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ORIGINAL RESEARCH

Safety and Efficacy of Interspinous Fixation Device via Lateral Transverse Approach in Patients with Lumbar Spinal Stenosis: A Single Center, Retrospective, Observational Study

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Background: Lumbar spinal stenosis (LSS) is a common degenerative spinal condition that limits function due to reduced space for neurovascular structures. Traditional direct open lumbar decompression (DOLD) is the standard treatment after conservative measures fail. Recently, minimally invasive options such as percutaneous image-guided lumbar decompression (PILD), interspinous spacers (ISS), and interspinous fixation devices (ISFD) have gained popularity for moderate LSS without spinal instability.

Objective: This retrospective study evaluated the safety and efficacy of ISFD in patients with LSS treated at our center.

Patients and Methods: Data from 45 patients (26 males, 19 females) treated with ISFD between January 2023 and October 2024 were analyzed. Adverse events and pain outcomes were recorded using numerical rating scale (NRS) scores at baseline, 2 weeks, 1 month, and 3 months post-procedure.

Results: Only one minor complication was reported on the procedure day. procedure day. Mean NRS pain scores improved from 7.5 (baseline) to 3.5 (2 weeks), 3.0 (1 month), and 3.5 (3 months) ($P < 0.001$). At 2 weeks, 50% of patients had pain reductions ≥51%; at 1 month, 57.4% experienced ≥51% reduction; and by 3 months, 73% had more than 50% pain reduction ($P < 0.001$), indicating significant pain improvement over time.

Limitations: This was a single-center retrospective study with a small sample size and relatively short follow-up time.

Conclusion: ISFD appears to be a safe and effective minimally invasive treatment for LSS. Larger randomized controlled trials are needed to compare devices and refine procedural techniques.

Keywords: lumbar spinal stenosis, stenosis, interspinous fusion device, lumbar spinal fusion, adjacent segment disease, interspinous fixation device, minimally invasive spine, posterior lateral arthrodesis

Introduction

Lumbar spinal stenosis (LSS) is a common degenerative condition of the spine associated with significant functional limitations. Its prevalence is approximately 11% of the general population[1,2] and close to 50% in those over the age of 60,[3,4] although not all cases are symptomatic. LSS can be classified as congenital or acquired due to degenerative changes or surgery. Common causes of acquired LSS include disc herniation, degenerative disc disease, hypertrophic facet changes, osteophytes and ligamentum flavum hypertrophy. With progression of the disease, the patient could develop bladder/bowel incontinence, numbness and weakness in the lower extremities as well as gait instability. LSS is considered a clinical syndrome of buttock or lower extremity pain, which may occur with or without back pain. It is typically caused by a reduction of the space available for the neurovascular components centrally, at the lateral recess, and/or at the intervertebral foramina leading to the symptoms associated with the condition.[5] The intermittent compression of neurovascular structures leads to symptoms associated with neurogenic claudication (NC). Classic features of

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LSS on physical exams include forward flexion of the spine on standing and ambulation, limited range of motion, bilateral lower extremity weakness, decreased deep tendon reflexes and positive straight leg raise test. LSS is diagnosed by CT scan or MRI, with the latter being the gold standard.

Diagnostic technology and aging of the population have led to an increase in the diagnosis of LSS. LSS also accounts for the fastest growth of lumbar surgery above 65 years of age in the United States. These surgical procedures have risks and lead to significant costs, complications, re-hospitalizations and, often times, poor outcomes.[6] In 2022, a group of experts from the American Society of Pain and Neuroscience (ASPN) published best practices for minimally invasive lumbar spinal stenosis treatment (MIST 2.0) in order to provide guidance in the use of new emerging techniques.[2] Nonetheless, there is still a surprising lack of clarity and consensus regarding the most effective management strategies due to the constant evolution of the techniques.

Several conservative treatment options are currently available for the treatment of LSS with NC including pharmacologic treatment with nonsteroidal anti-inflammatory drugs, opioid analgesics, and neuropathic agents, as well as physical therapy, exercise, spinal manipulation, and lumbar epidural steroid injections. These treatment options have limited efficacy due to the mechanical and compressive nature of LSS. Traditional direct open lumbar decompression (DOLD) has been the standard of care for patients with refractory pain secondary to LSS after failed conservative treatment or severe symptoms. Direct open surgery is defined as a procedure requiring the surgeon to create a larger incision and operate utilizing traditional instrumentation as compared to a percutaneous or minimally invasive approach.

