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Review Article

A Review of Emerging Evidence for Utilization of a Percutaneous Interspinous Process Decompression Device to Treat Symptomatic Lumbar Adjacent-Segment Degeneration

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Abstract

Objective. Postlaminectomy syndrome diagnoses secondary to adjacent segment degeneration are a substantial and rising cause of morbidity in the United States. Emerging spinal cord neuromodulation technologies have produced successful outcomes for postlaminectomy neuropathic pain but are less effective in treating neurogenic claudication secondary to recurrent lumbar stenosis. Percutaneous interspinous process decompression systems can be used as a salvage treatment modality for persistent structural neurogenic claudication in postlaminectomy syndrome or after spinal cord stimulator implantation. **Methods**. This paper is a review of emerging evidence for efficacious utilization of percutaneous interspinous process decompression. **Results**. A recent pragmatic trial of subjects who underwent percutaneous interspinous process decompression for lumbar stenosis with intermittent neurogenic claudication reported that 63% (26/41) maintained minimal clinically important improvement in visual analog scale (VAS) leg pain, 61% (25/41) in VAS back pain, 78% (32/41) in function objective values, and 88% (36/41) reported satisfaction with treatment at 12 months postop. All subjects in a small case series of seven individuals with postlaminectomy adjacent-segment disease reported postoperative satisfaction scores of 3 or 4 on a 0–4 scale and were also able to decrease or wean completely off controlled pain medications. In another study, there was a significant decrease in average leg pain (60% improvement, $P < 0.0001$, $N = 25$) and axial low back pain (58% improvement, $P < 0.0001$, $N = 25$) in patients who underwent one- or two-level percutaneous interspinous process decompression as a rescue treatment for reemerging neurogenic claudication after spinal cord stimulator implantation. **Conclusions**. The spine often is a focus of progressive disease. Furthermore, mechanical changes associated with spinal instrumentation can lead to additional disease at adjacent levels. Many individuals will present with symptomatic neurogenic claudication recalcitrant to multimodal management strategies, including even the most sophisticated neuromodulation technologies. Implementation of salvage percutaneous interspinus process decompression implantation in cases of adjacent segment degeneration or incomplete spinal cord stimulation can decompress structural causes of neurogenic claudication while sparing the patient from more invasive surgical reoperation techniques.

Key Words: Interspinous Process Decompression; Adjacent Segment Degeneration; Lumbar Spinal Stenosis; Neurogenic Claudication; Postlaminectomy Syndrome.

Introduction

The number of spinal arthrodesis procedures performed within the United States increased from 174,223 to 413,171 cases per year between 1998 and 2008 [1]. Increased utilization is a result of the evolution of instrumentation, less invasive surgical techniques, and evolving technologies for decompression [2–6]. In practice, lumbar arthrodesis techniques are implemented for a vast array of indications once nonoperative treatment modalities fail. However, greater improvements in function and quality of life have been reported when lumbar arthrodesis is performed for diagnoses such as spondylolisthesis, scoliosis, and primary disc disease rather than diagnoses associated with surgical revision such as adjacent segment degeneration and pseudarthrosis [7].

Recurrent or persistent pain after lumbar decompression is categorized into "postlaminectomy" or "failed back" syndromes. Axial low back pain often results from iatrogenic instability or adjacent segment breakdown, whereas neuropathic leg pain commonly occurs secondary to recurrent neuroforaminal stenosis or postoperative perineural fibrosis [8,9]. Nonoperative treatment options for postlaminectomy syndrome include physical therapy, interventional pain techniques, pain-relieving medications, and pain psychology. Operative options range from spinal cord or dorsal root ganglion stimulation to extension of fusion construct/adjacent-level decompression and adhesiolysis. The annual incidence of surgery for adjacent-segment disease following posterior decompression and fusion (or open posterior lateral interbody fusion or circumferential fusion) has been reported to be 2.5% per year. This means that one in four individuals will require a repeat operation within 10 years of the initial arthrodesis. There are a number of risk factors for accelerated adjacent segment disease. These include age >60, termination of the fusion construct at the L5 level, arthrodesis of three or more levels, and stand-alone decompression of the segment adjacent to instrumented levels [10–12].

