PARADIGM SPINE

Improving Patient Value and Outcomes with Effective MIS Spine Technology

A discussion on innovative technology for spinal stenosis

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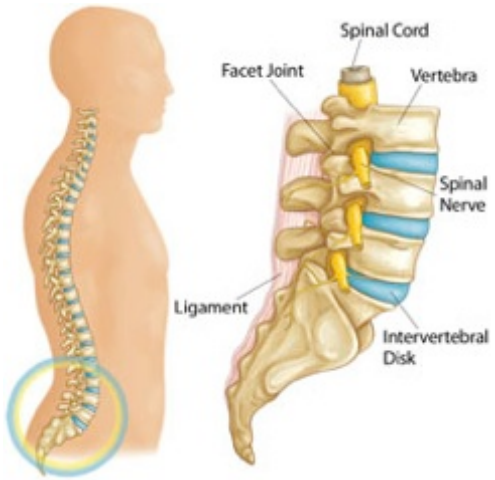
Agenda

- Lumbar Spinal Stenosis Overview and Market Opportunity
- Current Disease State Approach
- How the coflex® Device Meets an Unmet Need
- Clinical Evidence and Patient Outcomes
- coflex® Patient Selection and Patient Examples
- Coverage and Financing Strategies
- How to Best Work with Payer Providers

Lumbar Spinal Stenosis Overview

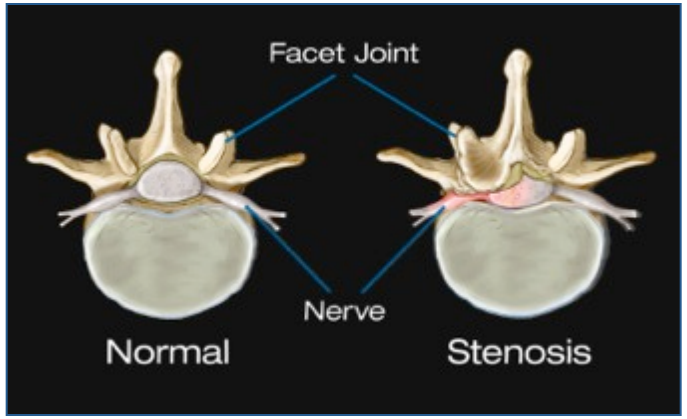
PREVALENT CONDITION



- LSS incidence: 8% - 11% of U.S. population[1]
- Most common indication for lumbar spine surgery in people >65 years of age[2]

CLINICAL PRESENTATION

Narrowing of Lumbar Spinal Canal

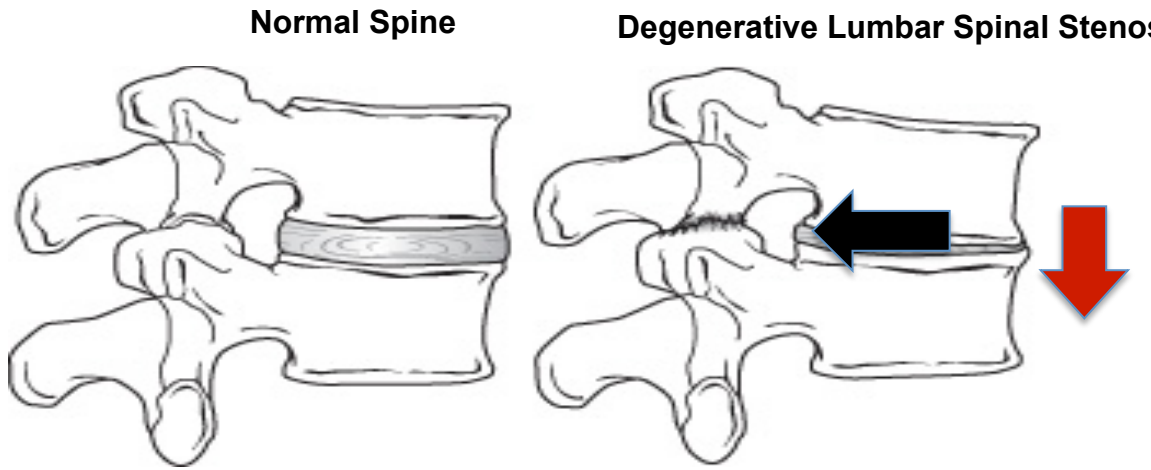


- Patients typically present with low back pain, radicular leg pain, or neurogenic claudication[1,2]

[1]Murphy DR, et al. *BMC Musculoskeletal Disorders* 2006, 7:16; [2]Weinstein JN, et al. *NEJM* 2008;358:794-810.

Lumbar Spinal Stenosis is a Degenerative Disease!

Deterioration of the Motion Segment



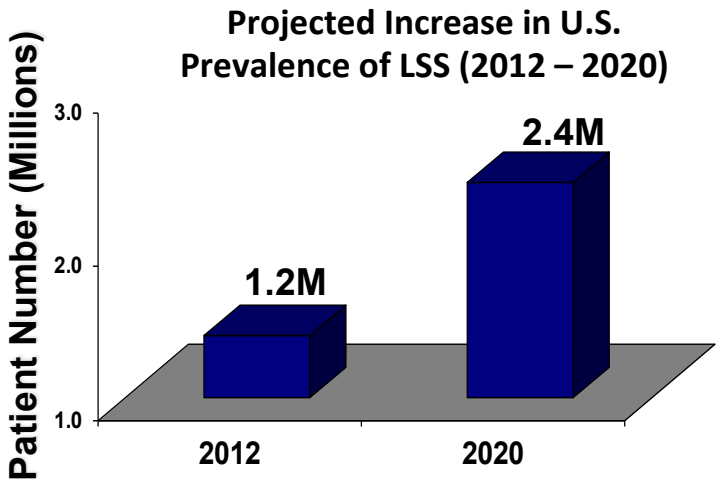
As the spine segment deteriorates, a number of changes occur that alter the biomechanics of the spine:

✓Forces are increasingly transferred to the posterior elements, resulting in the hyper-loading & breakdown of the facet joints (hypertrophy)

✓ As the pathology of the disc continues to deteriorate (i.e. loss of disc height), the aperture of the foramen continues to diminish & the ligamentum flavum begins to buckle & protrude into the central canal

Why Spinal Stenosis Is Relevant To Your Practice Today

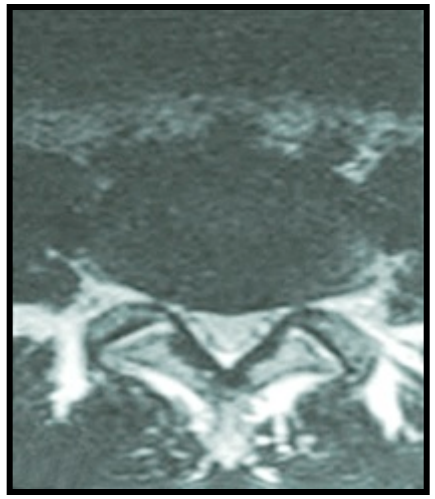
- Spinal stenosis is currently the largest diagnosed patient population in spine at approximately 1.4M*
- It is expected that this group will increase to 2.4M by the year 2020
- Over 600,000 of these patients choose surgical treatment each year
- On average, a spine practice treats over 100 stenosis patients per year, which is an average of 40%-50% of the total annual procedures performed+