To fill the treatment gap in this patient population, several minimally invasive options have become available in the past decade. Procedures such as percutaneous image-guided lumbar decompression (PILD), interspinous spacers (ISS), and interspinous fixation devices (ISFD) have gained popularity for patients with moderate LSS and no spinal instability. PILD involves a targeted, minimally invasive removal of hypertrophic ligamentum flavum and bony overgrowth under fluoroscopic or CT guidance, aiming to increase the canal and foraminal space without disrupting the bony anatomy or requiring implants. ISS are implanted between adjacent spinous processes to maintain distraction, limiting lumbar extension that exacerbates neural compression; however, ISS primarily offer symptom relief by indirect decompression without rigid stabilization, which may allow continued micro-motion at the treated segment. ISFD, in contrast, combine distraction with segmental stabilization by rigidly fixing the spinous processes, thereby restricting flexion, extension, and rotational movements. This mechanical stability can help unload facet joints, reduce abnormal motion, and potentially slow disease progression. Unlike ISS, ISFDs may facilitate earlier mobilization and reduced risk of implant migration or failure. Collectively, these approaches offer varying degrees of invasiveness, biomechanical impact, and durability, providing tailored options based on patient pathology and surgeon preference.

Despite the growing adoption of ISFD for LSS, several important evidence gaps remain that limit comprehensive understanding of their long-term clinical utility. One major gap is the lack of robust data on long-term outcomes beyond short-term pain relief and functional improvement. While early studies consistently demonstrate significant reductions in pain scores and symptom improvement within the first few months post-procedure, evidence regarding durability of these effects over multiple years is scarce. This raises questions about the potential for symptom recurrence, implant longevity, and rates of reoperation or revision surgery. Additionally, the impact of ISFD on adjacent segment disease (ASD) has not been clearly elucidated.

Another critical area lacking consensus is the variability among device designs and their biomechanical implications. ISFDs vary widely in materials, fixation mechanisms, and implant geometry, which may influence stability, fusion rates, and complication profiles. Some devices incorporate rigid fixation with integrated bone graft chambers aimed at promoting arthrodesis, while others function more as dynamic stabilizers. The heterogeneity of these designs complicates direct comparisons across studies and limits the ability to generate generalized recommendations. Furthermore, differences in surgical technique, implant sizing, and patient-specific factors such as bone quality or spinal alignment add layers of complexity to outcome interpretation.

Lastly, comparative effectiveness data remains limited. Few head-to-head trials exist comparing ISFD to alternative treatments like ISS, traditional decompression, or instrumented fusion. Without such data, it is challenging to delineate optimal patient selection criteria, weigh risks versus benefits, and establish evidence-based treatment algorithms.

Addressing these gaps through well-designed prospective studies, longer follow-ups, and device-specific investigations is crucial to fully define the role of ISFD in managing LSS.

The purpose of this retrospective databased analysis was to further investigate the efficacy and safety of ISFD in patients suffering from LSS in our center. This study examines if the previously published trials are consistent with outcomes in a real-world cohort of patients in interventional pain practices following ISFD.

Methods

WCG Western IRB approval was obtained. This retrospective study had no patient-identifying information for analysis, was of low risk to patients, and patient data confidentiality complied with the Declaration of Helsinki. The study was exempted under 45 CFR § 46.104(d), because the research involves the use of identifiable private information/biospecimens; and information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily by ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.

Data were retrospectively analyzed from January 2023 to October 2024 on patients that had undergone percutaneous ISFD by experienced interventional physicians in a single center. Data was collected from electronic medical records and entered into an Excel sheet. Data included patient demographics, adverse events and pre- and post-procedure pain scores.

