PARADIGM SPINE

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 of 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.

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THANK YOU

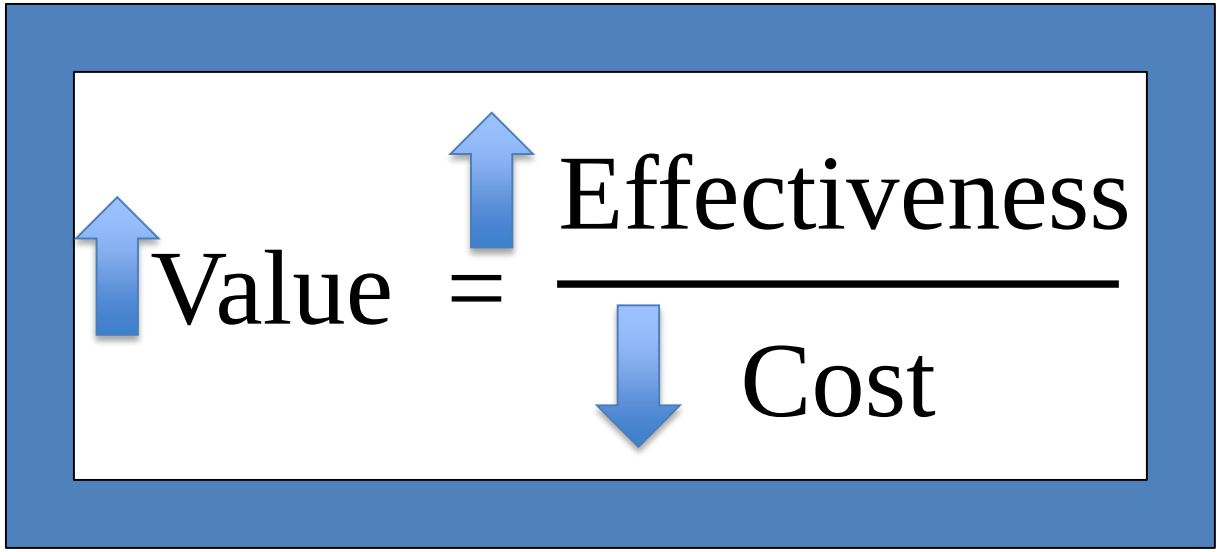
Becker’s and Dr. Chappuis

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



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)

coflex®

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

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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).

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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!

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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**

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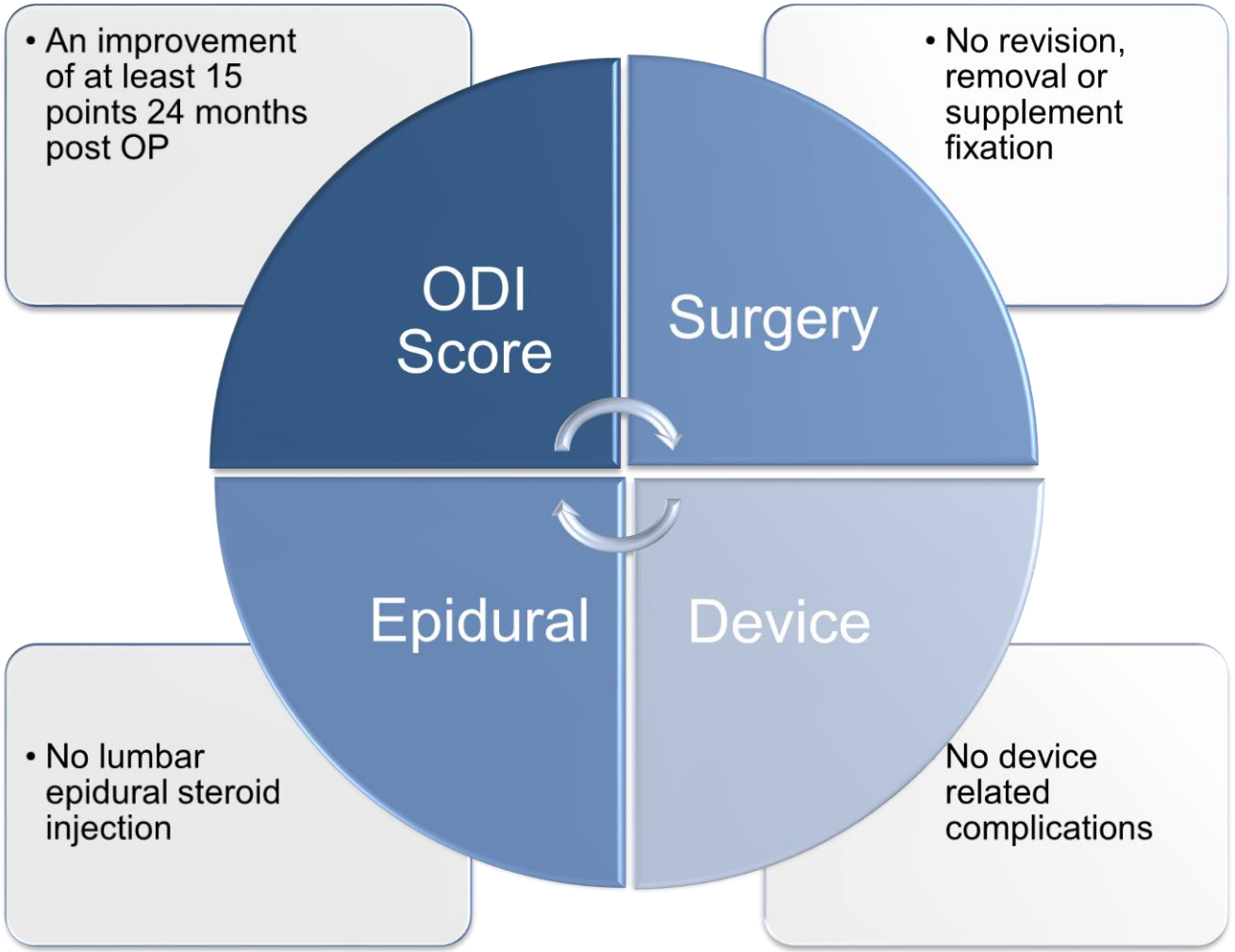
Clinical Composite Success Rate



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Composite Clinical Success Outcomes

	coflex®	Fusion Control
Subjects at Baseline	215	107
	coflex® 66.2%	Fusion 57.7%
	Total of 135 coflex® subjects achieved CCS	Total of 60 fusion subjects achieved CCS
- Lost to Follow-Up	11	3
- Re-Op Failures	23	8**
- Injections	19	10
- Sensory/Motor Deficits	1	6
- 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.

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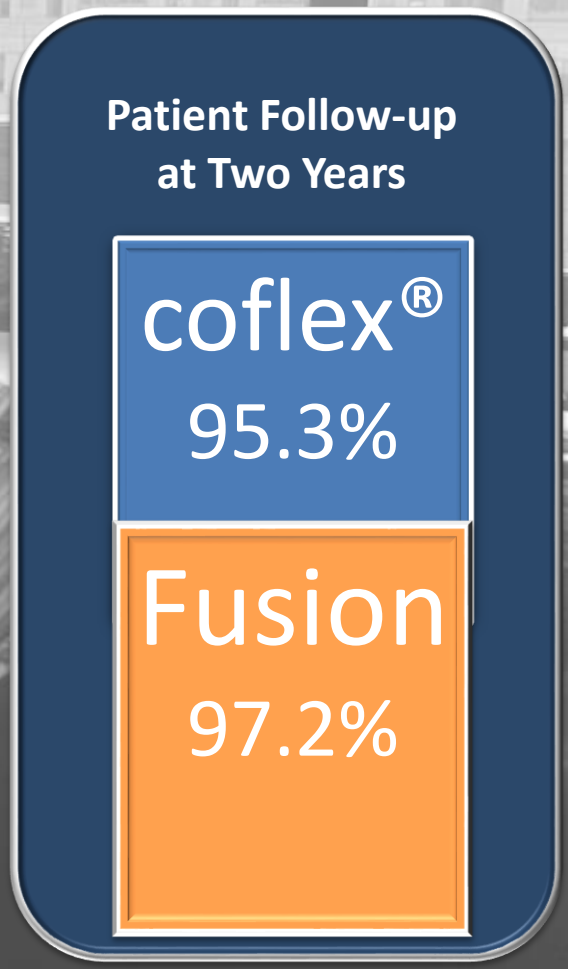
Accomplishments

- 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)



Spine

SPINE Volume 38, Number 18, pp 1529-1539

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

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]

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

Clinical article

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

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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 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 (ODI), back and worse leg visual analog scale (VAS) scores, 12-Item Short Form Health Survey, Zurich Claudication Questionnaire (ZCQ), and radiographic outcomes at a minimum of 2 years. The FDA criteria for overall device success required the following to be met: IS-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 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 ODI, 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 of94) and 62.5% of fusion controls (30 of 48) ($p = 1.000$). The reoperation rate was higher in the coflex cohort (14 [14.1%] of99) 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.

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

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

Mitigating Adverse Event Reporting Bias in Spine Surgery

Joshua D. Auerbach, MD, Kevin B. McGowan, PhD, Marci Halevi, BS, Michael C. Gerling, MD, Alok D. Sharan, MD, Peter G. Whang, MD, and Greg Maislin, MS, MA

Investigation performed at Bronx-Lebanon Hospital Center, Bronx, New York, Albert Einstein College of Medicine, Bronx, New York, Musculoskeletal Clinical Regulatory Advisers, Washington, DC, Paradigm Spine, New York, NY, Lutheran Medical Center, Brooklyn, New York, Yale University School of Medicine, New Haven, Connecticut, and Biomedical Statistical Consulting, Wynnewood, Pennsylvania

Background: Recent articles in the lay press and literature have raised concerns about the ability to report honest adverse event data from industry-sponsored spine surgery studies. To address this, clinical trials may utilize an independent Clinical Events Committee (CEC) to review adverse events and readjudicate the severity and relatedness accordingly. We are aware of no prior study that has quantified either the degree to which investigator bias is present in adverse event reporting or the effect that an independent CEC has on mitigating this potential bias.

Methods: The coflex Investigational Device Exemption study is a prospective randomized controlled trial comparing coflex (Paradigm Spine) stabilization with lumbar spinal fusion to treat spinal stenosis and spondylolisthesis. Investigators classified the severity of adverse events (mild, moderate, or severe) and their relationship to the surgery and device (unrelated, unlikely, possibly, probably, or definitely). An independent CEC, composed of three spine surgeons without affiliation to the study sponsor, reviewed and reclassified all adverse event reports submitted by the investigators.

Results: The CEC reclassified the level of severity, relation to the surgery, and/or relation to the device in 394 (37.3%) of 1055 reported adverse events. The proportion of adverse events that underwent reclassification was similar in the coflex and fusion groups (37.9% compared with 36.0%, p = 0.56). The CEC was 5.3 (95% confidence interval [CI]: 2.6 to 10.7) times more likely to upgrade than downgrade the adverse event. The CEC was 7.3 (95% CI, 5.1 to 10.6) times more likely to upgrade than downgrade the relationship to the surgery and 11.6 (95% CI, 7.5 to 18.8) times more likely to upgrade than downgrade the relationship to the device. The status of the investigator's financial interest in the company had little effect on the reclassification of adverse events.