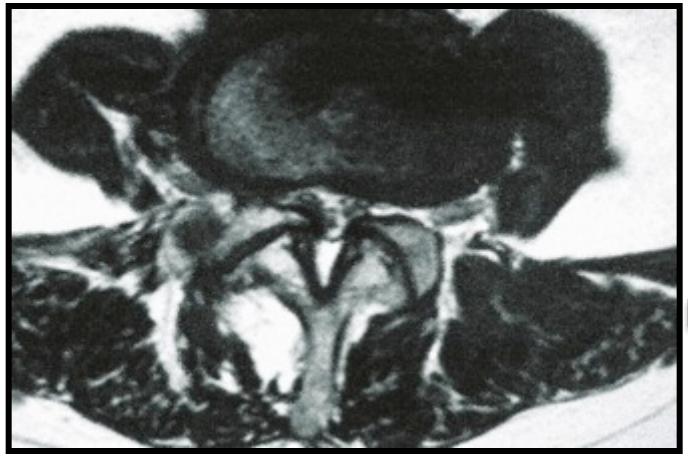
LSS is the largest growing patient demographic in spine care

* 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.
+ Third party market intelligence data.

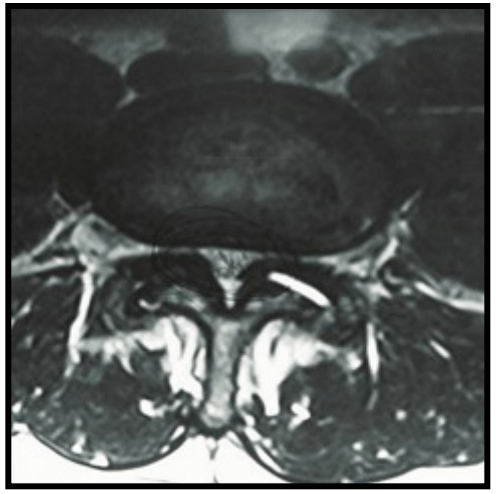
Lumbar Spinal Stenosis Degenerative Continuum



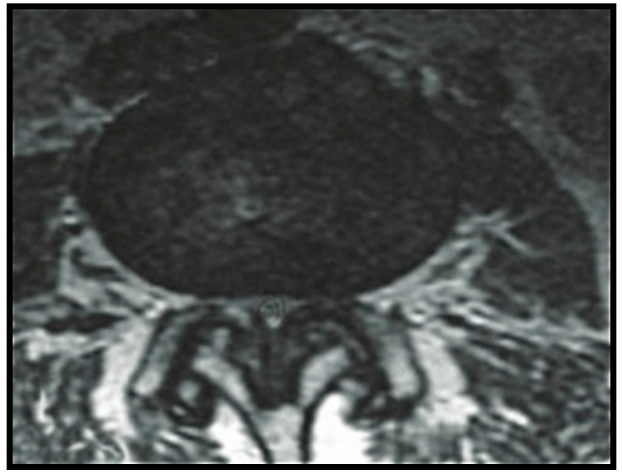
Intermittent Neurogenic Claudication
NIC



LSS Etiology:Acquired Degeneration **NIC** Limited LBP



Mild to Moderate
Degeneration Limited LBP

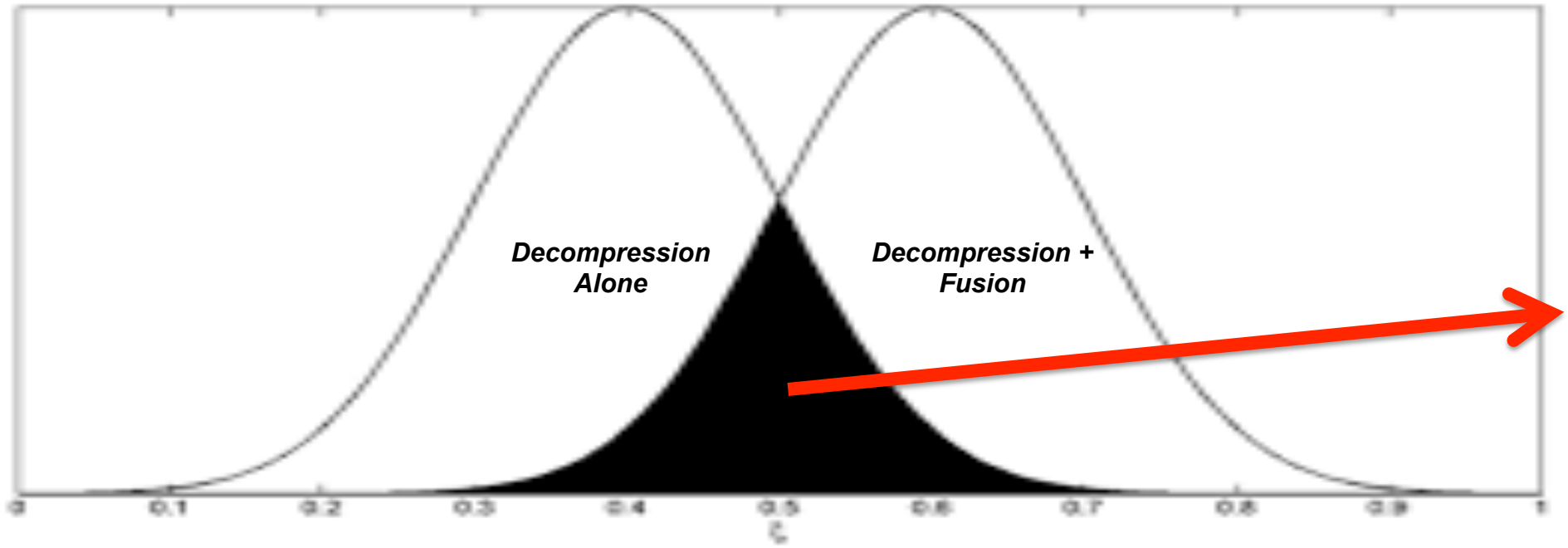


Moderate to Severe Degeneration
Significant back pain (>leg pain)
Stable

Do these patients improve over time with conservative therapy?

What definitive treatment options are available for these patients?

Current Treatment Approach to Disease Continuum



How do you treat those advanced degenerative lumbar spinal stenosis patients in between?