Patients considered for ISFD placement via the lateral transverse approach were carefully selected based on comprehensive clinical and radiographic parameters. The clinical criteria were the following: (a) presence of moderate LSS symptoms, such as neurogenic claudication, radicular leg pain, or lower back pain limiting walking distance or daily activities; (b) symptoms refractory to at least 3 to 6 months of conservative treatment, including physical therapy, medications, and/or epidural steroid injections; (c) absence of severe neurological deficits that would necessitate urgent decompression; (d) functional impairment significant enough to justify intervention but without indication for more invasive fusion surgery. Imaging inclusion criteria included: (a) axial MRI demonstrating facet joint gapping or effusions at the target level; (b) sagittal MRI, X-ray, or CT showing loss of posterior disc height and abnormal disc angulation at the involved segment; (c) flexion/extension X-rays revealing more than 3 mm of vertebral translation in the sagittal plane or greater than 15% of vertebral body width at the target level; (d) abnormal changes in segmental angulation on flexion/extension X-rays; (e) presence of degenerative spondylolisthesis Grade I at the involved level on sagittal imaging; (f) diagnostic imaging confirming central, lateral recess, or foraminal stenosis attributable to chronic degenerative pathology.

The statistical analysis was performed using descriptive statistics and paired t-tests for comparing pre- and post-procedure numerical rating scale (NRS) pain scores at 2-weeks, 1- and 3-month follow ups; the p-value was considered significant if ≤ 0.05. The analysis of variance (ANOVA) was conducted to examine the differences in pain scores across different time points. Each procedure was counted once, regardless of whether multiple levels had been treated during the same date of service. There were missing follow-ups at different durations, and the mean scores were adjusted accordingly to reflect only pain scores for patients with complete follow-ups.

Procedure Methods

The Minuteman® G5 Fusion Plate by Spinal Simplicity, LLC (Overland Park, Kansas) was used for all cases with lateral approach. (Figure 1) After the induction of general anesthesia, the patient was positioned prone on a Wilson frame with appropriate protective padding. The procedure area was prepped and draped in the usual sterile fashion. AP and lateral fluoroscopy were utilized throughout the entire procedure. When the lateral approach was utilized for insertion of the ISFD, skin marks were made on the lateral aspect of the back corresponding to the inferior edge of the spinous process at the target level, the superior edge of the inferior spinous process, and the corresponding facets. The skin and muscle were then infiltrated with 2% lidocaine and 0.5% bupivacaine with epinephrine at the surgical site. A skin incision was made on the lateral aspect of the patient's back corresponding with the level previously marked. Hemostasis was obtained at this point, as well as throughout the case using the Bovie® electrocautery. A guide wire was then inserted through the incision and into the target posterior interspace. Soft tissue dilators of gradually increasing size were then inserted over the guide wire, creating a pathway to the posterior interspace. A tissue retractor was then inserted over the dilators and brought into contact with the lateral aspect of the facet at this level. Through the tissue retractor, a bone rasp was inserted

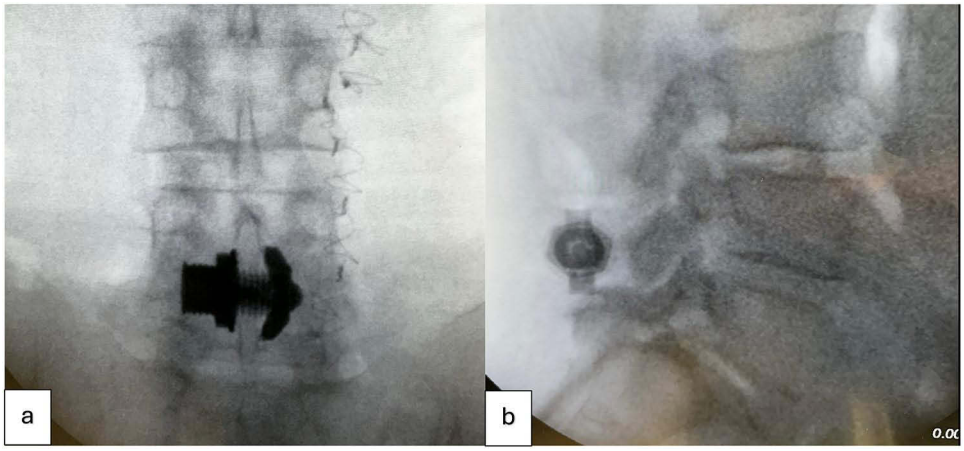

Figure 1 (**a**) AP fluoroscopic view of ISFD, lateral approach; (**b**) Lateral fluoroscopic view of ISFD, lateral approach.
Abbreviations: ISFD, interspinous fixation device; AP, anterior-posterior.