Spinal cord stimulation has been an indicated treatment modality for postlaminectomy syndrome since gaining approval from the US Food and Drug Administration (FDA) in 1989 [13]. North et al. published a randomized controlled trial (RCT) comparing outcomes in subjects with postlaminectomy syndrome who were assigned to either undergo implantation of an early-generation conventional stimulation system or proceed with repeat decompressive spine surgery. In this study, nine of 19 (47%) individuals with successful stimulator trials and subsequent permanent implantation reported >50% improvement in pain and high levels of satisfaction at the 24-month follow-up, whereas only three of 26 (12%) individuals who underwent repeat spine surgery achieved successful outcomes [14]. North et al. later published a cost-utility comparison of treating postlaminectomy syndrome with either early generations of spinal cord stimulation technology or reoperation. They reported that spinal cord stimulation was both more clinically effective and significantly less expensive than reoperation procedures (mean cost per patient success was $117,901 for spinal cord stimulation; no reported cases of success for reoperation despite mean per-patient expenditure of $260,584) [15]. The authors of these studies concluded that conventional spinal cord stimulator implantation should be offered early for individuals with postlaminectomy syndrome as an alternative to repeat decompressive spine surgery.

Recent advances in spinal cord stimulation technology include novel waveforms that provide paresthesia-independent or improved paresthesia-based therapeutic options to the patient [16,17]. Kapural and colleagues published high-level evidence in the SENZA RCT study. This study followed 198 subjects randomized to receive either a high-frequency paresthesia-independent implant (87% postlaminectomy syndrome) or conventional stimulation system (86% postlaminectomy syndrome). The authors reported that 71/90 subjects (78.7%) in the high-frequency stimulation (10kHz) group, as opposed to 41/81 subjects (51%) in the control group (conventional tonic stimulation), reported >50% improvement in back and leg pain sustained up to one year after implantation [17]. These subjects have been followed out to two years with sustained reduction in symptoms [18]. In contrast, a Spanish RCT by DeAndres showed results that were significantly worse for both high frequency - 10 kHz (HF-10) and tonic stimulation in equally matched groups over one year [19]. Deer and colleagues, in an FDA pivotal investigational device exemption, showed that a novel burst waveform was statistically superior to tonic stimulation over 12 months [16]. These mixed results are somewhat indicative of the duality of the therapy, with outcomes ranging from a substantial percentage of subjects reporting 100% pain relief in the SENZA trial to approximately 23% of patients failing treatment and requiring explantation in another study [17,20].

In spite of strong data in support of spinal cord stimulation for the treatment of postlaminectomy syndrome, some implanted patients fail to meet clinical success criteria. The rate of unanticipated spinal cord stimulator explantation, inclusive of all types of conventional and high-frequency neurostimulation devices, has been reported to be approximately 7.9% per year [21]. Incomplete pain relief has been cited as the primary indication for device explantation in approximately half of all cases [21,22]. Although technical factors that may contribute to incomplete pain relief are well documented (lead migration, incomplete paresthesia coverage), persistent neurogenic claudication secondary to lumbar stenosis is the leading cause of spinal cord stimulation treatment failure [23].

Interspinous process decompression (IPD) devices were designed to provide a stand-alone method of

treating neurogenic claudication secondary to lumbar stenosis without disrupting the anterior and middle spinal column elements. Systems such as the original Wallis system (Abbott) and X-STOP (Medtronic) function through two key mechanisms. First, longitudinal distraction between posterior spinal elements is created at the symptomatic level to relieve neuroforaminal stenosis. Second, these devices generate a relative focal kyphosis between the two segments that reduces ligamentum flavum projection into the central canal [24–26]. Together, these mechanisms work to increase central canal and neuroforaminal diameter while decreasing impingement on the traversing nerve roots by hypertrophied soft tissue structures.