Neurogenic Claudication

Leg & Back Pain

Stable Spondylolisthesis

Gross Instability

Severity of the LSS Disease State

Tradeoffs of Current Treatment Solutions for Lumbar Spinal Stenosis

Positive Attributes

Decompression Only

- **Potentially Minimally Invasive**
- **Suggests Lower Risk**
- **Immediate relief of leg pain**
- **Lower cost**
- **Faster recovery**
- **Performed in Outpatient or ASC**

Decompression w/ Lumbar Fusion

- **Addresses instability at index level** (Herkowitz)
- **Relief of leg and lower back pain**
- **Durability (mechanical)**
- **Extensive Decompression**
- **Address facet based issues**

Negative Attributes

- **Potentially destabilizes the spine**
- **Undefined duration of relief**
- **Does not address back pain**
- **Does not address degenerative cascade**

- **Highly invasive / long time frame for recovery**
- **Contributes to adjacent level disease**
- **Long delay to normal activity**
- **Continued use of pain medication**
- **High reoperation rate**

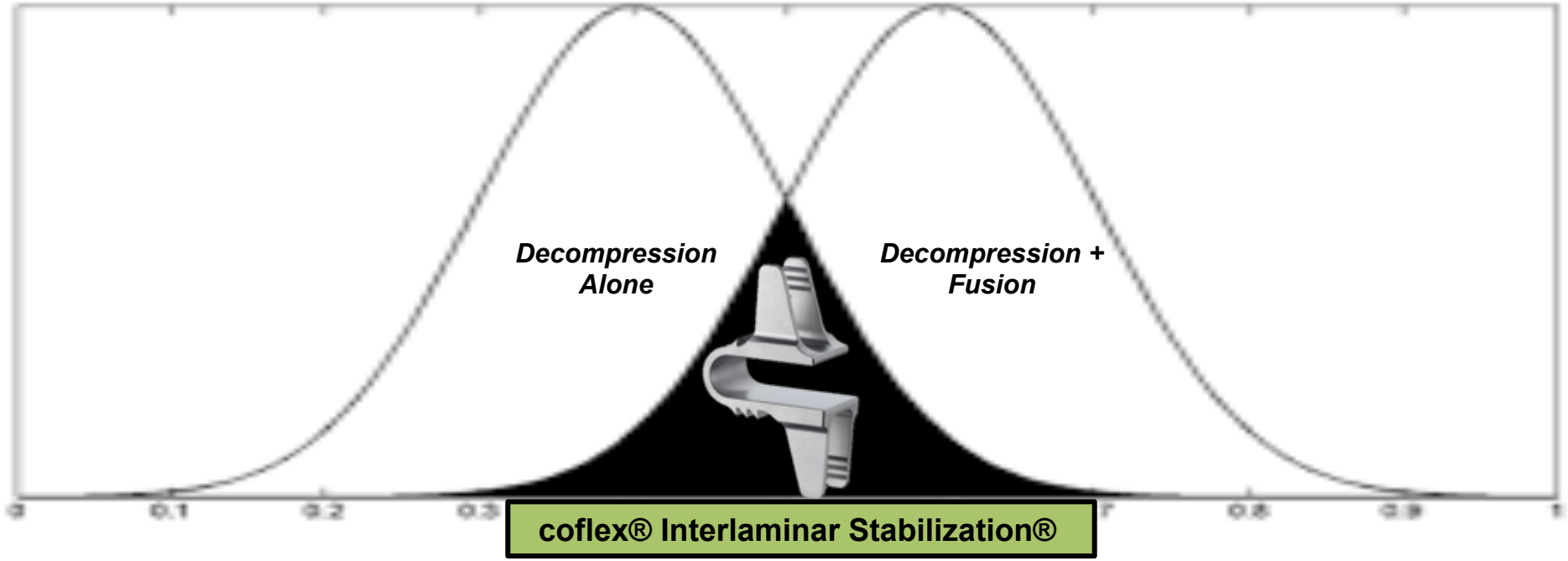
Less Invasive

More Invasive

If There Were a Game-Changing Solution to Treat Patients with Advanced Degenerative Lumbar Spinal Stenosis, *What Would it Look Like?*

- Addresses **ALL** Lumbar Spinal Stenosis symptoms (leg and back pain)
- Proven outcomes with Level 1 data showing superior outcomes to current treatments options
- Quicker patient return to activities prior to experiencing symptoms
- Helps prevent disease degeneration & preserves natural kinematics
- Minimally invasive procedure (MIS)
- Product/procedure can performed in both Inpatient/Outpatient settings of care
- Highly differentiated & highly marketable procedure/technology

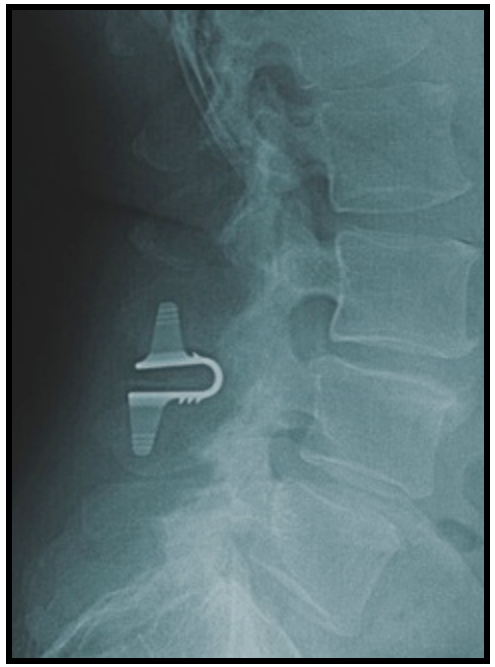
coflex® Meets an Unmet Clinical Need!

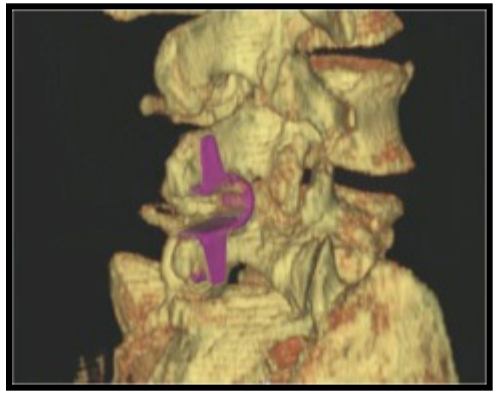


Neurogenic Claudication	Leg & Back Pain	Stable Spondylolisthesis	Gross Instability

Severity of the LSS Disease State

Now You Can Provide an Effective MIS Solution
For a Large Portion of Your Advanced Degenerative LSS Patients





coflex® Interlaminar Stabilization®

Motion Preserving Non-Fusion Neutral Stabilization Post Decompression for Advanced Degenerative Lumbar Spinal Stenosis

Single-piece implant made of titanium alloy
5 anatomical sizes
Can be used for 1- and 2-Level implantation
2-part functional design allows for:

Non-Fusion Interlaminar Stabilization

- Implanted within interlaminar space and loads on laminar bone (3-5 x stronger vs spinous process)
- Maintains foraminal height and off-loads the facets

Motion Preservation

- Implant compresses in extension and allows for flexion
- Maintains sagittal balance and lordosis
- Maintains physiologic adjacent segment kinematics

