

Interspinous Process Decompression With The Superior[®] Spacer For Lumbar Spinal Stenosis: Real-World Experience From A Device Registry

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Background: Interspinous process decompression (IPD) with stand-alone spacers has demonstrated excellent long-term clinical benefit for patients with lumbar spinal stenosis (LSS).

Methods: IPD used the Superior[®] Indirect Decompression System (Vertiflex, Carlsbad, CA, USA). Perioperative and clinical data were captured via a registry for patients treated with IPD for LSS with intermittent neurogenic claudication. Three-hundred sixteen physicians at 86 clinical sites in the US participated. Patient data were captured from in-person interviews and a phone survey. Outcomes included intraoperative blood loss, procedural time, leg and back pain severity (100 mm VAS), patient satisfaction and treatment approval at 3 weeks, 6 and 12 months.

Results: The mean age of registry patients was 73.0 ± 9.1 years of which 54% were female. Mean leg pain severity decreased from 76.6 ± 22.4 mm preoperatively to 30.4 ± 34.6 mm at 12 months, reflecting an overall 60% improvement. Corresponding responder rates were 64% (484 of 751), 72% (1,097 of 1,523) and 75% (317 of 423) at 3 weeks, 6 and 12 months, respectively. Back pain severity improved from 76.8 ± 22.2 mm preoperatively to 39.9 ± 32.3 mm at 12 months (48% improvement); 12-month responder rate of 67% (297 of 441). For patient satisfaction at 3 weeks, 6 and 12 months, 89%, 80%, and 80% were satisfied or somewhat satisfied with their treatment and 90%, 75%, and 75% would definitely or probably undergo the same treatment again. In the phone survey, the rate of revision was 3.6% (51 of 1,426).

Conclusion: These registry findings support the clinical adoption of minimally invasive IPD in patients with neurogenic claudication associated with LSS.

Keywords: Superior[®], interspinous spacer, lumbar spinal stenosis, neurogenic claudication, decompression

Introduction

Approval of a second-generation, stand-alone intervertebral spacer by the US Food and Drug Administration in 2015 has led to renewed enthusiasm for the use of interspinous process decompression (IPD) as an effective treatment option for symptomatic lumbar spinal stenosis (LSS). Increasing utilization of minimally invasive IPD has been buttressed by a growing body of published clinical evidence showing durable condition-specific outcomes through 5 years of follow-up,¹ clinically significant improvement in health-related quality of life,² and an associated reduction in opioid analgesia after IPD.³

Primarily designed to limit spinal extension, interspinous spacers effectively prevent neurogenic and radicular symptoms resulting from neurovascular compression that recurs during postural extension in LSS. With broadening commercial

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utilization of IPD among an expanding range of physician specialties, it remains imperative to monitor the impact of this intervention on the quality of patient care and associated clinical outcomes.⁴

A medical device registry was established at several clinical sites in the US to track the ongoing performance and clinical utility of IPD with a stand-alone interspinous spacer in a real-world clinical practice setting.⁵ Herein, we provide characterization of patients enrolled in the registry with respect to perioperative factors and postoperative clinical outcomes.

Materials And Methods

A post-market registry was initiated at 86 geographically dispersed clinical sites in the US involving 316 physicians. This multi-center medical device registry was undertaken to evaluate the ongoing utilization of the Superion® Indirect Decompression System (Vertiflex, Carlsbad, CA, USA) in the management of patients with an established diagnosis of LSS associated with neurogenic claudication (Figure 1). The primary aim of the registry is to prospectively collect a set of perioperative and clinical outcomes among patients treated with stand-alone IPD for symptomatic LSS. The study protocol and consent forms were approved by an independent institutional review board (Western Institutional Review Board, Puyallup, WA USA, No. 20160638), and all patients provided written informed consent.

Characterization and description of the device system, procedural details and surgical technique have been published previously.^{6,7} Briefly, the device may be implanted under general anesthesia, conscious sedation (i.e. monitored

anesthesia care [MAC]), or local anesthesia. The patient is placed prone with the spine in a flexed position. A percutaneous approach is used for insertion of a specialized cannula via sequential dilation, to allow for cannula positioning within the interspinous space. Once the cannula is in place, a sizing tool is employed to determine the proper device size. The Superion is then inserted through the cannula and under fluoroscopic guidance is deployed between adjacent vertebral spinous processes at the indicated level. The insertion instrumentation is then removed, leaving the implant in place. The rigid implant serves to maintain the desired spacing between the spinous processes while still preserving motion.

The Superion is indicated to treat skeletally mature patients suffering from painful walking, numbness, and/or cramping in the legs (neurogenic claudication) secondary to a diagnosis of moderate degenerative lumbar spinal stenosis, with or without Grade 1 spondylolisthesis, as confirmed by advanced radiographic imaging. Superion is indicated for those patients with impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, numbness, and/or cramping, with or without back pain, and who have undergone at least 6 months of non-operative treatment.⁸ Superion may be implanted at one or two adjacent lumbar levels in patients in whom treatment is indicated at no more than two levels, from L1 to L5.

