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Int J Spine Surg 2018, 12 (1) 64-69
doi: https://doi.org/10.14444/5011
https://www.ijssurgery.com/content/12/1/64

The International Journal of Spine Surgery
2397 Waterbury Circle, Suite 1,
Aurora, IL 60504, Phone: +1-630-375-1432

International Journal of Spine Surgery, Vol. 12, No. 1, 2018, pp. 64–69
https://doi.org/10.14444/5011

Spinal Stenosis in the Absence of Spondylolisthesis: Can Interlaminar Stabilization at Single and Multi-levels Provide Sustainable Relief?

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ABSTRACT

Background: In the absence of spondylolisthesis, fusion procedures are generally not recommended. However, decompression alone often does not provide long-term clinical success of intractable leg and back pain. Decompression with interlaminar stabilization (ILS) offers a new option within the clinical continuum of care by providing a nonfusion surgical alternative. The objective of this study is to examine the sustainability of decompression with ILS and to understand the clinical success at either 1 or 2 levels as a surgical treatment for nonspondylolisthesis patients with spinal stenosis.

Methods: Under an FDA-regulated investigational device exemption (IDE) study, a total of 322 patients were enrolled in the prospective, randomized trial. This investigation focuses only on the subset of patients (116 total) from this overall cohort who were treated with decompression plus ILS at 1 or 2 levels and who did not present with spondylolisthesis preoperatively. The patients were assessed before and after surgery up to 60 months.

Results: At 60-month follow up, there was no statistically significant difference in ODI $\geq$ 15 point improvement between patient populations (81.6% of 1 level, 90.3% of 2 level). At 60 months, 83.1% of 1 level and 86.3% of 2 level patients did not require a secondary surgical procedure. At 60 months, 94.7% of 1 level and 100% of 2 level reported $\geq$20 mm improvement in Visual Analogue Scale leg pain. Patients reported improvement in their physical state according to Short Form-12 scores (89.3% of 1 level, 88.9% of 2 level). Patient satisfaction at 60 months was 97.4% for 1 level and 93.3% for 2 level.

Conclusions: The therapeutic sustainability for the treatment of spinal stenosis without spondylolisthesis with ILS at 1 or 2 levels in the lumbar region has been shown to be safe and efficacious for patients who have failed conservative treatment.

Clinical Relevance: Decompression with ILS offers a nonterminal surgical option for the treatment of the symptomology of spinal stenosis, a progressive degenerative condition, that potentially can provide longer durability and stability than decompression alone.

Cervical Spine

Keywords: interlaminar stabilization, ILS, spinal stenosis, nonfusion surgical alternative

INTRODUCTION

Intractable leg and/or back pain limiting activities commonly manifest with the aging process, resulting from a narrowing of the spinal canal and foramen also known as spinal stenosis. When conservative treatment options fail, surgical intervention can be necessary to alleviate the pressure on the nerve by reestablishing the space in the foramen and spinal canal.[1–3] Surgical management option levels of efficacy have been reported to vary with regard to associated morbidities and perceived durability.[2–8] In the absence of instability or deformity (nonspondylolithesis), fusion procedures are generally not recommended. In fact, a recent study by Försth et al.[9] that reviewed 247 cases showed decompression with fusion did not result in better clinical outcomes at 2 and 5 years compared to decompression alone. Sigmundsson et al.[4,10] recently reported on a series of 5100 patients treated for spinal stenosis without spondylolisthesis and found that, although leg pain was reduced, the ratio of satisfaction/dissatisfaction was 1:1. Further, although the majority of patients in the study had a decompression alone, those that underwent a fusion procedure did not correlate to better satisfaction. In recent years, newer surgical options such as interlaminar stabilization (ILS) utilizing a non-

fusion technique have provided a surgical treatment alternative.[1,2,7,8,11,12]

Previously, ILS (Coflex, Paradigm Spine, New York, NY), examined under a United States Food and Drug Administration (US FDA) investigational device exemption (IDE) clinical trial, was shown to have durable outcomes when compared to posterolateral fusion in the setting of postdecompression stabilization for stenotic patients with up to a Grade I spondylolithesis.[13,14] At 5 years postoperative, decompression and ILS was shown to provide sustainable management of moderate to severe spinal stenosis while maintaining motion and protecting foraminal height for exiting nerves.[13]

The objective of this paper is to focus on a subset of patients from the original IDE trial that preoperatively presented with moderate to severe spinal stenosis without spondylolisthesis. The hypothesis was that this subset of patients would experience better clinical outcomes when treated with ILS compared to fusion when undergoing either a single or 2-level procedure.

