



A Prospective, Observational, Open-Label, Non-Randomized, Multicenter Study Measuring Functional Outcomes in a Novel Interspinous Fusion Device in Subjects with Low Back Pain: REFINE Study

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ABSTRACT

Introduction: Lumbar degenerative disease and the accompanying pain and dysfunction affect a significant number of patients in the USA and around the world. As surgery and innovation are moving towards minimally invasive treatments, this study looks to explore interspinous fixation as a standalone posterior approach to treat lumbar degenerative disc disease in the presence of neurogenic claudication and spinal stenosis.

Methods: This study was approved by an institutional review board (IRB) and is actively enrolling in a single-arm, multicenter,

prospective, open-label fashion. Patients are followed with reporting at 3 months, and 12 months for primary endpoint analysis of efficacy and safety based on improved composite endpoints relative to baseline, with success defined as greater than 20 mm back pain reduction in Visual Analog Scale 100 mm (VAS) while standing or walking, greater than 20 mm leg pain reduction in VAS while standing or walking, Zurich Claudication Questionnaire (ZCQ) improvement of 0.5 or greater in two or three domains, Oswestry Disability Index (ODI) improvement of a least 10 points and no reoperations or revisions at the index level(s). Secondary endpoints included a multidimen-

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sional assessment in the Patient-Reported Outcomes Measurement Information System (PROMIS) 29 v2.1 and Patient Global Impression of Change (PGIC).

Results: In this interim 3-month analysis, 82% of patients reported they were improved from the procedure, while 65% of patients demonstrated clinical meaningful improvement in their pain and function, as defined by the VAS, ODI, and ZCQ. There was only one adverse event and no complications were identified at last clinic research follow-up visit.

Conclusions: This interim analysis of the first 20% of the enrolled patients out to 3 months was to determine safety of the procedure and report on adverse events, acknowledging the heterogeneity of surgical specialty. Further follow-up and greater numbers are needed as the study is ongoing.

Trial Registration: ClinicalTrials.gov identifier, NCT05504499.

Keywords: Degenerative disc disease; Spinal stenosis; Neurogenic claudication; Interspinous fixation

Key Summary Points

The treatment of lumbar spinal stenosis has a large unmet treatment need that bridges the gap between conservative measures and invasive surgical procedures.

This study was conducted to determine the utility of using interspinous fusion devices as a standalone therapy for the treatment of lumbar spinal stenosis.

This publication demonstrates that the use of this novel interspinous fusion device by the interventional pain community is both effective and safe at 3 months follow-up.

INTRODUCTION

The landscape of spine surgery is changing. As did the acknowledgement of minimally invasive techniques to improve safety and at least maintain efficacy of treatments for patients in the cardiac space, the renaissance is also occurring in the spine.

Degenerative disc disease is a common condition of the aging spine, and may contribute to a variety of painful symptoms, including radiculopathy, neurogenic claudication, and back pain. There are a number of mechanical sequelae that result from these degenerative processes of the intervertebral disc, which may manifest in the anterior, middle, and posterior columns of the spine. Symptoms of degenerative disc disease can be successfully managed on the spectrum of treatment options, from conservative measures such as physical therapy and regional injection treatments, to more intensive measures such as invasive surgical decompression and/or fusion options [1, 2].

The space in between was created to minimize surgical complications and to avoid protracted recovery periods by looking for minimally invasive options, including interspinous spacers (ISS) or percutaneous image-guided lumbar decompression, with debulking of the ligamentum flavum, with excellent results represented in multiple multicenter, prospective, randomized comparative studies, with follow-up out to 2–5 years [3, 4]. These minimally invasive options bridge the gap between conservative measures and more invasive larger open surgical procedures. This can potentially deliver options to those patients who are not traditional surgical candidates secondary to medical comorbidities, or for those wishing to avoid a more invasive option.

Determining approach is critical and patient candidacy paramount in selecting the right patient for the right therapy. Direct comparison of 2-year results of ISS and decompressive laminectomies found ISS offers a less invasive

treatment that reduces the potential for comorbidities, necessity for future operations, and is less disruptive to the spinal anatomy providing greater options for future surgical interventions with equivalent clinical outcomes [4]. The landmark multicenter SPORT trial compared decompressive laminectomy to conservative non-operative care in patients with spinal stenosis with neurogenic claudication and found that the surgical group had significantly greater improvement in pain and function at 4-year follow-up [5]. Further, a meta-analysis of lumbar fusions for degenerative diseases looked at patient reported outcomes from 65 studies including disability, pain scores, and patient satisfaction. Fusion has been shown to be evidenced for spondylolisthesis, and patients who were randomly assigned to fusion care were four times as likely to be satisfied, attained 34% greater pain relief, and saw a 40% improvement of preoperative disability when compared to those who received non-operative care [2]. Evidence for fusion for stenosis without spondylolisthesis is limited in this meta-analysis; however, this did not distinguish among fusion approaches.