The Superion device (Vertiflex, Inc., San Clemente, CA; percutaneous IPD) is a low-profile evolution of previous IPD systems that can be implanted *percutaneously* between symptomatic vertebral levels on an outpatient basis. This technique has a number of potential advantages and imparts results that parallel the open technique. First, percutaneous IPD implantation has received approval from the FDA to be performed under monitored anesthesia care. As a result, percutaneous IPD implantation can be performed with a reduced total operative time and decreased risk of perioperative complications compared with interspinous spacers implanted by an open technique. In addition, indirect decompression has been shown to produce similar improvements in quality of life measures compared with open-procedure IPD devices [27]. One major concern with open-procedure IPD systems is the long-term durability of clinical improvement. Studies have reported the rate of revision decompression at the index level to be as high as 58% within two years of open-procedure X-STOP implantation [28]. However, percutaneous IPD devices preserve posterior stabilizing elements of the spine, which prevents excessive physiological motion at the implanted level, theoretically lowering the risk of future segmental instability [29].

There is emerging clinical evidence that percutaneous IPD systems are effective in treating lumbar spinal stenosis–associated sequela (Table 1). A prospective, multicenter randomized controlled trial reported that treatment with percutaneous interspinous process decompression (N = 190) was noninferior to a control group treated with an X-STOP interspinous process spacer (N = 201) when used to address moderate lumbar spinal stenosis with intermittent neurogenic claudication. At two years postop, both groups demonstrated similar improvement in leg pain clinical success (76% [percutaneous IPD], 77% X-STOP, $P < 0.05$), back pain clinical success (67% [percutaneous IPD], 68% X-stop, $P = 0.90$), Oswestry Disability Index clinical success (63% [percutaneous IPD], 67% X-STOP, $P = 0.61$), and similar ZCQ patient satisfaction scores (1.66 [percutaneous IPD], 1.52 X-STOP, $P < 0.05$) [30]. Secondary analysis of the interspinous process decompression treatment arm of this trial determined that ~50% (94/190) of subjects were using opioid medications at baseline, which decreased to 13% (20/150) at 24 months and 7.5% (8/107) at 60 months postop [31]. Furthermore, a recent pragmatic trial of subjects that underwent percutaneous interspinous process decompression for lumbar stenosis with intermittent neurogenic claudication reported that 63% (26/41) maintained minimal clinically important improvement in VAS leg pain, 61% (25/41) in VAS back pain, 78% (32/41) in function objective values, and 88% (36/41) reported satisfaction with treatment at 12 months postop [32].

With the knowledge that neurogenic claudication symptoms are a significant cause of spinal cord stimulation failure, the advent of novel percutaneous IPD systems has the potential to allow patients minimally invasive treatment of adjacent segment degeneration in the form of lumbar spinal stenosis. In this way, percutaneous interspinous process spacers have been studied as a salvage therapy in subjects with adjacent segment degeneration after lumbar fusion or incomplete relief from spinal cord stimulation (Figure 1). All subjects in a small case series of seven individuals with postlaminectomy adjacent-segment disease reported postoperative satisfaction scores of 3 or 4 on a 0–4 scale (0 least, 4 most) and that patients were also able to decrease or wean completely off opioid/opiate pain medications [33]. Another study presented at the 2019 North American Neuromodulation Society Annual Meeting followed 25 patients who underwent one- or two-level percutaneous interspinous process decompression as a rescue treatment for recurrent neurogenic claudication after spinal cord stimulator implantation. In this case series, there was a significant decrease in average leg pain (60% improvement, $P < 0.0001$) and axial low back pain (58% improvement, $P < 0.0001$). Opioid utilization was also significantly decreased in the study group, with 17 of 19 individuals completely tapering off opioids at the time of final follow-up (median = 42 days after IPD implantation) [34].

