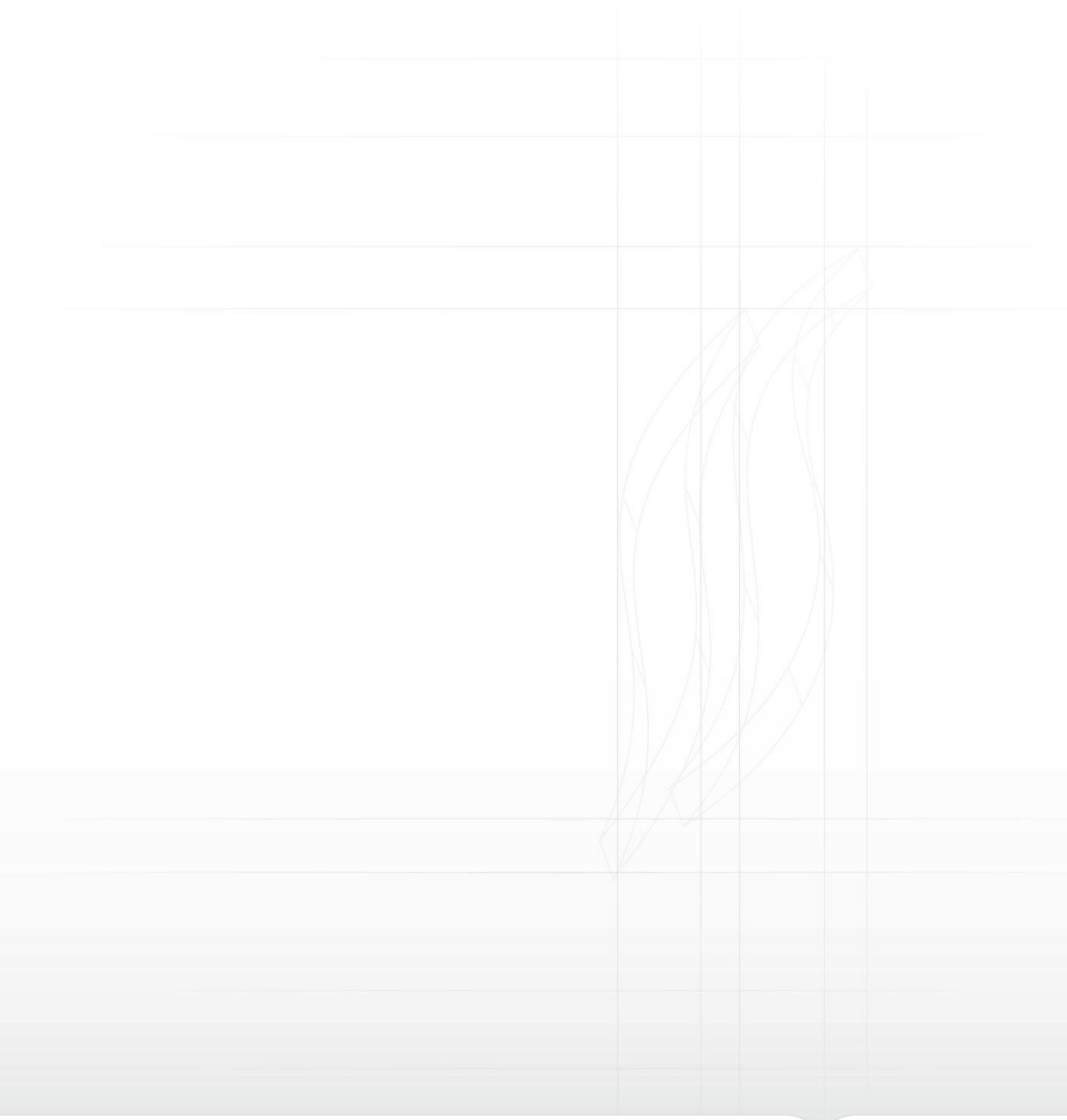


Interlaminar Decompression & Stabilization

Reginald Davis, M.D., FAANS, FACS – Director of Clinical Research



Disclosures





Background

- Device meant to stabilize the spine without fusion following decompression surgery
 - Preserves motion at the index level and adjacent levels
- Intended for one or two levels between L1-L5
- Moderate to severe stenosis in the lumbar spine should be present
 - Symptoms in legs and buttocks with or without axial pain
- Contraindications:
 - Prior fusion at the index level
 - Compromised vertebral bodies at the index level
 - Spondylolisthesis greater than or equal to grade II
 - Axial pain only
 - Osteoporosis