Fusion did provide greater relief than non-operative care in patients with chronic low back pain without clinically significant stenosis or spondylolisthesis [2]. Five randomized control trials reported results with fusion between 16% and 18% improved in terms of back and leg pain as compared to non-operative care [2]. Anterior interbody fusion (ABF) and posterolateral fusion with pedicle screws (PLF) in patients with discogenic low back pain resulted in a significant decrease in Visual Analog Scale 100 mm (VAS) pain scores, with greatest relief following ABF, compared to conservative treatment [6]. To evaluate the use of a standalone interspinous fixation device to offer a minimally invasive option, but also increase the patients served by allowing for fixation in patients that had developed increased spondylolisthesis or micro instability with facet joint fluid, this device may offer a solution. Biomechanically, interspinous fusion has been demonstrated to deliver immediate flexion–extension balance and provide effective stabilization for arthrodesis while preserving motion [7, 8]. Advantages include

small skin incisions, minimally invasive, minimal muscle dissection, shorter operative times, and favorable efficacy [9]. The use of interspinous fusion (ISF) in solitary as a treatment was performed by Postacchini et al. who demonstrated in a prospective study that a standalone ISF, with minimally invasive decompression in stenotic patients showing degenerative spondylolisthesis, provided fusion and highly significant improvement in all outcome measures at a 2-year follow-up [10].

This study will evaluate the effectiveness and safety of the use of Aurora Spine ZIP™ MIS Interspinous Fusion System and bone graft material in single or two-level fusion in patients with chronic low back pain that present with degenerative disc disease (DDD) with concurrent neurogenic claudication. Devices included in this study are the Aurora Spine ZIP™ (Carlsbad, CA) MIS Interspinous Fusion System and bone graft material. The device is a bilateral locking plate system which attaches to the spinous processes of the posterior noncervical spine (T1–S1) from an interlaminar approach. The implants have superior and inferior spinous process articulations and a central bone graft chamber. Specific to this interspinous fusion system are certain biomechanical characteristics such as prevention of extension by acting as a rigid block in the interspinous space. Its rigid structure immobilizes the posterior elements including the lamina and spinous processes reducing motion in all three spinal columns for both flexion and extension. In conjunction with autologous bone grafting via surgical decortication and the use of exogenous allograft the device can lead to bony fusion with rigid interlaminar fixation, as well as indirect decompression.

The Aurora Spine ZIP™ is used to treat DDD (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), and/or tumor. The studied indication is lumbar degenerative disease resulting in back pain with lower extremity symptoms and neurogenic claudication. The clinical benefits of interspinous devices have been described in previous studies based on certain biomechanical

characteristics such as prevention of extension by acting as a rigid block in the interspinous space. The Zip device is a true fusion device with a rigid structure designed to immobilize the posterior elements including the lamina and spinous processes in all planes of motion, as well as to reduce motion in all three spinal columns in both flexion and extension. In conjunction with autologous bone grafting via surgical decortication and the use of exogenous allograft, we anticipate the device to lead to bony fusion of the posterior column at similar rates as pedicle screw fixation. Future data will evaluate the rate of fusion resulting from rigid interlaminar fixation with the Zip device.

METHODS

Designs and Sites

This clinical investigation is a prospective, observational, open-label, non-randomized, multicenter study. IRB approval was provided by Western IRB (IRB #20211168). It is designed to collect clinical follow-up data on patients undergoing interspinous interlaminar fusion with bone graft performed on an ambulatory basis by interventional pain physicians, orthopedic, and neurosurgeons. All patient data collected were de-identified to provide patient data confidentiality and compliance with the Declaration of Helsinki. The protocol and IRB were each approved by the local governing entities of each involved institution. All enrolled subjects provided voluntary written informed consent to participate. Subjects were allowed to ask questions and were given a copy of the informed consent.

