diseases-NYU, New York, NY; ‡The Spine Institute, Santa Monica, CA; and §Department of Orthopaedics, Bronx-Lebanon Hospital Center, Albert Einstein College of Medicine, Bronx, NY.

Acknowledgment date: October 15, 2012. First revision date: February 15, 2013. Second revision date: April 24, 2013. Acceptance date: April 29, 2013.

The device(s)/drug(s) that is/are the subject of this manuscript is/are Now FDA-approved and no longer under investigation.

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Relevant financial activities outside the submitted work: consultancy, royalties, payment for lecture, payment for manuscript preparation, patents, payment for development of educational presentations.

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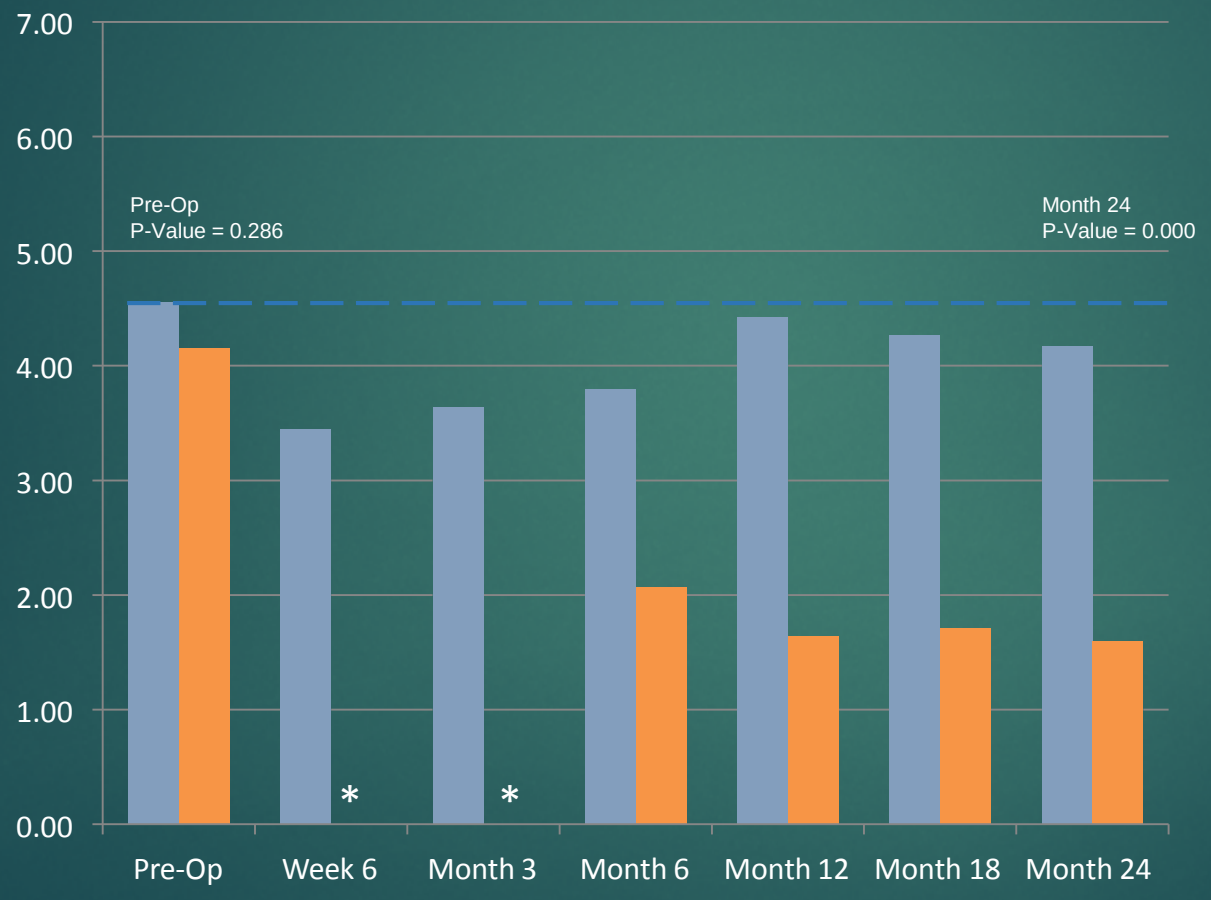
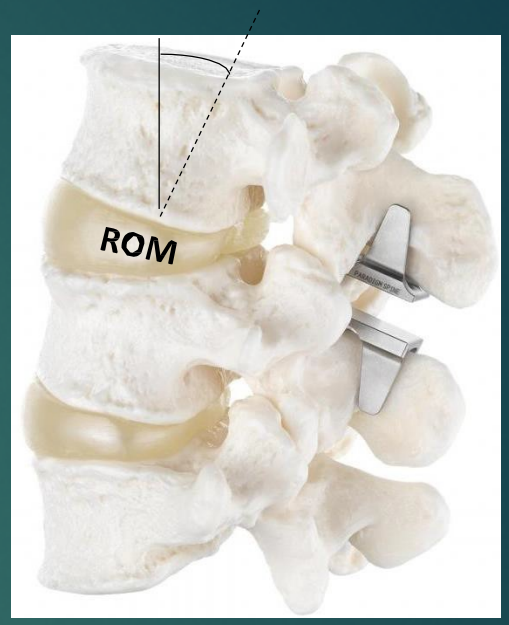
DOI: 10.1097/BRS.0b013e31829a6d0a

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]

ROM at Level of Implant (Degrees)



***Not evaluated for Fusion**



coflex® **maintains** Index Level **Motion** at 24 Months

ROM Above Level of Implant (Degrees)

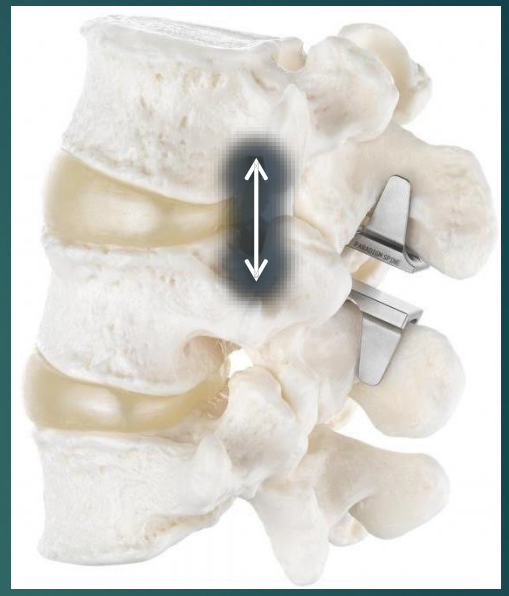
***Not evaluated for Fusion**

coflex®

Fusion

coflex® **protects adjacent Segments** from excessive Motion at 24 Months

Foraminal Height – X-Ray Analysis (mm)



coflex® **maintaints foraminal Height** at 24 Months

17.6 at 36 months
17.4 at 48 months

DOI: 10.317112013.4.SPINEI2636
©AANS,2013

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 E r rico, 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 (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 (001), 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: IS-point reduction in 001, 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 coftex 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 001, VAS back, VAS leg, and ZCQ, with no significant group differences, with the exception of significantly greater ZCQ satisfaction with coftex at 2 years. FDA overall success was achieved in 62.8% ofcoflex subjects (59 of 94) and 62.5% of fusion controls (30 of 48) ($p = 1.000$). The reoperation rate was higher in the coflex cohort (14 [14.1%] of 99) compared with fusion (3 [5.9%] 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 coftex 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 coftex 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 (CiinicaiTrials.gov). (http://thejns.orgldoilabs//0.317112013.4.SPINEI2636)

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

Abbreviations used in this paper: AE =adverse event; BMP = bone morphogenetic 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.