Conclusions: Thirty-seven percent of adverse events were reclassified by the CEC; the large majority of the reclassifications were an upgrade in the level of severity or a designation of greater relatedness to the surgery or device.

Clinical Relevance: An independent CEC can identify and mitigate potential inherent investigator bias and facilitate an accurate assessment of the safety profile of an investigational device, and a CEC should be considered a requisite component of future clinical trials.

Disclosure: One or more of the authors received payments or services, either directly or indirectly (i.e., via his or her institution), from a third-party in support of an aspect of this work. In addition, one or more of the authors, or his or her institution, has had a financial relationship, in the thirty-six months prior to submission of this work, with an entity in the biomedical arena that could be perceived to influence or have the potential to influence what is written in this work. No author has had any other relationships, or has engaged in any other activities, that could be perceived to influence or have the potential to influence what is written in this work. The complete **Disclosures of Potential Conflicts of Interest** submitted by authors are always provided with the online version of the article.

A commentary by Jeffery L. Stambaugh, **MD, MBA,** is linked to the online version of this article at jbjs.org.

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EXCELLENCE THROUGH PEER REVIEW

FOUNDED IN 1903 BY THE AMERICAN ORTHOPAEDIC ASSOCIATION IN 1903
THE OFFICIAL SCIENTIFIC PUBLICATION OF THE AAOS

Commentary & Perspective

In the Eye of the Beholder

Commentary on an article by Joshua D. Auerbach, MD, et al.: "Mitigating Adverse Event Reporting Bias in Spine Surgery"

Jeffery L. Stambaugh, MD, MBA

Auerbach et al. should be congratulated on the publication of their paper on mitigating bias in the reporting of adverse events in spine surgery. Equal praise is deserved by Paradigm Spine, the corporate sponsor of the Level-I, prospective, randomized multicenter study of the coflex interlaminar stabilization device, for incorporating a Clinical Events Committee (CEC) for the readjudication of the study's adverse events and device-related complications end point.

It has been said that "the data is the data." The rub is often in the interpretation and presentation of those data, which are complicated by a wide variety of biases—both perceived and real. This process is even more likely exposed to biases when subjective rather than objective ratings are involved. The primary issue addressed by Auerbach et al. is the fact that adverse events and complications tend to be underreported by the principal investigator or those intimately involved in the study, who may or may not have additional financial or other conflicts of interests. Certainly, there seems to be a human tendency to minimize the bad and maximize the good. This does not imply malice or dishonesty. Regardless, this tendency is a source of observational bias[1].

In this study, the CEC members, three independent blinded spine surgeons, were commissioned to recategorize adverse events into one of three severity categories (mild, moderate, severe) and also to reassess the relationship of reported complications to the device or surgery in one of five categories (unrelated, unlikely, possibly, probably, or definitely). These are subjective rankings, although numerical values could be applied. Furthermore, these independent spine surgeons were knowledgeable, were trained, and had no financial interest in or relationship to the study sponsor or investigators. These physicians reviewed the complications in one day and repeated the process about two years later, demonstrating that their subjective ratings were consistent and reliable over that period of time.

Thirty-seven percent of the reported adverse events and complications were reclassified by the CEC. The vast majority of these, 89%, were upgraded. Of those upgraded in relatedness, about 10% to 20% moved from the lower three rankings (unrelated, likely, possibly) to a probable or definite ranking. It is important not to extrapolate or infer any significance of this fact. It simply means that these independent evaluators were stricter on average in their rankings. It does not mean that the data were different, nor does it imply clinical significance, much less a good or bad interpretation. Interestingly, potential financial conflicts of interest were not demonstrated to be a factor in the reassignment or readjudication of adverse events and related complications in this study.

The concept of an independent, blinded evaluator is not new, nor is the use of a CEC concept. The authors rightly recognize that this is apparently the first time that reporting bias has been analyzed in the setting of an industry-sponsored device trial with this degree of rigorous statistical evaluation[2,3]. The use of independent blinded evaluation, specifically by a CEC, is worth further application, corroboration, and correlation, specifically when it comes to industry-sponsored or third-party-sponsored research.

The bottom line is that a CEC concept seems like a suitable and needed checkrein for third-party-sponsored studies. A CEC provides an independent, impartial perspective that may differ substantially from those of individuals more directly involved in the industry-sponsored study[4]. The authors are careful not to imply any clinical significance of the readjudication observed in this study. However, it is noteworthy that the three members of the independent blinded committee had a different perspective regarding the severity and relatedness of adverse events in about 37% of such occurrences. The goal of reducing the effect of investigator bias, especially in such ratings of an observational and subjective type, is valid. These findings likely apply to objective findings as well and help encourage progress toward the ultimate goal of openness and transparency in research. The use of a CEC as well as other methods that aim to decrease conflict of interest, bias, and other inherent limitations necessitate further investigation. Unfortunately at this time, industry-sponsored studies still remain inherently flawed by their very nature[5].

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PARADIGM SPINE

coflex® vs. Fusion Cost Savings (Inpatient Setting)

Metrics	Medicare
Case Volume (Scaler)	1
Fusion Inpatient Payment	$23,326.53 [1]
coflex® Inpatient Payment	$10,929.33 [1]
Fusion Reoperation Rate 1 Year	4.73% [2]
coflex® Reoperation Rate 1 Year	3.40% [3]
Fusion Reoperation Rate 2 Year	12.23% [2]
coflex® Reoperation Rate 2 Year	6.00% [3]

Costs Including Reoperation	
1 Year Cost Fusion (Inpatient)	$24,429.87
1 Year Cost *coflex*® (Inpatient)	$11,300.93
2 Year Cost Fusion (Inpatient)	$26,179.36
2 Year Cost *coflex*® (Inpatient)	$11,585.09

Savings After Payment	
1 Year Savings	**$13,128.95**
2 Year Savings	**$14,594.27**

*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

ClinicoEconomics and Outcomes Research

Dovepress
open access to scientific and medical research

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

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Greg Maislin[3]
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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 laminotomy 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 costs and 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 claims analyses 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 cost 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 38.8% 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 an increased need for management of this condition. Treatments for which there is evidence of effectiveness include pharmacologic use, intramuscular calcitonin, epidural steroid injections, and surgery.[2] While surgical decompression, with or without instrumented

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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

The Role of Stabilization

Pre 2012 Post Decompression for Stenosis

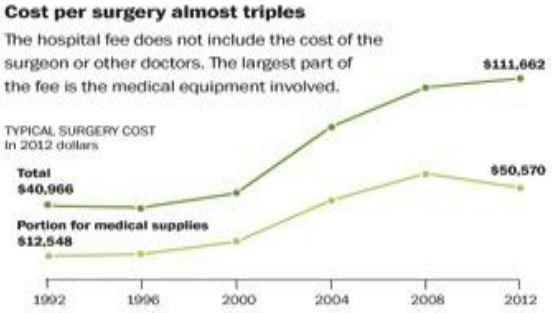
- ***Fusion stabilization*** for back pain and or instability
- ***No motion preservation*** device approved
- ***Intended clinical effect*** may be a year away for fusion

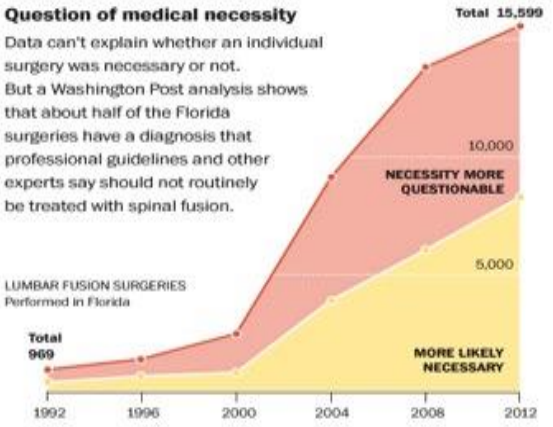
Post Oct 2012 PMA Approval coflex®

- ***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**

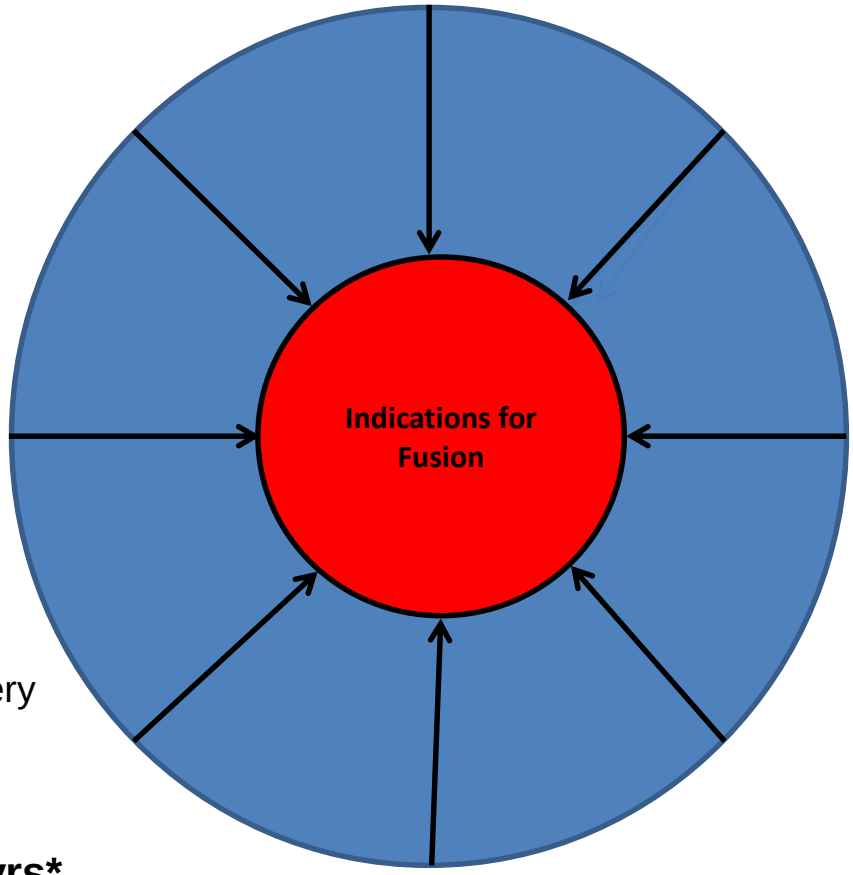
- **465,000 fusions in the US in 2011**

Washington Post Business 10/28/2013

Macro Trends In Treatment of Spinal Stenosis

PARADIGM SPINE

- **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)

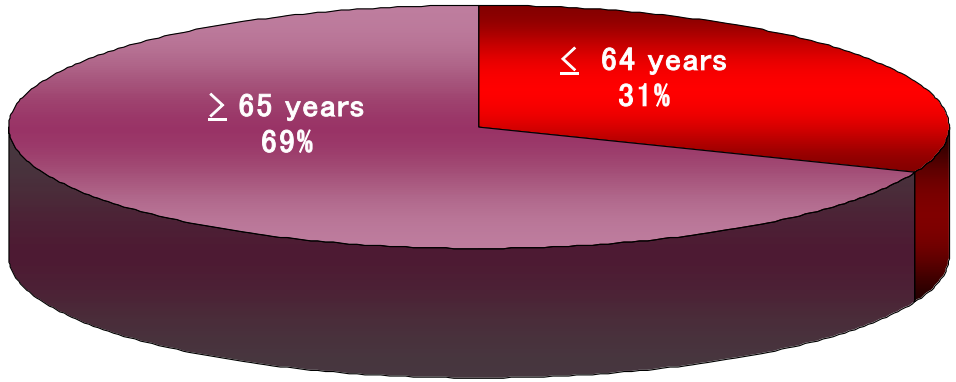


* U.S. Centers for Disease Control and Prevention (CDC) 2011 data.