Patient Population

Patients were enrolled in the study if they were at least 18 years of age, have at least 1–2 symptomatic lumbar degenerative disc disease at adjacent levels, from T1 to S1, with or without grade I spondylolisthesis, MRI with at least mild to moderate spinal stenosis at the index level, non-operative treatment for at least 3 months,

ZCQ physical function, greater or equal to 2.0 at baseline as assessment, presence of neurogenic claudication, baseline VAS of greater than 50 mm on a 100-mm scale. Baseline characteristics are summarized in Table 2. Key exclusion criteria included greater than a grade II spondylolisthesis on flexion and extension films with 3-mm instability or had previous lumbar spine surgery. Subjects were recruited from patients that presented to participating sites who met all of the inclusion and none of the exclusion criteria per protocol.

Interventions

After appropriate enrollment, as defined by the research protocol, the patient underwent the interspinous fixation (see anteroposterior radiograph in Fig. 1). It has been previously defined by Falowski et al. in a retrospective study demonstrating safety and efficacy [11]. Of note, prior to the procedure, all patients

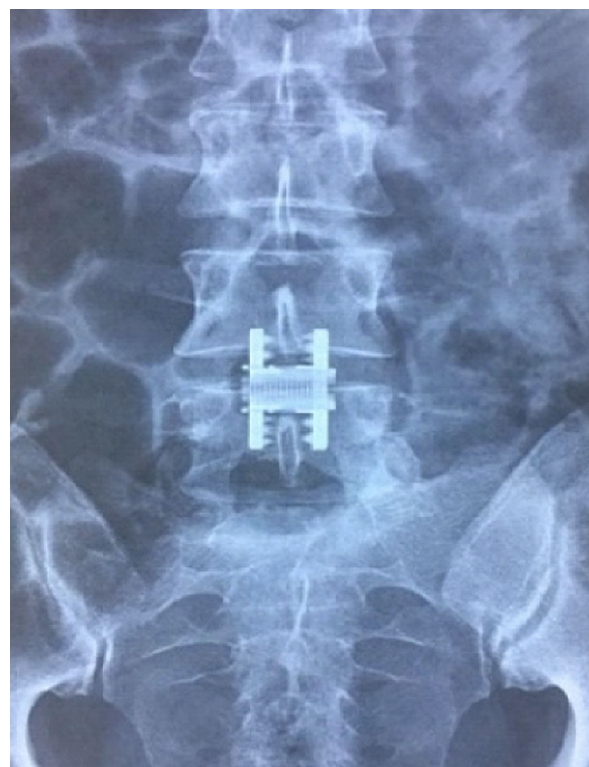


Fig. 1 Anteroposterior radiograph of the deployment of the interspinous fixation device

received an authorization through their commercial or government payer insurance prior to completion of surgery.

Follow-up

Patients enrolled had appropriate imaging reviewed and failure of conservative therapy as defined in the protocol per principal investigator. The medical monitor served to approve all patients enrolled and active. Patients were identified and enrolled, implanted, and followed immediately postoperatively as per standard of care by site, and scheduled visits occurred at month 1, 3, 6, and 12. Enrollment goal was set at 100 patients, with potential follow-up out to 60 months.

Endpoints

Baseline demographic information and procedural detail were captured.

Primary endpoints are to evaluate efficacy and safety at 3 and 12 months based on improved composite endpoints relative to baseline, with success defined as greater than 20 mm pain reduction in Visual Analog Scale 100 mm (VAS) Back while standing or walking, greater than 20 mm pain reduction in VAS Leg while standing or walking, Zurich Claudication Questionnaire (ZCQ) improvement of 0.5 or greater in two or three domains, ODI improvement of at least 10 points and no reoperations or revisions at the index level(s).

The Oswestry Disability Index (ODI) [12] is used to measure a patient's permanent functional disability and is considered the gold standard of low back functional outcome tools. This questionnaire was designed to provide information as to how a patient's back or leg pain affects their ability to manage in everyday life. For each of the 10 sections the total possible score is 5. The score is a percentage calculated by the total scored divided by 50 (total possible score) \times 100. The interpretation of the scores is described in Table 1.