over the guide wire, to decorticate and reduce the hypertrophied facet joint allowing access to the full posterior interspace and further advancement of the tissue retractor to posterior midline. The graduated tap was then inserted over the guide wire under fluoroscopy and advanced into the posterior interspace. Once tactile feedback and resistance was achieved, indicating adequate decortication, the guidewire was removed. The sizing holes of the tap were visualized under fluoroscopy, and the appropriate hardware size was determined. The tap was removed, and the tissue retractor was left in place. The tap was examined to confirm decortication and removal of tissue was achieved. The appropriately sized insertion adapter was attached to the distal end of the hardware inserter. A posterior plate was attached to the inserter, filled with demineralized bone matrix, and then threaded into the target posterior interspace, with several rotations of the inserter, through the tissue retractor. After the fixed plate of the implant came into contact with the cortex of the lateral aspect of the interspinous-interlaminar junction, the extension plate of the implant was deployed on the contralateral side. The hardware was then tightened to a fixed position with the spikes of both plates embedded into the cortex of the bone. The inserter was then removed, and the tissue retractor was left in place. Antibiotic irrigation was used to irrigate the site through the dilator. The incision was then closed using a combination of deep and superficial wound closure using 0 Vicryl suture. After this, the skin was closed with 4–0 Monocryl subcuticular running suture. Pressure dressings and Steri-Strips^{TM} were applied to the sites. The patients were contacted within 24hrs to inquire about their condition.

Results

This retrospective study included data from a total of 45 patients (26 males, 19 females) with diagnosis of LSS that received ISFD at our center between January 2023 and October 2024. (Figure 2) There was only one complication reported on a procedure day but without any clinical significance. A spinous process fracture occurred upon tightening of the fixation hardware due to poor bone quality. No further complications were reported in the immediate post-procedure period or during the 3-month follow-up visits.

Efficacy data included pre-procedure, 2-week, 1-month and 3-month follow-up NRS pain scores when available. The average age was 78.3 ± 5.3, 79 and 77.5 for men and female, respectively. All patients carried the diagnosis of lumbar central spinal stenosis with or without NC, with an average pain duration of 7.8 ± 6.0 years and the most common pain location being low back with bilateral radicular symptoms, (n = 10, 22%). Subjects who received ISFD lateral approach were included in the analysis with a total of 47 levels treated and 2 patients receiving multilevel procedures 90 days apart with a maximum of 2 levels. All patients received ISFD using the lateral approach. No ISSs were included in the analysis, however, 3 patients who had been previously implanted with ISS were exchanged with ISFD. The most common level for ISFD implant was L4-5 (n = 36, 77%), followed by L3-4 (n = 7, 15%), L2-3 (n = 3, 6%) and L5-S1 (n = 1, 2%). Seventy-seven percent (n = 36) of patients were receiving medications during their evaluation and treatment period, including opioids (n = 22), anticonvulsants (n = 18), muscle relaxants (n = 12), NSAIDS (n = 11), other adjuvants