The coflex® Investigational Device Exemption (IDE) Trial

A Landmark Study in Lumbar Spinal Stenosis

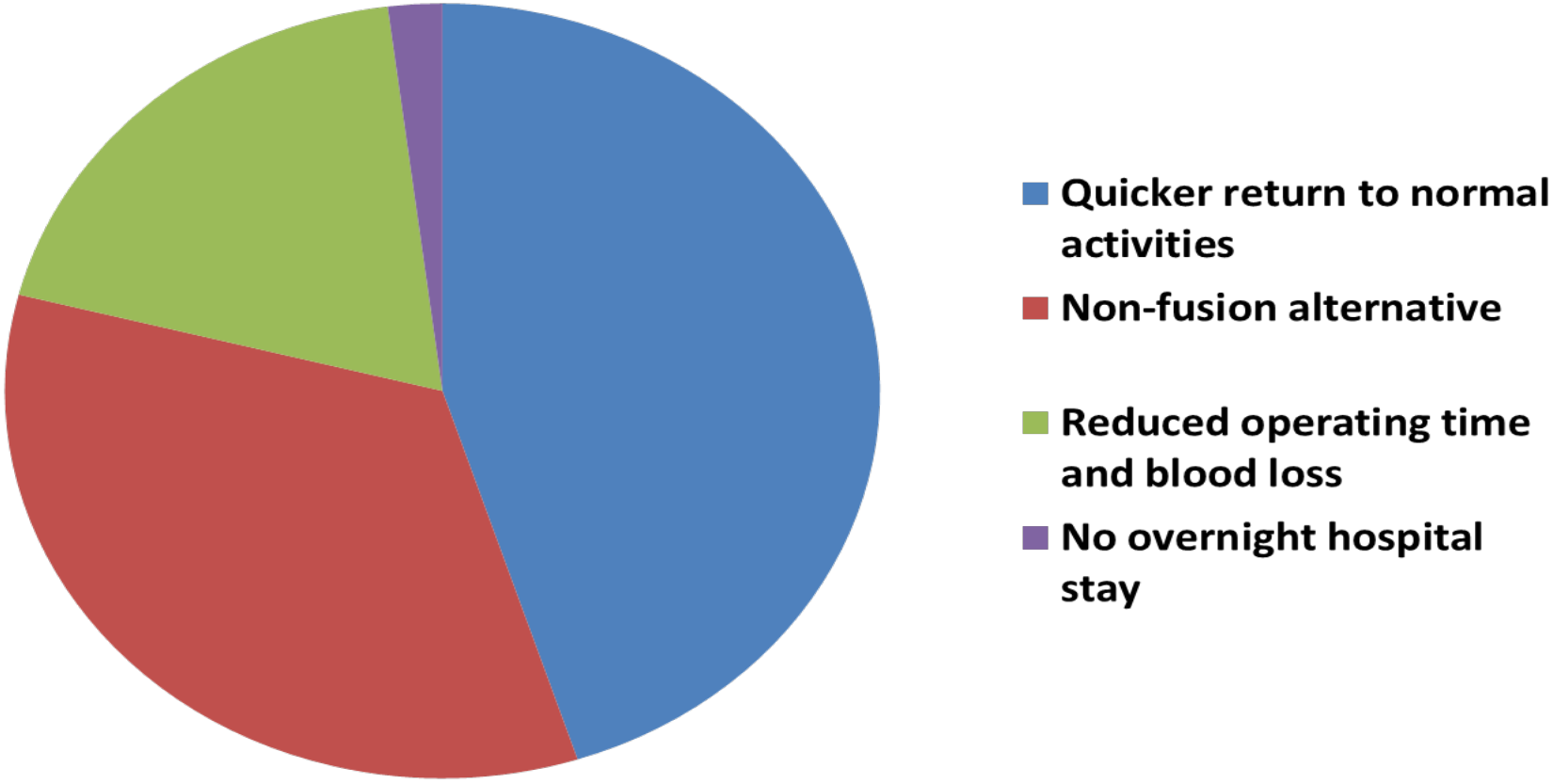
- **Unprecedented amount of Level 1 clinical and radiographic data**
- **95% follow-up at 2 years** sets a new standard
- **First LSS IDE study to complete enrollment with a fusion control group**
- **First orthopedic device PMA with an independent CEC** to blindly evaluate and adjudicate all adverse events with binding decisions on sponsor
- First spine study to include **all lumbar epidurals as failures**
- Study designed to address every issue previous IDEs and panels cited as design flaws

Clinical Evidence

- SPINE: 2-Year Study Results
- JNS: 2-Year Spondy Cohort Study Results
- JBJS: Adverse Event Reporting Bias
- The Spine Journal: In-Vivo Posterior Loading
- SPINE: Influence of Preoperative Back Pain
- Asian Spine Journal: Role of coflex® as Adjunct to Decompression
- ClinicoEconomics Research: Comparative Cost Effectiveness

Patients Were Asked:

WHAT WOULD BE YOUR KEY CONSIDERATION IN DECIDING WHAT TYPE OF PROCEDURE TO HAVE TO ADDRESS MODERATE TO SEVERE LUMBAR SPINAL STENOSIS?



Independent Survey of 100 Respondents. January 2014.

Patient Outcomes

Compared to fusion patients in the clinical study, patients receiving coflex® experienced:

- HIGHER PERCENTAGE OF PATIENT SATISFACTION
- FASTER RELIEF OF SPINAL STENOSIS SYMPTOMS
- LASTING RELIEF OF SPINAL STENOSIS SYMPTOMS
- EARLIER IMPROVEMENT IN PAIN AND FUNCTION
- LASTING IMPROVEMENT IN PAIN AND FUNCTION
- EARLIER IMPROVEMENT IN PHYSICAL FUNCTION
- LASTING IMPROVEMENT IN PHYSICAL FUNCTION
- BACK AND LEG PAIN RELIEF
- LESS BLOOD LOSS, SHORTER OPERATING TIME, SHORTER HOSPITAL STAY

94%

of coflex® patients were satisfied

compared to 87% of fusion patients

90%

of coflex® patients had early relief

compared to 77% of fusion patients

88%

of coflex® patients had lasting relief

compared to 78% of fusion patients

Claims based on comparison to pedicle screw fusion in FDA PMA P110008, October 2012.

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%).

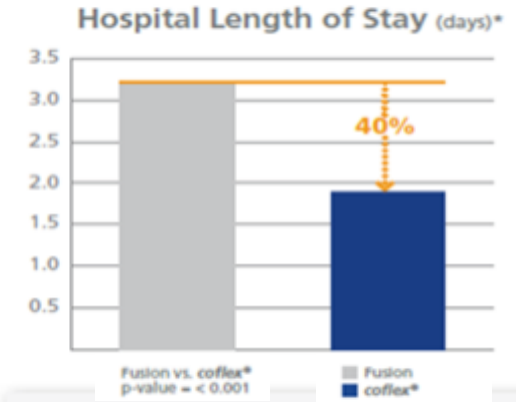
Shorter Operating Time - **coflex®** surgeries were 36% faster compared to fusion surgeries (98 minutes vs. 153 minutes).