The Zurich Claudication Questionnaire (ZCQ) is a self-administered measure to evaluate symptom severity, physical function, and

Table 1 ODI assessment

0–20%: minimal disability	The patient can cope with most living activities. Usually no treatment is indicated apart from advice on lifting, sitting, and exercise
21–40%: moderate disability	The patient experiences more pain and difficulty with sitting, lifting, and standing. Travel and social life are more difficult and they may be disabled from work. Personal care, sexual activity, and sleeping are not grossly affected and the patient can usually be managed by conservative means
41–60%: severe disability	Pain remains the main problem in this group but activities of daily living are affected. These patients require a detailed investigation
61–80%: crippled	Back pain impinges on all aspects of the patient's life. Positive intervention is required
81–100%	These patients are either bed-bound or exaggerating their symptoms

surgery satisfaction in lumbar spinal stenosis (LSS). The ZCQ quantifies severity of symptoms, physical function characteristics, and patient's satisfaction after treatment. The scale relates to symptoms over the past month. There are 12 questions related to Symptom severity scale (questions I–VII, possible range of score is 1 to 5) and Physical function scale (questions VIII–XII, possible range of score is 1 to 4) and a further six questions to measure treatment outcome. The result is expressed as a percentage of the maximum possible score, which increases with worsening disability.

Secondary endpoints included a multidimensional pain functional assessment as a Patient Reported Outcome Measurement Information System (PROMIS) 29 v2.1, Pain Impact Score (calculated from the PROMIS 29), opioid consumption related to study related pain,

health care consumption, and imaging analysis at 12 months, and global impression of change relative to baseline at 3 and 12 months (PGIC).

The PROMIS 29 is a validated 29-item profile instrument that assesses eight universal domains (not disease-specific): physical function, anxiety, depression, fatigue, sleep disturbance, ability to participate in social roles and activities, pain interference, and pain intensity [13–18]. The first seven domains are assessed with four questions each; pain intensity is measured with a single 11-point numeric rating scale (NRS) from 0 (no pain) to 10 (worst imaginable pain). High scores represent more of the domain being measured. Thus, on symptom-oriented (negatively worded) domains of PROMIS 29 (anxiety, depression, fatigue, pain interference, and sleep disturbance), higher scores represent worse symptomatology. On the function-oriented (positively worded) domains (physical functioning and social role) higher scores represent better functioning. The Pain Impact Score (PIS) is a derivative of the PROMIS 29 that ranges from 8 (low impact) to 50 (high impact). The PIS is calculated by adding the raw scores for pain intensity [0–10] and pain interference [4–20] along with the inverted raw score for physical function [4–20].

Statistical Analysis

For patient self-reported assessments including the VAS, ODI, PROMIS 29, PGIC, and quantitative outcomes, paired *t* test was performed. Analysis of variance (ANOVA) regression analysis was utilized to identify and verify the correlations reported. The data analysis was performed utilizing IBM SPSS statistics.

RESULTS

Eight centers participated in the study, spanning neurosurgery and interventional pain management specialties, with enrollment that began on March 21, 2021 and is currently actively enrolling.

Table 2 Baseline characteristics

Age (mean) in years, mean (SD)	69.68 (11.28)
Female, <i>n</i> (%)	20 (53%)
Visual Analog Scale (VAS)	
Back pain, mean (SD)	75
Leg pain, mean (SD)	74
Oswestry Disability Index (ODI), mean (SD)	48 (16)
Zurich claudication questionnaire	
ZCQ Back, mean (SD)	7.4 (1.8)
ZCQ Leg, mean (SD)	7.3 (2.4)
ZCQ symptom severity, mean (SD)	3.49 (0.75)
ZCQ physical function, mean (SD)	2.89 (0.42)
Tobacco use	
Yes	34%
No	57%
Unknown	9%
Employment status	
Retired	50%
Employed	38%
Disabled	3%
Unemployed	9%
PROMIS 29v2.1	
PROMIS SF v1.0 Pain Interference 4a, mean (SD)	67.1 (3.9)
PROMIS SF v1.0 Sleep Disturbance 4a, mean (SD)	55.8 (8.9)
PROMIS SF v1.0 Fatigue 4a, mean (SD)	58.8 (9.4)
PROMIS SF v1.0 Anxiety 4a, mean (SD)	50.7 (9.5)
PROMIS SF V1.0 Depression 4a, mean (SD)	51.2 (10.8)
PROMIS SF v2.0 Ability to Participate in Social Roles and Activities 4a, mean (SD)	36.3 (5.9)