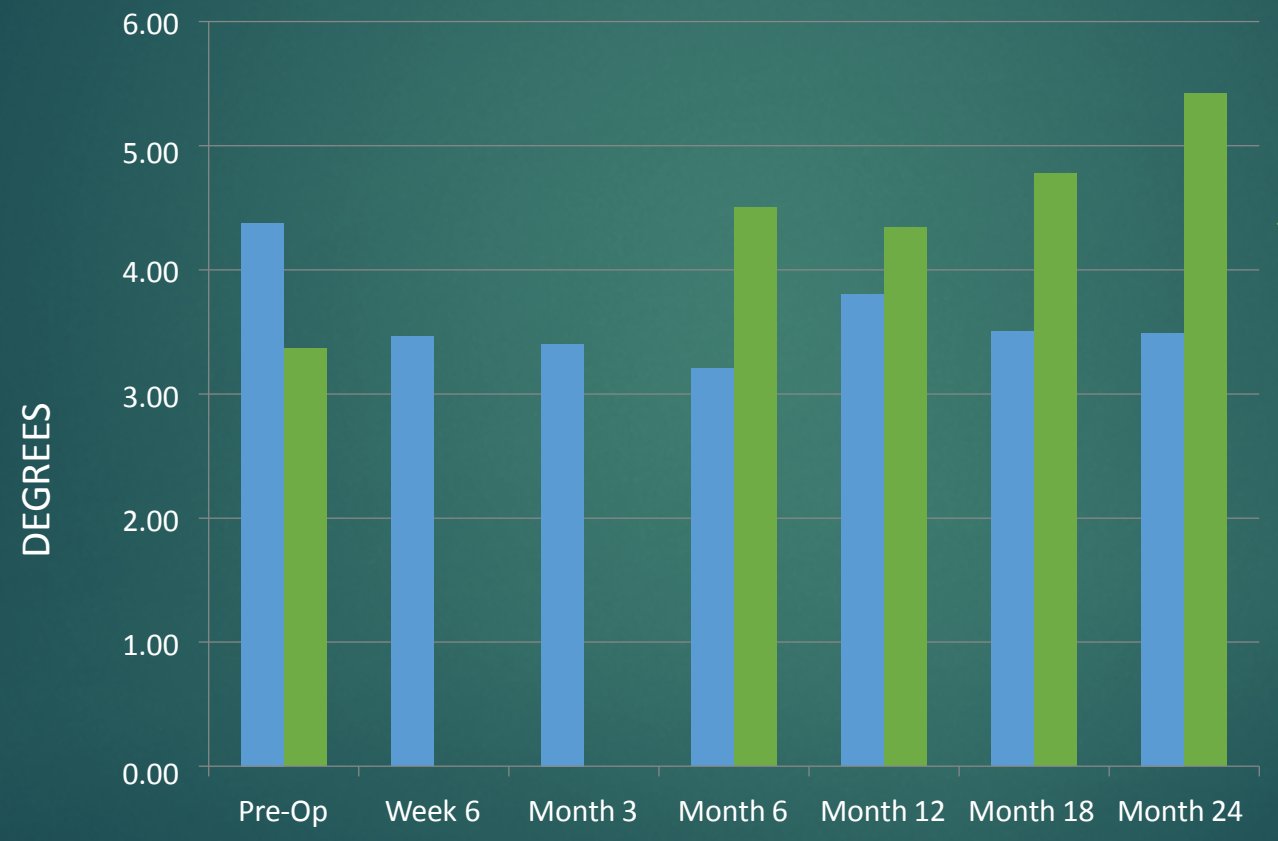
INCE the classic article from Herkowitz and Kurz4 in 1991 in which fusion significantly outperformed decompression alone in a prospective, randomized controlled trial, lumbar spinal fusion has been the standard

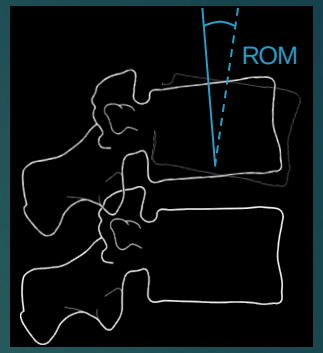
This article contains some figures that are displayed in color online but in black-and-white in the print edition.

Confidential

Spondy: ROM Above Level of Implant (Degrees)

Month 24 P-Value = 0.007

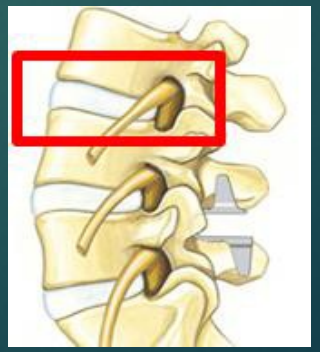




Fusion Hypermobile

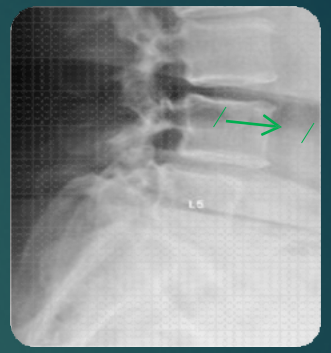
coflex®

Fusion



Spondy: Translation Above Level of Implant (mm)

Month 24 P-Value = 0.115



How and why is coflex® providing benefit?

#1 Relief of Stenosis Pathology

- The spinal surgeon provides a direct, open, visualized minimally invasive microsurgical decompression

- >90%

#2 Role of the DEVICE

- coflex® provides interlaminar, motion preserving stabilization, facet unloading, and maintains foraminal height while preserving adjacent level kinematics
- Augments and protects the decompression

- 10%

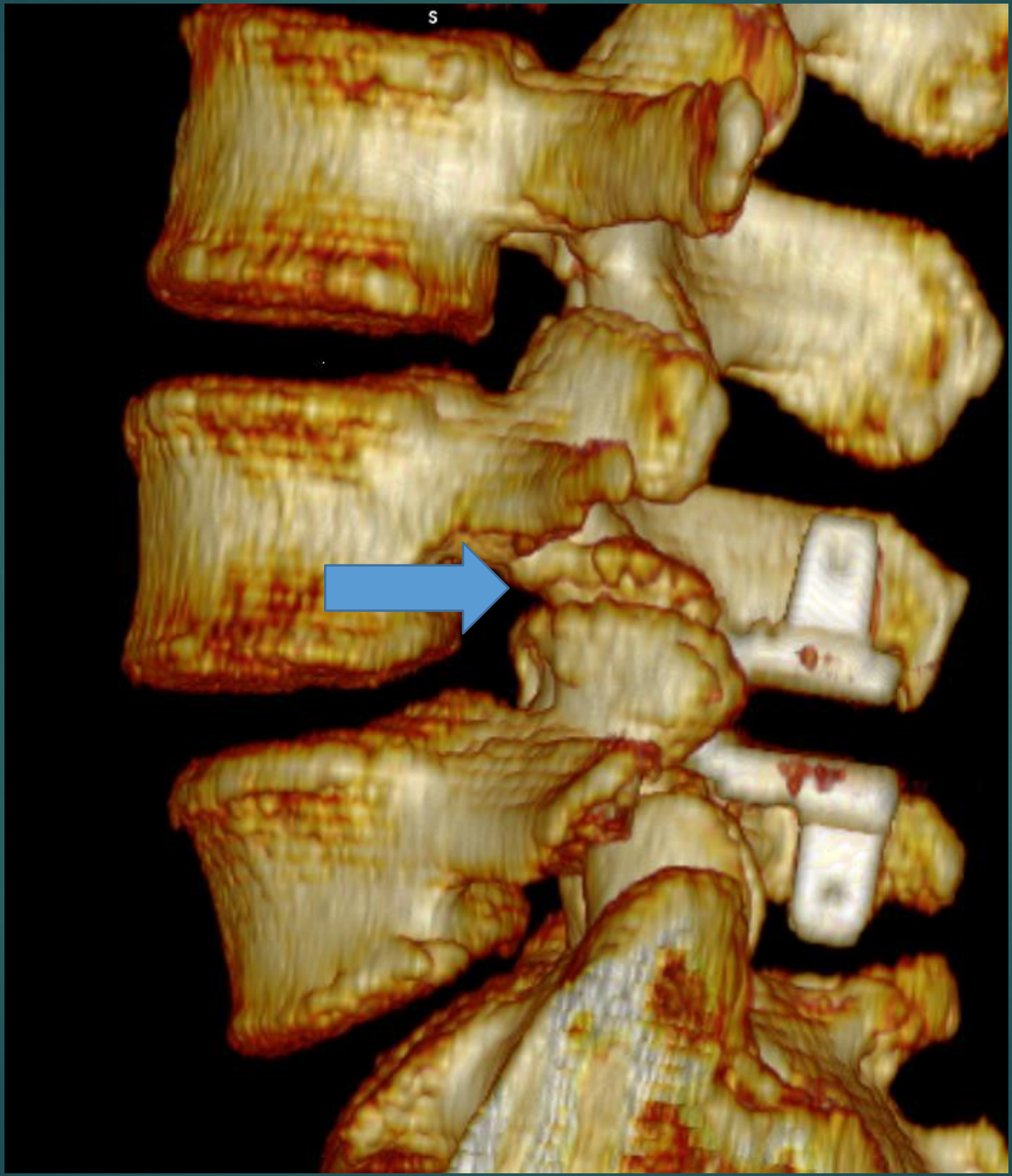
coflex® for back pain

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!!!***

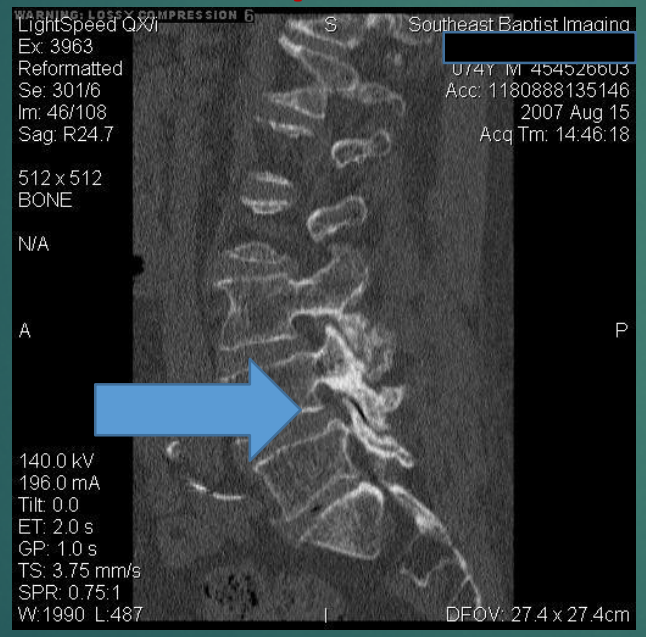
* Surgical versus Nonsurgical Therapy for Lumbar Spinal Stenosis
James N. Weinstein, D.O., M.S., Tor D. Tosteson, Sc.D., Jon D. Lurie, M.D., M.S., Anna N.A. Tosteson, Sc.D., Emily Blood, M.S., Brett Hanscom, M.S., Harry Herkowitz, M.D., Frank Cammisa, M.D., Todd Albert, M.D., Scott D. Boden, M.D., Alan Hilibrand, M.D., Harley Goldberg, D.O., Sigurd Berven, M.D., and Howard An, M.D., for the SPORT Investigators*
The New England Journal of Medicine 358;8 www.nejm.org 794 February 21, 2008



