Article

ASSESSING SPINOPLASTY IN RELATION TO SINGLE AND DOUBLE INTERSPINOUS SPACER APPLICATIONS: A STRATEGY FOR AUGMENTING POSTERIOR ARCH STABILITY AND PREVENTING SURGICAL FAILURE

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ABSTRACT

Lumbar spinal canal stenosis (LSCS) is among the most prevalent degenerative conditions in older individuals. Treatment failure can occur, typically associated with bone remodeling or fractures of the spinous processes. Polymethylmethacrylate (PMMA) augmentation of the posterior arch (spinoplasty, SP) has recently been suggested for cases of neoplastic involvement. This investigation assessed the effectiveness of SP as a preventive therapy prior to the placement of an interspinous spacer (IS). Additionally, we explored the possibility of addressing patients who had previously received IS implants that subsequently failed by introducing a second spacer at the same level alongside accessory SP. Between January 2009 and August 2021, 593 patients with LSCS were treated with CT-guided percutaneous IS implantation in our facility. Starting from January 2011, all patients diagnosed with osteoporosis underwent prophylactic SP before the spacer's insertion. Furthermore, in cases of re-stenosis attributed to bone remodeling and/or fractures, a second similar device was placed after strengthening the spinous processes with PMMA, aimed at reopening the stenotic spinal canal. Among patients who received prophylactic treatment before spacer placement, no re-stenosis was noted during the follow-up period of three to twelve months. Patients who underwent secondary spacer implantation at the same level following posterior arch augmentation once again reported alleviation of symptoms, with no further bone remodeling detected during follow-up evaluations. In conclusion, prophylactic SP prevents the failure of individual spacers due to bone remodeling/fractures and facilitates failure repair through the introduction of a second spacer at the same level.

KEYWORDS: *spine, lumbar canal stenosis, spacer, prophylaxis*

INTRODUCTION

Lumbar spinal canal stenosis (LSCS) ranks as one of the most common degenerative disorders in senior patients, typically causing neurogenic claudication, numbness, and weakness in the lower limbs, potentially resulting in paraparesis (1). Chronic radicular nerve ischemia, secondary to compression of the radicular veins associated with the spinal canal

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and/or foraminal stenosis, is often cited as the root cause of these symptoms, while distraction of the posterior arch frequently presents a solution to the condition, as supported by various biomechanical studies (2, 3). Although conventional surgical decompression is viewed as a definitive solution for LSCS, percutaneous interspinous spacers (IS) have recently emerged as a treatment option, promoting distraction of the spinous processes, alleviating the compression caused by interspinous ligaments, and mitigating the progressive syndrome while alleviating lower limb radiculopathy (4, 5). Furthermore, the indications for IS implantation have recently expanded to include lumbar discogenic pain, facet joint syndromes, disc herniation, and low-grade instability (6).

Unfortunately, approximately 7% to 13% of patients treated with IS report early recurrence of symptoms due to fractures and/or remodeling of the posterior laminae, often linked to localized bone tenderness (such as osteoporosis or excessive stress overload), which diminishes the distraction achieved previously, including in patients treated with innovative soft non-metallic polyetheretherketone (PEEK) devices (7). Vertebroplasty is widely recognized as the preferred technique for strengthening vertebral bone, and numerous applications beyond the vertebral bodies (e.g., sacral fractures and tumoral involvement of the posterior arch) have been suggested (8-17). This study investigated the potential of preventing bone remodeling of the laminae in osteoporotic patients slated for IS implants through pre-operative posterior arch augmentation [spinoplasty (SP)] using prophylactic CT-guided Polymethylmethacrylate (PMMA) injection into the posterior arch. Additionally, we considered treating patients who previously received traditional IS implants that later failed by performing localized SP and placing a second IS device anteriorly or posteriorly to the initial implant at the same level.

MATERIALS AND METHODS

Between January 2009 and August 2021, 593 patients with LSCS underwent CT-guided percutaneous IS implantation at our department. The ages of the patients varied from 56 to 82 years (mean age 73 years). Among them, 505 patients presented symptoms related to spinal canal stenosis (11 at L2/L3, 102 cases at L3/L4, and 379 at L4/L5, with 13 cases involving both L3/L4 and L4/L5 levels). At the same time, 88 exhibited severe localized foraminal stenosis (24 cases with unilateral, and 64 with bilateral stenosis) related to LSCS, as well as grade I spondylolisthesis (47 patients) with or without (41 patients) disc degeneration. All patients were subjected to clinical evaluations, and assessments of the quality of life and self-rated pain were conducted using a visual analog scale (VAS). The pre-operative average VAS score was 8.4.