Table 2 continued

PROMIS SF v1.0 Physical Function 4a, mean (SD)	32.5. (2.9)
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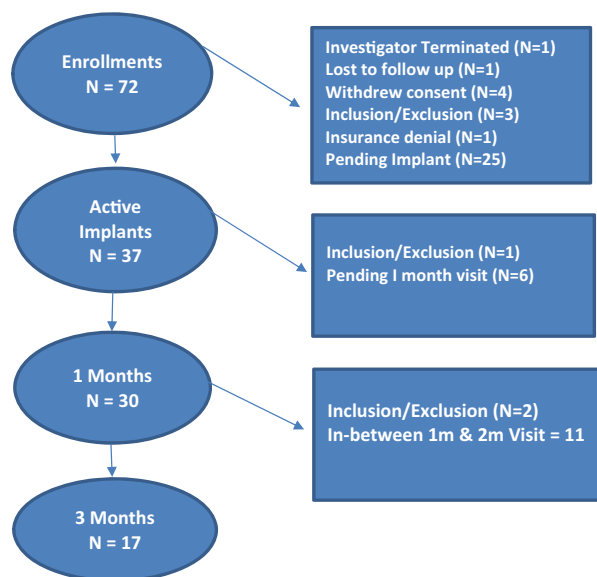


Fig. 2 Study-related activity

Patient Population

Baseline characteristics are summarized in Table 2.

Patient Activity

This data represents an interim analysis of safety and efficacy at 3 months in an ongoing study. Future analysis will report on the complete data set of this multicenter, prospective, single-arm study. Currently there are 54 active patients, 11 terminated patients and 32 implanted. Nineteen represent nearly a fifth of the goal enrollment. See Fig. 2. This represents a single-arm, prospective, multicenter study with follow-up anticipated with primary endpoint at 3 months and 12 months, with follow-up out to 5 years.

Table 3 Surgical characteristics

Specialty of surgeon	
Pain physician	63%
Neurosurgeon	37%
Index level of treatment	
L1–2	1
L3–4	16
L4–5	15
L5–S1	1
Single or adjacent treatment	
Single level	31
Adjacent level	1
Fluoroscopy time in mins, mean (SD)	1.4 (1.4)
Hospital length of stay in days, mean (SD)	0 (0)
Anesthesia type	
MAC (monitored anesthesia care)	44%
General	56%

Surgical Information

Surgical data was acquired and verified. Please see Table 3.

Clinical Outcomes

Patient’s pain intensity was measured using a VAS 100 mm, documented from baseline as a difference to document change for back and for leg (Fig. 3), with success defined as greater than 20 mm reduction while standing and walking. Success according to ZCQ was defined as an improvement from baseline of 0.5 or greater in two or three domains, while the ODI improvement of at least 10 points and no reoperations or revisions at the index level(s). Figure 4 shows the ODI improvement results. Table 4 summarizes the outcome measures.

Secondary endpoints included a multimodal assessment including a PROMIS 29 v2.1 and

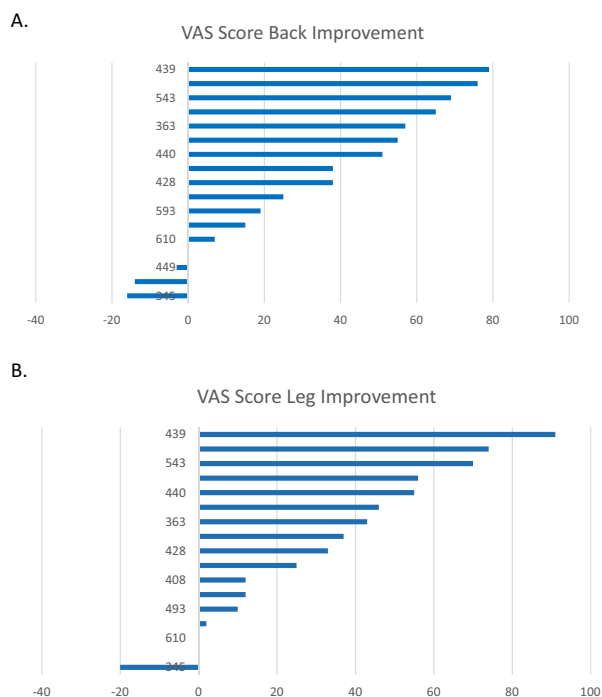


Fig. 3 Tornado graph of pain intensity change from baseline at 3 months for back (a) and leg (b)