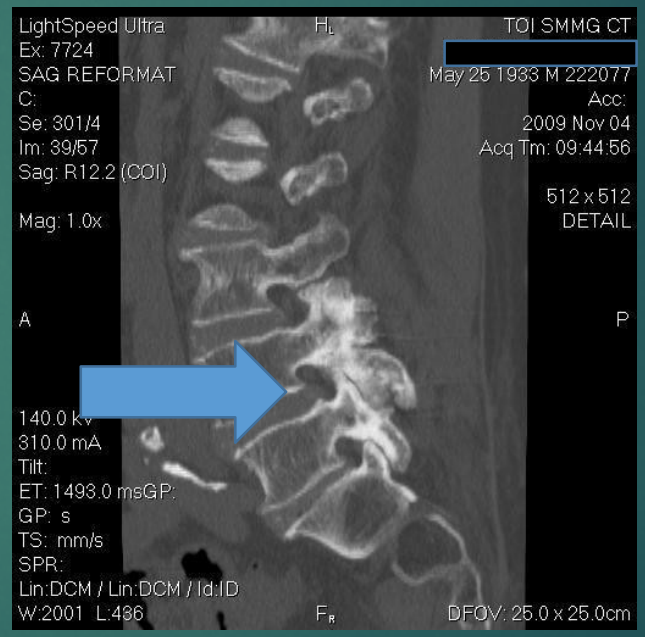
06-104

24 month CT post-foraminotomy and maintenance of foraminal height

Pre-op CT



Month 24 CT



15-205

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”)

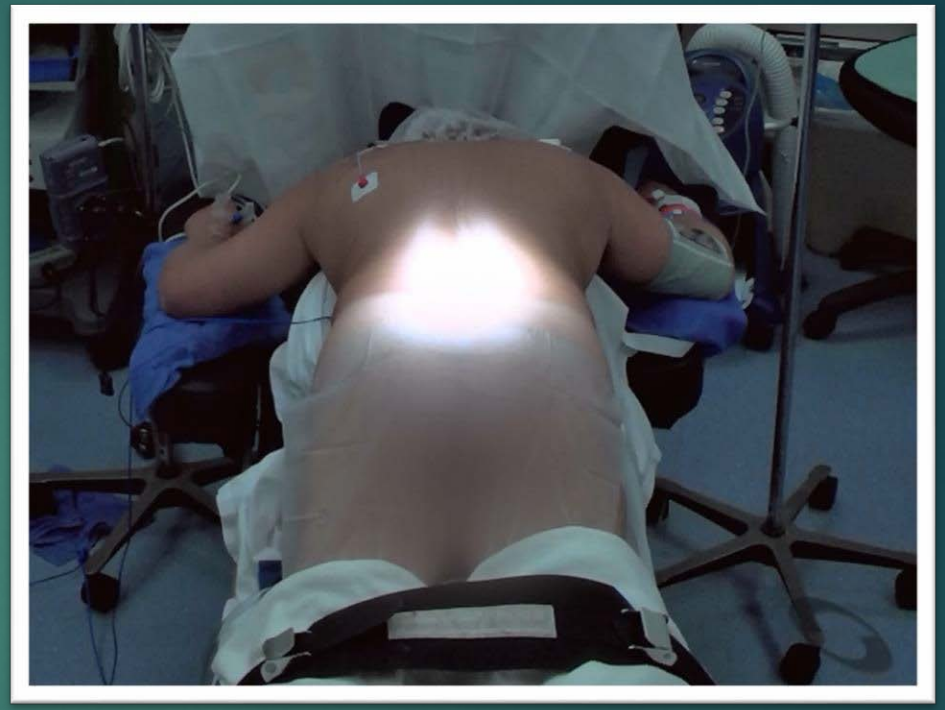
Results: 19.4% D+IS subjects experienced a TF (17 reops & 2 epidurals) compared to 30.4% D (16 reops
& 15 epidurals). D+IS pts had significantly less m24 narcotic use compared to D pts (11.1% vs 25.8%,
p=0.044). 41 D+IS and 45 D pts had no-TF and thus had a m24 evaluation. Superiority of D+IS in terms 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.

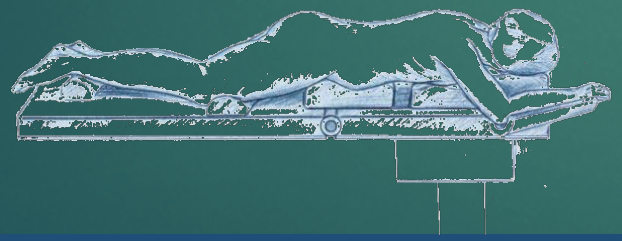
Conclusion**: Decompression with interlaminar stabilization resulted in measurably and significantly better functional outcomes, lower treatment failure rates, and less use of oral narcotic pain medications compared with decompression alone.**

Surgical Preparation

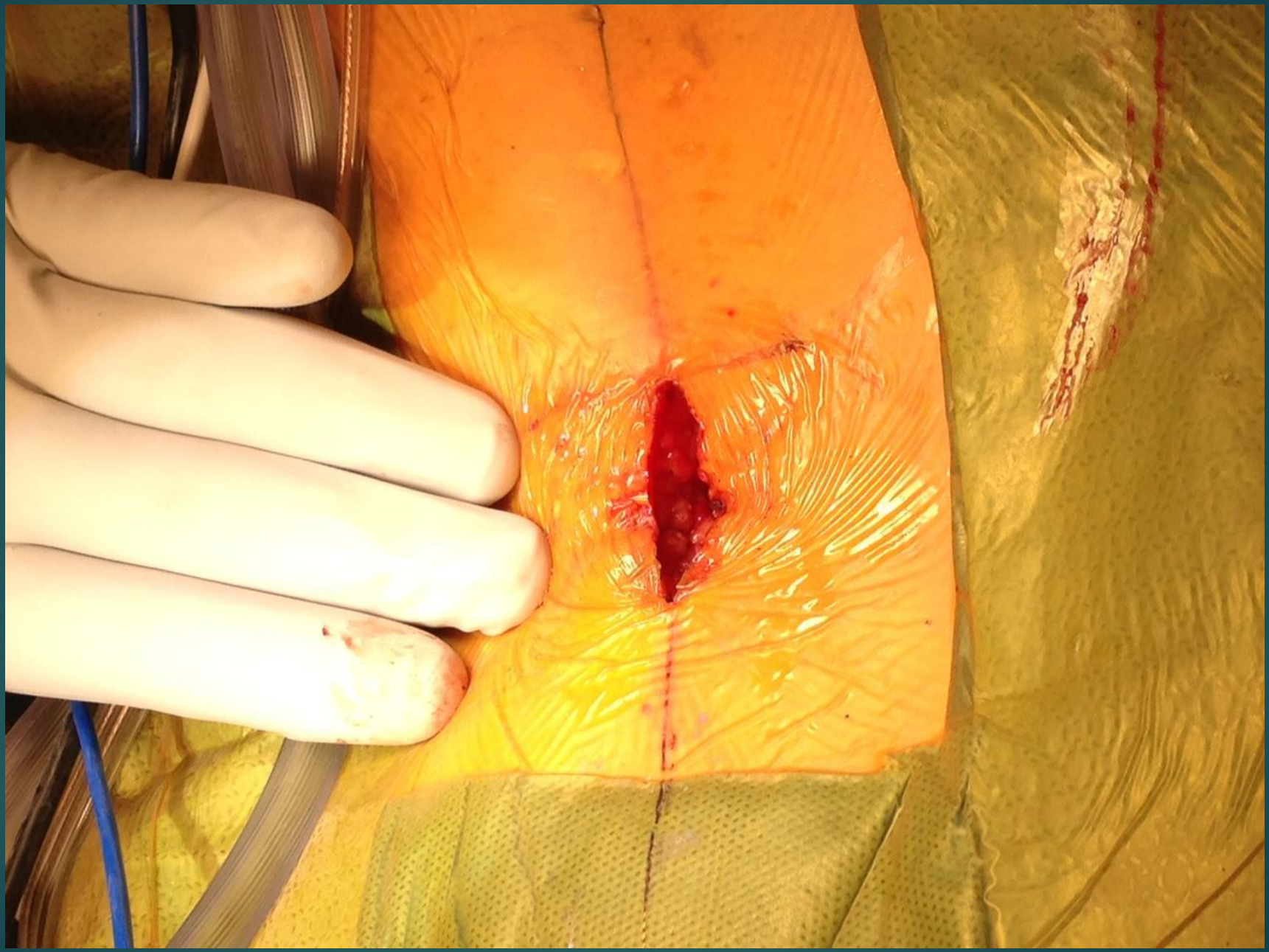
- Patient is placed in prone position on surgical frame.
  A Jackson and/or Andrews table/frame can be used.