Design & Target Market

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

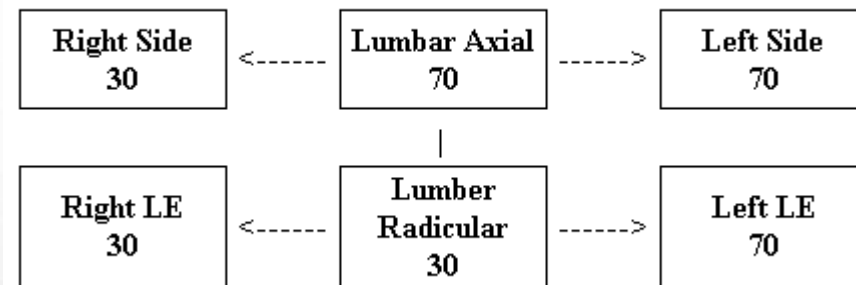
- *coflex*® is compressible in extension
- Axial force shock absorption
- Maintains sagittal balance and lordosis
- Maintains physiological adjacent segment kinematics

PATIENT PROFILE	<ul style="list-style-type: none"> • Intermittent neurogenic claudication • Insignificant back pain • Early or infrequent symptomatology 	<ul style="list-style-type: none"> • Intermittent neurogenic claudication • Insignificant back pain • Too sick for general anesthesia 	<ul style="list-style-type: none"> • Mild to moderate stenosis • Insignificant back pain 	<ul style="list-style-type: none"> • At least moderate stenosis • Significant back pain (> leg pain) • No instability 	<ul style="list-style-type: none"> • At least moderate stenosis • Significant back pain (> leg pain) • Up to Grade I spondylolisthesis (stable) • Degenerative lumbar scoliosis ≤ 25° Cobb Angle 	<ul style="list-style-type: none"> • Severe stenosis • Dominant back pain • Unstable spondylolisthesis > Grade I • Degenerative lumbar scoliosis > 25° Cobb Angle • Unstable isthmic spondylolisthesis
	TREATMENT	<ul style="list-style-type: none"> • Modification of daily activities 	<ul style="list-style-type: none"> • Decompression • Interspinous distraction 	<ul style="list-style-type: none"> • Decompression 	<ul style="list-style-type: none"> • Decompression + <i>coflex</i>® 	<ul style="list-style-type: none"> • Decompression + fusion



Case Study - History

- 60 year old white female with lumbar spine issues
- BMI of 26.93
- No previous spine surgeries
- **CHIEF COMPLAINT:** States that she has had low back pain for the past 4 months since falling at work on 9/9/14. Pain is constant and is progressively getting worse.





Case Study – Present Illness

- Patient has experienced low back pain for 4 months
 - Pain in back, buttocks, groin and posterior leg and lateral calf with numbness/tingling in the left foot
 - Bending, Prolonged Sitting/Standing/Walking and any activity aggravates symptoms
 - Daily activities affected
 - Ice and Medication reduces pain
- Failed conservative treatments
 - Anti-inflammatory medication, pain management, physical therapy, ESIs
- Intensity - On a scale of 1-10, with 10 being the worst pain imaginable, the patient reports their average pain level when resting as 2-10, daily as 2-10, when active as 9-10, now as 8-9



Case Study – Physical Examination

- Spinal Exam

- No Scar
- Deep Tendon Reflexes = Patellar left: 1+. Patellar right: 1+. Achilles left: 2+. Achilles right: 2+.
- Pedal Pulses = Dorsalis Pedis: 2+. Posterior Tibial: 2+.
- No LE Edema, no UE Edema
- No atrophy
- Heel walk = Left, normal: Right, normal
- Toe walk = Left, normal: Right, normal
- Gait = Normal