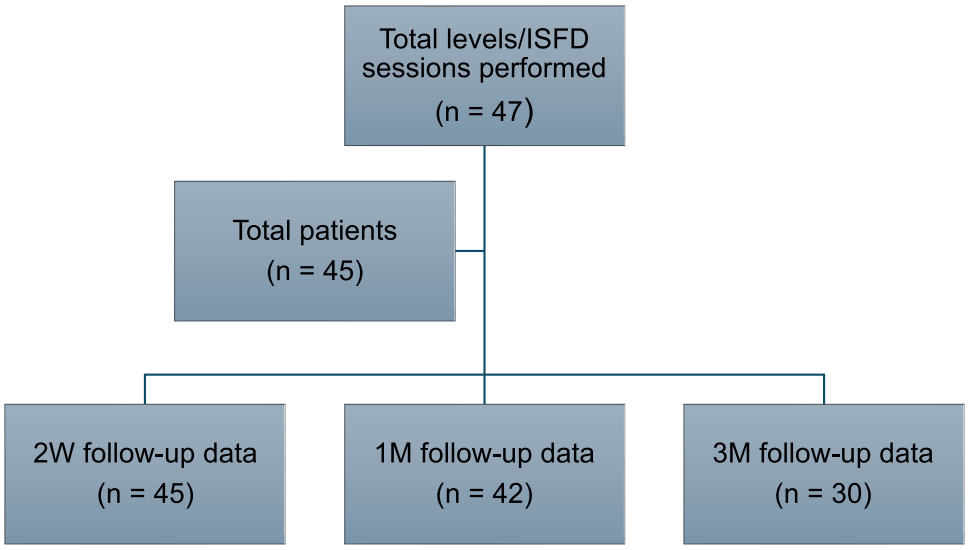

Figure 2 Flowchart for retrospective data review.
Abbreviations: ISFD, interspinous fixation device; W, week; M, month.

(n = 6) and simple analgesics (n = 2). Eighty-six percent (n = 19) of the patients on opioids had MME < 50, with an average of 26, and 13.6% (n = 3) with MME between 50 and 100, average of 67 (Table 1).

The efficacy of ISFD was measured with pre and post procedure NRS pain scores (Figure 3). The mean NRS pain score was 7.5 (n = 47), 3.5 (n = 45), 3 (n = 42) and 3.5 (n = 30) at pre-procedure, 2-week, 1-month and 3-month follow-up (P < 0.001), respectively. Data was missing at the 1- and 3-month follow-up visits. At the 2-week follow up, 34%, 16%, 32% and 18% of patients (n = 45) had NRS pain score reduction between 76–100%, 51–75%, 26–50% and 0–25% (P ≤ 0.001), respectively. At that time interval, 2 patients experienced no pain relief, and 1 patient was lost to follow up. At the 1-month follow-up visit, 40.4%, 17%, 30% and 10.6% of patients (n = 42) had NRS pain score reduction between

Table 1 Patient Characteristics and Procedures Conditions

Characteristics	All (n = 45)	ISFD (n = 47)
Gender		
Male	26 (58)	
Female	19 (42)	
Age, years	78.3 ± 5.3	
Male	79	
Female	77.5	
Diagnosis – LSS		
Mild		9 (19.2)
Mild to moderate		3 (6.4)
Moderate		11 (23.4)
Moderate to Severe		9 (19.2)

(*Continued*)

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Table 1 (Continued).

Characteristics	All (n = 45)	ISFD (n = 47)
Severe		15 (32)
Pain duration, years	7.8 ± 6.0	
≥0.5 to <1	9 (20)	
≥1 to 5	24 (53.3)	
6 to 10	3 (6.7)	
10+	9 (20)	
Pain location		
Low back	10 (22.2)	
Low back w BH	10 (22.2)	
Low back w LH	2 (4.3)	
Low back w RH	3 (6.7)	
Low back w BLE	10 (22.2)	
Low back w LLE	6 (13.4)	
Low back w RLE	4 (9)	
Medications	36	
Simple analgesics	2 (5)	
NSAIDS	11 (27.5)	
Anticonvulsants	18 (55)	
Muscle Relaxant	12 (30)	
Other adjuvants analgesics	6 (17.5)	
Opioids	22 (60)	
MME < 50	19 (86)	
MME 50-100	3 (13.6)	
ISFD level		
L2-3		3 (6)
L3-4		7 (15)
L4-5		36 (77)
L5-S1		1 (2)
ISFD approach		
Lateral		47 (100)

Abbreviations: NSAIDS, nonsteroidal anti-inflammatory drugs; MME, morphine milligram equivalents; LSS, lumbar spinal stenosis; BH, bilateral hips; LH, left hip; RH, right hip; BLE, bilateral lower extremities; LLE, left lower extremity; RLE, right lower extremity; ISFD, interspinous fixation device.