Additionally, pre-operative EMG evaluation of the lower limbs and a lumbar CT-MR examination were conducted. We utilized two different types of PEEK-coated IS devices: one featuring a pair of metallic wings for encasing the spinous process (In-Space®, Synthes-DePuy, Switzerland) and a second comprising a fully PEEK spiral body without external wings (Helifix®, Alphatec, CA, USA). The size of the IS varied between 8mm and 14mm (9 patients received 8mm devices, 162 patients received 10mm, 388 patients received 12mm, and 34 patients received 14mm devices), with each patient treated at a single level. At the same time, dual-level treatment was performed only in four cases. The procedure was conducted under local anesthesia with analgosedation (18), directly within a CT suite, where CT scans were used to place the K-wire in the selected interspinous space via a posterolateral entry, employing a small skin incision measuring 5-10 mm. A C-arm mounted on the CT cradle served as a radiological guide for the placement of progressive dilators (ranging from 8 mm to 14 mm depending on the situation), culminating in the insertion of the IS device under fluoroscopic direction. The total duration of the procedure was approximately 30 to 45 minutes.

To prevent IS treatment failure linked to osteoporosis, starting in January 2011, all candidates for IS implants underwent a bone mineral density scan (BMD) to identify any osteoporotic conditions. Out of the 593 patients, 149 (approximately 25.1% - Group A) had severe osteoporosis, necessitating prophylactic posterior laminae augmentation with PMMA before the placement of IS implants.

Follow-up clinical evaluations were conducted at one, three, and 12 months post-procedure. In 65 out of 593 patients treated before January 2011 (approximately 11% - Group B), symptoms initially resolved after one month (with a mean VAS value of 1.7), only to return, with the VAS score rising back to 7.4 over one to twelve months (mean three months). All patients experiencing recurrent symptoms underwent a new CT examination (spiral CT, 1mm thickness, sagittal 2D reconstructions, mA rates lowered to a minimum of 20 mA), which revealed bone remodeling of the spinous processes, encasing the IS, thus restoring original stenosis. For patients in Group A, posterior arch augmentation was performed under CT guidance using a C-arm technique, whereby a 13G needle was introduced into the spinous processes in a sagittal orientation (123 patients) or through a parasagittal oblique route (31 patients), injecting 1-2 cc of PMMA into the laminae.

The IS device was introduced immediately afterward, according to the previously outlined technique. 54 out of the 65 Group B patients who suffered a failure of their initial IS treatment due to bone remodeling were offered prophylactic

SP treatment along with the insertion of a second IS device at the same level as the preceding one, aimed at elevating the interspinous space once more. All patients underwent SP treatment following the previously described procedure, with particular care taken regarding the targeted area for PMMA deposition (immediately above and below the site designated for the second implant). Subsequently, the second IS was introduced, with three cases inserted posteriorly and twelve cases placed anteriorly, based on the available space as indicated by pre-operative 2D CT reconstructions (Fig. 1, 2A, B). Follow-up CT studies were conducted at one, three, and twelve months, adhering to the established protocol.

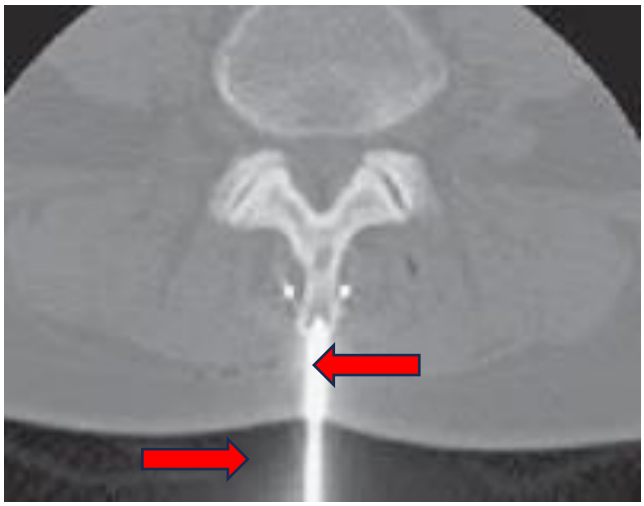

Fig. 1. *Posterior arch augmentation was performed by introducing a Jamshidi needle into the spinal processes at the L3 and L4 levels (**arrows**).*