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]



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.

Source: Verispan, 2004

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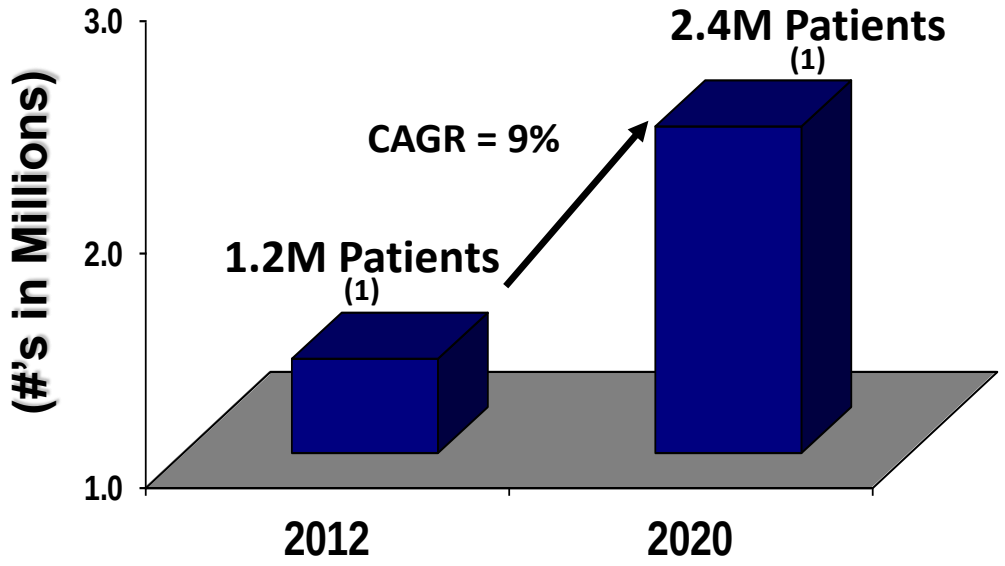
U.S. Market For Spinal Stenosis Patients (2012-2020)



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.

Spine

SPINE Volume 38, Number 7, pp 591–596

HEALTH SERVICES RESEARCH

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*

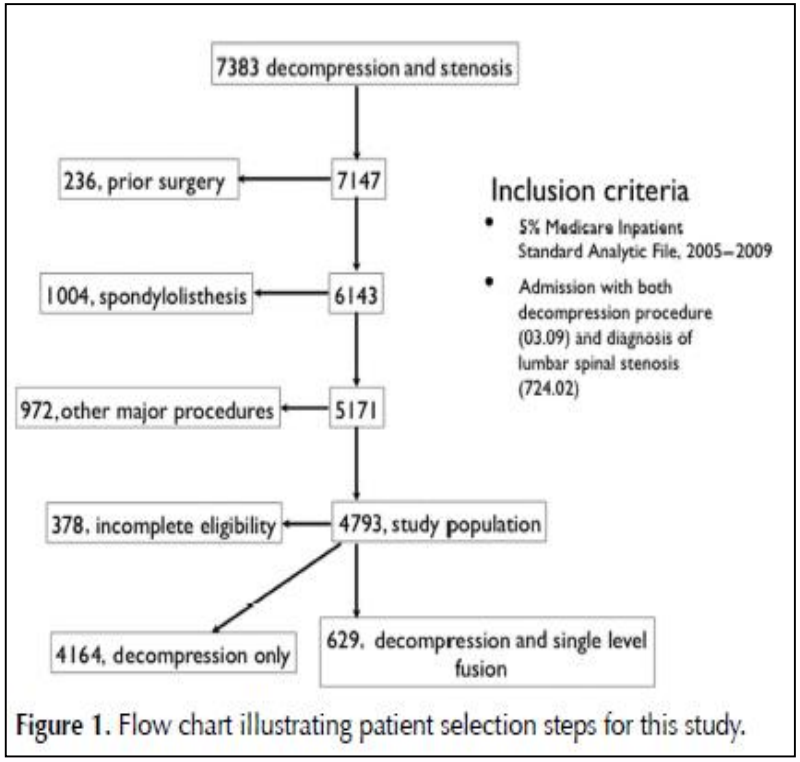


Figure 1. Flow chart illustrating patient selection steps for this study.

PARADIGM SPINE

What is the Perfect Patient?

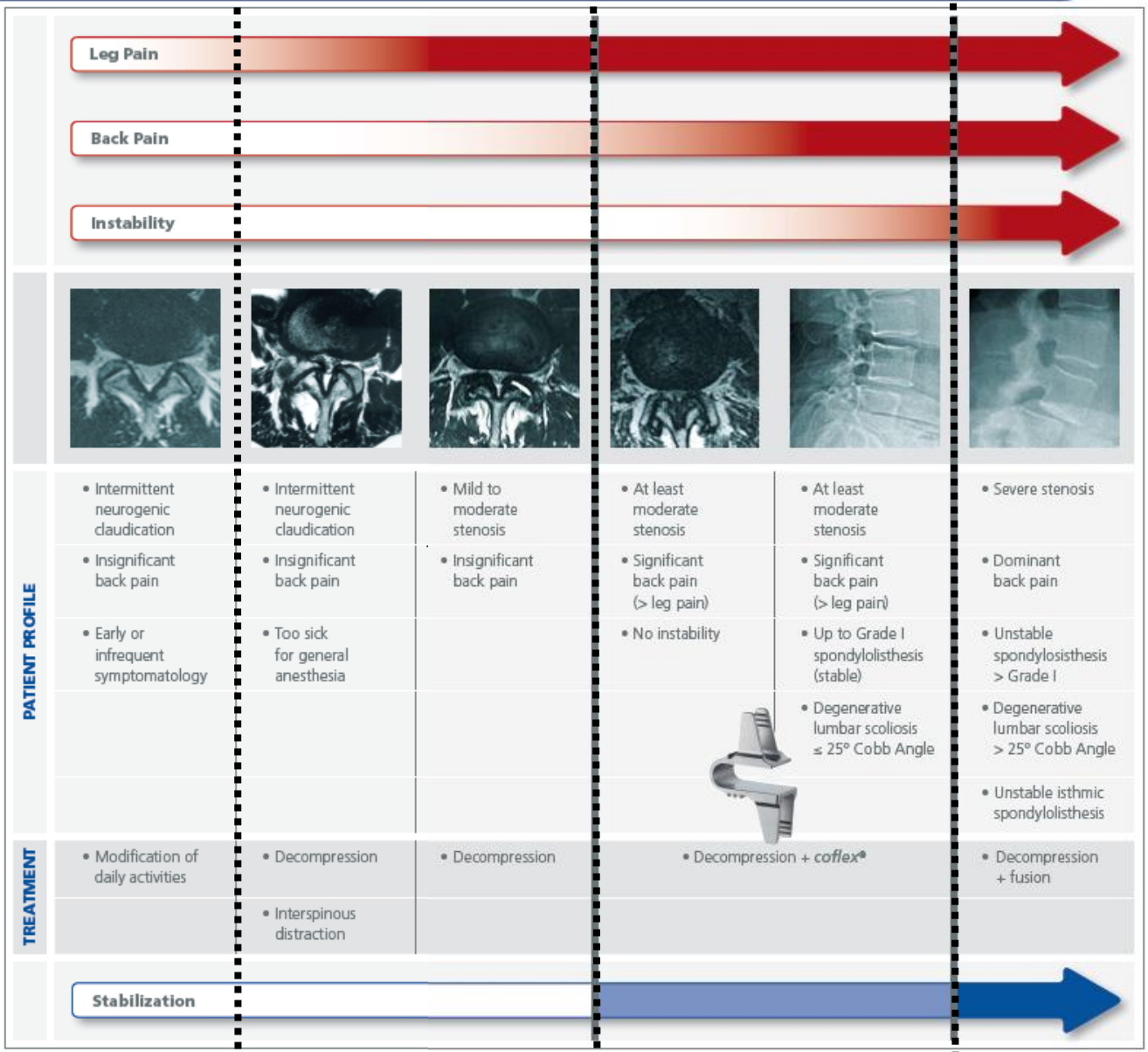
- Conservative Care
- Previous Treatments, ESIs
- Patient Expectations
- Patient Selection
- The First Patient – Images and Goals