Case Study – Physical Examination Continued

- Spinal Exam – Sensory/Palpation
 - Dermatomes
 - Left – Lumbar : Normal
 - Right – Lumbar : Normal
 - Spinal Tenderness
 - Lumbar : Normal
- Spinal Exam – Range of Motion
 - Lumbar – Thoracic : Flexion painful. Hyperextension painful. Lateral Flexion painful: Bilateral. Lateral Flexion limited: Bilateral. Rotation painful: Left.



Case Study – Physical Examination Continued

- Spinal Exam – Provocative Tests

- Cervical Tests

- Clonus test – Left: negative. Right: negative
- Hoffman's Test – Left: negative. Right: negative

- Lumbar Tests

- Babinski's test – Left: negative. Right: negative
- Lasegue's test – Left: negative. Right: negative
- Straight Leg Raise (seated) – Left: positive. Right: negative
- Patrick's Test – Left: negative. Right: negative
- Romberg test – Negative

- Spinal Exam – Muscle Strength

- Lumbar: Hip Abduction normal. Hip Adduction normal. Knee Flexion normal. Knee Extension normal. Gastrocnemius normal. Tibialis Anterior normal. Peroneals normal. Extensor Hallucis Longus normal



Case Study – Imaging Dictation

- L4/5: Degenerative Disc Disease, Bulging Disc, Annular Tear/HIZ, Spinal Stenosis, Foraminal Stenosis, Lateral Recess Stenosis, Facet Degen/Hypertrophy, Osteophytes, Spondylolisthesis.
- L5/S1: Degenerative Disc Disease, Bulging Disc, Annular Tear/HIZ, Foraminal Stenosis, Facet Degen/Hypertrophy, Osteophytes.



Case Study – Preoperative Images





Case Study – Surgery

- Lumbar Laminotomies with Bilateral Foraminotomies, L4-5.
L4-5 Posterior Spinal Instrumentation (Coflex).
 - Surgery Time: 1hr, 1min
 - Estimated Blood Loss: 320mL
 - Complications: None

