*Investigative Study*

# THE APPLICATION OF INTERSPINOUS SPACERS IN CONJUNCTION WITH SPINOPLASTY TREATMENT: INSIGHTS FROM OUR EXPERIENCE

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**ABSTRACT**

Lumbar spinal canal stenosis and foraminal stenosis of the lumbar spine are widespread degenerative conditions that may lead to neurogenic claudication, significantly affecting patients' functionality and overall quality of life. Recently, percutaneous interspinous devices (PIDs) have surfaced as a minimally invasive substitute treatment option. This study outlines a twenty-year experience at a singular center with PIDs and evaluates the adjunctive use of spinous process augmentation (spinoplasty) to enhance clinical outcomes. The cases included were collected up to 2023. A retrospective cohort study was executed involving 900 consecutive patients who sought treatment at a specialized spine clinic, with 788 ultimately undergoing intervention. Inclusion criteria encompassed substantial stenosis, failure of conservative management approaches, and electromyographic verification. Within this cohort, 288 individuals received a PID alone, while 500 underwent concurrent polymethyl methacrylate (PMMA) augmentation of the adjoining spinous processes. Follow-up evaluations were conducted at 3 and 12 months utilizing the Zurich Claudication Questionnaire (ZCQ) and the Oswestry Disability Index (ODI). Results: both groups demonstrated considerable improvements in ZCQ scores (from 3.2 to 1.3) and ODI metrics (from 32 to 21), in addition to high levels of patient satisfaction (mean score of 1.7). The incidence of symptom recurrence due to complications was significantly lower in the cohort receiving spinous process augmentation compared to the group treated exclusively with PIDs (<1% vs 10,76%). The results of this investigation underscore the effectiveness of percutaneous interspinous devices in the management of lumbar spinal stenosis. Furthermore, the findings indicate that the combination of spinous process augmentation with PID treatment reduces the likelihood of symptom recurrence.

**KEYWORDS**: *spine, lumbar spinal canal stenosis, LSCS, lumbar foraminal stenosis, LSFS, neurogenic claudication, spinous process augmentation, spinoplasty*

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## INTRODUCTION

Lumbar spinal canal stenosis (LSCS) and lumbar foraminal stenosis (LSFS) are degenerative disorders associated with aging, capable of inducing neurogenic claudication that severely compromises the functional status of afflicted patients (1). These conditions are prevalent, with estimates suggesting that as many as 47% of individuals over the age of 60 may experience some form of symptoms. Given the aging demographic, it is anticipated that this issue will intensify in forthcoming years (1).

The primary driver of these diseases involves constriction of the central spinal canal or neural foramina in the lumbar region. Numerous concurrent pathologies frequently exacerbate this narrowing, such as disc herniations, facet joint arthropathy, and thickening of the ligamentum flavum. Additionally, venous ischemia resulting from compression of blood vessels surrounding the spinal nerves has been documented (1). Such narrowing is often aggravated by trunk extension, which amplifies the natural lordosis of the lumbar spine, while flexion tends to alleviate the condition by promoting a more kyphotic posture. This pathophysiological mechanism is at the core of the classic symptomatology associated with lumbar spinal stenosis (LSS): progressive pain in the back, buttocks, and lower extremities, which intensifies with ambulation (typically when the individual is in an extended posture) and is relieved through sitting or lying down (in a flexed position). Dynamic MRI studies have visually substantiated these alterations in the spinal canal (1-4).

Initial management is commonly conservative, incorporating physical therapy, analgesics, and local interventions like epidural or foraminal injections of anesthetics and corticosteroids. If conservative strategies fail, standard surgical interventions for LSS involve decompression through either laminectomy or laminotomy, with or without posterior fusion. Interspinous spacers or percutaneous interspinous devices (PIDs) have been developed as a less invasive treatment alternative for this condition. These devices are intended for placement between adjacent spinous processes, utilizing minimally invasive surgical techniques or percutaneous guidance by imaging (5, 6). They function alongside intact interspinous ligaments and paravertebral muscles to prevent excessive lordosis of the spine, mimicking the way patients alleviate their symptoms through forced flexion. Evidence supports their superiority over conservative treatment methods, as well as their non-inferiority compared to traditional decompression surgeries. Furthermore, there is documentation of symptomatic relief and improvement in conditions associated with LSCS and LSFS (7). However, a significant drawback in comparison to conventional surgical options is the incidence of device malfunction, symptomatic recurrence, and the necessity for subsequent surgeries, often connected to issues like bony remodeling or fractures of spinous processes (8-10).