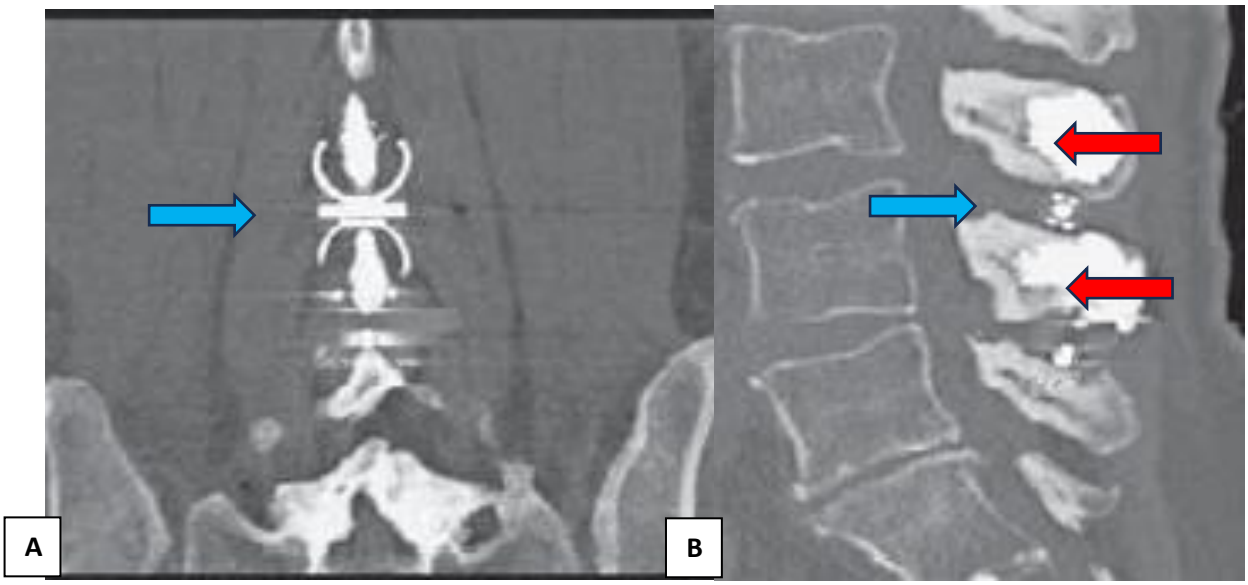

Fig. 2. ***A**): CT coronal view; **B**): sagittal view; After PMMA injection (**red arrows**), a new device (InSpace®, fully Peek, bilateral metal fins) was introduced at the L3/L4 level (**blue arrows**).*

RESULTS

No complications related to PMMA injection were reported among patients in Group A who underwent prophylactic SP, and minimal extra-lamina leakage was observed in just one patient, who exhibited no symptoms attributable to the slight paraspinous leakage. There was no recurrence of LSCS-related symptoms reported during follow-up evaluations spanning three to twelve months, with the mean value on the VAS scale dropping to 2. Follow-up CT examinations

revealed sustained distraction of the interspinous space and foramina at the treated level, with no remodeling of the posterior arch occurring thanks to PMMA augmentation at the final one-year follow-up control (Fig. 3, 4, 5 A-B). In the 65 patients who received a second IS device at the same level (Group B), the symptoms that recurred after the initial IS implant failure were completely resolved following the second treatment (prophylactic SP combined with IS implantation), and they remained asymptomatic at the follow-up checkup encompassing one to twelve months. No further symptoms were observed in patients with dual IS implants.

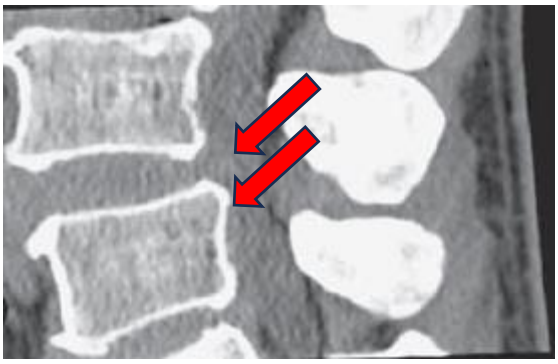

Fig. 3. *Re-treating spinal canal stenosis recurrence related to bone remodeling. Preliminary CT scan documents segmental canal stenosis (**arrows**).*

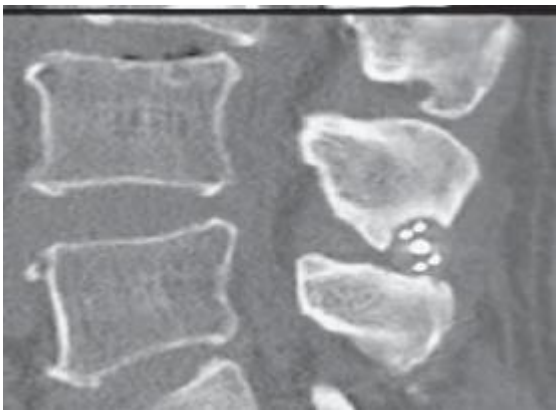

Fig 4. *After 60 days, because of the spinous process of bone remodeling, the patient experienced a recurrent syndrome related to re-stenosis.*