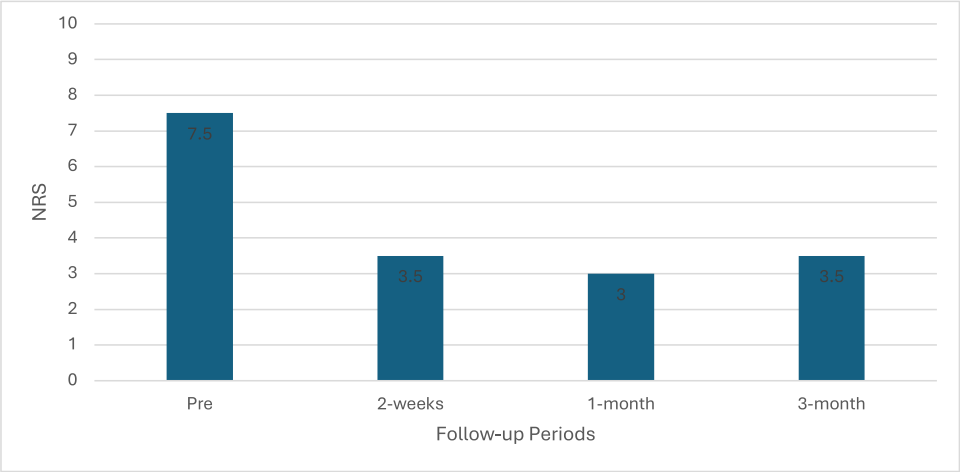

Figure 3 Mean NRS at pre-procedure and follow-up periods.
Abbreviation: NRS, numerical rating scale.

76–100%, 51–75%, 26–50% and 0–25% ($P \leq 0.001$), respectively. One patient had no pain relief at this follow up visit. At the 3-month follow-up visit, 73% of patients (n = 30) had NRS pain score reduction above 50%, ($P \leq 0.001$). Four patients reported no pain relief at 3-month follow-up visit.

Discussion

Interspinous process devices are minimally invasive implants that were introduced in the field of spine surgery as an alternative to traditional instrumentation. ISFD is a valuable tool in the treatment of moderate LSS and degenerative disc disease which has decreased morbidity and significant efficacy. These devices have evolved and can be divided in two categories: indirect decompression with and without rigid. Both devices are implanted in a similar way, with either posterior or lateral approach, to open the space between interspinous processes and indirectly decompress the spinal canal. Regardless of the paucity of existing scientific literature for ISFD, there is an increased interest in the development and utilization of this type of minimally invasive technique to avoid the need for DOLD. A systematic literature review conducted by Faulkner et al,[7] compared ISFD to traditional methods of posterior pedicle screw fixation (PSF). It was concluded that ISFD that is accompanied by interbody cage (IBC) is considered a credible and an effective minimally invasive option for the treatment of mild to moderate LSS and stable low-grade spondylolisthesis when compared to the traditional posterior spinal instrumentation.

ASD is a known complication after PSF that has been well documented in the literature and is very present in clinical practice. The use of ISFD has been studied as a potential solution to decrease the incidence of ASD in this patient population. A retrospective study published by Bae et al[8] compared the clinical and radiographic outcomes of an ISFD with those of extended PSF for symptomatic ASD. Data from 109 patients was included, ISFD (n = 48) and PSF (n = 61). The mean incision length, operative time, blood loss, and length of hospital stay were significantly lower in the ISFD group ($P < 0.001$). Postoperative back and leg pain were relieved in both groups ($P < 0.001$). The mean preoperative VAS scores were 8.3 ± 1.3 and 8.5 ± 1.1 in the ISFD and PSF groups, respectively. After 36 months, the VAS decreased to 2.8 ± 1.1 and 2.7 ± 1.2 for the ISFD and PSF groups, respectively ($P < 0.001$). At 36 months, 10 of the 56 patients (17.9%) in the PSF group had developed additional radiographic ASD compared with 2 of 44 patients (4.5%) in the ISFD group. The ISFD technique resulted in a lower ASD incidence compare with the PSF, however, this did not reach statistical significance.[8]

Despite the current dispute on different placement approaches, lateral versus posterior, ISFD was developed to provide a rigid fixation between spinous processes limiting the flexion motion allowed by ISS and to avoid revision surgery. Besides the indirect decompression of the spinal canal, ISFD limits posterior process movement with the use of a graft component. Currently, multiple options exist on the market for ISFD that are placed using the posterior approach.