Osteoporosis contributes to both the fragility and height reduction of vertebral bodies and spinous processes (11-12). The positioning of a PID increases the load borne by the spinous processes, rendering them susceptible to fractures (11-15). To mitigate this risk, augmenting the spinous processes using PMMA is employed to enhance the structural integrity of the underlying bone. Preliminary clinical and cadaveric studies have suggested that prophylactic spinoplasty can diminish the failure rate of PIDs. This investigation aims to retrospectively assess nearly twenty years of experience with PIDs and to contrast the device failure rates between patients who underwent preventive spinoplasty and those who received PIDs alone.

## PATIENTS AND METHODS

*Patient selection*

A retrospective review of cases was performed for patients between January 2009 and December 2023. Nine hundred consecutive patients presenting chronic neurogenic claudication, with or without radicular symptoms, were assessed at a specialized spine facility for the potential of percutaneous interventions. Institutional review board approval was secured for data collection and publication.

*Baseline assessment*

Pain severity was assessed using the Zurich Claudication Questionnaire (ZCQ), well-regarded for its accuracy in gauging LSS (16). Disability levels were quantified through the Oswestry Disability Index (ODI) (17). All participants underwent lumbar MRI using a 1.5 T scanner (Intera, Philips, Erlagen, Germany) in accordance with established protocols. Sagittal T1-weighted spin-echo, T2-weighted fast spin-echo, and T2-STIR sequences were obtained, with a 2-3 mm section thickness and a 0.3 mm intersection gap, in addition to axial T2-weighted fast spin-echo sequences. Assessment of LSS was conducted based on the qualitative grading system proposed by Schizas (18), which is considered

to reflect the clinical severity of the condition more accurately than traditional measurements, as it incorporates the actual morphology of the dural sac (Fig. 1) (19).

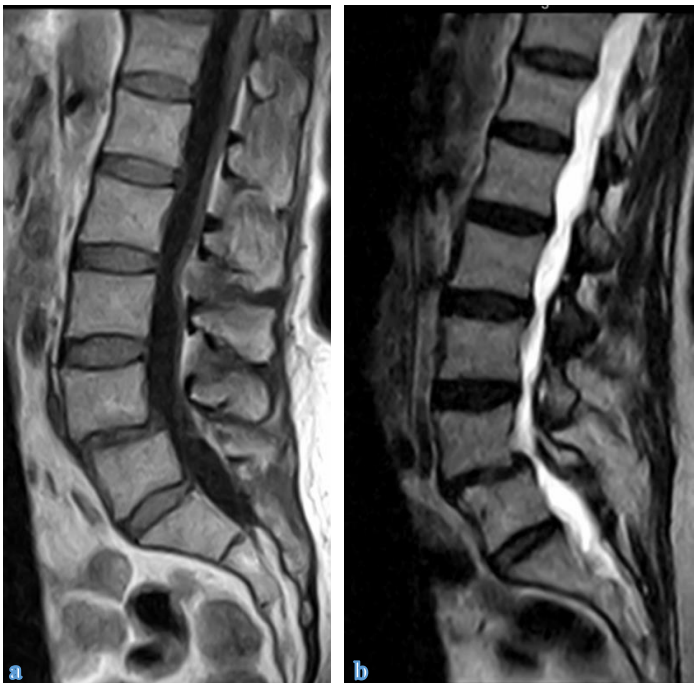


**Fig. 1**. *A): Preoperative sagittal MRI in supine position showing segmental canal stenosis L4-L5 in 1st-degree listhesis according to Meyerding; B): Preoperative sagittal MRI under load confirming Meyerding grade I listhesis of L4 compared to L5 with segmental canal stenosis.*

*Inclusion criteria*

Eligible patients were individuals with grade C or D stenosis or grade B who had not experienced improvement through conservative measures. These patients subsequently underwent a non-contrast CT scan of the lumbar spine (General Electric, Milwaukee, WI, USA) with a section thickness of 1.2 mm and underwent additional preoperative electromyography of the lower extremities to confirm at least moderate nerve conduction impairment.