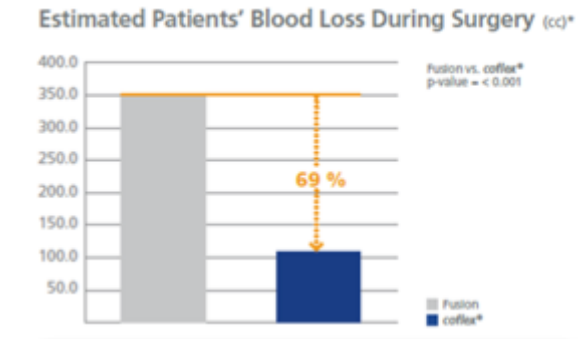
Shorter Hospital Stay - **coflex®** patients spent 40% less time in the hospital compared to fusion patients (1.9 days vs. 3.2 days).

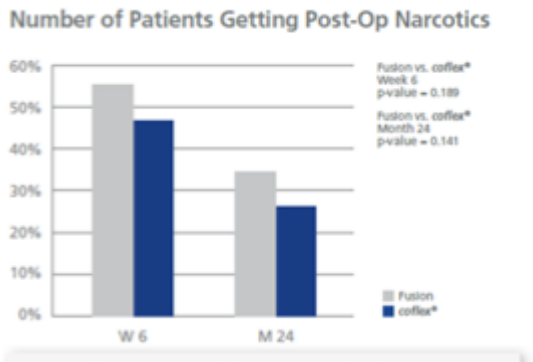
Less Blood Loss - **coflex®** patients had less blood loss during surgery compared to fusion patients (110cc vs. 349cc).

Stability In The Treatment Area - At 2 years, **coflex®** patients retained their pre-operative range of motion (within 10%) and 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 and above the treatment area, and fusion patients saw a 25-50% increase in unnatural motion at the areas below and above the treatment area.







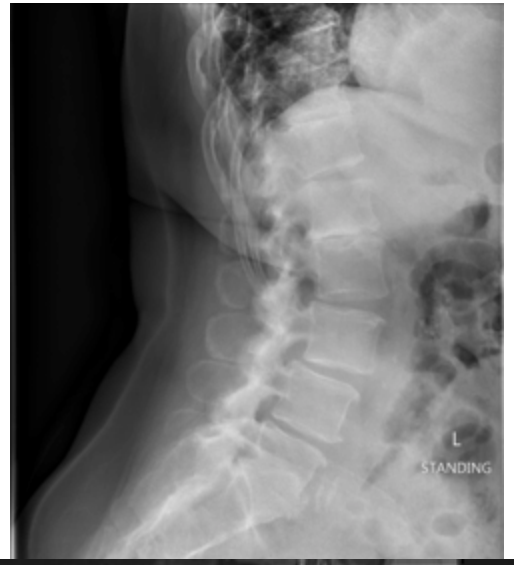
Claims based on comparison to pedicle screw fusion in FDA PMA P110008, October 2012.

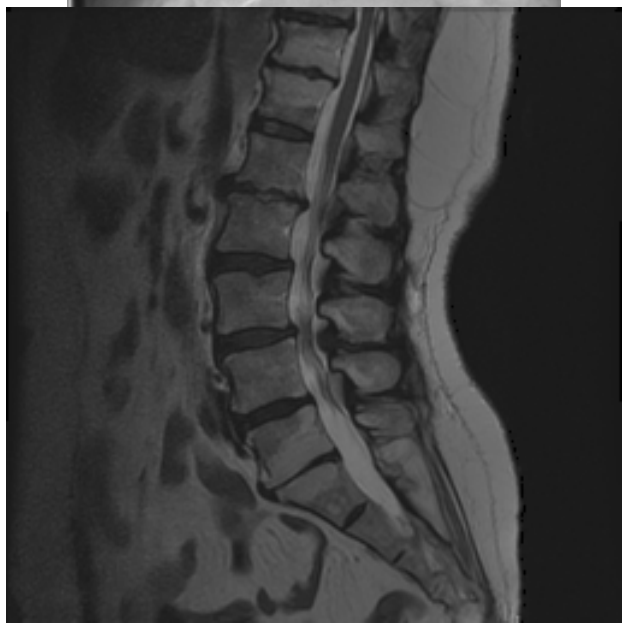
coflex® Patient Examples

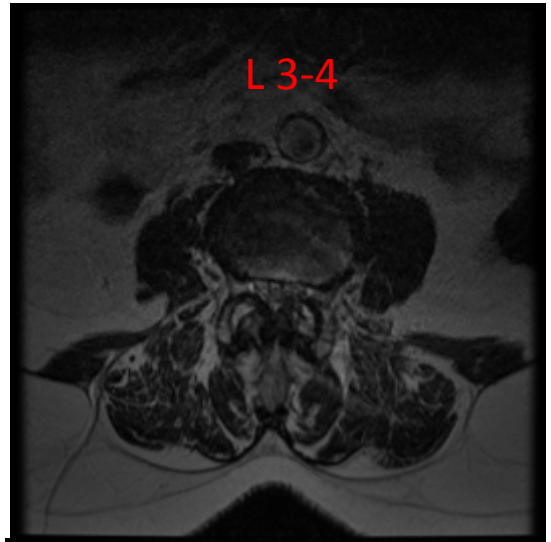
Case Study 1

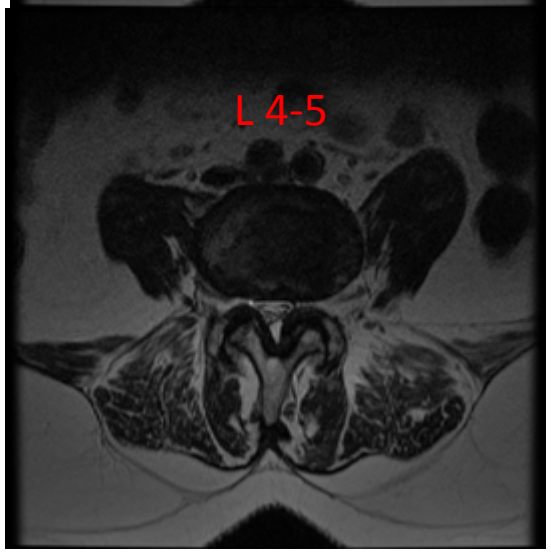
- 63 yo female with neurogenic claudication R>L, LBP as well but secondary issue to legs
  - VAS Back 70
  - VAS Legs 90
  - ODI 66

- Sx chronic – several years failed PT, Chiro, ESI
- Confounding variable is need for R THA