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There is only a paucity of literature comparing these devices. A study conducted by Chin et al[9] evaluated fixation strengths by bench testing static disassembly and pullout strength of two dissimilar ISFD designs and locking mechanisms, dual-locking symmetrically versus single-locking asymmetric ISFD plate design. The dual-locking ISFD experienced 94.81% higher resistance to pullout compared to the single-locking ISFD in static pullout testing ($P < 0.05$), due to its notably larger footprint area of 69.8%. Gross failure for both ISFD implant designs occurred at a foam block-block interface. In static disassembly testing, dual-locking ISFD required 60.7% higher force over single-locking asymmetric ISFD.[9]

Falowski et al[10] conducted a multicenter retrospective analysis to evaluate safety and efficacy of a novel minimally invasive lumbar ISFD. Thirty-two patients with lumbar degenerative disc disease and secondary LSS treated with ISFD were included in the review. The analysis included changes in VAS and post-procedural serious adverse effects. There was a 67% reduction in VAS, 8.1 to 2.65, from the pre-operative to the post-operative period, respectively. No adverse events, reoperation or device explants were reported within the first 90 days post-procedure. Even though this study had many limitations, it demonstrated the efficacy and safety of an ISFD performed in an outpatient setting.[10]

A single-arm, multicenter, prospective, open-label clinical trial by the same group explored ISFD as a standalone posterior approach to treat lumbar degenerative disc disease in the setting of LSS with NC, determine safety and efficacy; and report adverse events. This is the 3-month interim analysis of the first 20% of enrolled patients, however they are expected to follow up at 12 months and out to 5 years. Patients were enrolled in the study, if they had at least 1–2 symptomatic lumbar degenerative disc disease at adjacent levels from T1 through S1, with or without grade 1 spondylolisthesis, MRI findings with at least mild-to-moderate spinal stenosis at the index level. At the time of this publication, there were 54 active and 32 implanted patients. At 3-months, 82% of patients reported improvement from the procedure. Sixty-five percent of patients demonstrated clinical meaningful improvement in their pain and functional status, as defined by the VAS, ODI, and ZCQ. There was a mean improvement from baseline in PROMIS 29 with statistical significance for all but anxiety and depression, and only one adverse event with no complications identified.[11]

More recently, Skoblar et al[12] evaluated radiographic outcomes in patients who received minimally invasive ISFD. Patients from a single United States private practice (N = 110) who received ISFD in 2020 were invited to receive a follow up CT Scan for assessment of the arthrodesis post ISFD (mean 459 days, 177–652). A total of 69 levels were assessed in 43 patients with 92.8% of the levels considered fused. A small number of spontaneously healed spinous process fractures (5.8%) were identified on imaging; however, there were no instances of ISFD mechanical failure or reoperation.[12] In a prospective, multicenter study, Pencle et al[13] explored the use of ISFD to increase foraminal height in patients with severe disc collapse secondary to advanced degenerative disc disease. The study included patients with more than 50% decrease in foraminal volume, treated between December 2019 and December 2020, with a follow-up visit in July 2021. All the patients had an increase in foraminal height, maintained on follow up and improvement in VAS and ODI. There was no evidence of spinous process fractures, complication, device failure, or revisions. However, the group concluded that an increase in foraminal height may not be as significant for patients with less severe disc degeneration.[13]

Spinal stenosis patients treated with midline decompression and ISFD, used as a stand-alone treatment for inter-spinous-interlaminar fixation, at L4-5 and L5-S1, showed improved outcome scores and low complication and revision rates at five years and were comparable to historical open laminectomy data. A prospective comparative cohort study led by Chin et al[14] evaluated the outcomes of an ISFD used as a stand-alone treatment for LSS at L5-S1 and L4-5 compared to historical data on DOLD. The study included 100 patients treated with midline decompression using ISFD at L4-5, L5-S1 with a 5-year follow up. Fifty-five and 45 patients underwent ISFD at L4-5 and L5-S1, respectively. In the L4-5 cohort, mean VAS and ODI scores improved by 80% and 66% ($P < 0.001$) respectively; whereas, for the L5-S1 group, the mean VAS pain score that decreased by 75% and ODI improved by 63% ($P < 0.001$). Comparable DOLD data showed decreases in VAS and ODI scores by 51% and 62% ($P < 0.05$). For ISFD, there was a total of one L4-5 revision (1.8%) and two L5-S1 revisions (4.4%). The reoperation rate for DOLD at five to ten years varied up to 24%.[14] An earlier retrospective study conducted by Chin et al[15] tried to demonstrate the long-term outcomes (5-year follow-up) of ISFD at L4-5 for degenerative spinal stenosis. A total of 122 surgical cases from September 2011 to October 2016 were reviewed. Fifty-six patients had ISFD at L4-5. Two-year VAS and ODI showed significant improvement from 8.1 ± 1.2 to