*Exclusion criteria*

Patients presenting stenosis attributable to bony spurs, ossification of the ligamentum flavum, or facet joint hypertrophy were excluded from the study. Other exclusion factors included severe contact or subluxation of adjacent spinous processes, obesity (with a BMI >30 kg/m²), spondylolysis, and prior surgeries on the lumbar spine.

*Treatment*

Six-hundred-eighty-eight patients qualified for treatment based on predefined criteria and provided standard informed consent. A combined CT/fluoroscopy-guided approach was applied per local institutional protocols. Patients were positioned prone, and mild intravenous sedation (fentanyl 1-3 μg/kg/hour) was utilized. A preprocedural CT scan validated the targeted anatomical level, followed by the infiltration of 5 to 10 mL of 2% lidocaine into the deep paraspinal musculature and adjacent periarticular region for local anesthesia. A small incision (5-10 mm) was made to insert a 6 mm K-wire into the interspinous space via a posterolateral approach, subsequently confirmed with low-dose CT scans. Incremental dilatation of the soft tissues was performed, maintaining a 12 mm dilator in place. Using fluoroscopic guidance, various-sized probes were introduced into the interspinous space to release the interspinous ligament and determine the ideal size for the PID. Once sufficient measurements were obtained, the selected PID was deployed within the interspinous space. The wire, dilator, and holder were removed, and the incision was sutured. A follow-up CT scan was conducted postoperatively to ensure correct PID placement and to evaluate for any immediate complications (Fig. 2).

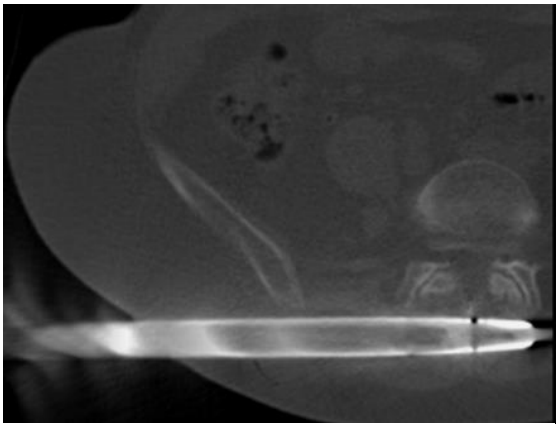

**Fig. 2**. *Intraoperative control CT scan.*

Three types of PIDs were utilized: the In-space (Depuy Synthes, MA, USA), a PEEK-covered spacer with metallic wings; the Helifix (ATEC Spine, CA, USA), a fully PEEK spiral body; and the Lobster (Techlamed, Italy), a titanium device covered in PEEK. The sizes of PIDs ranged from 8 to 14 mm. Starting in January 2011, prophylactic augmentation of the posterior arch with PMMA was performed before all PID implantations based on promising outcomes reported in earlier studies (Fig. 3 A-C). This procedure was conducted in a similar CT-guided manner, with a 13 G needle inserted into the superior and inferior spinous processes through either a midline sagittal or parasagittal approach. A volume of 1-2.5 mL of PMMA was injected into the spinous processes. The PID was placed immediately afterward or within a month depending on the clinician's preference to optimize patient

comfort or to allow for some natural reactive sclerosis to develop as desired (Fig. 4 A-C).