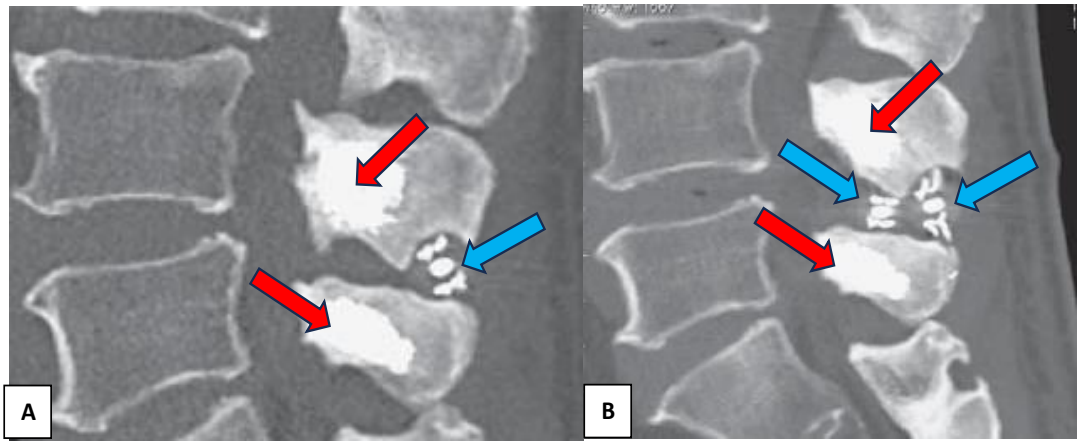

Fig. 5. ***A, B)****: Planning a second IS introduction anteriorly to the former, PMMA augmentation (****red arrows****) was obtained in the anterior half of the laminae and spinous process, then the guidewire was placed anteriorly to the first spacer, and a second device was finally deployed, reopening the interspinous space (****blue arrows****).*

DISCUSSION

Biomechanical research emphasizes the notion of "dynamic stabilization" of the posterior arch, circumventing the need for posterior fusion: the insertion of IS reduces discal loading, thus avoiding local anterior spinal column stress, aligning with contemporary concepts of the "functional spinal unit" (19-24). While traditional posterior stabilization and fixation techniques utilizing open surgery have been employed for several years, interest has surged in developing percutaneous stabilization systems. Fully percutaneous procedures have the significant advantage of minimizing surgical duration and postoperative recovery time and do not necessitate general anesthesia, proving to be well tolerated and accepted by patients. Previously, older, fully titanium devices were replaced by PEEK-coated IS, which was aimed at reducing mechanical stress between the device and the bony posterior arch. Nevertheless, complications related to remodeling of the posterior laminae, along with a return to original stenosis, may arise even in these cases. Augmentation of the pedicle and transverse processes has been documented, demonstrating pain relief in neoplastic involvement without reported complications (21). The posterior arch of the vertebra can be easily fortified through PMMA injection, achieved by placing a 13 to 15G needle into the spinal processes along the midline or employing a parasagittal oblique approach to reach the laminae directly (8).

A small volume of PMMA (generally between 1 to 3 cc) introduced under fluoroscopic guidance is straightforward to perform, and the PMMA remains within the spongy bone due to the laminae's thick cortex. By implementing prophylactic SP, IS placement has been sustained in our patient cohort, eliminating the risk of recurrent syndromes even after one year of follow-up. Introducing an IS following SP does not require a different approach or specific precautions. Currently, in cases of spacer failure due to remodeling and/or fracture of the spinous processes, more invasive open surgical interventions are commonly perceived as the sole recourse to decompress the spinal canal once more. Surgical decompression typically entails bilateral laminectomy and posterior interbody fusion with the application of screws and rods under general anesthesia. Complications associated with scarring and/or osteoporosis have been reported with conventional surgical methods (22-24). For this reason, re-treatment utilizing local anesthesia is advisable, particularly in elderly patients.

In our cohort of patients experiencing failure with previously implanted IS devices, we achieved resolution of recurrent LSCS by repositioning a second device at the same level, with spinous processes safeguarded through prophylactic posterior arch augmentation. While deploying a second IS device at the same level is not extensively documented in the literature, the technique appears straightforward for patients with prior IS implant failures and adequate space adjacent to the former spacer. When adequate distraction is accomplished through the placement of a second device,

both clinical symptoms are markedly alleviated or vanish entirely, thereby yielding new decompression of the central spinal canal and/or foramina.

CONCLUSIONS

Posterior arch augmentation emerges as a promising technique to avert IS failures in patients with spinal canal stenosis undergoing percutaneous spacer placement. It represents a user-friendly technique suitable for all patients at risk of fractures or bone remodeling resulting from osteoporosis or other skeletal stress conditions. The failure of a previously implanted IS device related to bone remodeling or fracture in patients without prophylactic SP can be effectively addressed through targeted SP and inserting a second IS device, restoring distraction and mitigating the recurrent clinical syndrome associated with re-stenosis.

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