PARADIGM SPINE

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

PARADIGM SPINE



~600,000 Patients

~286,000* Patients

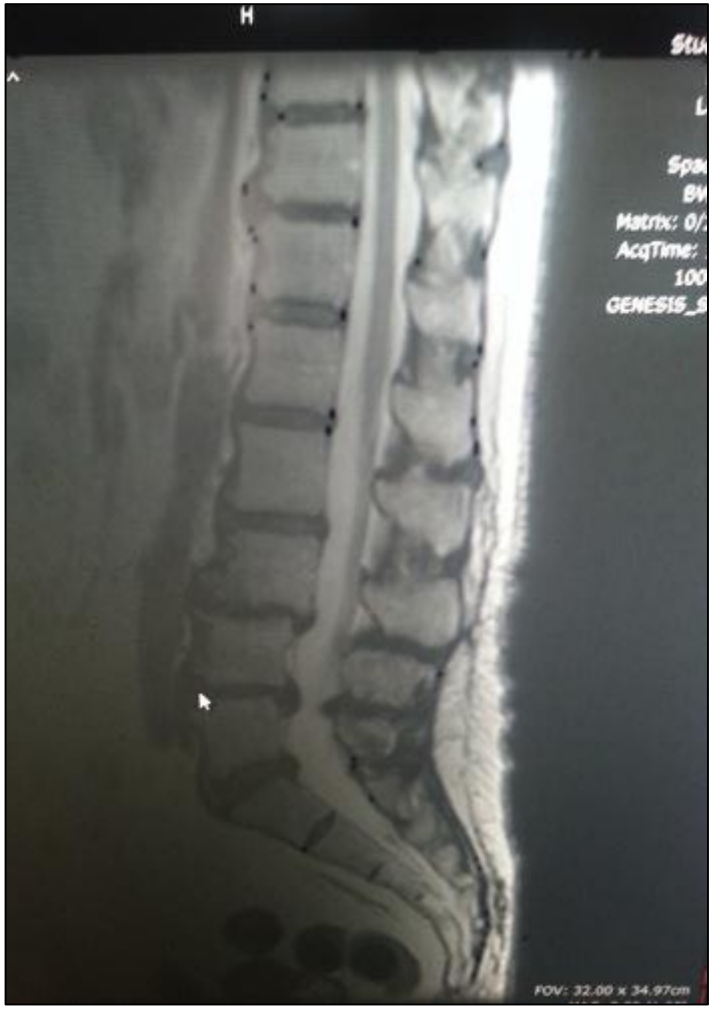
~261,000* Patients

~106,000* Patients

*

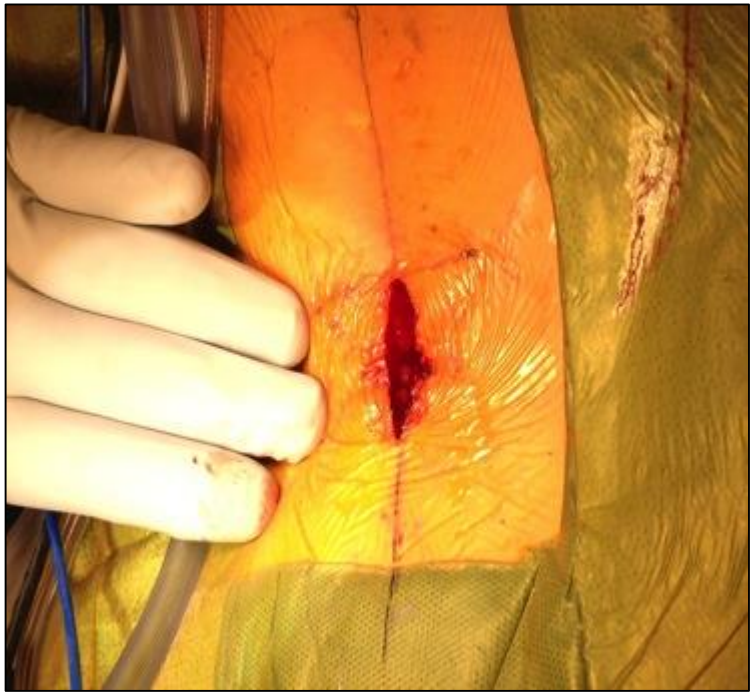
PARADIGM SPINE

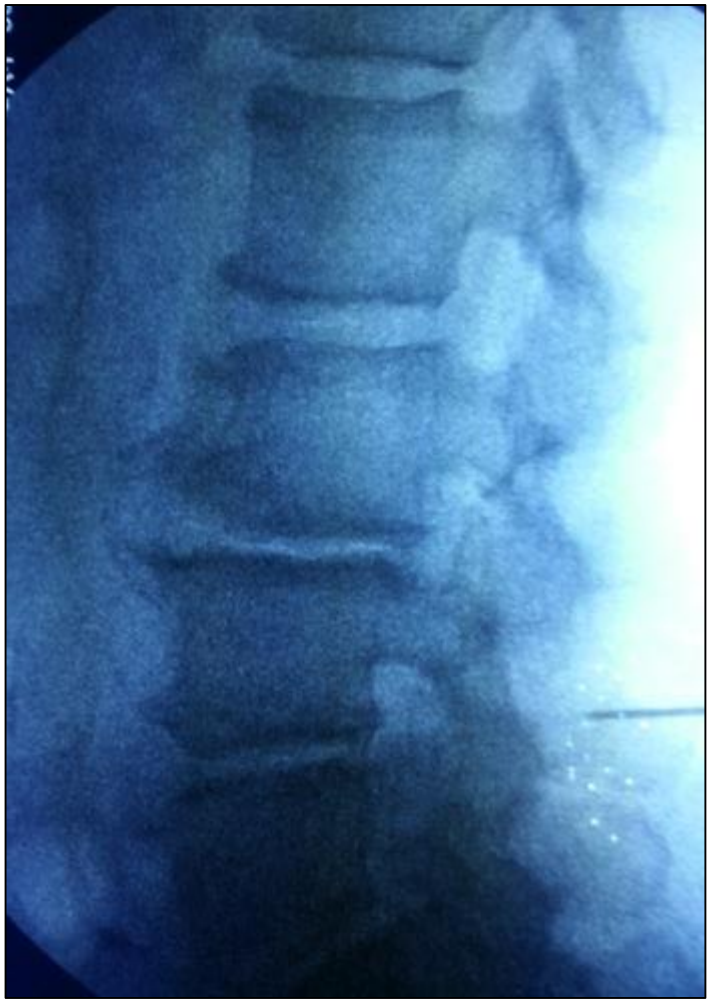
Pre-Op MRI



PARADIGM SPINE

Incision and Localization





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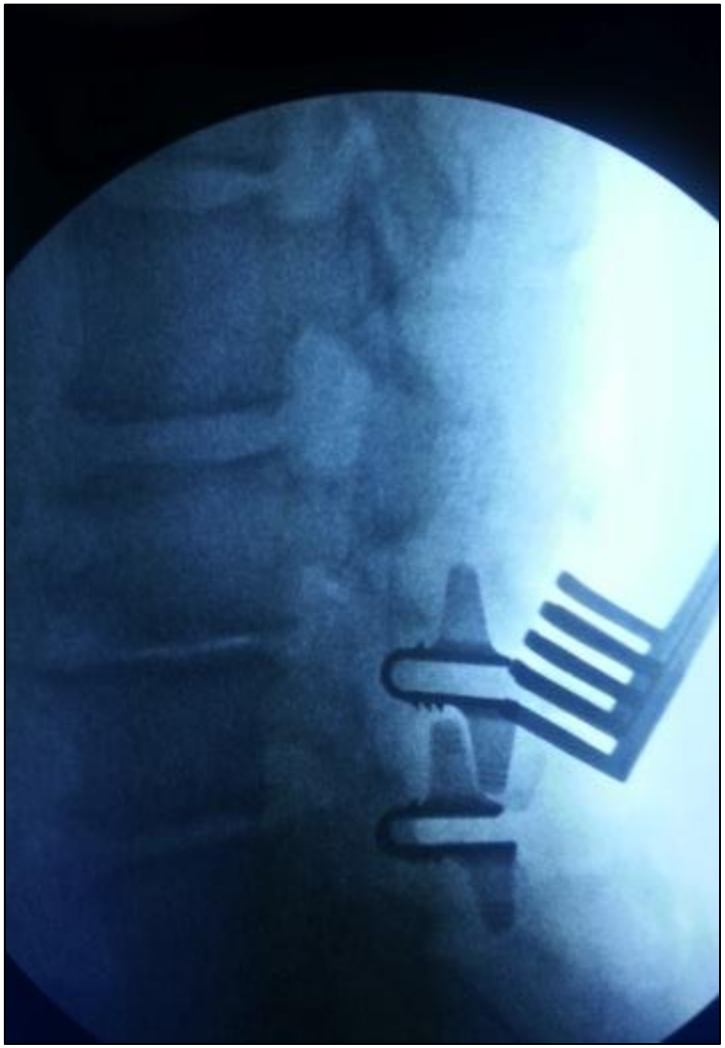
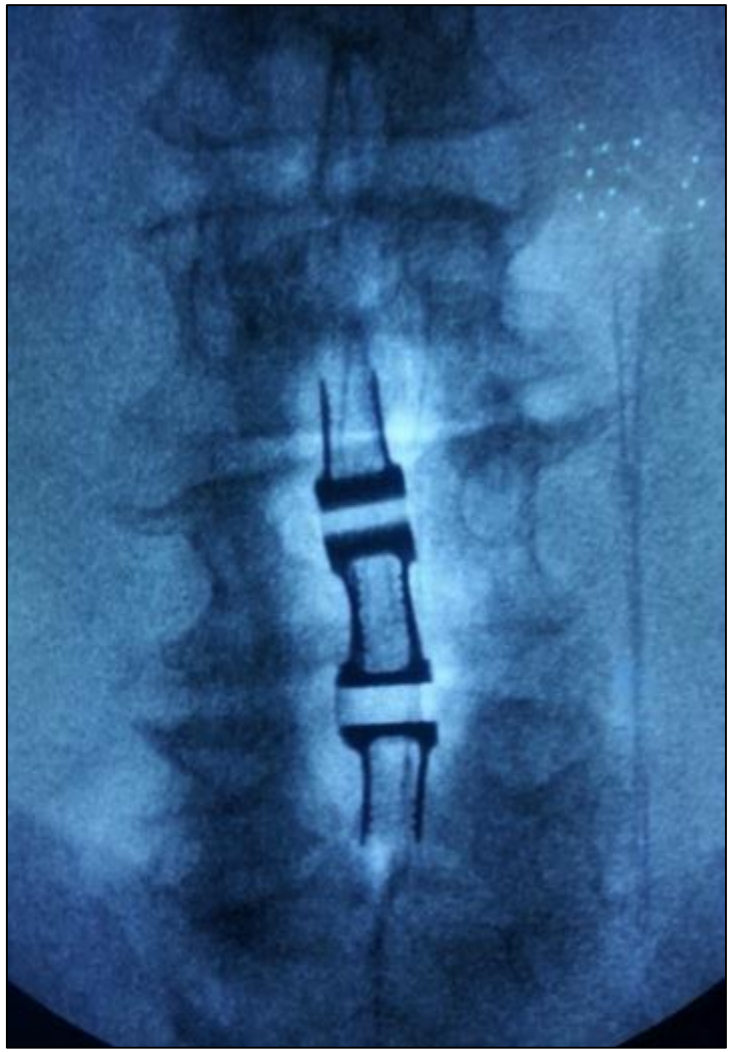
Lateral Fluro Intraop and AP X-Ray