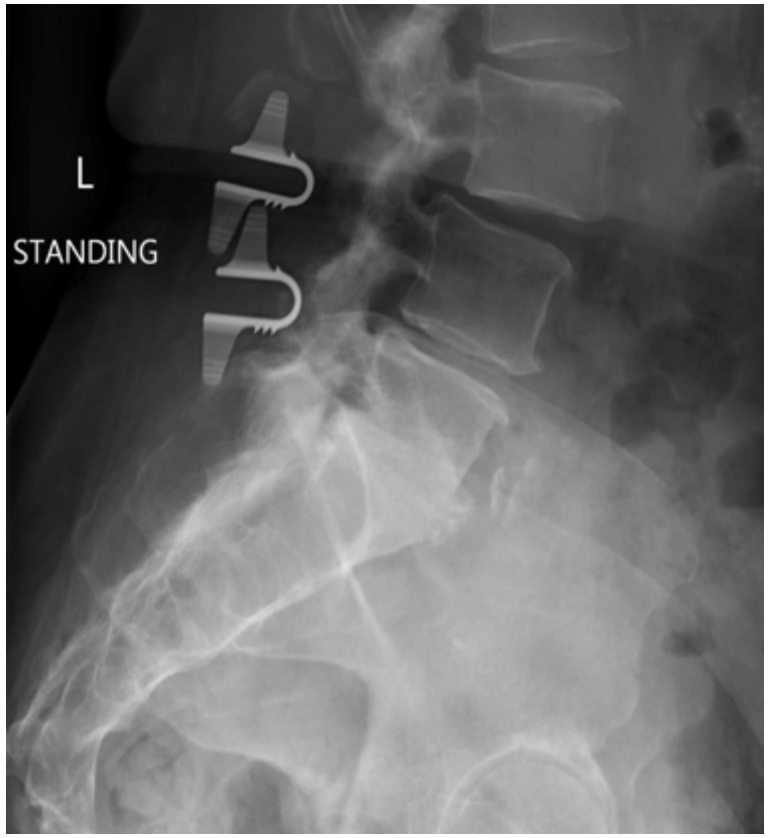


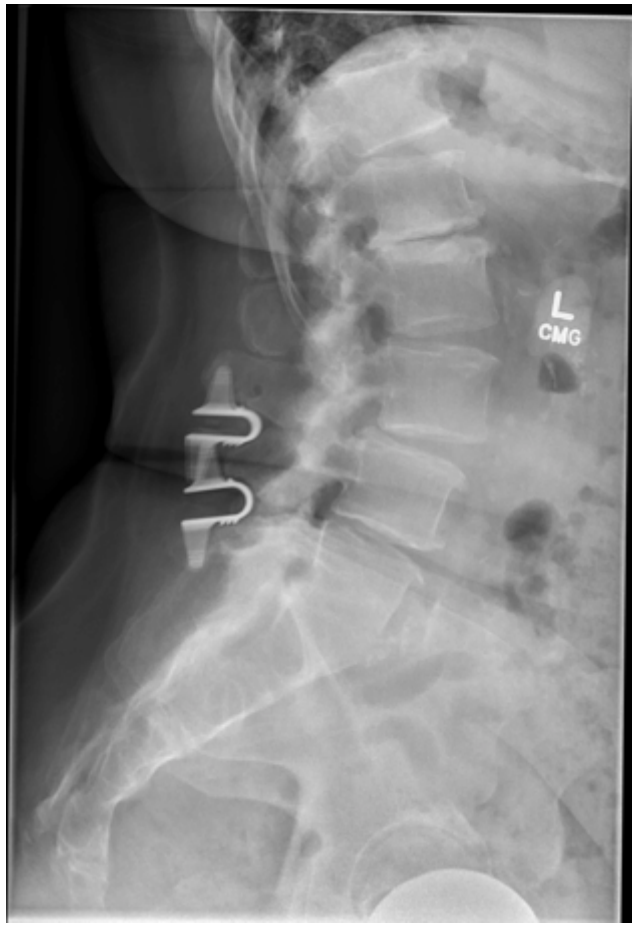


coflex® Patient Examples

- Spinous process fracture, otherwise no significant issue
- Healed Fx without any obvious issues

Outcome	VAS Back	VAS Legs	ODI
Pre-op	70	90	66
6 weeks	40	0	50
3 months	30	20	40
6 months	24	26	24
1 year	0	0	16
2 years	4	4	8