METHODS

Davis et al.[6] previously provided a full description of the study design and inclusion/exclusion criteria. Under an FDA-regulated IDE study, a total of 322 patients from 21 sites in the US were enrolled between 2006 and 2010 in the prospective, randomized trial. The 2 main criteria for enrollment in the study were patient-reported minimum Oswestry Disability Index (ODI) score of 20 out of 50 (40%) and a Visual Analogue Scale (VAS) back pain score of at least 50 out of 100. Study subjects were blinded until after surgery. This investigation focuses only on the subset of patients (116 total) from this overall cohort who were treated with the Coflex device at 1 or 2 levels and did not present with spondylolisthesis preoperatively (65 in the 1-level Coflex group and 51 in the 2-level Coflex group).

Surgical Technique and Device Description for Coflex

The Coflex device is an ILS device that is fixed to the laminar bone. It is composed of titanium alloy and is available in 5 different sizes ranging from 8 to 16 mm in 2 mm increments. The main device goal is to unload the facet joints, stabilize the motion segment, and maintain the direct neurological decompression. Utilizing a standard midline incision, the supraspinous ligament is either retracted laterally or resected for later repair. A high-speed burr or rongeur is used to remove a minimal amount of bone from the spinous process in order to safely access the interlaminar space and provide maximum bone-implant contact upon implantation. Simultaneously, a laminotomy followed by direct visualized, open, microsurgical decompression are performed. Trials are inserted into the interlaminar space to confirm correct sizing. Under fluoroscopic imaging, the device is introduced into the interlaminar space. After final placement, the wings are gently crimped.

Clinical Outcome Measurements

Clinical outcome assessments were made at baseline and at each of the following postoperative time points: 6 weeks and 3, 6, 12, 18, 24, 36, 48, and 60 months. Outcome measures evaluated included ODI, Short Form-12 (SF-12), VAS back and leg scores, and the Zurich Claudication Questionnaire (ZCQ). Neurological evaluation including motor, sensation, and reflex assessments were compared to preoperative assessment and considered a success if maintained or improved. Once a patient had either an injection or a secondary procedure, the patient was deemed a failure and no longer part of the analysis. All endpoints were evaluated for patients at each time point that had not had an epidural injection or secondary procedure.

Radiographical Outcome Measures

In the ILS cohort, upright neutral lateral, flexion, and extension radiographs were obtained at each time point. All radiographical images were sent from the study sites directly to and were evaluated by an independent core radiography laboratory (Medical Metrics Inc., Houston, Texas).

Statistical Analysis

Linear improvements were analyzed for each patient-derived questionnaire out to the 60-month visit, and comparative analysis using Fisher exact tests and standardized effect sizes were performed.

RESULTS

Demographics, Accountability, Intraoperative Data

The overall patient demographics showed no statistically significant differences between treatment groups in age, gender, race, smoking status,

Table 1. Demographics and intraoperative data.

Variable	1 Level (n = 65), Mean (SD)	2 Level (n = 51), Mean (SD)	*P*
Patient demographics			
Gender			.008
Male (%)	31 (47.7)	37 (72.5)	
Female (%)	34 (52.3)	14 (27.5)	
Age	59.5 (9.6)	63.4 (10.4)	.015
BMI	29.5 (4.1)	29.1 (3.7)	.544
Smoker			.383
Yes (%)	9 (13.8)	4 (7.8)	
No (%)	56 (86.2)	47 (92.2)	
Comorbidities			
Cardiovascular (%)	38 (58.5)	34 (66.7)	.442
Musculoskeletal (%)	30 (46.2)	29 (56.9)	.268
Endocrine (%)	18 (27.7)	13 (25.5)	.835
Interoperative data			
Interoperative time	82.4 min (39.2)	106.4 min (30.8)	
Estimated blood loss	88.5 cm^3 (87.5)	143.3 cm^3 (179.3)	
Length of hospital stay	1.85 d (1.02)	106.4 d (30.8)	

Abbreviations: BMI, body mass index; SD, significant difference.

body mass index, baseline ODI, surgical level, or prior surgical treatment (Table 1). The distribution of surgical levels for 1-level procedures showed 1 at L2-L3 (0.86%), 10 at L3-L4 (8.62%), 52 at L4-L5 (44.83%), and 2 at L5-L6 (1.71%). For 2-level procedures, 4 at L2-L4 (3.45%), 46 at L3-L5 (39.66%), and 1 at L4-L6 (0.86%).