- For the surgical decompression as well as for appropriate interlaminar distraction a neutral position or a slight kyphosis may be advantageous.





Important to Note:
Avoid creating either a kyphotic or hyper-lordotic curve at the spinal segment to be operated on.



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 Better Effectiveness = Greater Value

Customer Service & Logistical On-Boarding

PARADIGM SPINE

What If There Was A New Technology Alternative In Spine

~$40,000 - $70,000 manufacturer's cost (including implants)

(Variability in implants per patient, per surgeon)

Paradigm's costs are a fraction of traditional sets

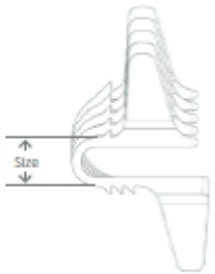
(5 implants; 60% prob. 2 of 5 used)

It All Changes: Working Capital, Logistics, Inventory, Sales Support!

The Paradigm Spine, LLC coflex® Start-Up Kit

coflex® Implant

Color Code on Implant Box	Size	Article Number
	16mm	UQI00016
	14mm	UQI00014
	12mm	UQI00012
	10mm	UQI00010
	8mm	UQI00008



Material:
Wrought titanium 6-aluminium 4-vanadium alloy according to ISO 5832-3

The coflex® implant is delivered in sterile packaging.

Sterilization Tray

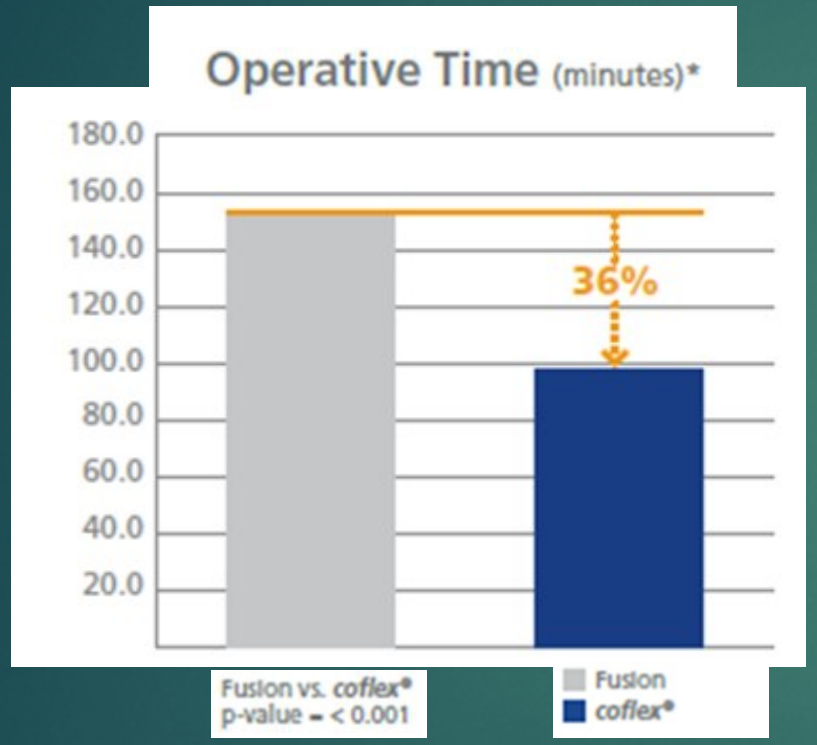
Bending Pliers

Crimping Pliers

Implant Trials

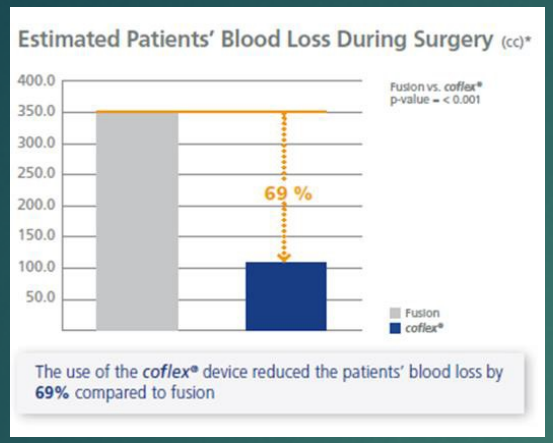
"The coflex® procedure saves on average $8,776 per case" (1)

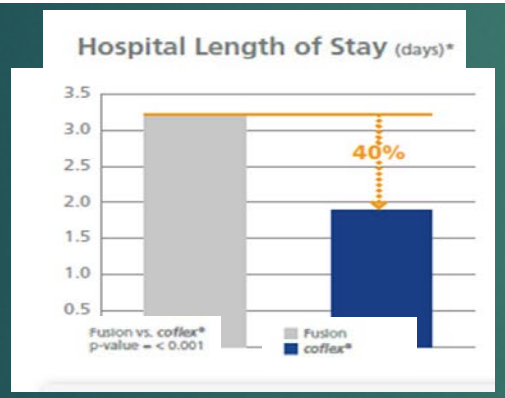
coflex® Is Cost Effective!

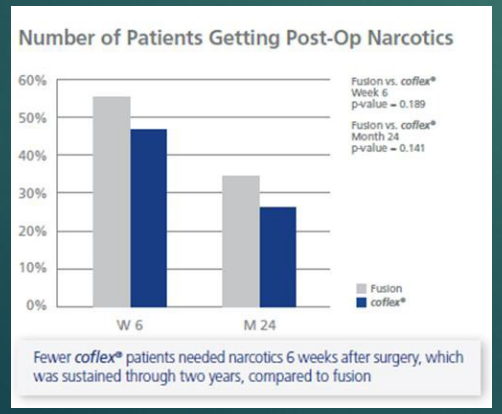


- Each coflex® procedure frees up ~2 hours of OR time!
  - ✓ 55 less minutes of operative time
  - ✓ 30-45 less minutes of set-up time
  - ✓ 30-45 less minutes of breakdown time
- **That's a $3,600 savings @ $30 min. For OR time cost!**

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).

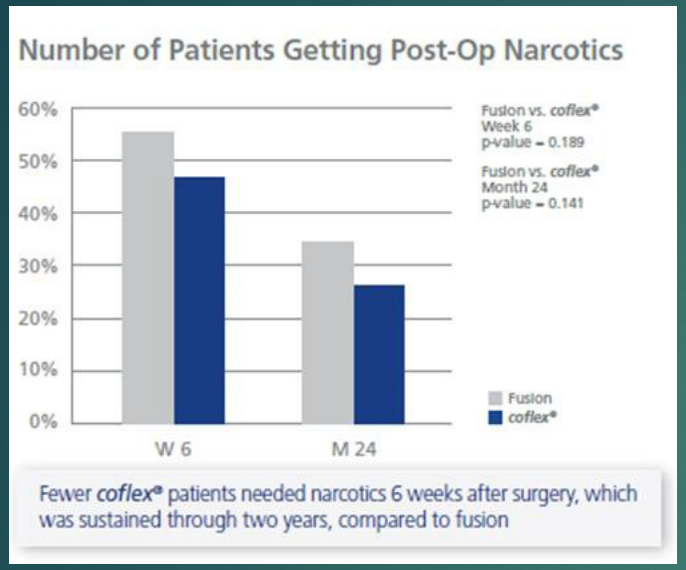
Shorter Hospital Stay - ***coflex***® patients spent 40% less time in the hospital compared to fusion patients (1.9 days vs. 3.2 days).

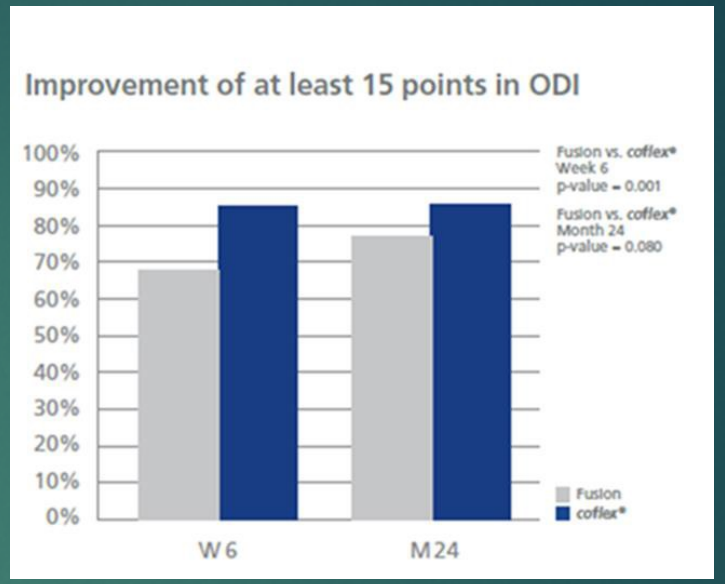
Less Blood Loss - ***coflex***® patients had less blood loss during surgery compared to fusion patients (110cc vs. 349cc).