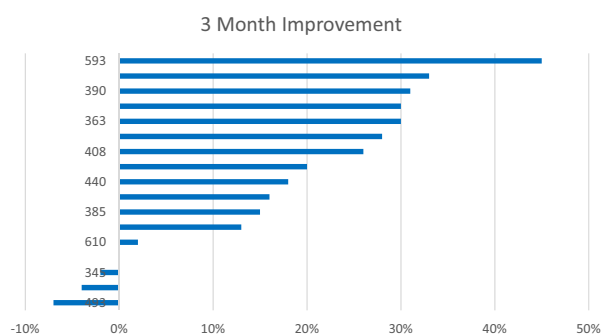


Fig. 4 Tornado plot of percentage ODI improvement from baseline pain at 3 months

PGIC investigating patient satisfaction and global impression of change (Tables 5, 6).

Safety Analysis

Adverse events were monitored throughout the study activity, including worsening pain, infection, hardware malfunction, and bleeding (Table 7). All AEs were recorded and the likelihood of relation to the treatment procedure or

Table 4 Pain and functional outcome measures as primary endpoints

VAS	
Back baseline, mean (SD)	75
Average improvement, mean (SD)	33 (31.6)
($p < 0.001$)	0.000544
Improvement > 20 mm, n (%)	10 (58%)
Leg Baseline, mean (SD)	
Average improvement, mean (SD)	32 (30.7)
($p < 0.001$)	0.000542
Improvement > 20 mm, n (%)	10 (58%)
ZCQ	
Back change	3.3
Leg change	3.3
Symptom severity change	1.17
Physical function change	0.74
ODI	
Baseline, mean (SD)	48 (16)
Average improvement, mean (SD)	17 (15)
($p < 0.001$)	0.000246
Improvement > 10, n (%)	12 (70%)

device. One patient had worsening pain after surgery, which resolved completely with no interventions required.

DISCUSSION

This data represents the first prospectively acquired data set for use of a standalone fixation device for the treatment of degenerative disc disease in the presence of neurogenic claudication and symptomatic spinal stenosis. This study is active and enrolling, with the goal of 100 patients at 3 months and 12 months, and planned follow-up to 5 years. The data presented an interim analysis at 3 months to evaluate safety and efficacy.

Table 5 PROMIS 29 v2.1 table of mean improvement in scores at 3 months from baseline

PROMIS 29 v2.1	Mean (SD); p value
PROMIS SF v1.0 Pain Interference 4a	7.9 (9.1); 0.003
PROMIS SF v1.0 Sleep Disturbance 4a	7.9 (9.8);0.004
PROMIS SF v1.0 Fatigue 4a	9.2 (10.9); 0.003
PROMIS SF v1.0 Anxiety 4a	2.9 (8.3); 0.174
PROMIS SF V1.0 Depression 4a	4.7 (8.9); 0.045
PROMIS SF v2.0 Ability to Participate in Social Roles and Activities 4a	7.4 (7.3); 0.001
PROMIS SF v1.0 Physical Function 4a	4.8 (5.7); 0.003

Table 6 PGIC assessment for patient cohort and interim analysis at 3 months

PGIC score (description) n, (%)	Number of patients n (%)
1. Very much improved	3 (18%)
2. Much improved	6 (35%)
3. Minimally improved	5 (29%)
4. No change	2 (12%)
5. Minimally worse	1 (6%)

Table 7 Adverse events

Adverse events	
Total AEs	1
SAEs	0
Mortality	0
Ongoing AEs	0
Completed SAE/AEs	1
Device or procedure related SAE/AEs	0

The interspinous fusion therapy as a standalone therapy has never been studied in a prospective multicenter fashion. The Coflex is an interlaminar device approved in the lumbar spine from L1 to L5 and includes a decompression before stabilization with the device. It was studied in a multicenter randomized control trial in comparison to decompression with pedicle screws and represented the Coflex as a viable alternative to pedicle screw fixation to treat lumbar spinal stenosis when combined with decompression [19]. The Aurora device does not require direct decompression.

The PrimaLOK device was studied retrospectively in 53 patients to treat spinal disorders, including stenosis, herniated disc, degenerative disc disease, and spondylolisthesis, with a 22-month follow-up on average with pain index score rating from 7.17 to 4.48, suggesting that the use of an independent interspinous fusion system could provide similar results to a pedicle screw instrumentation or interbody cage [20]. This study did not represent a standalone system, unlike the Zip device. These were reviewed in a MIS technology review [21].