1.5 ± 1.1 and 42.9 ± 14.3 to 14.8 ± 5.1. There was 1 revision case with removal of ISFD and open hemilaminectomy decompression.[15]

Many pain physicians advocate for the minimally invasive lateral ISFD approach since it avoids disruption of the supraspinous ligament and may decrease the recovery time. Several studies have compared technique with the traditional lumbar decompression method. A cadaveric, vitrobiomechanical study conducted by Hedman et al[16] investigated segmental multidirectional stability and maintenance of foraminal distraction of a laterally placed ISFD compared to commonly used pedicle and facet screws posterior fixation instrumentation when combined with lumbar IBC. Six human cadaver lumbar spine specimens were subjected to nondestructive quasistatic loading in the following states: intact; ISFD alone and with lateral IBC; lateral lumbar IBC with bilateral pedicle screws; lateral lumbar IBC with unilateral pedicle screws; and lateral lumbar IBC with facet screws. All implant configurations significantly restricted flexion-extension motion compared with intact ($p < 0.05$). No significant differences were found in flexion-extension when comparing the different posterior implants combined with lateral IBC. All ISFD provided comparable neuroforaminal distraction and maintained distraction during flexion and extension. The combination of lateral lumbar ISFD with IBC effectively stabilizes the spine and maintained neuroforaminal distraction comparable to pedicle or facet screws.[16]

A multi-center, prospective, randomized controlled trial conducted by Baranidharan et al[17] compared the efficacy of a minimally invasive, laterally implanted ISFD to DOLD in treating LSS. A total of 48 participants were randomly assigned to ISFD or DOLD. Mean reduction of ODI from baseline levels was between 35% and 56% for ISFD ($p < 0.002$), and 49% to 55% for DOLD ($p < 0.001$) for all follow-up time points. Mean reduction of ISFD group leg pain was between 57% and 78% for all time points ($p < 0.001$), with 72% to 94% of participants having at least 30% reduction of leg pain from 8-weeks through 24-months. Walking distance for the ISFD group increased from 66% to 94% and sitting-to-standing repetitions increased from 44% to 64% for all follow-up time points. An 89% fusion rate was assessed in a subset of ISFD participants. There was only one healed and non-symptomatic spinous process fracture observed within 24 months. The study demonstrated successful two-year safety and clinical outcomes for the ISFD with significant surgery-related advantages compared to DOLD.[17]

In this article, we discussed the results of 45 patients who underwent ISFD procedures in our outpatient clinic. Only one procedure-related complication was reported while attempting ISFD at L5-S1. This adverse event did not have any clinical relevance. From the collected data, we concluded that at the 3-month follow-up visit, 73% of patients ($n = 30$) had NRS pain score reduction above 50%, ($P \leq 0.001$) which is consistent with previous prospective studies. Some follow up data was missing past the two-week follow-up appointment. We plan to collect data for up to 12-months post procedure. Patients treated with ISFD oftentimes improve in several weeks post treatment and do not return to clinic unless they develop pain in other areas or different spinal pathology. Only 4 patients, had no pain relief at their 3-month follow-up visit. This shows that ISFD is a safe and effective therapy for patients with LSS that required a minimally invasive procedure.

The study has several limitations as this was a retrospective analysis with some missing follow-up pain scores and a short follow-up period. As any other retrospective study, it is not possible to adjust for all confounders. Further long-term prospective studies are needed to compare the different techniques and devices available.

Conclusion

The use of ISFD for patients suffering from LSS is a well-established interventional procedure that have shown significant pain reduction and proven to be safe when compared to DOLD. Even though there is a paucity of data regarding these procedures and conflicting opinions between interventional pain management physicians and spine surgeons, several studies and real world data have demonstrated its efficacy. In terms of safety, it is always important to identify patient-specific eligibility for these procedures to improve outcomes and minimize adverse events. The results of this single center, retrospective, observational study are consistent with the results of larger prospective studies.

Data Sharing Statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

Ethical Approval Statement

WCG Western IRB approval was obtained.

Patient Consent Statement

WCG approval exempts the need for informed consent under 45 CFR § 46.104(d).

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

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