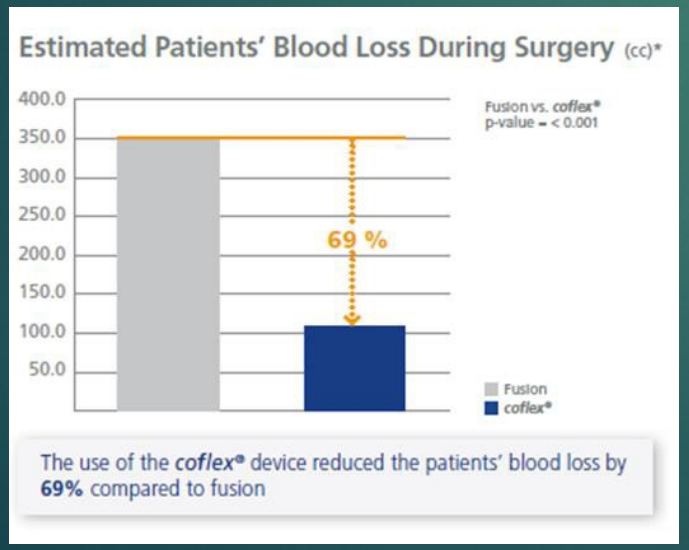
Stability In The Treatment Area - At 2 years, ***coflex***® patients retained their pre-operative range of motion (within 10%) & translation (within 5%) at the area of treatment.

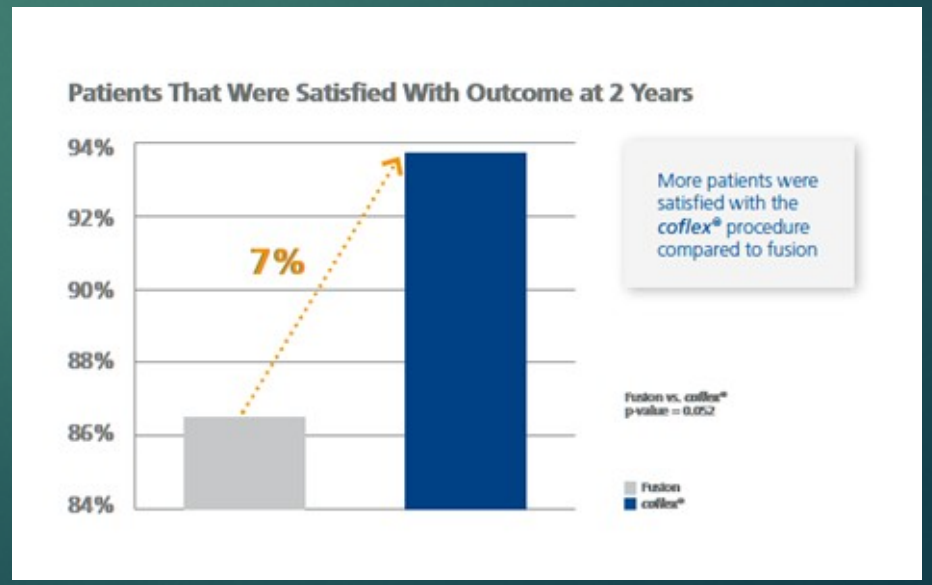
More Natural Movement At Treatment Area & Surrounding Spinal Segments - At 2 years, ***coflex***® patients retained their pre-operative range of motion (within 15%) at the areas below & above the treatment area, & fusion patients saw a 25-50% increase in unnatural motion at the areas below & above the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

coflex® Patients Do Better Faster = A True MIS Procedure

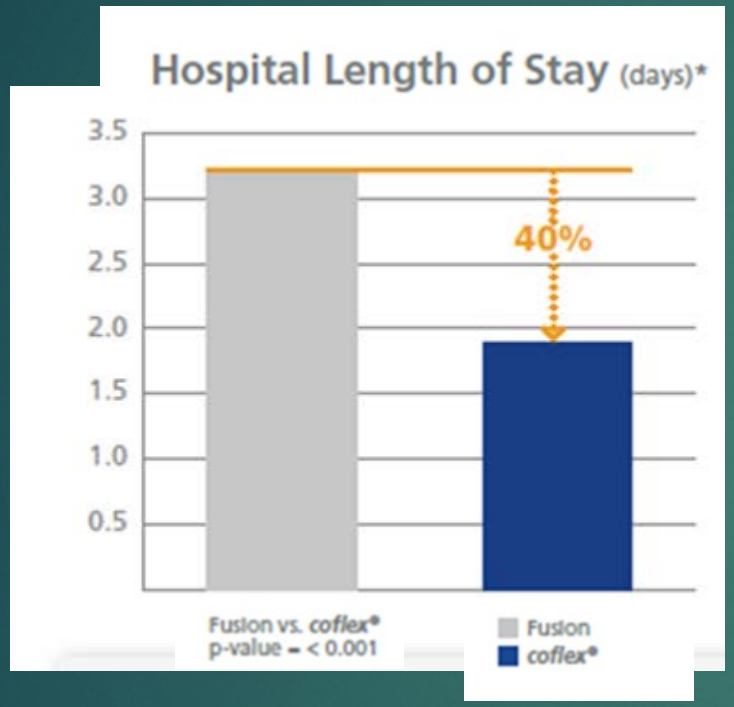








coflex® Directly Impacts Hospital Costs!



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

[1] Comparative 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

coflex® Favorable Length of Stay Comparison

Study			Average LOS (days)
coflex® Study[1]	Interlaminar stabilization device		**1.9**
SPORT SpS[2]	Lateral Recess / Foraminal Subset (n=160)		2.4
MS-DRG 460[3]	Spinal Fusion, Except Cervical without MCC		3.7
MS-DRG 490[3]	Back & Neck Proc. Except Spinal Fusion with CC/MCC* or Disc Device / Neurostimulator	4.3	2.7**
MS-DRG 491[3]	Back and Neck Procedures Except Spinal Fusion without CC/MCC*	2.1	

* CC/MCC = Comorbid Complications/Major Comorbid Complications

** Combined LOS calculated for DRGs 490 and 491 using 27% / 73% respective breakdown per 2009 National Statistics outcomes by patient and hospital characteristics for Diagnosis Related Group.

1. PMA P110008: FDA Summary of Safety and Effectiveness Data.
2. SPORT Spinal Stenosis (2-year results): patients with lateral recess and/or foraminal stenosis, underwent decompression surgery without fusion, and up to 2 levels, excluding central stenosis only (n=160). Data from Dartmouth.
3. DRG Expert 2012.

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

ClinicoEconomics and Outcomes Research

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Open Access Full Text Article

ORIGINAL RESEARCH

Comparative cost effectiveness of Coflex® interlaminar stabilization versus instrumented posterolateral lumbar fusion for the treatment of lumbar spinal stenosis and spondylolisthesis

Jordana Kate Schmier[1]
Marci Halevi[2]
Greg Maislin[3]
Kevin Ong[4]

[1]Health Sciences, Exponent Inc., Alexandria, VA, USA; [2]Paradigm LLC, New York, NY, USA; [3]Biomedical Statistical Consulting, Wynnewood, PA, USA; [4]Biomedical Engineering, Exponent Inc., Philadelphia, PA, USA

Introduction: Symptomatic chronic low back and leg pain resulting from lumbar spinal stenosis is expensive to treat and manage. A randomized, controlled, multicenter US Food and Drug Administration investigational Device Exemption clinical trial assessed treatment-related patient outcomes comparing the Coflex® Interlaminar Stabilization Device, an interlaminar stabilization implant inserted following decompressive surgical laminectomy in the lumbar spine, to instrumented posterolateral fusion among patients with moderate to severe spinal stenosis. This study uses patient-reported outcomes and clinical events from the trial along with external expected resource utilization to determine cost effectiveness.

Methods: A decision-analytic model compared outcomes over 5 years. Clinical input parameters were derived from the trial. Oswestry Disability Index scores were converted to utilities. Treatment patterns over 5 years were estimated based on clinical analysis and expert opinion. A third-party payer perspective was used; costs (in $US 2013) and outcomes were discounted at 3% annually. Sensitivity analyses examined the influence of key parameters. Analyses were conducted using Medicare payment rates and typical commercial reimbursements.

Results: Five-year costs were lower for patients implanted with Coflex compared to those undergoing fusion. Average Medicare payments over 5 years were estimated at $15,182 for Coflex compared to $26,863 for the fusion control, a difference of $11,681. Mean quality-adjusted life years were higher for Coflex patients compared to controls (3.02 vs 2.97). Results indicate that patients implanted with the Coflex device derive more utility, on average, than those treated with fusion, but at substantially lower costs. The net advantage was greater when evaluating commercial insurance payments. Subgroup analyses found that the cost advantage for Coflex relative to fusion was even larger for two-level procedures compared to one-level procedures.