Spinal stenosis in the presence of neurogenic claudication can be treated with many treatments, including surgical decompression with laminectomy, with or without fusion, epidural injection, percutaneous image guided lumbar decompression, or interspinous spacer, to name a few. The interspinous spacer (ISS) is different than the interspinous fusion (ISF), as this is an indirect decompression strategy that also offers stabilization by fusion. This was discussed with the patient during the surgical discussion.

Regarding patient safety, there was one adverse event reported, with none that were device or surgery related. Given that this procedure was performed by both neurosurgeons and pain physicians, with the majority being performed by the pain physicians, this data demonstrates the safety of the procedure at 3 months.

Pain intensity reduction, functional improvements, and patient satisfaction demonstrate benefit with the procedure from baseline. Indeed, 82% of the patients reported they were improved from the procedure. Nearly 65% patients achieved the benchmark of

treatment success, and although only 3 months in, which clearly suggests immediate improvement from the procedure. All but three patients were self-reported improved by the procedure, while functional improvement was noted for 65% patients with improvement in ZCQ for symptoms and function. Functional improvement, as measured by ODI improved by 17, on average.

As stated, the PROMIS 29 v2.1 is a multidimensional tool with domains of pain intensity, function, sleep, and the psychological effects of dysfunction. Pope et al. reported on patients presenting to spine and pain centers across the USA, benchmarking typical scores across the PROMIS 29 v2.1, and typical of the population represented here [22]. Higher scores indicate more disability for negatively worded instruments, whereas higher scores demonstrate improvement for positively worded instruments. There was a mean improvement from baseline for the PROMIS 29, with statistical significance, for all but anxiety and depression. Overall, all but three patients self-reported satisfaction with the procedure, measured by the PGIC.

Limitations

Limitations to the study include being a single-arm, prospective study investigating the safety and efficacy of a device for spinous process fixation to treat degenerative disc disease in the face of neurogenic claudication and spinal stenosis. It is not a randomized study. Further, the patient cohort was limited to those approved for the procedure.

CONCLUSIONS

This interim data analysis of approximately a fifth of the patient recruitment goal serves as a planned safety analysis of the procedure. As most surgical complications occur within the first 90 days, our analysis reveals that the first consecutive 17 patients enrolled in this study show no device-related complications, suggesting safety in the hands of both neurosurgeons and interventional pain physicians. Further,

pain intensity, function, sleep, anxiety, fatigue, pain interference, physical function, and social participation also demonstrated improvement.

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Compliance with Ethic Guidelines. IRB approval was provided by Western IRB (IRB #20211168). All patient data collected were de-identified to provide patient data confidentiality and compliance with the Declaration of Helsinki. The protocol and IRB were each approved by the local governing entities of each involved institution. All enrolled subjects provided voluntary written informed consent to participate. Subjects were allowed to ask questions and were given a copy of the informed consent.

Data Availability. No public access to data sets are available as the study is still in process.

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REFERENCES

1. Deer TR, Grider JS, Pope JE, et al. The MIST guidelines: the lumbar spinal stenosis consensus group guidelines for minimally invasive spine treatment. *Pain Pract.* 2019;19(3):250–74.