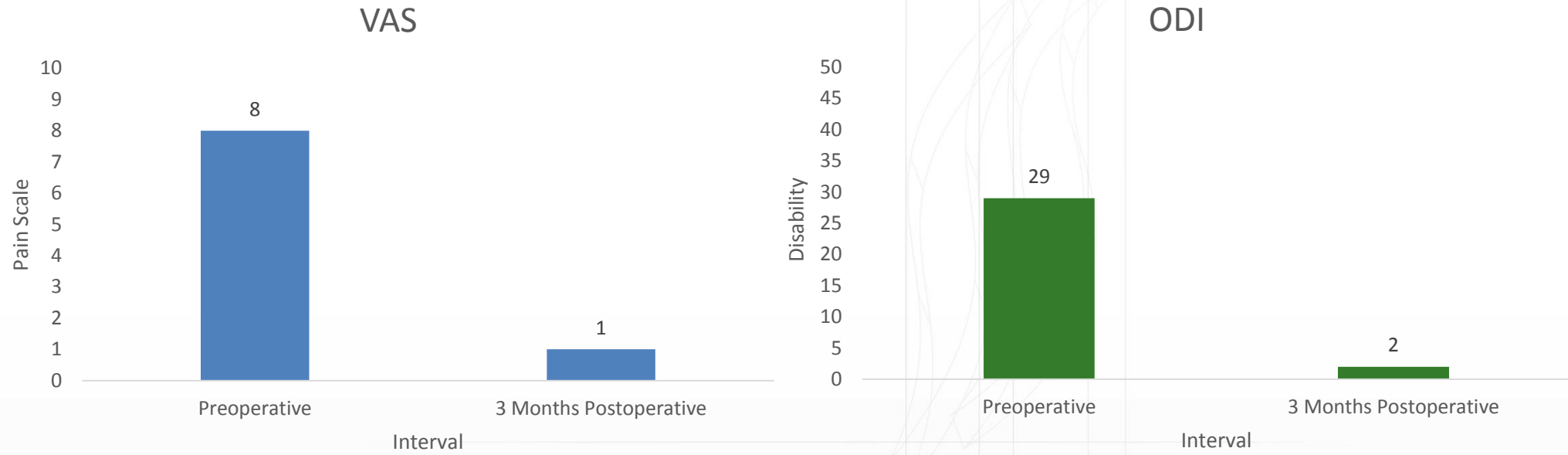


Case Study – Postoperative Images





Case Study – Outcomes



- The patient returned to their usual occupation in less than one month



Industry Coflex Study

- Decompression and Coflex vs. Decompression and fusion
 - Multicenter, prospective randomized (2:1) trial at 21 US sites
 - Coflex N=215 and Fusion N=107
- Clinical outcomes measures collected at baseline, 6 weeks, 3 months, 6 months, 12 months, 18 months, and 24 months postoperatively
 - Oswestry Disability Index
 - Short-Form 12
 - Zurich Claudication Questionnaire
 - Visual Analog Scale
 - Back and leg

Davis, R. J., Errico, T. J., Bae, H., & Auerbach, J. D. (2013). Decompression and coflex interlaminar stabilization compared with decompression and instrumented spinal fusion for spinal stenosis and low-grade degenerative spondylolisthesis. *SPINE*, 38 (18), 1529-1539.



Inclusion and Exclusion Criteria

TABLE 1. Inclusion Criteria
Inclusion Criteria
1. Radiographical confirmation of at least moderate lumbar stenosis, which narrows the central spinal canal at 1 or 2 contiguous levels from L1–L5 that require surgical decompression. Moderate stenosis is defined as more than 25% reduction of the anteroposterior dimension compared with the next adjacent normal level, with nerve root crowding compared with the normal level, as determined by the investigator on CT Scan or MRI. The patient may have, but is not required to have for inclusion in the study:
a. Facet hypertrophy and subarticular recess stenosis at the affected level(s);
b. Foraminal stenosis at the affected level(s);
c. Up to grade I stable degenerative spondylolisthesis (Meyerding classification) or equivalent retrolisthesis as determined by flexion/extension radiograph:
i. For single-level disease, there may be up to a grade I stable spondylolisthesis or equivalent retrolisthesis at the affected level as determined on flexion/extension films by the investigator.
ii. For 2-level disease, there may be up to a grade I stable spondylolisthesis or equivalent retrolisthesis at only 1 of the 2 contiguous affected levels, as determined on flexion/extension films by the investigator. Patients with up to grade I stable spondylolisthesis at 2 contiguous levels are excluded, but patients with up to grade I stable spondylolisthesis at 1 level and equivalent retrolisthesis at the adjacent level may be included.
d. Mild lumbar scoliosis (Cobb angle up to 25°).
2. Radiographical confirmation of the absence of angular or translatory instability of the spine at index or adjacent levels (instability as defined by White & Panjabi: Sagittal plane translation >4.5 mm or 15% or sagittal plane rotation >15° at L1–L2, L2–L3, and L3–L4; >20° at L4–L5 based on standing flexion/extension radiographs).
3. VAS back pain score of at least 50 mm on a 100 mm scale.
4. Neurogenic claudication as defined by leg/buttocks or groin pain that can be relieved by flexion such as sitting in a chair.
5. Patient has undergone at least one epidural injection at any prior time point, and at least 6 mo of prior conservative care without adequate and sustained symptom relief.
6. Age between 40 and 80 yr.
7. Oswestry Low Back Pain Disability Questionnaire score of at least 20/50 (40%).
8. Appropriate candidate for treatment using posterior surgical approach.
9. Psychosocially, mentally, and physically able to comply fully with this protocol, including adhering to scheduled visits, treatment plan, completing forms, and other study procedures.
10. Personally signed and dated informed consent document prior to any study-related procedures indicating that the patient has been informed of all pertinent aspects of the trial.
<i>CT indicates computed tomography; MRI, magnetic resonance imaging.</i>