The prevalence of individuals who are >10 years post–lumbar arthrodesis with concomitant adjacent segment degeneration continues to rise every year. Many of these individuals will present with symptomatic neurogenic claudication recalcitrant to multimodal management strategies, including even the most sophisticated neuromodulation technologies. Implementation of salvage percutaneous IPD implantation can decompress structural causes of claudication while sparing the patient from more invasive surgical treatment options, such as fusion construct extension, that have been shown to result in only modest clinical improvement.

Conclusions

The spine is vulnerable to progressive disease. Furthermore, mechanical changes associated with spinal instrumentation

Table 1. Emerging evidence of IPD treatment outcomes

Study	Study Type	No. of Patients	Follow-up Period	Criteria	Outcomes Measured
Patel et al. (Spine 2015)	Multicenter randomized controlled study	391	24 mo	LSS with intermittent neurogenic claudication	VAS (leg and back), ODI, patient satisfaction
Nunley et al. (JPR 2018)	Post hoc analysis of randomized controlled study	190	24 mo, 60 mo	LSS with intermittent neurogenic claudication	Long-term narcotic use
Deer et al. (ASRA 2018)	Multicenter prospective registry	578	3 wk, 6 mo, 12 mo	LSS with intermittent neurogenic claudication	VAS (leg and back), blood loss, procedure time, patient satisfaction
Mehta and Misercola (ASRA 2018)	Single site retrospective case series	7	<1 y postprocedure	LSS adjacent to a prior lumbar fusion	VAS (leg, back, and overall), narcotic use, patient satisfaction
Deer et al. (NANS 2019)	Multicenter retrospective review	32	Median follow-up length (range) was 42 (21–240) d	LSS treated following ineffective spinal cord stimulation	VAS (leg and back), narcotic use, duration of previous SCS use

Abbreviations: IPD, interspinous process decompression; LSS, Lumbar Spinal Stenosis; SCS, spinal cord stimulation; VAS, visual analog scale.

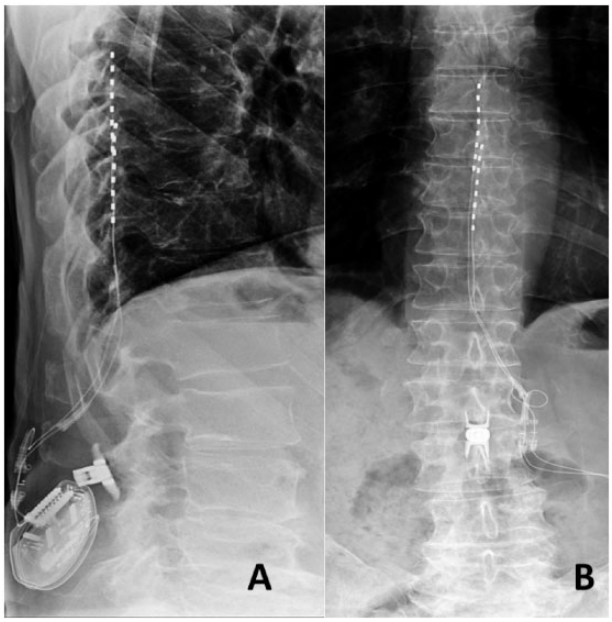

Figure 1. A and B) Lateral and anteroposterior image of percutaneous interspinous process decompression implanted as a salvage device after ineffective spinal cord stimulation therapy.

can lead to additional disease at adjacent levels. Many individuals will present with symptomatic neurogenic claudication recalcitrant to multimodal management strategies, including even the most sophisticated neuromodulation technologies. This has led to extension of the instrumentation in many cases. The possibility of less invasive therapies should be considered in this patient group. Indirect lumbar decompression via interspinous spacer is an emerging minimally invasive technique for patients with a history of implanted spinal cord stimulators or spinal instrumentation who continue to experience symptoms due to progressive neurogenic claudication.

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