Intraoperative data showed an average surgery time of 82.4 ± 39.2 min for 1-level patients and 106.4 ± 30.8 min for 2-level patients for ILS patients and was not statistically different. Hospital stay was consistent between the 2 groups with a median stay of 2 days and a maximum stay of 4 days (1 level: 1.85 ± 1.02 days; 2 level: 1.86 ± 0.92 days; $P = 1.0$).

Clinical Outcomes

The overall combined clinical success (CCS) criteria consisted of the combination of 4 individual criteria (ODI, no reoperations or epidural injections, no persistent new or increasing sensory or motor deficit, and no major device-related complications). The results of each outcome measure will be presented followed by overall success. Secondary endpoints will also be reported.

Oswestry Disability Index (ODI)

The ODI is a measure of the severity of back pain and disability, and 15-point improvement from baseline for each patient was considered clinically relevant. Regardless of treatment, patients showed statistically significant improvement in ODI scores at all follow-up periods compared to baseline (Figure 1). At the 24-month follow-up time, 15-point improvement was recorded in 87.8% of 1-level and 82.9% of 2-level patients ($P = .559$). Similarly, at 60 months, there was 15-point improvement in 81.6% of 1-level and 90.3% of 2-level patients ($P = .494$). There was no statistical difference between 24 and 60 months within either treatment group.

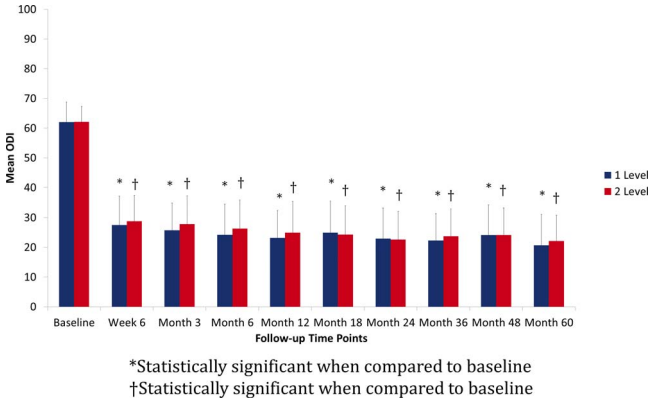

Figure 1. Mean Oswestry Disability Index (ODI). *Statistically significant when compared to baseline. †Statistically significant when compared to baseline.

No Secondary Surgery or Epidural Injections

Secondary surgical procedures were defined as any revision, removal, or reoperation of the implant or supplemental fixation within the index level of the lumbar region. At 24 months, 90.8% in the 1-level group and 92.2% patients in the 2-level group did not require a secondary surgical procedure. There was no statistically significant difference between the treatment groups ($P = 1.00$). Furthermore, at 60 months, 83.1% of 1-level and 86.3% of 2-level patients still had not required secondary intervention and were not statistically different ($P = .797$). Of the 16 patients that required a secondary surgery over the course of the study, 8 were not related, 2 unlikely, 4 possibly, and 2 definitely related to the device. The first case that was reported by the surgeon as definitely related to the device was a female patient who, at 8 months postoperatively, presented with a L5 spinous process fracture secondary to osteoporosis and a fall. The device was removed, and the patient underwent revision surgery requiring a decompression with laminoforaminotomy and posterolateral fusion at L4-L5. The second case reported as definitely implant related was also reported as surgically related. In the primary surgery, the patient underwent a 2-level Coflex procedure at L3-L4 and L4-L5. At 23 months postop, the patient underwent revision surgery due to the component loosening at L4-L5 and a herniated disc L4-L5 and underwent a fusion

Table 2. Overall success.

	Patient Group		
	1 Level	**2 Level**	***P***
ODI (>15 points)			
24 months	87.8%	82.9%	.559[a]
60 months	81.6%	90.3%	.305[b]
No secondary surgery or epidural injection			
24 months	81.5%	84.3%	.806[a]
60 months	69.2%	70.6%	.874[b]
Neurological success			
24 months	94.3%	97.8%	.621[a]
60 months	87.0%	97.4%	.086[b]
No device-related complications			
24 months	100.0%	98.0%	.440[a]
60 months	100.0%	98.0%	.257[b]
Overall success			
24 months	68.9%	69.4%	1.000[a]
60 months	48.3%	60.9%	.201[b]