TABLE 2. Exclusion Criteria
Exclusion Criteria
• More than 2 vertebral levels requiring surgical decompression.
• Prior surgical procedure that resulted in translatory instability of the lumbar spine [as defined by White & Panjabi]. ³¹
• More than 1 surgical procedure at any combination of lumbar levels.
• Prior fusion, implantation of a total disc replacement, complete laminectomy, or implantation of an interspinous process device at any lumbar level.
• Radiographically compromised vertebral bodies at any lumbar level(s) caused by current or past trauma or tumor (e.g., compression fracture).
• Severe facet hypertrophy that requires extensive bone removal that would cause instability.
• Isthmic spondylolisthesis or spondylolysis (pars fracture).
• Degenerative lumbar scoliosis (Cobb angle > 25°).
• Disc herniation at any lumbar level requiring surgical intervention.
• Osteopenia: A screening questionnaire for osteopenia, SCORE (simple calculated osteoporosis risk estimation), will be used to screen patients who require a DEXA bone mineral density measurement. If DEXA is required, exclusion will be defined as a DEXA bone density measured T score of ≤ -1.0 (The World Health Organization definition of osteopenia).
• Back or leg pain of unknown etiology.
• Axial back pain only, with no leg, buttock, or groin pain.
• Morbid obesity defined as a body mass index >40.
• Pregnant or interested in becoming pregnant in the next 3 years.
• Known allergy to titanium, titanium alloys, or MR contrast agents.
• Active or chronic infection—systemic or local.
• Chronically taking medications or any drug known to potentially interfere with bone/soft tissue healing (e.g., steroids), not including a Medrol (Methylprednisolone) dose pack.
• History of significant peripheral neuropathy.
• Significant peripheral vascular disease (e.g., with diminished dorsalis pedis or posterior tibial pulses).
• Unremitting back pain in any position.
• Uncontrolled diabetes.
• Known history of Paget disease, osteomalacia, or any other metabolic bone disease (excluding osteopenia, which is addressed earlier).
• Cauda equina syndrome, defined as neural compression causing neurogenic bowel (rectal incontinence) or bladder (bladder retention or incontinence) dysfunction.
• Fixed and complete motor, sensory, or reflex deficit.
• Rheumatoid arthritis or other autoimmune diseases.
• Known or documented history of communicable disease, including AIDS, HIV, active hepatitis.
• Active malignancy: a patient with a history of any invasive malignancy (except nonmelanoma skin cancer), unless he/she has been treated with curative intent and there has been no clinical signs or symptoms of the malignancy for at least 5 years. Patients with a primary bony tumor are excluded as well.
• Prisoner or ward of the state.
• Subject has a history of substance abuse (e.g., recreational drugs, narcotics, or alcohol).
• Subject is currently involved in a study of another investigational product for similar purpose.
• Currently seeking or receiving workman's compensation.
• In active spinal litigation.
<i>Primary location for DEXA scan should be the spine. In the event that the spine T score is in the osteopenic range (-1.0 to -2.5) then a T score from the hip may be obtained. If the T score from the hip comes back above -1.0 then, at the discretion of the investigator, the patient may be considered for inclusion in the study. Also, a hip DEXA may be used in the event that a spine DEXA cannot be obtained.</i>
<i>HIV indicates human immunodeficiency virus; DEXA, dual-energy X-ray absorptiometry.</i>

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Operative Details

TABLE 3. Summary of Operative Details Continuous Variables Coflex and Fusion Control Randomized Cohorts