PARADIGM SPINE

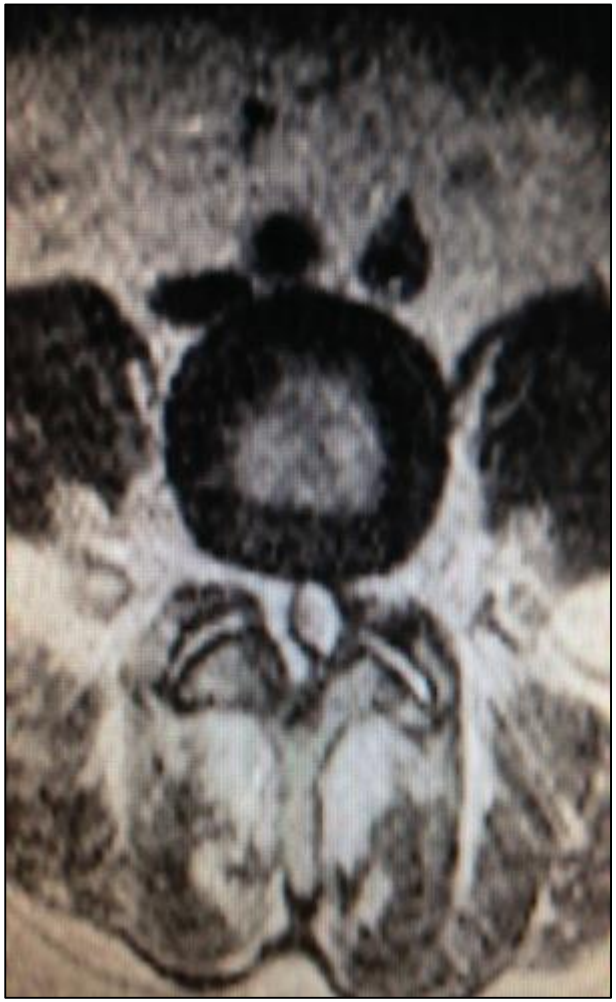
Case Study

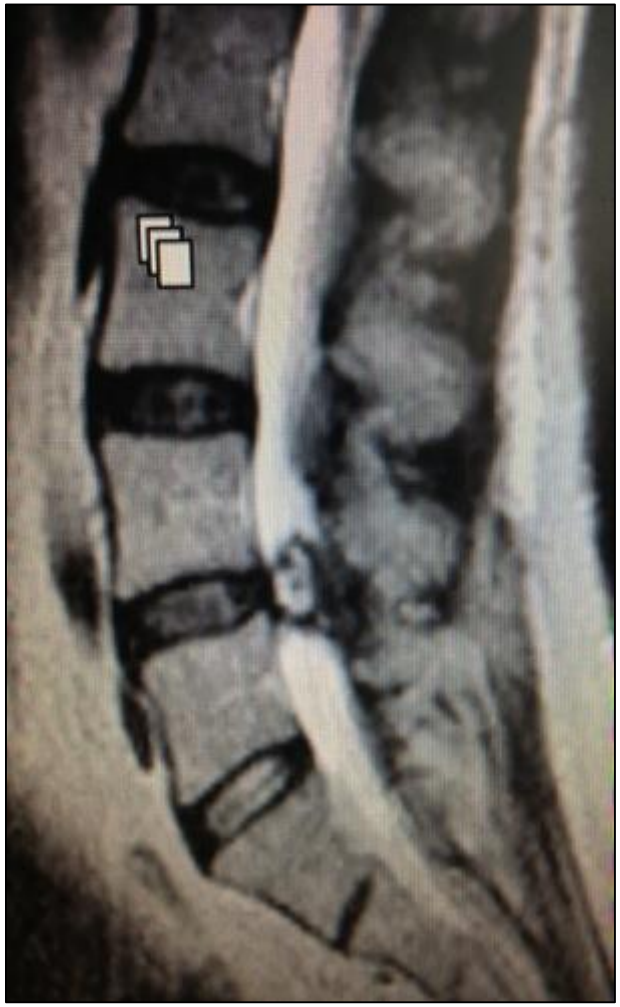
Patient Pre-Op

- 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

PARADIGM SPINE

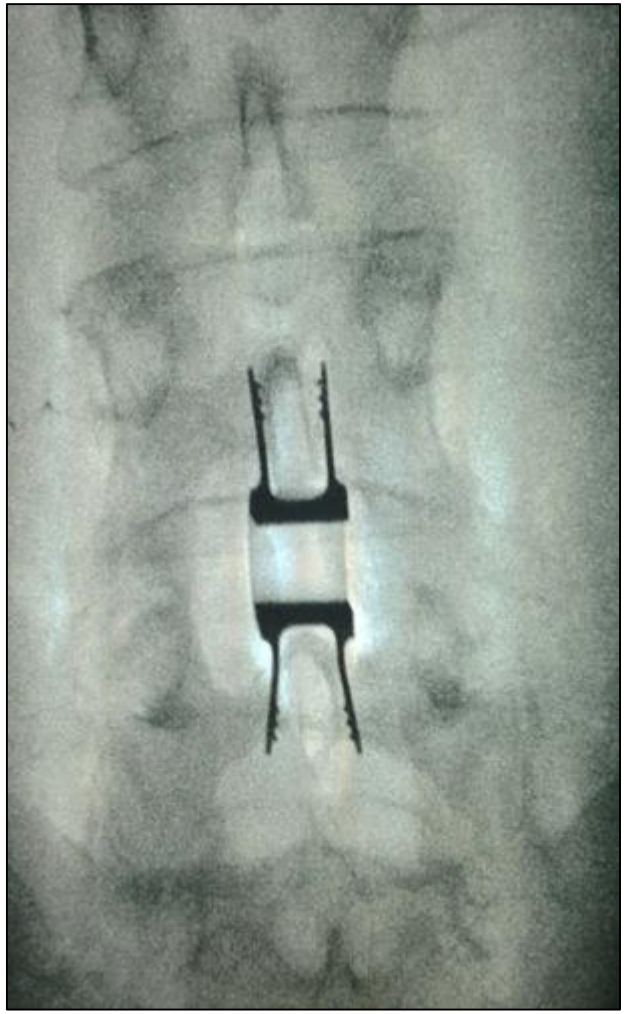
Pre-Op MRI

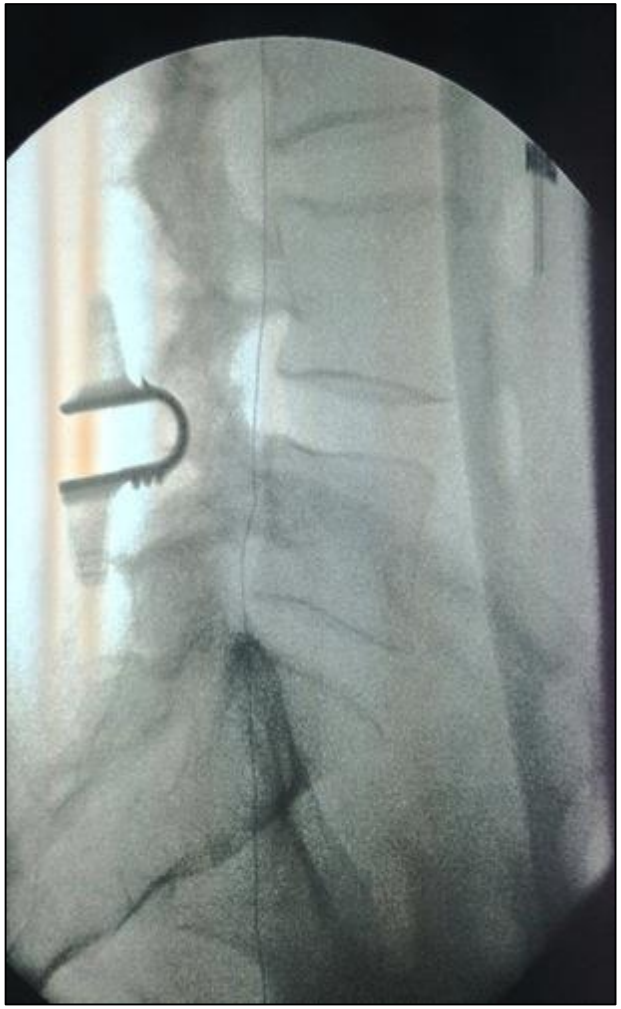




PARADIGM SPINE

Post-Op Films





12mm coflex® device

PARADIGM SPINE

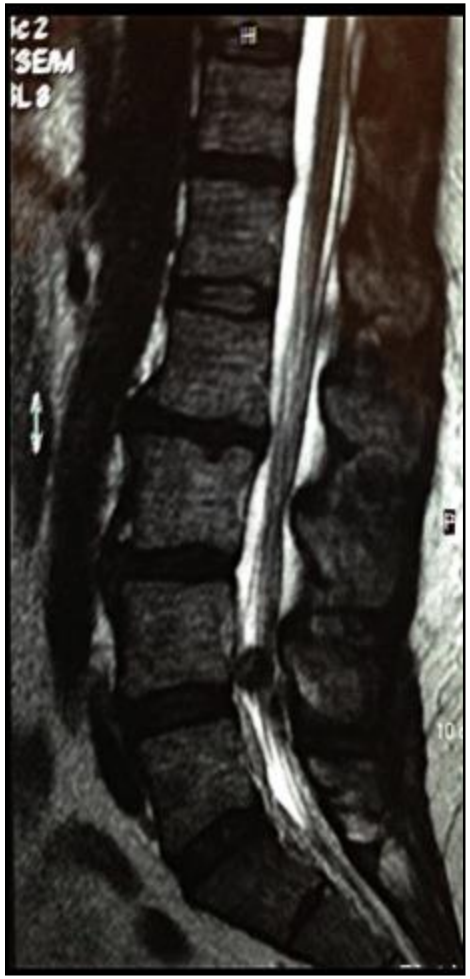
Case Study

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

PARADIGM SPINE

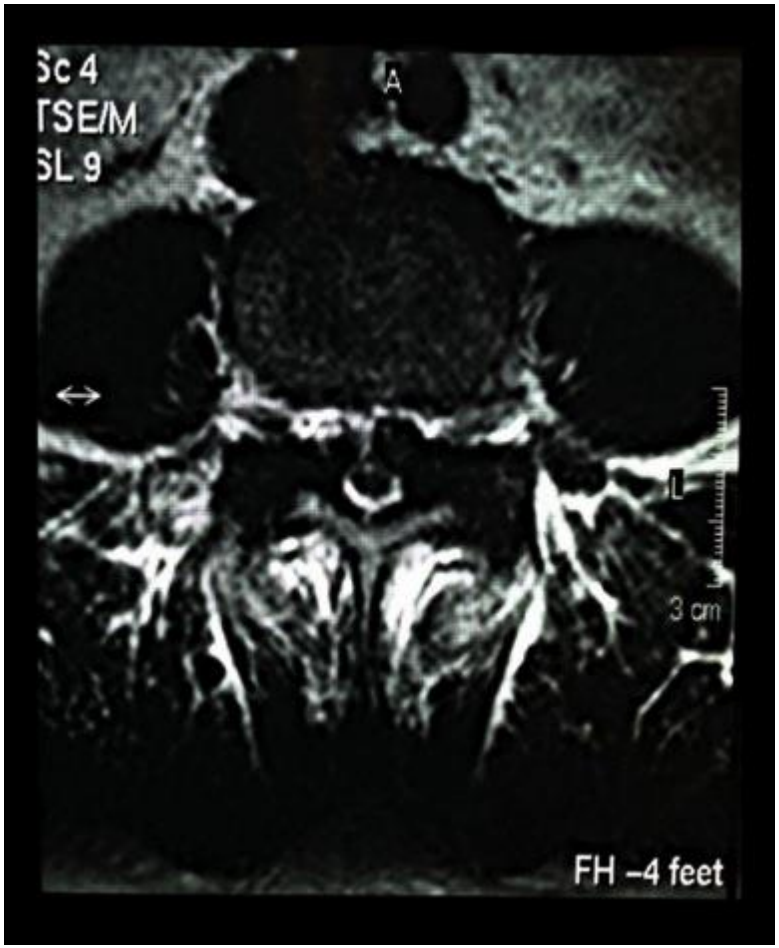
Pre-Op MRI

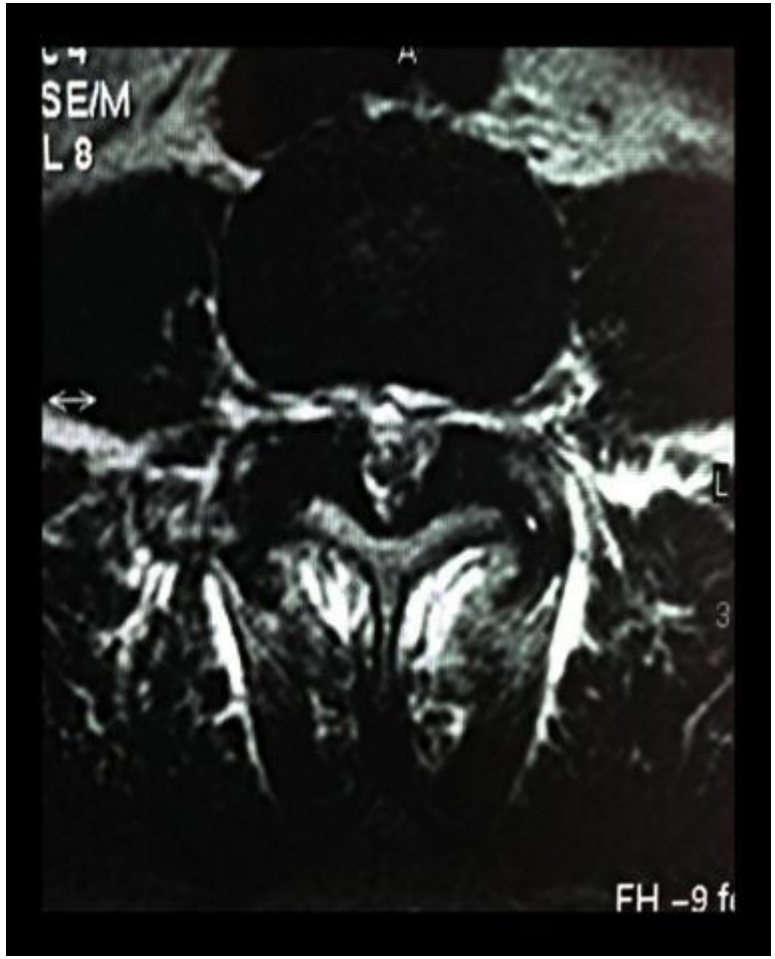


- Severe spinal canal stenosis is noted at L4-5
- There appears to be a Synovial cyst at L4-5 resulting in severe spinal stenosis
- Multilevel degenerative disc disease is also noted