Abbreviation: ODI, Oswestry Disability Index.
[a]Fischer's exact test.
[b]Chi-square test.

procedure. Of the 4 patients reported as possibly related who underwent revision surgery, 1 patient had a seroma. The Coflex was removed, a revision decompression was performed, and a new Coflex was implanted. Three cases were also considered surgically related where 2 cases were considered a progression of degeneration and increased pain where 1 was revised to posterolateral interbody fusion (PLIF), and the other case required a hemifacetectomy and cyst removal. The third case developed a L4 bilateral pars defect and instability spondylolisthesis at L4-L5, which was revised to PLIF from L4-S1 at 2.5 years postoperatively.

Epidural injections in the posterior lumbar region for pain relief were recorded. The majority of patients at 24 months did not require any epidural injections and was not different between treatments (1 level [89.2%]; 2 level [92.2%]; $P = .753$). Moreover, the percentage of patients not requiring epidural injections stayed largely consistent to 60 months where 84.6% of 1 level and 84.3% of 2 level and were not different between groups ($P = 1.00$).

Overall, for the endpoint of the combination of no secondary surgery or epidural injections, 81.5% of 1 level and 84.3% of 2 level were successful at 24 months and were not statistically significant different between treatments ($P = .806$). At 60 months, there was a decrease from 24 months, but there was not a difference between groups (1 level [69.2%]; 2 level [70.6%]; $P = 1.00$).

Neurological Success

Overall neurological success was determined by evaluating sensory, reflexes, motor, and straight leg raise test. The majority of patients reported no persistent new or increasing sensory or motor deficit and were not statistically different between treatment groups (24 months: 94.3% of 1-level and 97.8% of 2-level patients, $P = .621$; 60 months: 87.0% of 1 level and 97.4% of 2 level reported, $P = .121$).

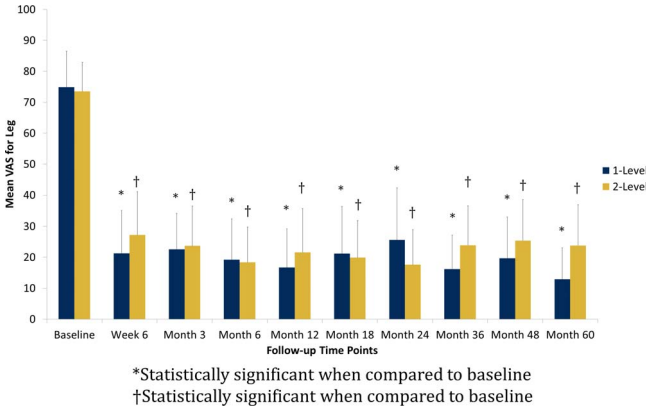

Figure 2. Mean Visual Analogue Scale (VAS) for leg pain. *Statistically significant when compared to baseline. †Statistically significant when compared to baseline.

Overall Clinical Success

The CCS is defined as success in all 4 clinical criteria presented above. At 24 months, the CCS was achieved in 68.9% of 1 level and 69.4% of 2 level and was not statistically different ($P = 1.0$). At 60 months, the CCS was achieved in 48.3% of 1 level and 60.9% of 2 level and also was not statically different ($P = .237$; Table 2).

Secondary Endpoints

Visual Analogue Scale (VAS) Pain

The assessment of VAS leg pain regardless of number of levels treated showed statistically significant improvement from preoperative levels at all follow-up time points (Figure 2). At 24 months, 98% of 1-level and 100% of 2-level patients achieved at least a 20-mm improvement in VAS leg pain. At 60 months, the substantial pain reduction was sustained with 94.7% of 1 level and 100% of 2 level recorded at least a 20-mm improvement. There was not statistical difference between treatment groups at either time point.

Short Form-12 (SF-12) Physical Component

Short Form-12 success was defined as any improvement from baseline in the composite score of the physical component. At 24 and 60 months, the majority of patients achieved improvement in their

Table 3. Zurich Claudication Questionnaire (ZCQ) data.

	Patient Group		
	1 Level (%)	2 Level (%)	*P**
ZCQ severity (>0.5)			
24 months	85.7	92.5	
60 months	81.6	83.9	0.803†
ZCQ physical (>0.5)			
24 months	83.7	85.4	
60 months	76.3	83.9	0.438†

*Fischer's exact test.
†Chi-square test.

physical state (24 months: 94.3% of 1-level and 97.8% of 2-level patients, $P = .621$; 60 months: 89.3% of 1 level and 88.9% of 2 level reported, $P = 1.00$).