1- and 2-Level Procedures	Coflex			Control			P*	Effect
	N	Mean	SD	N	Mean	SD		Size
Hospital LOS (d)	215	1.90	1.08	107	3.19	1.61	0.000	-1.01
Estimated blood loss (mL)	215	109.7	120.0	105	348.6	281.8	0.000	-1.27
Operative time (min)	214	98.0	41.1	107	153.2	55.5	0.000	-1.19
1-level procedures	N	Mean	SD	N	Mean	SD		
Hospital LOS (d)	138	1.86	1.14	68	2.87	1.45	0.000	-0.81
Estimated blood loss (mL)	138	98.0	96.3	66	290.9	207.7	0.000	-1.36
Operative time (min)	137	90.8	44.0	68	142.0	56.0	0.000	-1.06
2-level procedures	N	Mean	SD	N	Mean	SD		
Hospital LOS (d)	77	1.97	0.95	39	3.74	1.74	0.000	-1.40
Estimated blood loss (mL)	77	130.5	152.1	39	446.2	358.4	0.000	-1.31
Operative time (min)	77	110.9	31.8	39	172.7	49.3	0.000	-1.60

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Outcomes

TABLE 4. Coflex and Fusion Control Randomized Cohorts Descriptive Statistics for ODI Score

	Coflex Total Score				Fusion Control Total Score				<i>t</i> test	Effect
	N	Mean	SD	Median	N	Mean	SD	Median	<i>P</i> *	Size†
Preoperative	215	60.8	11.8	60.0	107	60.7	11.5	60.0	0.946	0.01
Month 24	162	22.0	18.6	20.0	86	26.7	21.3	23.0	0.075	-0.24

TABLE 5. Coflex and Fusion Control Randomized Cohorts Descriptive Statistics for the SF-12 Physical and Mental Health Component Scores

	Coflex Physical Component Summary				Fusion Controls Physical Component Summary				<i>t</i> Test	Effect
	N	Mean	SD	Median	N	Mean	SD	Median	<i>P</i> *	Size†
Preoperative	195	28.1	6.6	27.6	95	28.2	6.0	27.4	0.939	-0.02
Month 24	148	43.8	10.6	43.9	78	40.7	12.2	40.5	0.050	0.28

	Coflex Mental Health Summary				Fusion Controls Mental Health Summary				<i>t</i> test	Effect
	N	Mean	SD	Median	N	Mean	SD	Median	<i>P</i> *	Size†
Preoperative	195	45.5	13.0	45.9	95	44.9	12.2	43.6	0.695	0.05
Month 24	148	53.3	10.2	57.8	78	51.2	11.3	56.8	0.150	0.20

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Outcomes Continued

TABLE 6. Coflex and Fusion Control Randomized Cohorts Descriptive Statistics for Back and Max (Right, Left) Leg Pain VAS										
	Coflex Back Pain VAS				Controls Back Pain VAS				t Test	Effect
	N	Mean	SD	Median	N	Mean	SD	Median	P*	Size†
Preoperative	215	79.5	15.0	82.0	106	79.2	13.5	81.0	0.843	0.02
Month 24	162	23.6	26.2	12.0	86	27.0	29.3	13.0	0.345	-0.13
	Coflex Leg Pain (Worse Leg)				Controls Leg Pain (Worse Leg)				t Test	Effect
	N	Mean	SD	Median	N	Mean	SD	Median	P*	Size†
Preoperative	215	76.0	20.4	80.0	106	78.3	18.4	82.5	0.307	-0.12
Month 24	162	20.6	27.4	7.0	86	24.1	30.6	8.0	0.364	-0.12

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Outcomes Continued

TABLE 7. Coflex and Fusion Control Randomized Cohorts Descriptive Statistics for the Zurich Claudication Questionnaire										
	Coflex Symptom Severity				Fusion Control Symptom Severity				<i>t</i> Test	Effect
	N	Mean	SD	Median	N	Mean	SD	Median	<i>P</i> *	Size†
Preoperative	214	3.56	0.61	3.57	107	3.58	0.57	3.43	0.680	-0.05
Month 24	161	1.98	0.75	1.86	86	2.23	0.89	2.29	0.023	-0.30
	Coflex Physical Function				Fusion Control Physical Function				<i>t</i> Test	Effect
	N	Mean	SD	Median	N	Mean	SD	Median	<i>P</i> *	Size†
Preoperative	214	2.75	0.45	2.80	107	2.82	0.44	2.80	0.188	-0.16
Month 24	162	1.56	0.61	1.40	86	1.80	0.77	1.60	0.008	-0.35
	Coflex Satisfaction Score‡				Controls Satisfaction Score				<i>t</i> Test	Effect
	N	Mean	SD	Median	N	Mean	SD	Median	<i>P</i> *	Size†
Month 24	162	1.42	0.55	1.17	86	1.65	0.77	1.33	0.006	-0.36