PARADIGM SPINE

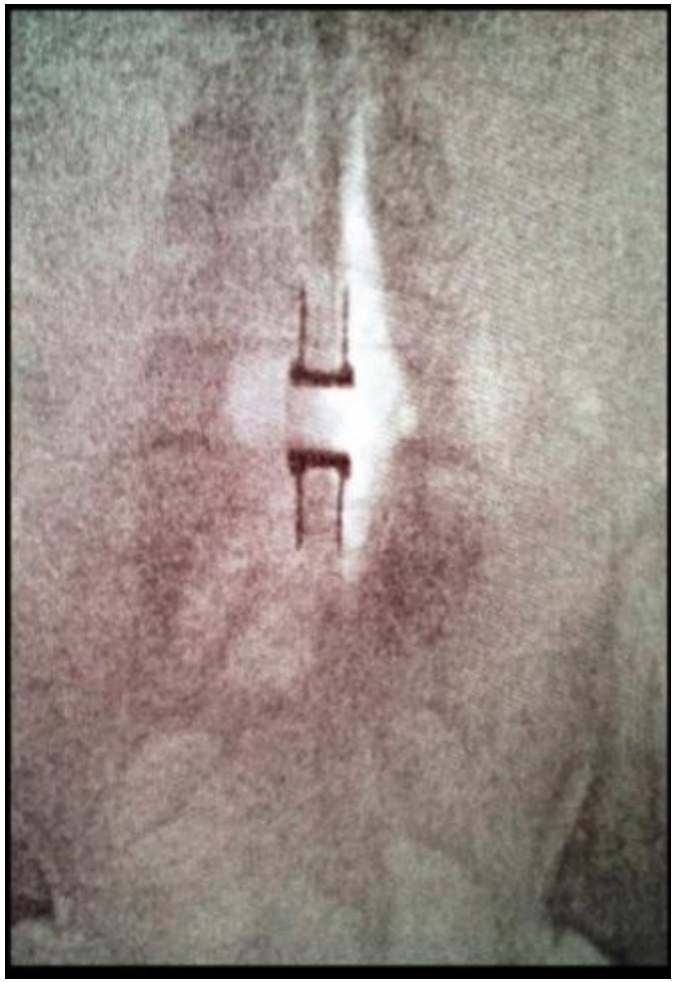
Post-Op Films

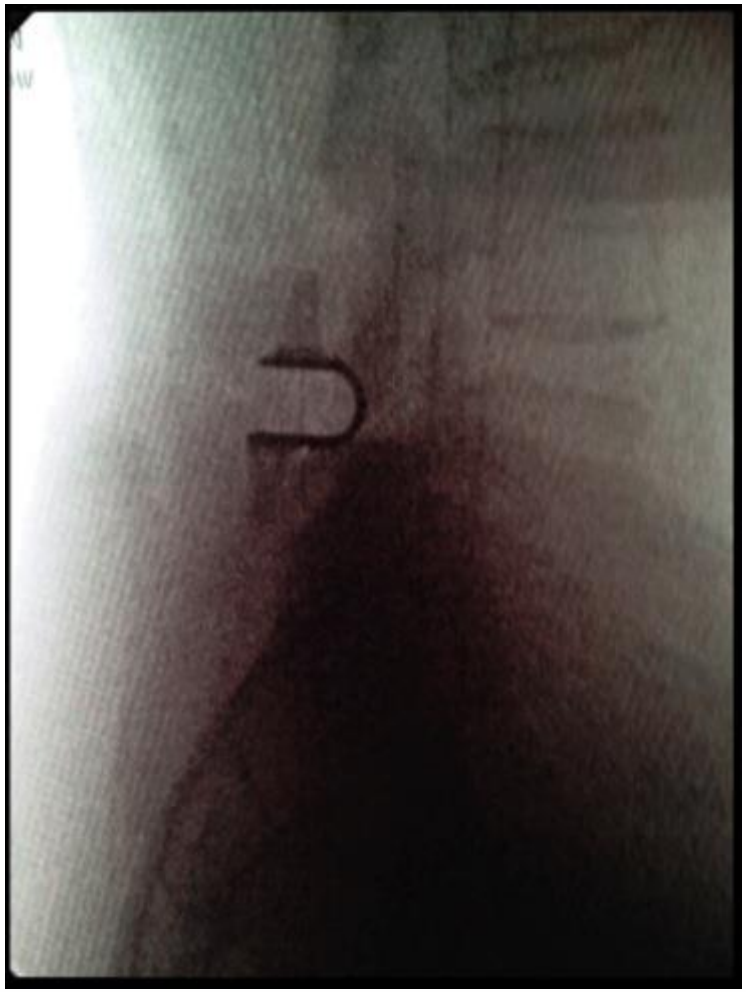




PARADIGM SPINE

Post-Op Films





PARADIGM SPINE

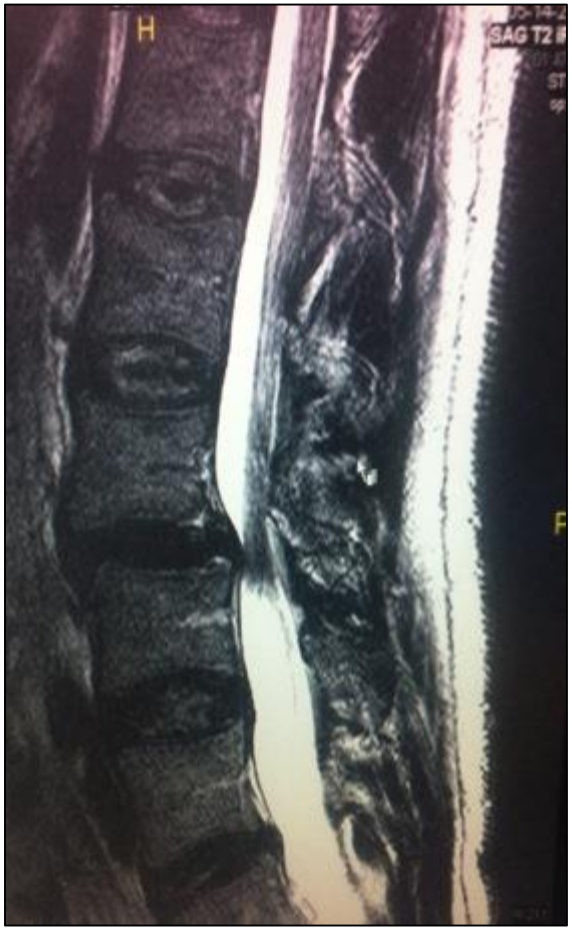
Case Study

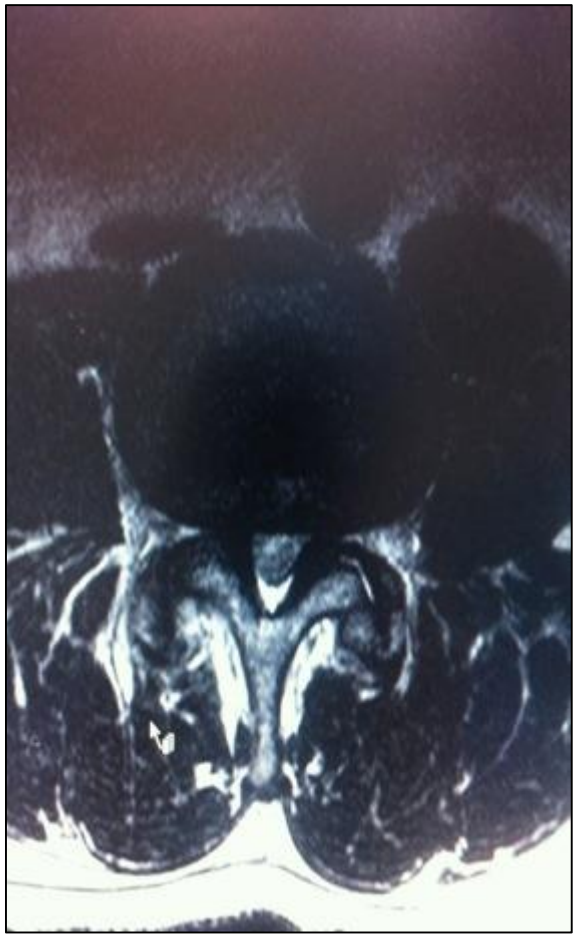
Patient Pre-Op

- 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

PARADIGM SPINE

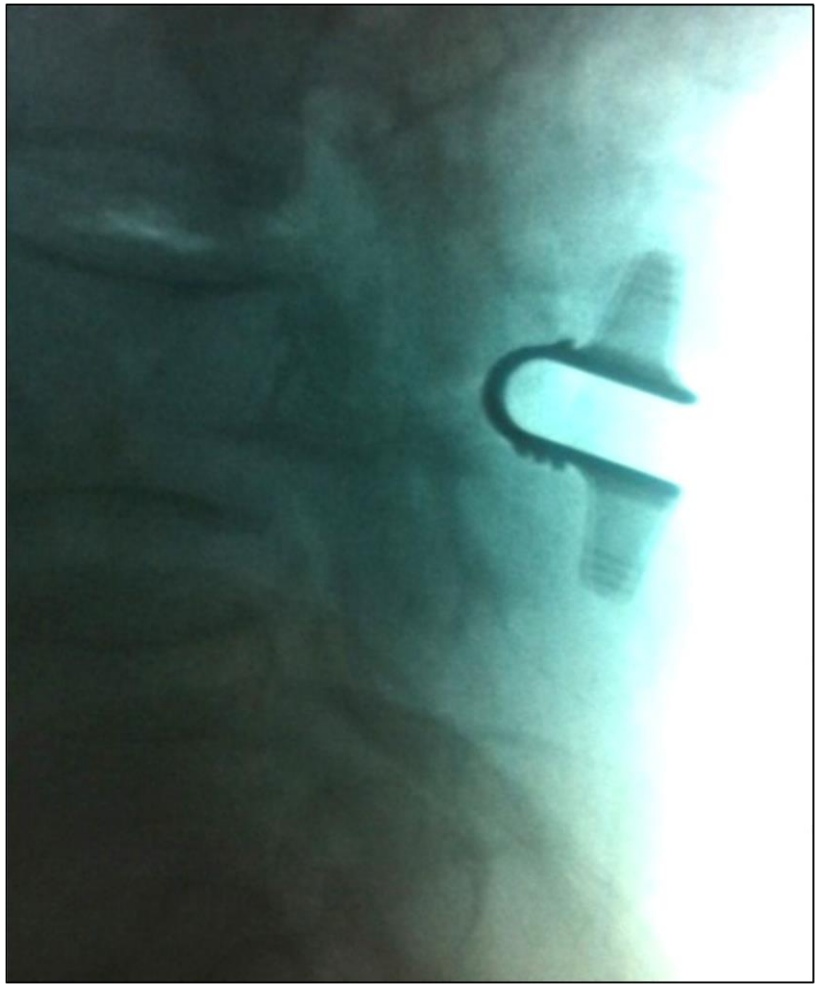
Sagittal and Axial MRI
No movement on Flex/Ext