2. Yavin D, Casha S, Wiebe S, et al. Lumbar fusion for degenerative disease: a systematic review and meta-analysis. Vol. 80, *Clinical Neurosurgery*. Oxford University Press; 2017. p. 701–15. www.neurosurgery-online.com. Accessed Dec 21, 2020.
3. Nunley PD, Patel VV, Gorndorff D, Lavelle WF, Block JE, Geisler FH. Five-year durability of stand-alone interspinous process decompression for lumbar spinal stenosis. *Clin Interv Aging*. 2017;12:1409–17.
4. Lauryssen C, Jackson RJ, Baron JM, et al. Stand-alone interspinous spacer versus decompressive laminectomy for treatment of lumbar spinal stenosis. *Expert Rev Med Devices*. 2015;12(6):763–9.
5. Weinstein JN, Tosteson TD, Lurie JD, et al. Surgical versus nonoperative treatment for lumbar spinal stenosis four-year results of the spine patient outcomes research trial. *Spine (Phila Pa 1976)*. 2010;35(14):1329–38.
6. Ohtori S, Koshi T, Yamashita M, et al. Surgical versus nonsurgical treatment of selected patients with discogenic low back pain: a small-sized randomized trial. *Spine (Phila Pa 1976)*. 2011;36(5):347–54.
7. Gonzalez-Blohm SA, Doulgeris JJ, Aghayev K, Lee WE, Volkov A, Vrionis FD. Biomechanical analysis of an interspinous fusion device as a stand-alone and as supplemental fixation to posterior expandable interbody cages in the lumbar spine: laboratory investigation. *J Neurosurg Spine*. 2014;20(2):209–19. <https://doi.org/10.3171/2013.10.SPINE13612>.
8. Karahalios DG, Musacchio MJ. Lumbar interspinous devices: fusion and motion sparing. In: Holly LT, Anderson PA, editors. *Essentials of spinal stabilization*. Springer; 2017. p. 321–34. https://doi.org/10.1007/978-3-319-59713-3_25.
9. Kim HJ, Bak KH, Chun HJ, Oh SJ, Kang TH, Yang MS. Posterior interspinous fusion device for one-level fusion in degenerative lumbar spine disease: comparison with pedicle screw fixation—preliminary report of at least one year follow up. *J Korean Neurosurg Soc*. 2012;52(4):359–64. <https://doi.org/10.3340/jkns.2012.52.4.359>.
10. Postacchini F, Postacchini R, Menchetti PPM, Sessa P, Paolino M, Cinotti G. Lumbar interspinous process fixation and fusion with stand-alone interlaminar lumbar instrumented fusion implant in patients with degenerative spondylolisthesis undergoing decompression for spinal stenosis. *Asian Spine J*. 2016;10(1):27–37. <https://doi.org/10.4184/asj.2016.10.1.27>.
11. Falowski SM, Mangal V, Pope J, et al. Multicenter retrospective review of safety and efficacy of a novel minimally invasive lumbar interspinous fusion device. *Pain Res*. 2021;31(14):1525–31. <https://doi.org/10.2147/JPR.S304957>.
12. Fairbank JCT, Pynsent PB. The Oswestry disability index. *Spine (Phila Pa 1976)*. 2000;25(22):2940–53.
13. Cella D, Riley W, Stone A, et al. The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005–2008. *J Clin Epidemiol*. 2010;63(11):1179–94.
14. Buckley DI, Eckstrom E, Morris C, et al. Performance of a patient reported outcomes measurement information system (PROMIS) short form in older adults with chronic musculoskeletal pain. *Pain Med*. 2015. <https://doi.org/10.1093/pm/pnv046>.
15. Amtmann D, Kim J, Chung H, Askew R, Park R, Cook K. Minimally important differences for PROMIS pain interference for individuals with back pain. *J Pain Res*. 2016;9:251–5.
16. Chen CX, Kroenke K, Stump TE, et al. Estimating minimally important differences for the PROMIS pain interference scales: results from 3 randomized clinical trials. *Pain*. 2018;159(4):775–82.
17. Lee AC, Driban JB, Price LL, Harvey WF, Rodday AM, Wang C. Responsiveness and minimally important differences for 4 patient-reported outcomes measurement information system short forms: physical function, pain interference, depression, and anxiety in knee osteoarthritis. *J Pain*. 2017;18(9):1096–110.
18. Norman GR, Sloan JA, Wyrwich KW. The truly remarkable universality of half a standard deviation: confirmation through another look. *Expert Rev Pharmacoecon Outcomes Res*. 2004;4(5):581–5.
19. Schmidt S, Franke J, Rauschmann M, Adelt D, Bonsanto M, Sola S. Prospective, randomized, multicenter study with 2-year follow-up to compare the performance of decompression with and without interlaminar stabilization. *J Neurosurg Spine*. 2018;28(4):406–15.
20. Sclafani JA, Liang K, Ohnmeiss DD, Gordon C. Clinical outcomes of a polyaxial interspinous fusion system. *Int J Spine Surg*. 2014;8:35.
21. Condez B, Parrish R, Camisa W, Leasure JM, Randall JC. Stability and decompression mechanics of several MIS lumbar fixation technologies: a biomechanical study. 2015. <https://www.semanticscholar.org/paper/Stability-and-Decompression-Mechanics-of-Several-A-Condez-Parrish/28db8c3dfde9e48f83add9eed9de36be38ef7f0>. Corpus ID: 209753176.

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22. Pope JE, Fishman M, Chakravarthy K, et al. A retrospective, multicenter, quantitative analysis of patients' baseline pain quality (PROMIS 29) entering into pain and spine practices in the United States: the ALIGN study. *Pain Ther.* 2021;10:539–50.