Davis, R. J., Errico, T. J., Bae, H., & Auerbach, J. D. (2013). Decompression and coflex interlaminar stabilization compared with decompression and instrumented spinal fusion for spinal stenosis and low-grade degenerative spondylolisthesis. *SPINE*, 38 (18), 1529-1539.



Study Conclusions

➤ Key Points

- ❑ Coflex interlaminar stabilization led to shorter surgical times, reduced hospital LOS, and less blood loss compared with instrumented spinal fusion for lumbar spinal stenosis with up to grade 1 degenerative spondylolisthesis.
- ❑ At 24 months, significant improvements were seen in the Coflex cohort compared with fusion in all ZCQ subdomains, SF-12 Physical Component, and a trend toward significance was seen in ODI.
- ❑ Fusions exhibited significantly increased angulation at the superior adjacent level, and a trend toward significant increase in superior level translation, at 2 years, compared with Coflex interlaminar stabilization.
- ❑ Based on the strict FDA criteria for overall success, Coflex succeeded in 66.2% of patients, compared with 57.7% of fusions at 2 years, demonstrating noninferiority.

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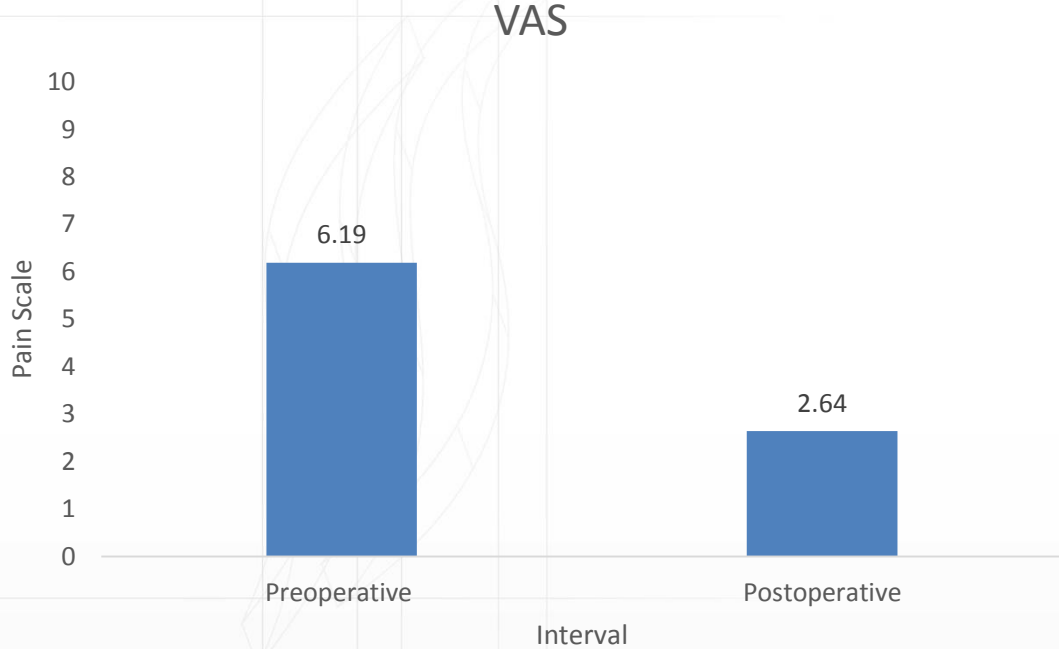
LSI Coflex Study – Materials & Methods