Conclusion: The Coflex Interlaminar Stabilization Device was found to be cost effective compared to instrumented posterolateral fusion for treatment of lumbar spinal stenosis. It provided higher utility at substantially lower cost.

Keywords: cost analysis, spine, treatment comparison

Introduction

Lumbar spinal stenosis (LSS), in which narrowing of the spinal canal results in pressure on nerves in the back and leg, affects as many as 38.5% of adults 60 years and older in the United States.[1] As the population ages, the prevalence of LSS is likely to increase, resulting in increased need for management of this condition. Treatments for which there is evidence of effectiveness include pharmacotherapy, physical therapy, epidural steroid injections, and surgery. While surgical decompression is often a conservative

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http://dx.doi.org/10.2147/CEOR.S59194

ClinicoEconomics and Outcomes Research 2014:6 125–131

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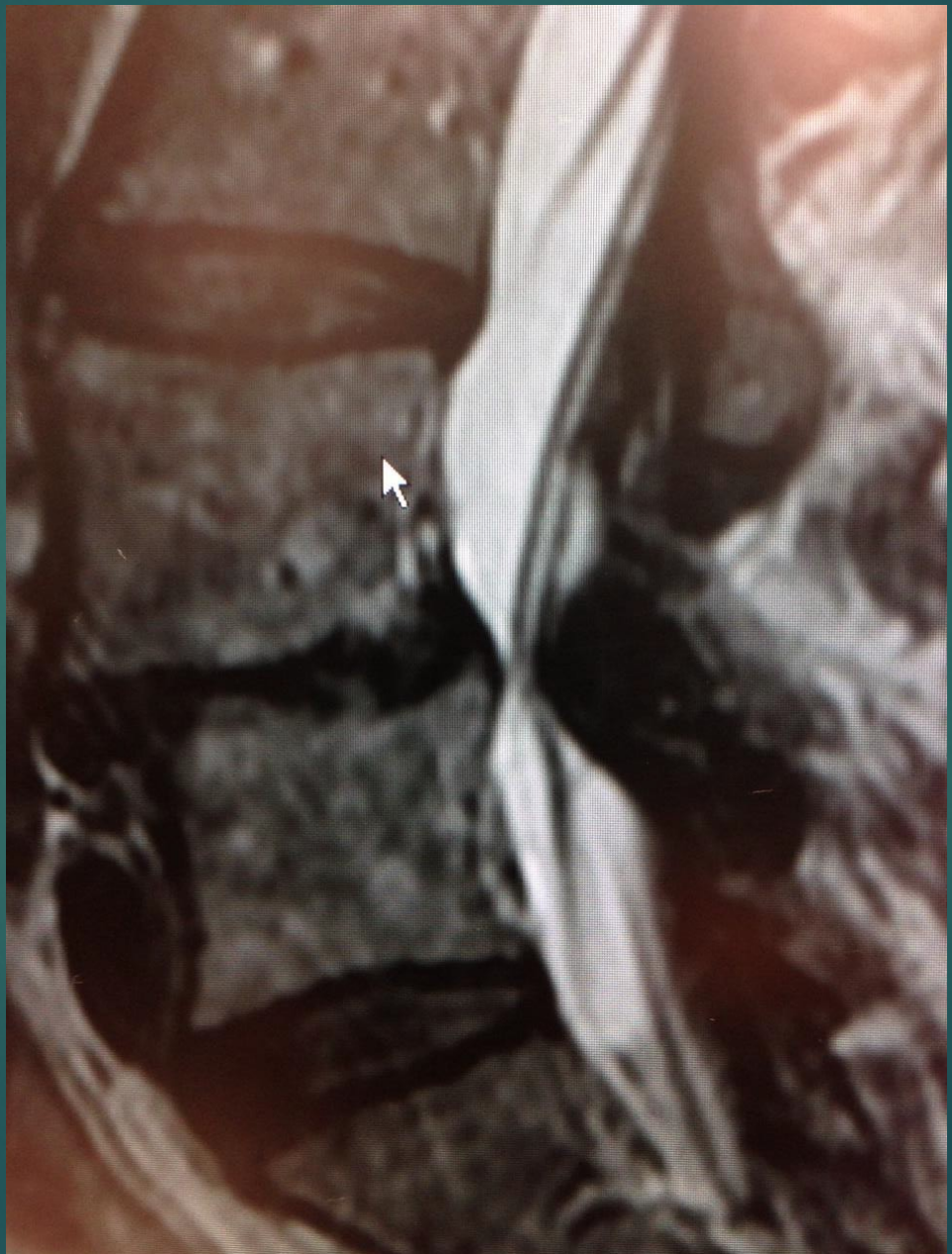
-Marci Halevi, Paradigm LLC, New York, NY, USA
-Greg Maislin, Biomedical Statistical Consulting, Wynnewood, PA, USA
-Kevin Ong, Biomedical Engineering, Exponent Inc., Philadelphia, PA, USA

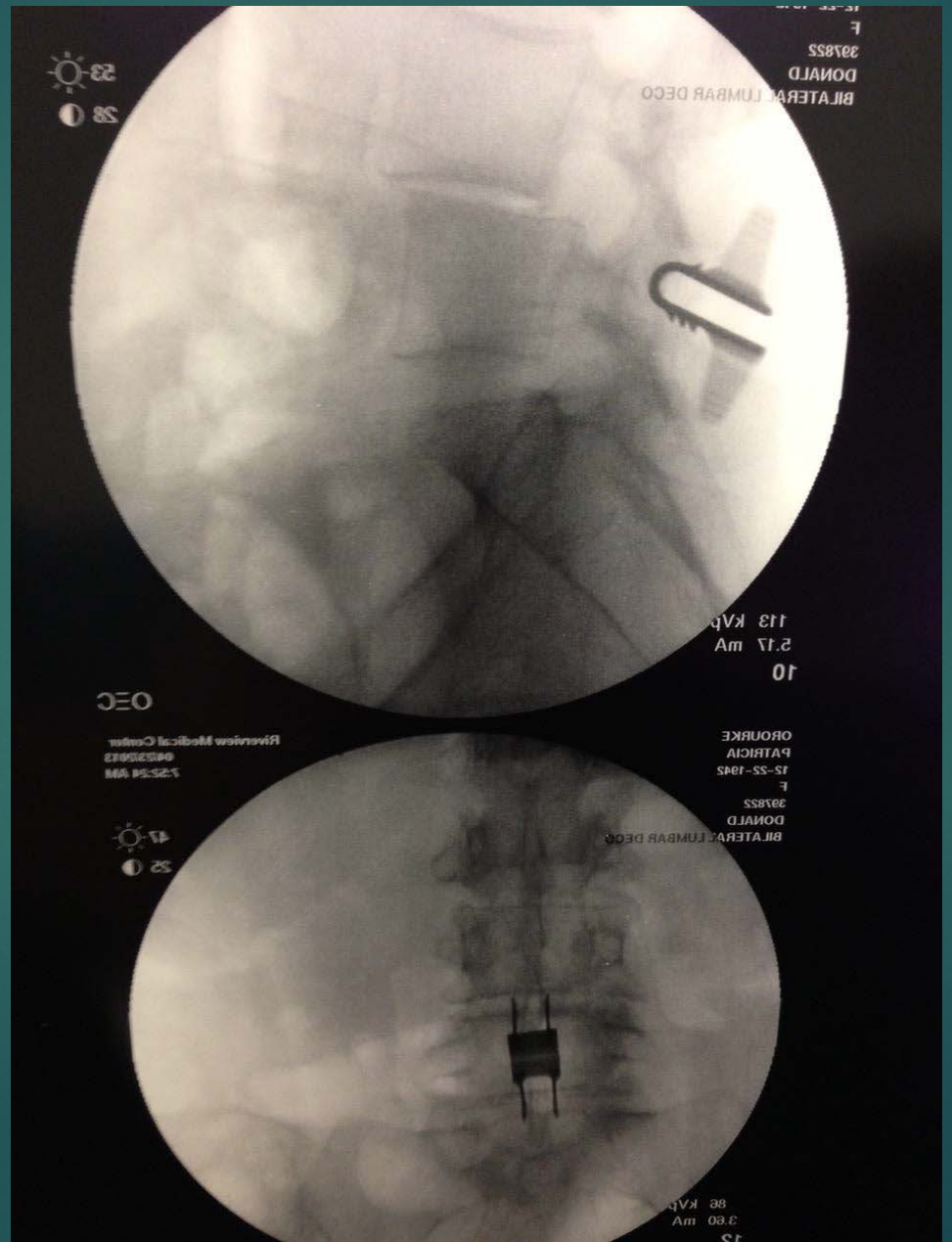
Conclusion:
The clinical and health insurance communities each have vested interest in identifying treatment options for moderate to severe LSS with and without spondylolisthesis that are both clinically beneficial and cost-effective. ***This study found that over five years, treatment with coflex® resulted 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®.**