PARADIGM SPINE

Post-Op Film

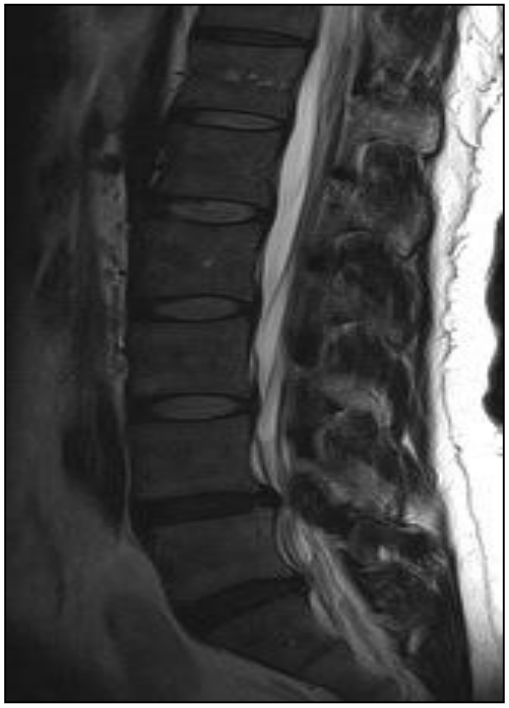
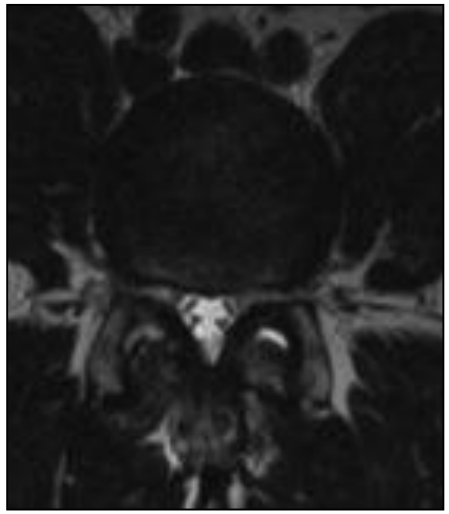
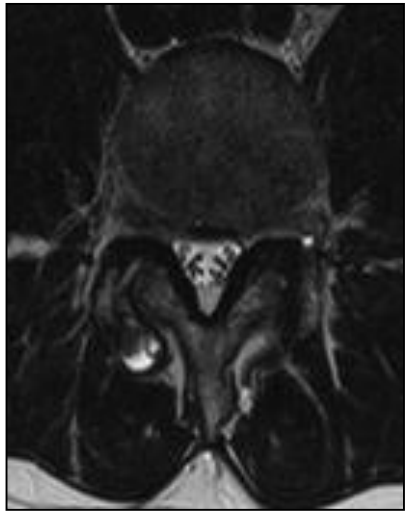
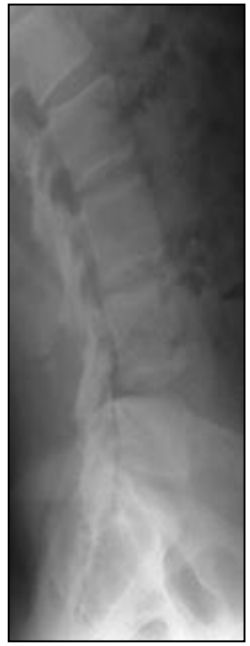
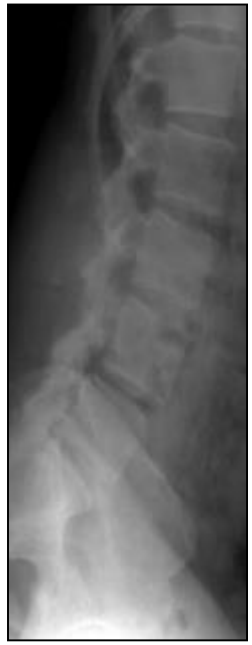


PARADIGM SPINE

Case Study

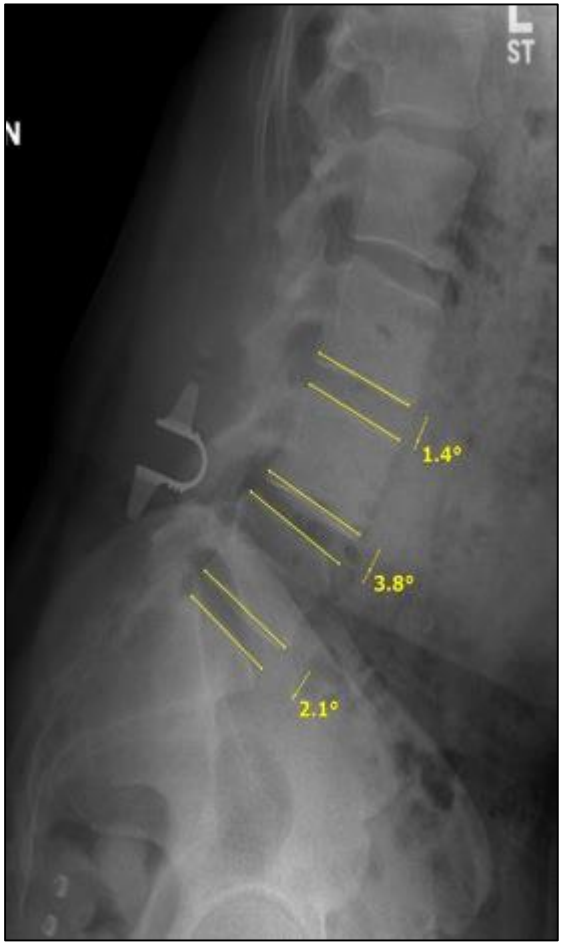
Patient Pre-Op

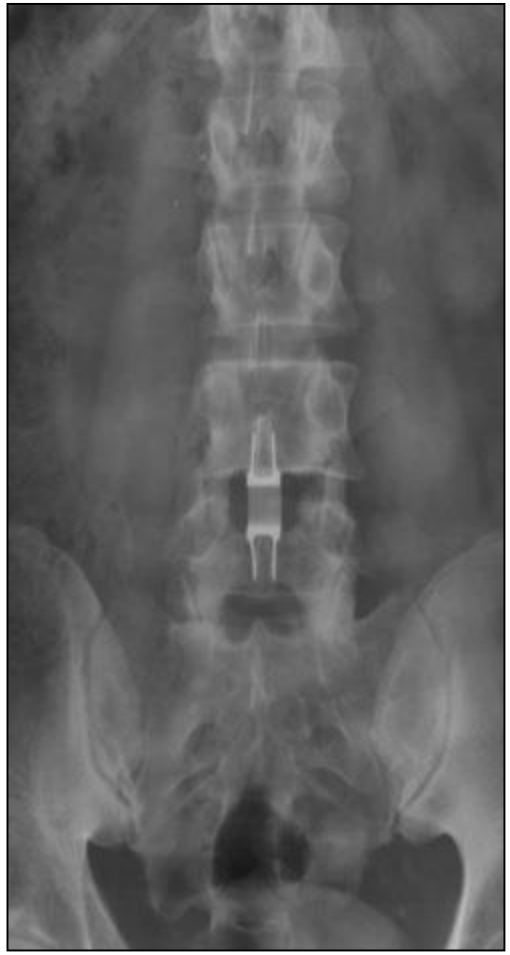
- 46M mechanical low back pain and right leg pain

PARADIGM SPINE

Post-Op Films





The coflex® Set Up

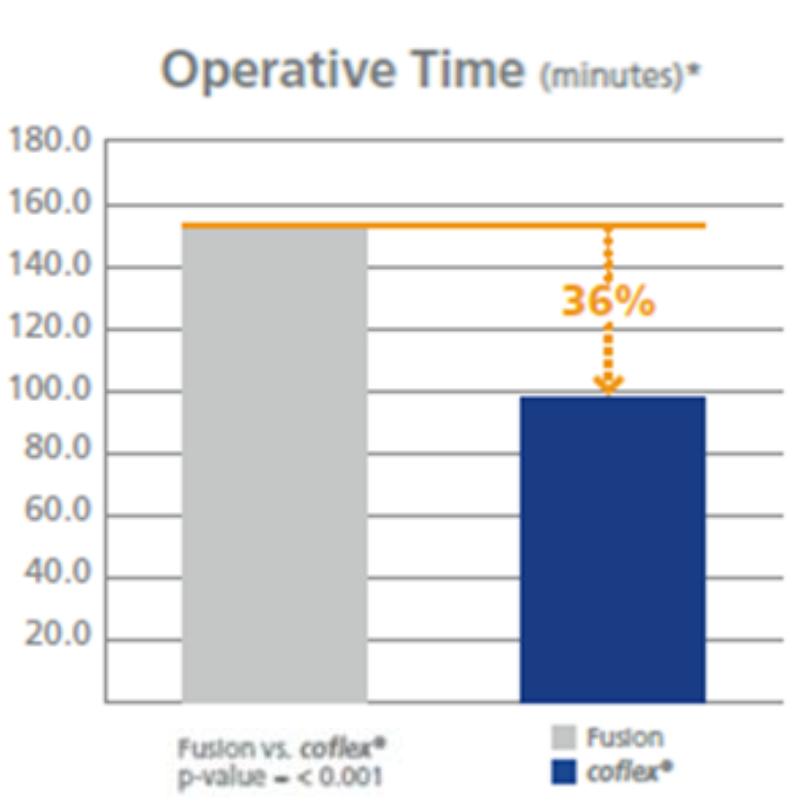
- Preop Education and Informed Consent
- Preop Planning and OR Set Up
- OR Management
- Post Op PACU Protocols
- First 6 Weeks