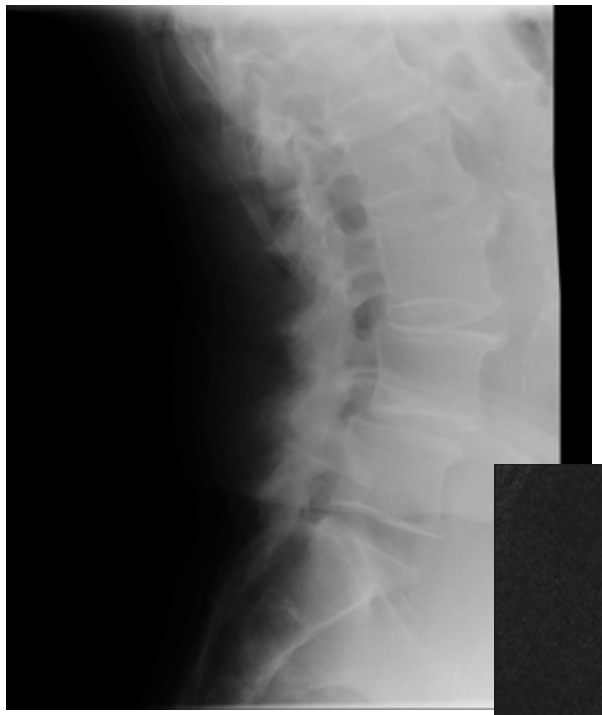


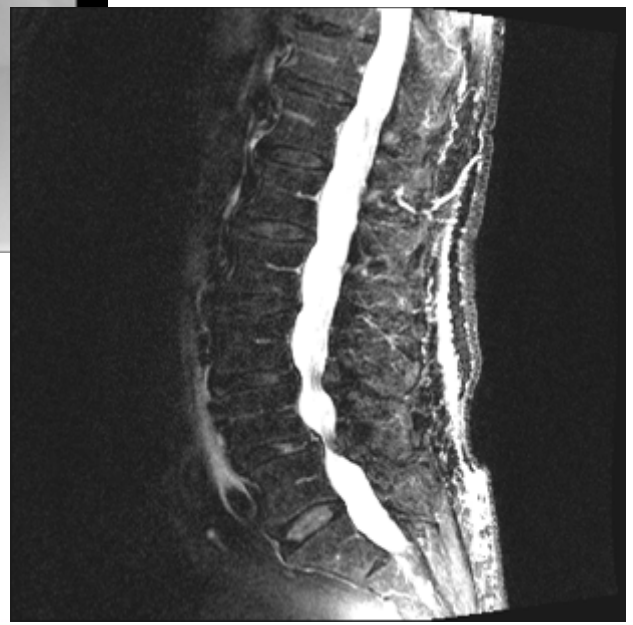


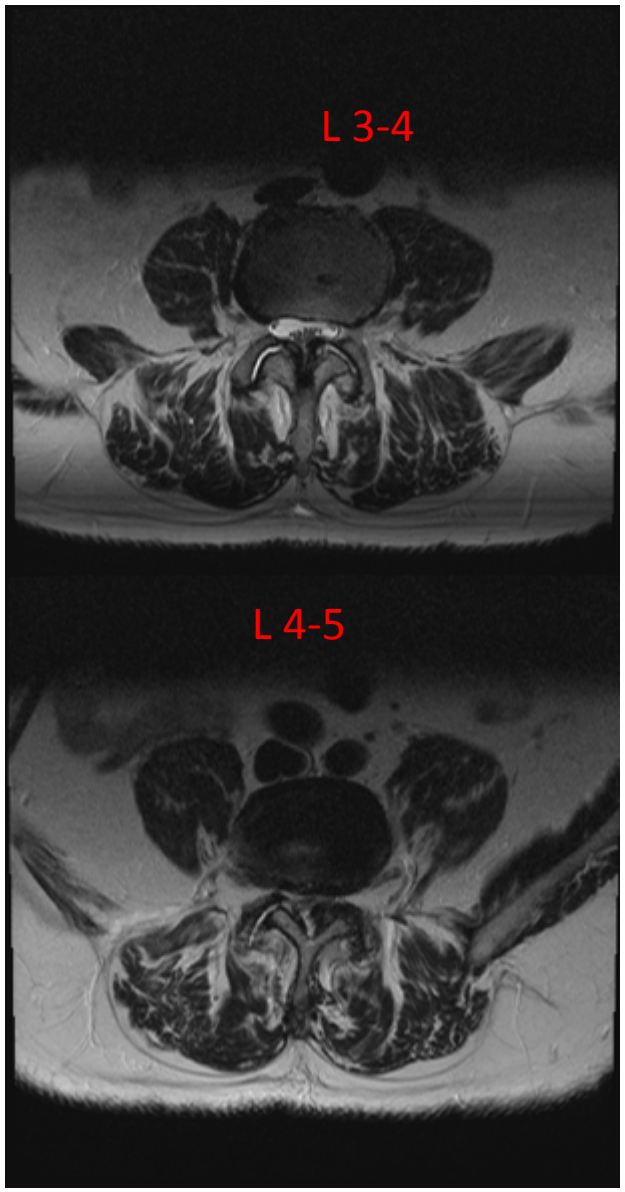
coflex® Patient Examples

Case Study 2

- 78yo male
  - VAS Back 100
  - VAS Legs 100
  - ODI 48
  - R>L leg pain, neurogenic claudication
- Failed years of PT and multiple rounds of ESI