Zurich Claudication Questionnaire (ZCQ)

The ZCQ is a disease-specific questionnaire designed to measure outcomes after treatment for spinal stenosis. In the ZCQ symptom severity component, 85.7% of 1-level and 92.5% of 2-level patients reported improvement of ≥ 0.5 as compared to preoperative score at 24 months and were maintained out to 60 months with similar findings of 81.6% of 1-level and 83.9% of 2-level patients. The second ZCQ component of physical function improvement of ≥ 0.5 as compared to preoperative score showed similar findings and were maintained out to 60 months (24 months: 83.7% of 1-level and 85.4% of 2-level patients, $P = 1.00$; 60 months: 76.3% of 1 level and 83.9% of 2 level reported, $P = .552$; Table 3).

Patient Satisfaction and Choice for Same Surgery

Regardless of number of levels treated, the majority of patients were satisfied with their surgery and would choose to have had the same surgery again. At 24 months, 91.8% of 1 level and 100% of 2 level were satisfied and 93.9% of 1 level and 100% of 2 level would choose the same surgical treatment again. At 60 months, the responses remained largely unchanged. Patient satisfaction was 97.4% of 1 level and 93.3% for 2 level. Further, same surgical treatment responses were 97.4% of 1 level and 93.3% of 2 level. There were no statistically significant differences between treatments for all of these components.

DISCUSSION

The therapeutic sustainability for the treatment of spinal stenosis without spondylolithesis with ILS at 1 or 2 levels in the lumbar region has been shown to be safe and efficacious for patients who have failed conservative treatment.[1,2,11] In all parameters analyzed, there was no statistically significant difference between undergoing a single or 2-level surgical procedure. There was only 1 device-related major complication representing less than 1% of this patient population showing the safety of Coflex for nonfusion stabilization after direct decompression for spinal stenosis. Over 90% of patients reported no persistent new or increasing sensory or motor deficits, were satisfied with their outcomes, and would choose the same surgical procedure again at all time points out to 5-year follow up. Moreover, over 97% of patients reported a clinically important difference of at least a 20% improvement in their leg pain and sustained that improvement through 60-month follow up. Finally, the specific analysis of severity of symptoms and functional improvement as it relates to spinal stenosis revealed that over 85% improvement in the severity of their symptoms and over 80% functional improvement sustained over the 5-year follow-up time period.

Interestingly, the nonspondylolithesis spinal stenosis patient is often considered not a candidate for traditional fusion surgery. Indeed, Försth et al.[9] have determined that fusion was unnecessary for these patients as it did not result in better outcomes compared to decompression surgery alone. Nonetheless, these patients experience chronic, disabling pain requiring intervention. When conservative treatment fails, this paper has shown that direct compression and stabilization with an interlaminar device, Coflex, is an appropriate and effective treatment. Moreover, while decompression surgery has been shown to provide relief of neurogenic claudication symptoms, surgery alone does not halt the degenerative process that resulted in the disease.[2] By implanting Coflex in the interlaminar space of the affected vertebral segment(s), the device stabilizes the laminectomy, ensuring long-term durability of the surgical outcomes.[15]

Recently, in a randomized, controlled trial comparing laminectomy plus fusion to laminectomy alone for grade 1 degenerative spondylolisthesis with spinal stenosis, the authors concluded that the addition of lumbar spinal fusion with instrumentation was associated with a clinically meaningful improvement in overall physical health.[16] Their data showed approximately a twofold difference on average in SF-36 and ODI improvement favoring the fusion group at 4-year follow up. Moreover,

there was a statistically significant difference in reoperation rates where the decompression-alone group had 34% compared to 14% in the fusion group at 4 years with an important note that the decompression-alone reoperations were all at the index level and the fusion group were all at an adjacent level. Although a different patient population than the nonspondylothesis patient group, it further shows the inadequacy of laminectomy alone as a sustainable solution.

Although it could be argued that there are higher hospital costs to performing an ILS in comparison to decompression alone, the true argument should be focused on the patient over the next 5 years. If the patient experiences less loss of work, less opiate use, less outpatient-based therapy, and less reoperations, these are true health-related measures, not what is the most economical for the hospital to perform today. Interlaminar stabilization has been shown to be a durable, sustainable solution in nonspondylolithesis patients by multiple health-related measures out to 5 years postoperatively.

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Published 30 March 2018