Value in the Patient Circle of Care

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

PARADIGM SPINE

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

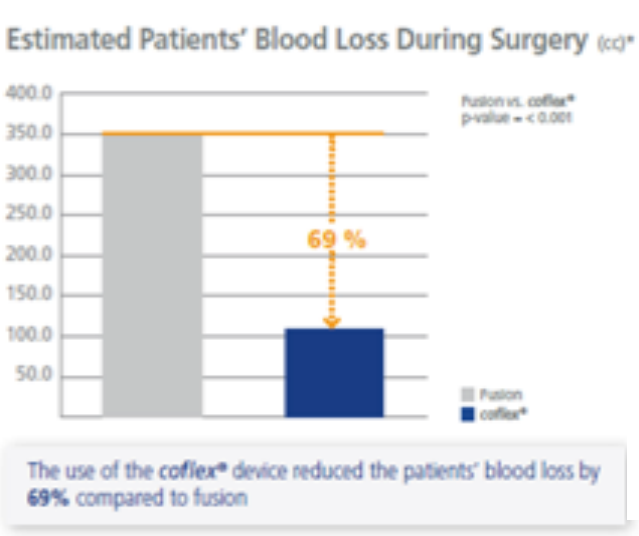
That's a **$3,600** savings @ $30 min. For OR time cost**!**

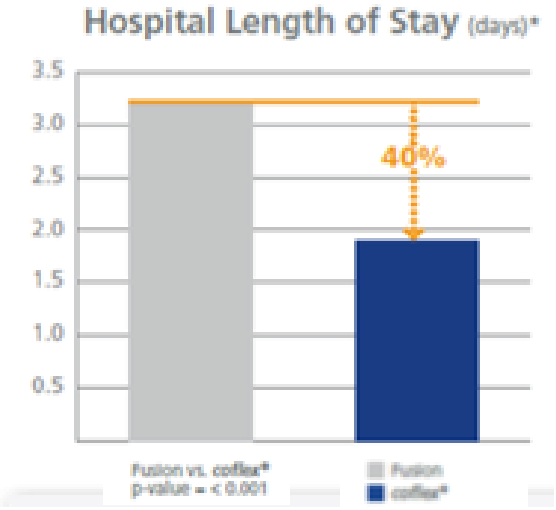
*Compared to fusion

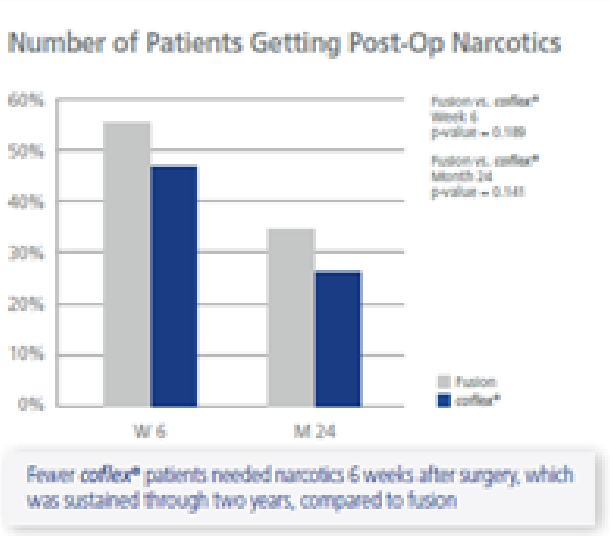
The coflex® Solution

PARADIGM SPINE

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).

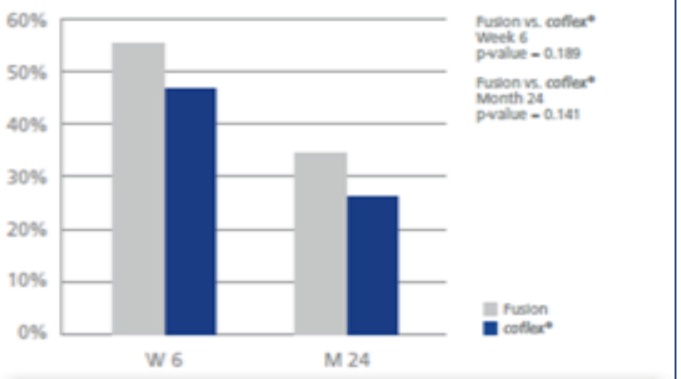
Stability In The Treatment Area - At 2 years, ***coflex***® patients retained their pre-operative range of motion (within 10%) & translation (within 5%) at the area of treatment.

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.

PARADIGM SPINE

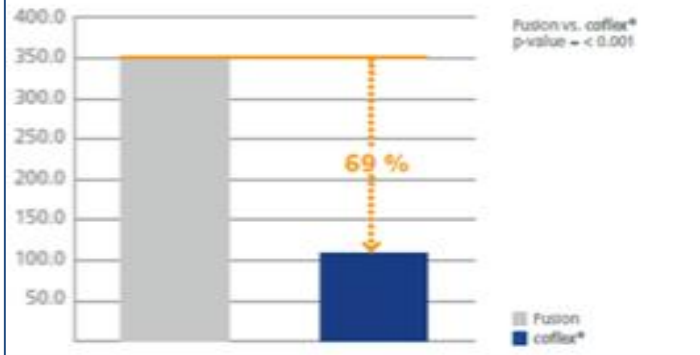
coflex® Patients Do Better, Faster

Number of Patients Getting Post-Op Narcotics



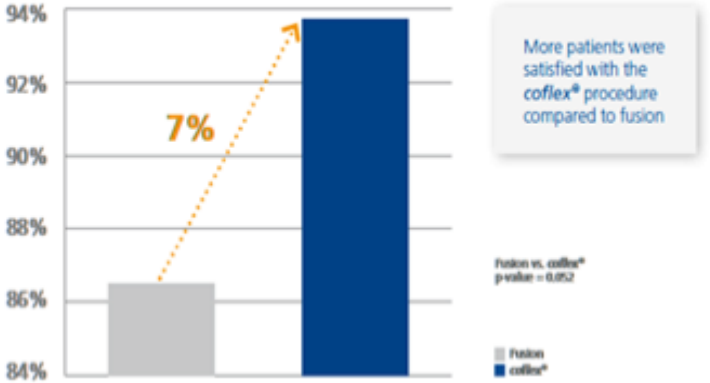
Fewer *coflex®* patients needed narcotics 6 weeks after surgery, which was sustained through two years, compared to fusion

Estimated Patients' Blood Loss During Surgery (cc)*

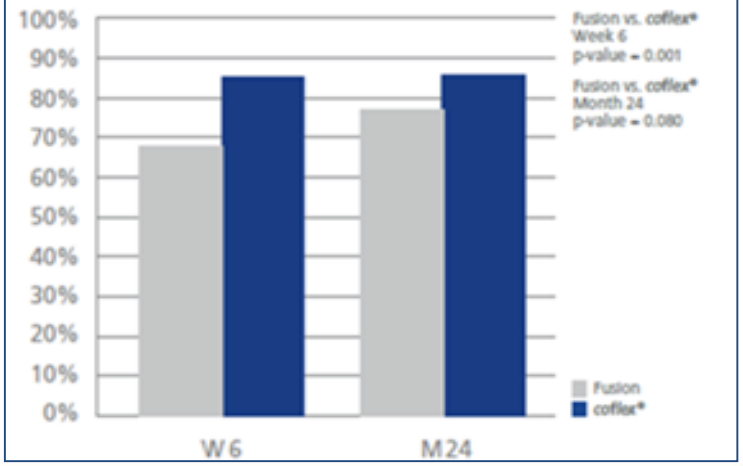


The use of the *coflex®* device reduced the patients' blood loss by **69%** compared to fusion

Patients That Were Satisfied With Outcome at 2 Years



Improvement of at least 15 points in ODI



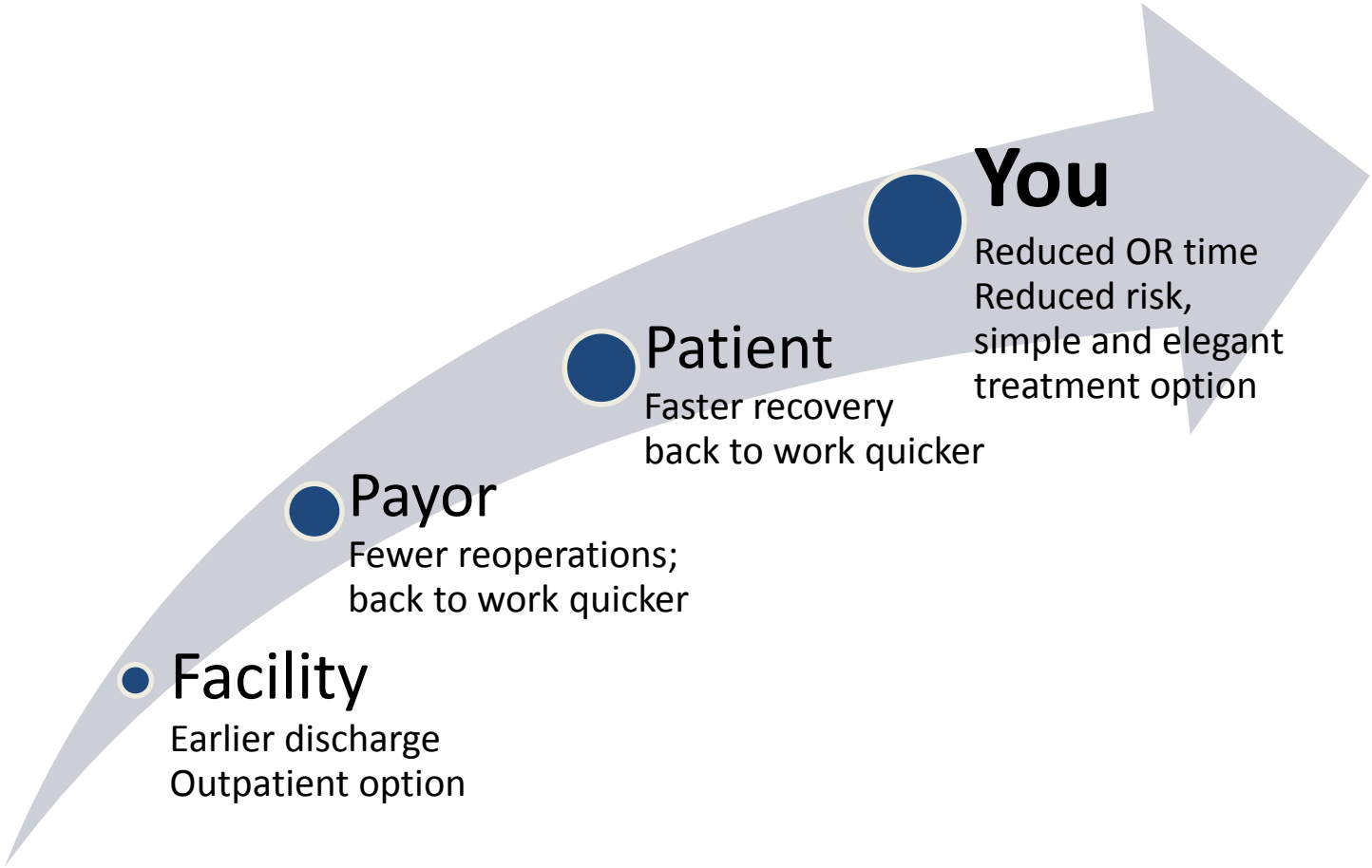
The Value Proposition
Cost Drivers: coflex® Addresses ALL

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

coflex®

Lower Cost For Equal Effectiveness = Greater Value

It is all about your time!



Thank You Dr. Chappuis!

Please visit www.paradigmspine.com
Please visit www.coflexsolution.com
Please visit editorial@beckershealthcare.com