- Retrospective review of prospectively collected outcomes
- Data was collected on 59 patients who underwent a minimally invasive decompression via laminotomy and foraminotomy and stabilization using Coflex between June, 2013 and July, 2016
 - Follow up ranges from 3 months to 3 years
 - Average follow up was 241 days
- Questionnaires (preoperative and postoperative)
 - Visual Analog Scale (VAS)
 - Self-reported pain with a possible score ranging from 0-10
 - Oswestry Disability Index (ODI)
 - Self-reported disability with a possible score ranging from 0-50
 - Return to Work (RTW)
 - Self-reported interval at which the patient returned to their usual occupation



LSI Coflex Study – VAS

Measure	N	Mean	Std. Dev.	P-Value
VAS				
Preoperative	59	6.19	2.53	<.001*
Postoperative		2.64	2.47	

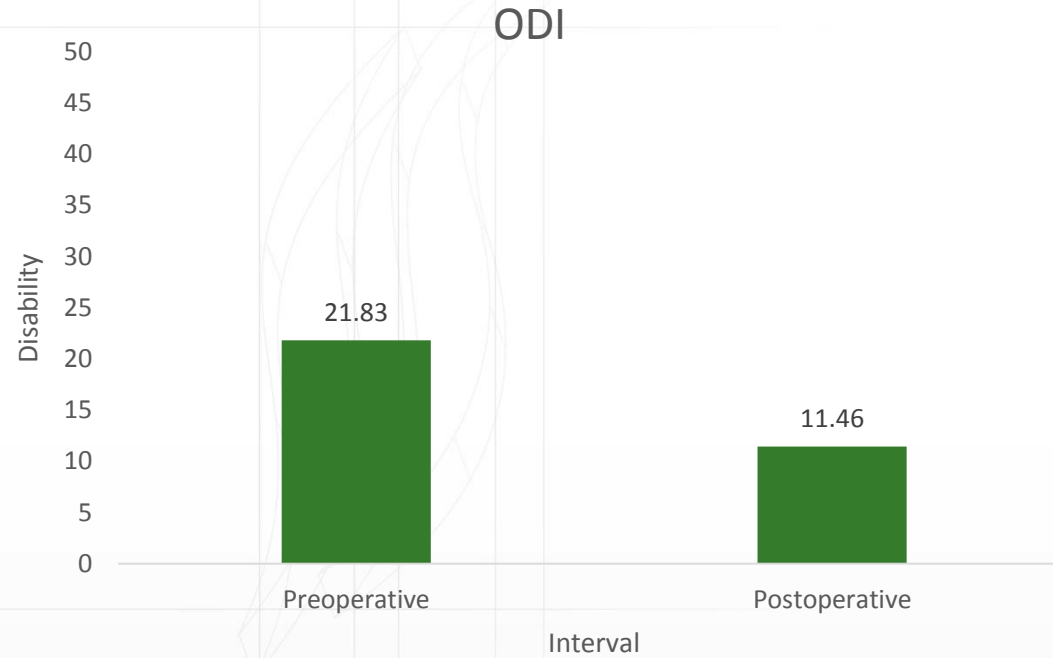


*Calculated using Student t-test in Stata



LSI Coflex Study – ODI

Measure	N	Mean	Std. Dev.	P-Value
ODI				
Preoperative	59	21.83	7.61	<.001*
Postoperative		11.46	8.88	



*Calculated using Student t-test in Stata



LSI Coflex Study – RTW

- 37 patients were used in the return to work analysis
 - 57 patients responded; 20 were removed for indicating *retired* or *homemaker*
- 31 (83.8%) patients reported returning to their usual occupation at follow up
 - 27 (73%) patients returned within 3 months
 - 11 (29.7%) patients returned in less than one month



Conclusion

- Industry studies coupled with LSI's outcomes suggest that decompression with Coflex for the treatment of lumbar spinal stenosis and spondylolisthesis (up to grade I) is a safe and effective alternative to lumbar fusion
- Recent findings also suggest that it is feasible to perform a decompression with Coflex in an ambulatory surgery center