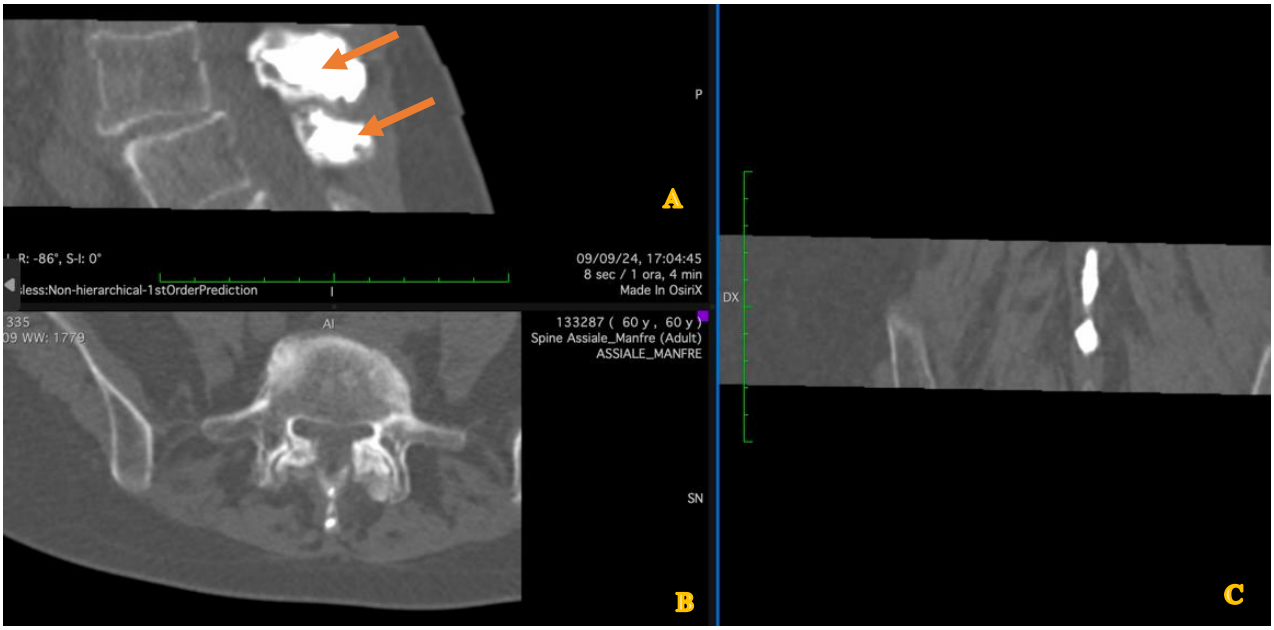


**Fig 3**. ***A-C)****: PMMA injection control* ***(arrows)****.*

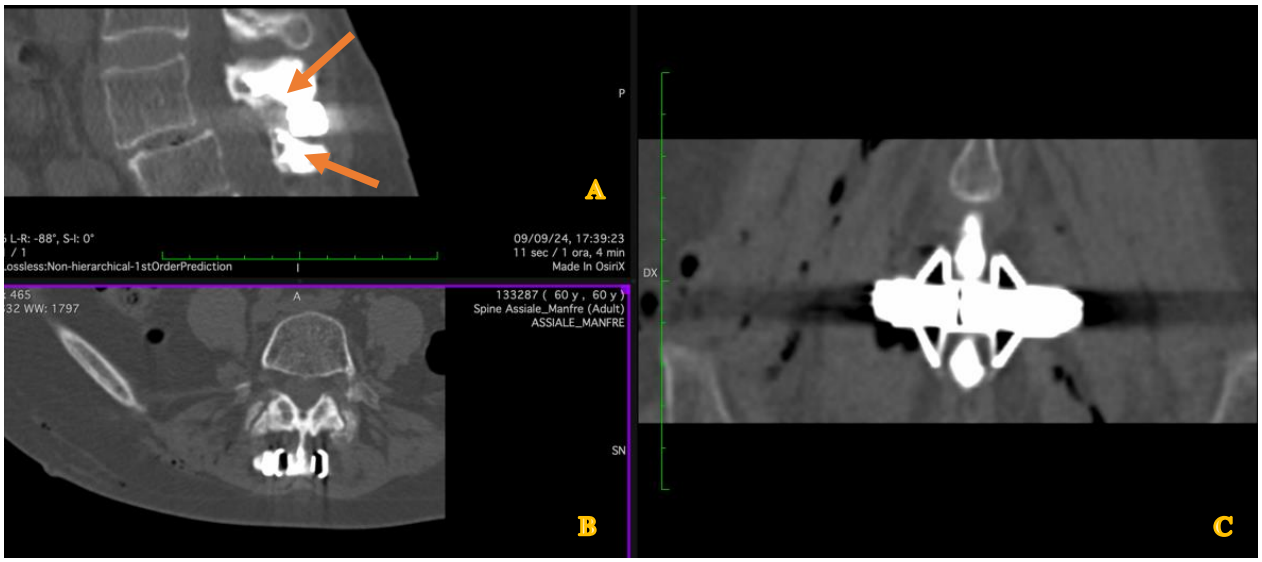


**Fig 4**. ***A-C)****: PMMA injection control* ***(arrows)****.*

*Outcomes*

Clinically meaningful improvement was defined as achieving at least a 0.5-point increase in ZCQ domains, a ZCQ patient satisfaction score of ≤2.5, and a minimum 10-point decrease in ODI. Follow-up assessments were performed at 3 and 12 months. Demographics and baseline characteristics of the patient population are summarized in Table I. The STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines were adhered to as much as possible during the reporting of this observational study.

**Table I**. *Demographics and baseline characteristics of the patient population*.

| Characteristics | Total | Group A n = 288 | Group B n = 500 |
|---|---|---|---|
| Median age and range (years) | 72 (56-82) | 72 (56-82) | 72 (59-83) |
| Gender ratio (male: female) | 1.31 | 1.30 | 1.31 |
| Mean baseline ZCQ: Symptom score ±SD | 3.2 | 3.2±0.4 | 3.2±0.6 |
| Mean baseline ZCQ: Function score ±SD | 2.2 | 2.2±0.3 | 2.1±0.4 |
| Mean baseline ODI score ±SD | 32 | 31±3.6 | 32±4.1 |
| Schizas grading | | | |
| B | 57 | 20 | 37 |
| C | 264 | 88 | 176 |
| D | 467 | 180 | 287 |
| Level treated | | | |
| L2/3 | 16 | 7 | 9 |
| L3/4 | 35 | 15 | 20 |
| L4/5 | 639 | 237 | 392 |
| L5/S1 | 98 | 39 | 59 |

## RESULTS

Of the 788 patients treated, 288 were exclusively managed with PIDs (group A), while 500 received both spinoplasty and PID (group B). The majority of patients in both groups presented with Schizas grade D LSS, indicative of advanced disease. All individuals reported functional impairment and symptomatology, with the most common surgical level being L4/5.

The procedure was classified as technically successful if the spacer was accurately positioned, confirmed by radiological imaging demonstrating enlargement of the spinal canal and local foramina, as well as a reduction in ligamentum flavum hypertrophy. In some patients with grade I spondylolisthesis, improvements in spinal alignment were also noted, although this was not a primary objective. At the 3-month follow-up, the findings illustrated a significant reduction in the ZCQ symptom score (from 3.2 to 1.3) and the function score (from 2.2 to 1.4), with an average patient satisfaction score of 1.7, and the ODI decreased from 32 to 21. These results were consistent across both patient cohorts, with minimal changes observed at the 12-month follow-up. No patients were lost to follow-up.

*Complications*

Within group A, 31 patients (10,76%) encountered a return of their original symptoms following initial improvement. Repeat CT scans indicated either fracture of the spinous processes or bony remodeling encircling the PID, resulting in a recurrence of original LSS symptoms. Fifteen of these patients chose to undergo another PID procedure with concurrent spinoplasty, of which twelve achieved complete symptom resolution and remained pain-free at the 12-month mark. The other three continued experiencing persistent symptoms and subsequently underwent traditional open-surgical decompression and posterior fusion.