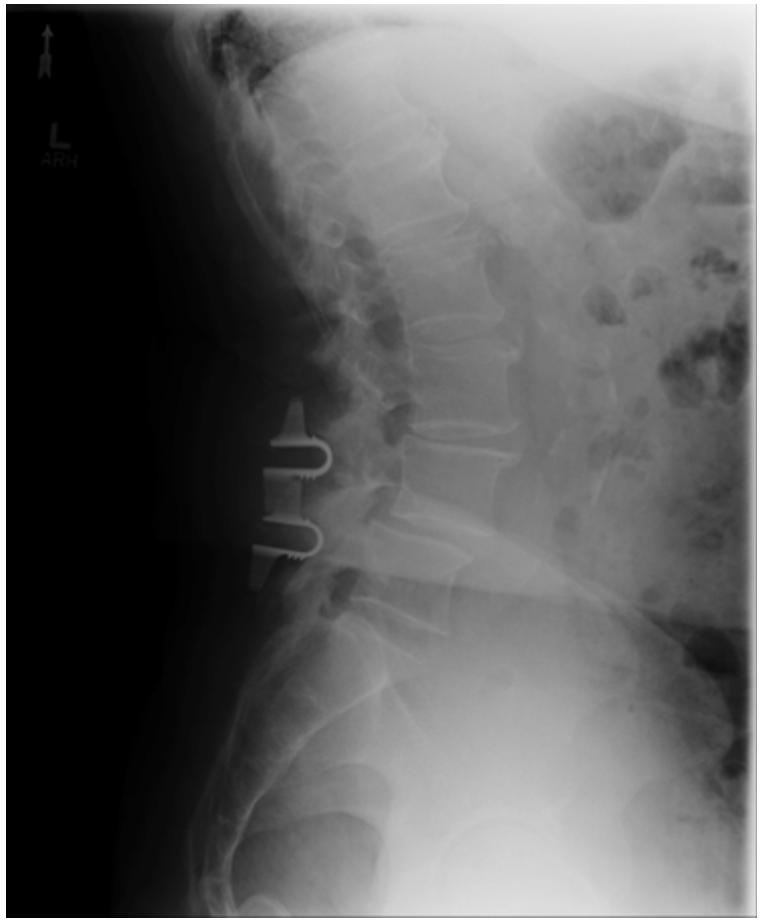


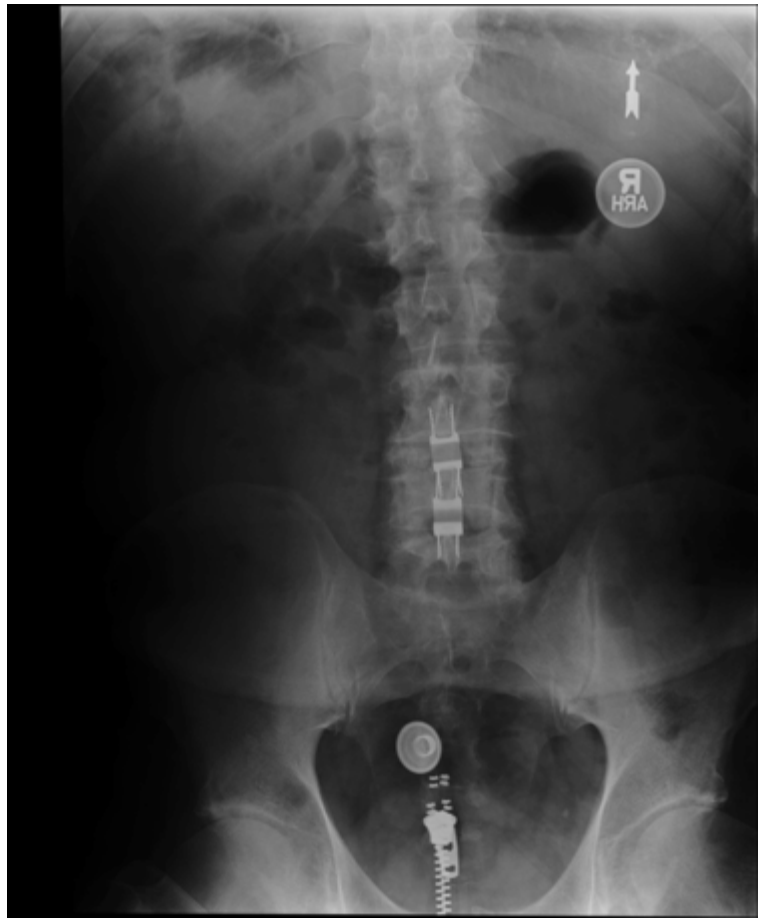


coflex® Patient Examples

- Outpatient procedure no complications

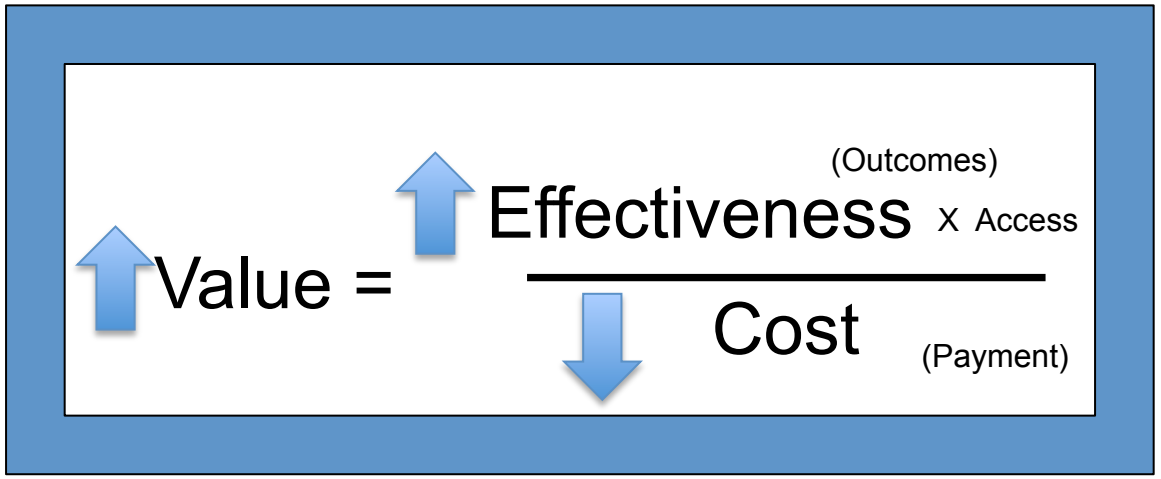
Outcome	VAS Back	VAS Legs	ODI
Pre-op	100	100	48
6 weeks	0	0	0
3 months	14	12	8
6 months	11	11	0
1 year	8	11	0





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



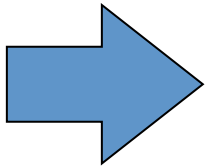
An Evolving Model: Incentives Aligned With Quality NOT Quality of Care

Lower Cost of Care = Greater Opportunity For All Stakeholders

Profit Drivers: Lower rate of surgery, less costly surgical options, fewer complications, patient choice

Current Model

High volume treatments
(moderate cost/quality)
benefits the hospital/surgeon



Tomorrow's Model

High value treatments
(low cost/high quality)
benefits the hospital/surgeon/payer

coflex® Makes Sense For Everyone Involved!

Surgeon

Reduced OR Time
Better Outcomes
Differentiated Treatment

Facility

Earlier Discharge
Efficient Turnover
Outpatient/ASC Option

Patient

Faster Recovery
Better Outcomes
Back To Work Quicker

Payor

Cost Effective Solution
Potentially Fewer Reoperations
Takes Costs Out Of System

Claims based on comparison to pedicle screw fusion in FDA PMA P110008, October 2012.

Disclaimer: *This information is for educational/informational purposes only and should not be construed as authoritative. Codes and values are subject to frequent change without notice. The entity billing Medicare and/or third party payors is solely responsible for the accuracy of the codes assigned to the services or items in the medical record. Therefore, health care providers must use great care and validate coding requirements ascribed by payors with whom they work. Paradigm Spine assumes no responsibility for coding and cannot recommend codes for specific cases. When making coding decisions, we encourage you to seek input from the AMA, relevant medical societies, CMS, your local Medicare Administrative Contractor and other health plans to which you submit claims. Items and services that are billed to payors must be medically necessary and supported by appropriate documentation. Paradigm Spine does not promote the off-label use of its devices. It is important to remember that while a code may exist describing certain procedures and/or technologies, it does not guarantee payment by payors. It is ultimately the responsibility of each individual provider to submit the appropriate request for reimbursement and supporting documentation to cover the procedure.*

Optimize Practices Around Coverage and Financing

Practice Initiated Activities

- Assure **healthy balance** of workers' compensation and private insurance & self pay patients with appropriate practice outreach:
  - ✓ Balance workers' comp patients, private insurance
  - ✓ Consider educational events utilizing Paradigm Spine educational resources
- Continue to explore all possible avenues for past coflex® cases for payment with private payers
- Consider offering ***American Healthcare*** Financing Option for patients interested in the program (consider organizing webinars with AHF for eligible patients)
- ***MCRA*** is an available resource for pre-authorization

Musculoskeletal Clinical Regulatory Advisers, LLC

Coverage Support

Musculoskeletal Clinical Regulatory Advisers, LLC

- MCRA's coding and coverage experts have over 50 years of combined healthcare policy and finance services experience, and have a proven track record servicing over 250 clients nationwide

- MCRA assists practice with day-to-day challenges related to appropriate coverage for coflex®

- MCRA's coverage services are experienced in working with payors to assist providers with:
  - ✓ Payor interaction
  - ✓ Providing the appropriate evidence to payors to support coverage
  - ✓ Current coding, coverage and payment information

MCRA Coverage Support Center:
888-796-8411

MCRA Coverage Access Management For coflex®

Musculoskeletal Clinical Regulatory Advisers, LLC

- ✓ The Coverage Access Program Seeks to Expedite Insurance Coverage through the Prior-Authorization Process to Support Patient Access for the Appropriate Treatment
- ✓ Facilitates Coverage through Pre-Authorization & Pre-Authorization Appeal and Submitting Appropriate Data
- ✓ Tracks Case Requests and Identifies Trends in Denial & Evidence Patterns

The **Coverage Access Program** Is Available to Facilitate **Patient Flow** Through the System, from Verifying Benefits & Eligibility to Pre-Authorization Approval, Providing Access to **Patients Requiring a coflex® Interlaminar Implant**

How to Best Work with Payer Providers

MCRA assists to resolve issues regarding coverage for coflex® cases

- Organize standing conference call with MCRA to discuss ongoing obstacles and challenges with coverage
- **MCRA is available to *discuss newly scheduled*** patients that may pose a challenge based on prior experience with case/insurer

Engage insurers to demonstrate clinical utility

- Present coflex® utility presentation to local insurers
- Show clinical presentation to educate on outcomes with coflex® versus fusion
- Consider involving patient advocates

Present coflex® outcomes to self-funded large employers to demonstrate clinical utility and economic outcomes

Thank you!
Questions?