Accepted Journal of ClinicoEconomics and Outcomes Research March, 2014

OROURKE
PATRICIA
12-22-1942
F
397822
DONALD
BILATERAL LUMBAR DECO
51
45
84 kVp
3.37 mA
1
OEC
Riverview Medical Center
04/23/2013
7:11:52 AM
OROURKE
PATRICIA
12-22-1942
F
397822
DONALD
BILATERAL LUMBAR DECO
49
26
112 kVp
5.13 mA
2



50 mm


BILATERAL LUMBAR DECO
DONALD
397822
F
10
5.17 mA
113 kVp
OROURKE
PATRICIA
12-22-1942
F
397822
DONALD
BILATERAL LUMBAR DECO
3.60 mA
86 kVp

PARADIGM SPINE

Coflex® Case Study 1

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

PARADIGM SPINE

Coflex® Case Study 1

PARADIGM SPINE

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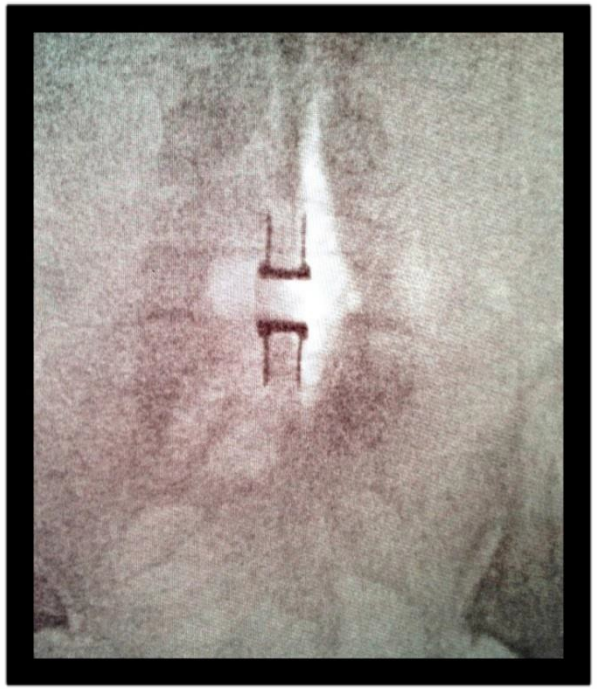
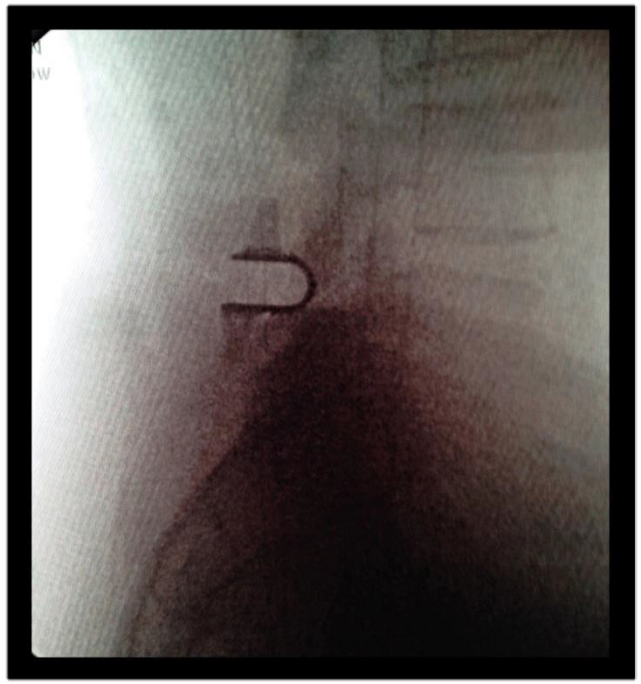
PARADIGM SPINE