In group B, one patient suffered a spinous process fracture necessitating surgical posterior decompression. Furthermore, one other patient experienced device migration, requiring surgical removal and re-implantation of a new device. This incident represented the only major device-related adverse event reported in either group. No other patients in group B reported a recurrence of symptoms at the 12-month evaluation. A Chi-square statistical analysis revealed a significant difference ($p<0.05$) in the occurrence of complications between the two groups. Despite the higher complication rate observed in group A, the overall occurrence remained low, and the quantitative impact on outcome measures was minimal. No immediate complications post-procedure was noted in either group, and no patient required additional conservative management such as epidural injections or nerve blocks following the procedure.

## DISCUSSION

Lumbar spinal stenosis has been managed for years through open surgical decompression; however, it comes with inherent risks such as blood loss, general anesthesia complications, and prolonged recovery times—all of which are particularly relevant for an older patient demographic that carries additional anesthetic risks. Minimally invasive interspinous spacers have proven to be non-inferior in terms of patient outcomes, and they provide distinct benefits regarding operational duration and reduced blood loss (2-26). This extensive cohort study corroborates existing literature, highlighting improvements in patient symptoms and functionality following interspinous spacer insertion, thereby reinforcing the safety profile of PIDs, with no immediate post-procedural complications recorded (24). Nevertheless, the most consistently reported negative outcome associated with interspinous devices is the elevated rate of required reoperations, particularly when compared to decompression surgery (23-25). The current study demonstrates a 10,76% recurrence rate of symptoms specifically in the PID-only subgroup.

The theories surrounding PID failure emphasize the role of osseous remodeling surrounding the spacer over time. This encompasses a degree of bone resorption, encasement, and erosion, alongside spinous process fractures. Previous literature has indicated an overall spinous process fracture rate of approximately 2.4%. Furthermore, finite element analysis has indicated that the PID, which is designed to support the vertebral structures during flexion and extension, fails to bear load effectively during lateral flexion, thereby increasing pressure on the spinous process.

Prior investigations into the optimal use of combined vertebral body augmentation and interspinous spacers have been documented in scenarios involving both compression fractures and LSS. The potential biomechanical advantages of PMMA augmentation of spinous processes were first theoretically demonstrated in cadaveric studies. Subsequently, investigations have illustrated in smaller cohorts the efficacy of spinoplasty, revealing fewer spinous process fractures in the augmented subgroup compared to those who did not receive this preventative measure.

This study showcases, on a significantly larger scale, that prophylactic augmentation of the spinous processes can substantially decrease both the rates of symptom recurrence and the need for reoperations. Only two patients in the spinoplasty group experienced repeated symptoms, both relating to either a spinous process fracture or device migration, contrasting with the 31 (10,76%) in the PID-only cohort. Notably, these two procedures can be performed concurrently, requiring only a minimal quantity of PMMA. However, despite several advantages, there appears to be no enhanced symptom relief resulting from the addition of spinoplasty. Currently, no study has conducted a direct comparison between traditional decompression approaches and PID plus spinoplasty. Such a comparison demonstrating similar reoperation rates would effectively address one of the primary barriers to the incorporation of PIDs in practice (23-39).

A primary limitation of this investigation involves the non-randomized, sequential distribution of patients, contrasting two groups across different time spans rather than concurrently. While baseline clinical and demographic characteristics are shown to be similar, there are no assurances that systemic differences in selection, procedural techniques, devices, or operator experience did not impact the results over time. Additionally, the single-center design of the study restricts the generalizability of the findings. Finally, given that some of the devices utilized may not be available universally or may have been superseded by more advanced models, practitioners should take this into account, albeit comparable results are anticipated with predicate devices.

## CONCLUSIONS

This research highlights the safety and efficacy of percutaneously inserted interspinous spacers for managing LSS within the largest single cohort reported to date. Furthermore, it suggests that preventive PMMA augmentation of the spinous processes in the vicinity of the insertion point may lead to reduced rates of device failure and reoperation. Future direct comparisons between conventional decompression techniques and integrated PID plus spinoplasty will offer greater clarity on the optimal utilization of PIDs in the treatment of LSS.

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