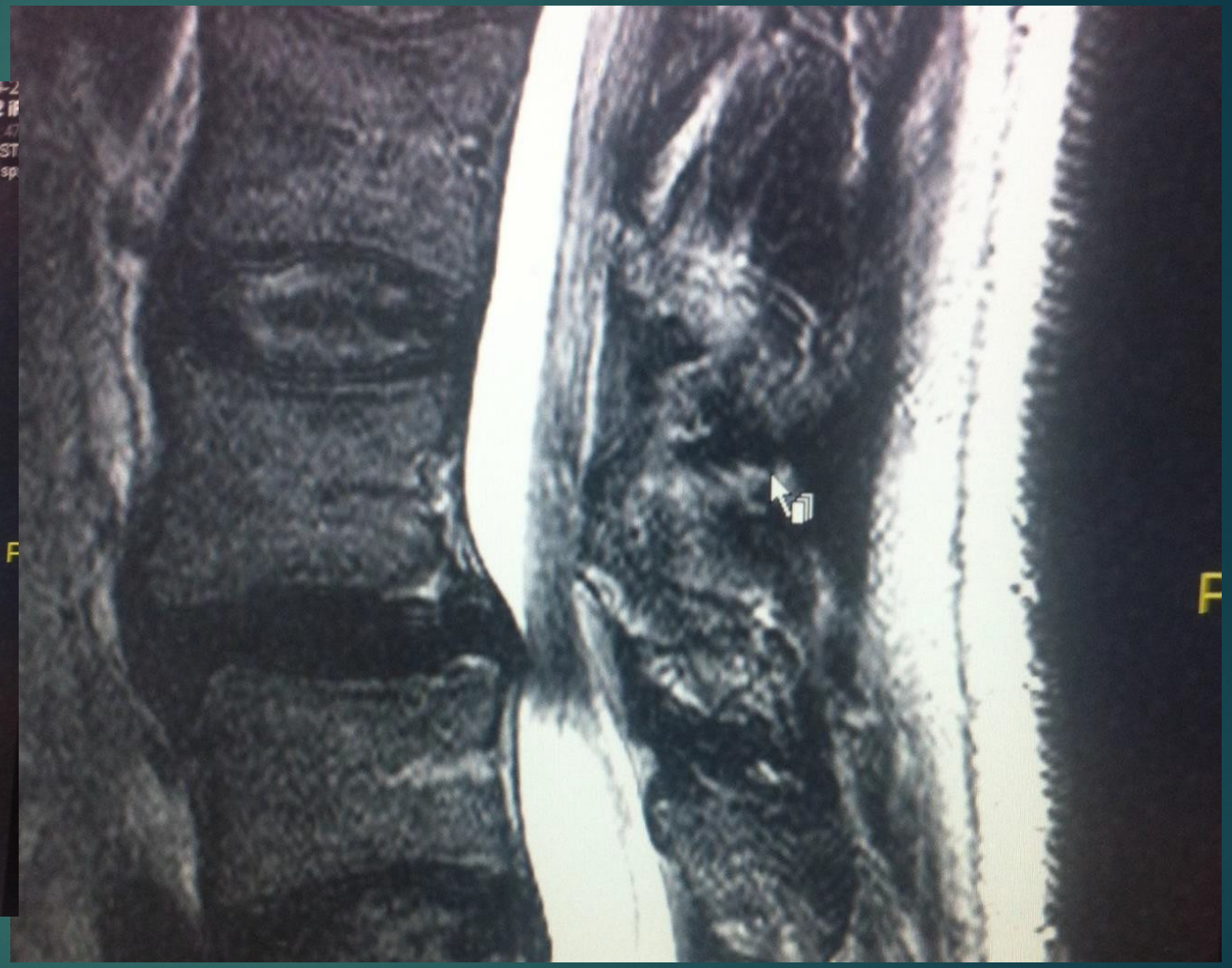
Coflex® Case Study 1





- 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

H
SAG T2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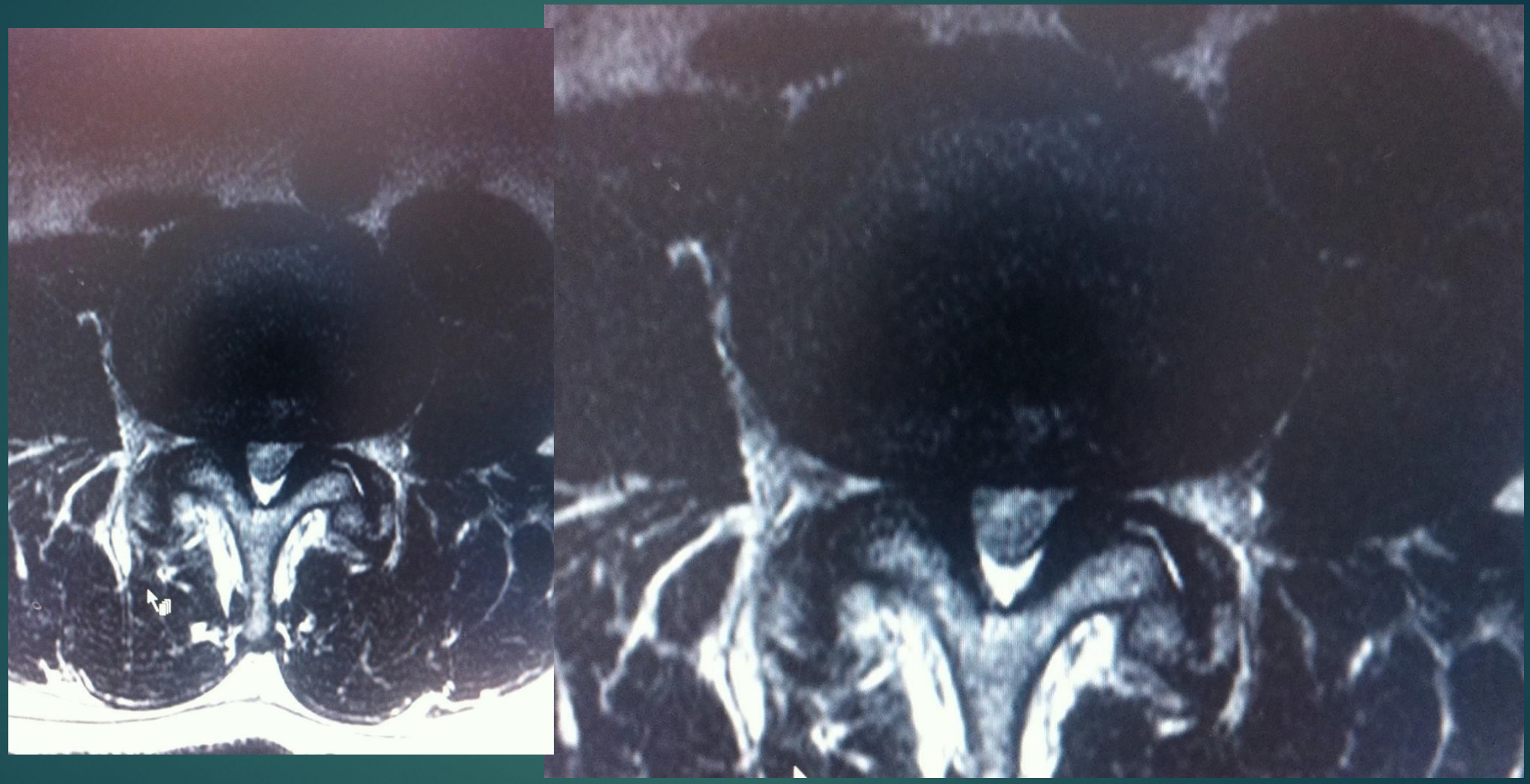
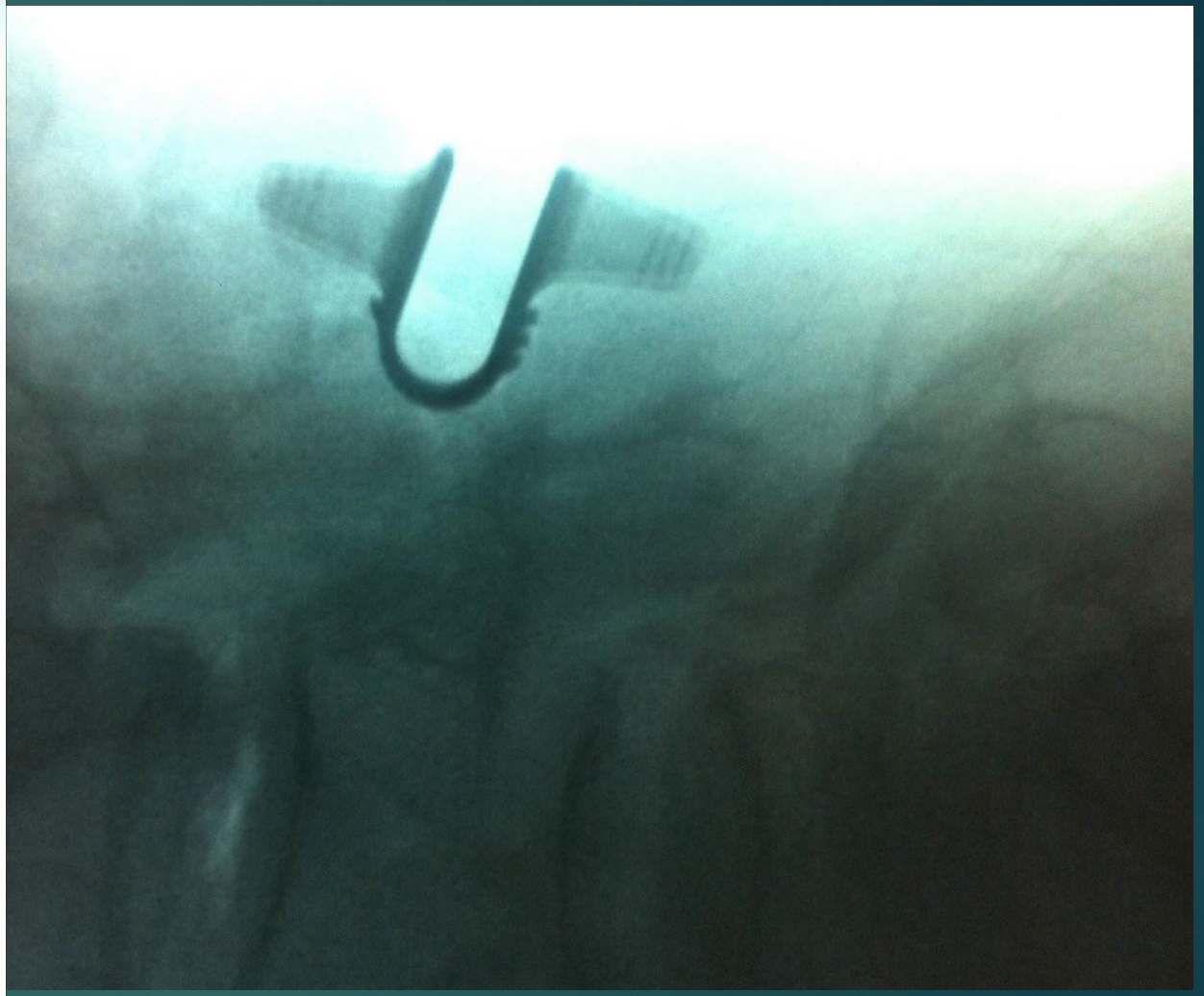
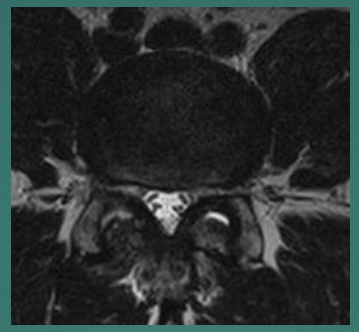
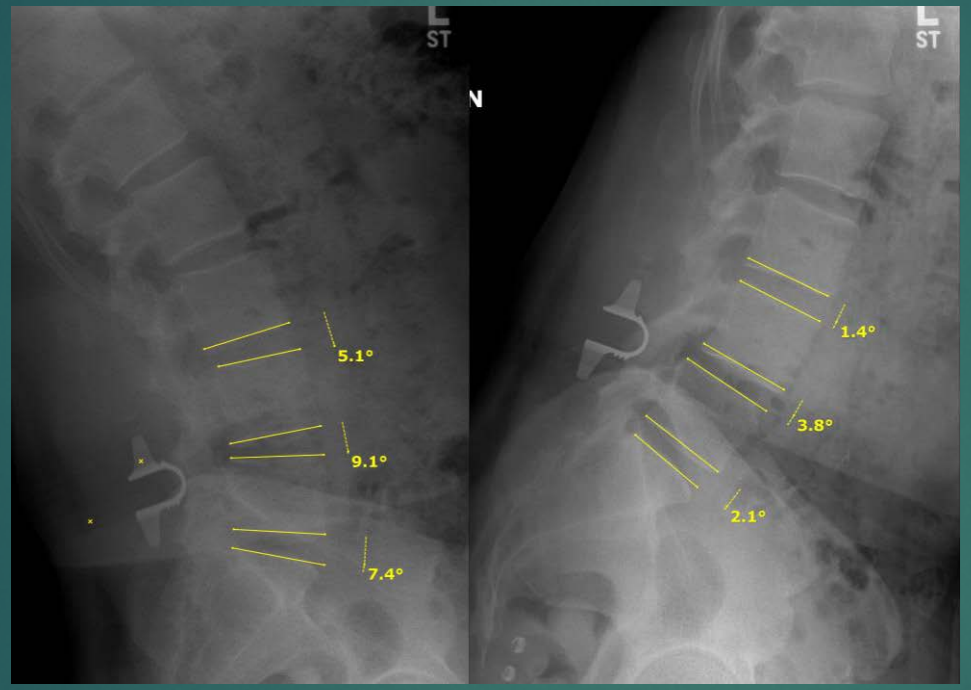




Case: 46M mechanical right leg and low back pain




ST
5.1°
9.1°
7.4°
ST
1.4°
3.8°
2.1°

“The coflex® solution”

- ✓ Significant opportunity to reduce cost in largest segment in spine (stenosis)
- ✓ Addresses the needs of patients with a **cost-saving** alternative to fusion
- ✓ Increased efficiencies & reduce costs = **Maximized Profits**
- ✓ FDA approved **On-Label** for a significant patient population
- ✓ True MIS procedure = improved clinical outcomes & patient satisfaction

Lower Cost For Better Effectiveness = Greater Value

DISCUSSION

THANK YOU