For this intended use, moderate degenerative lumbar spinal stenosis is defined as follows:

- 25% to 50% reduction in the central canal and/or nerve root canal (subarticular, neuroforaminal) compared to the adjacent levels on radiographic studies, with radiographic confirmation of any one of the following:
- Evidence of thecal sac and/or *cauda equina* compression,
- Evidence of nerve root impingement (displacement or compression) by either osseous or non-osseous elements,
- Evidence of hypertrophic facets with canal encroachment,
 - And associated with the following clinical signs:
- Presents with moderately impaired Physical Function defined as a score of ≥ 2.0 of the Zurich Claudication Questionnaire,
- Ability to sit for 50 mins without pain and to walk 50 feet or more.



Figure 1 Superion® indirect decompression system.
Note: Image courtesy of Vertiflex, Inc.

Data collection in this registry was captured from in-person interviews and a phone survey, and included intraoperative blood loss and procedural time. Patient-reported outcomes comprised leg and back pain severity by 100 mm visual analog scale prior to IPD as well as at 3 weeks, 6 and 12 months, post-operatively. At each follow-up interval, patient satisfaction with the procedure was queried as satisfied, somewhat satisfied, somewhat dissatisfied, or dissatisfied. Overall patient impression of and treatment approval with IPD was characterized as definitely yes, probably yes, probably not or definitely not with respect to whether the patient would repeat the treatment.

For clinical outcomes, data from the in-person interviews and the phone survey were combined. Mean leg and back pain severity was computed and illustrated graphically by follow-up interval. Responder rates were computed for leg and back pain (≥ 20 mm improvement), patient satisfaction (satisfied/somewhat satisfied), and treatment approval (yes/probably yes).

Results

The mean age of registry patients was 73.0 ± 9.1 years including 54% females. Average intraoperative blood loss was 6.1 ± 7.3 mL and the mean operative duration was 44.1 ± 24.9 mins.

Combining outcome data from the registry and phone survey, the maximum number of patients providing pain severity data was 2,090, 759, 1,553 and 445 at baseline, 3 weeks, 6 and 12 months, respectively. For patient satisfaction and treatment approval, the maximum number of patients providing follow-up data was 751, 1,542 and 443 at 3 weeks, 6 and 12 months, respectively.

Mean leg pain severity decreased from 76.6 ± 22.4 mm preoperatively to 33.0 ± 29.9 mm at 3 weeks, 33.1 ± 34.0 mm at 6 months, and 30.4 ± 34.6 mm at 12 months, reflecting an overall 60% improvement (Figure 2). Corresponding responder rates were 64% (484 of 754), 72% (1,097 of 1,523) and 75% (317 of 423) at 3 weeks, 6 and 12 months, respectively.

Back pain severity improved from 76.8 ± 22.2 mm preoperatively to 37.5 ± 29.6 mm at 3 weeks, 41.9 ± 32.5 mm at 6 months, and 39.9 ± 32.3 mm at 12 months (48% improvement) (Figure 2), with 3 weeks, 6- and 12-month responder rate of 61% (457 of 752), 67% (1,033 of 1,539) and 67% (297 of 441), respectively.

For patient satisfaction at 3 weeks, 6 and 12 months, 89% (669 of 751), 80% (989 of 1,235), and 80% (296 of 368) were satisfied or somewhat satisfied with their treatment and 90% (674 of 750), 75% (1,151 of 1,542), and

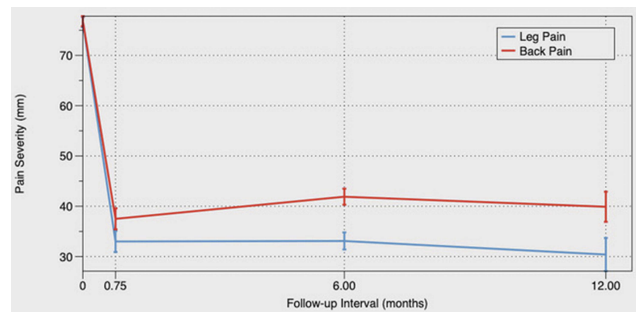


Figure 2 Leg and back pain severity by follow-up interval (mean \pm 95% CI).

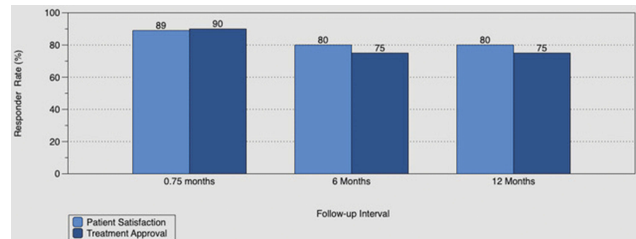


Figure 3 Responder rates for patient satisfaction and treatment approval by follow-up interval.

75% (331 of 443) would definitely or probably undergo the same treatment again (Figure 3).

Of 1,426 patients participating in the phone survey, 51 patients (3.6%) reporting a revision or reoperation during a 6–12-month follow-up due to inadequate symptom amelioration with IPD.

Discussion

Following FDA approval, real-world experience with stand-alone IPD mirrors the clinical improvements in pain, functional outcomes and patient satisfaction achieved in a regulated clinical trial setting.⁷ The degree of improvement is robust across all condition-specific outcomes, with a large proportion of patients reporting clinically significant gains at 3 weeks post-procedure in this registry. Findings from a randomized controlled trial likewise demonstrated that symptom relief with IPD is immediate, with improvements that are maintained through 5 years of follow-up.^{1,9}

The minimally invasive nature of IPD implantation allows for the procedure to be performed in an ambulatory surgical center (ASC) under monitored anesthesia care. Most IPD procedures are now undertaken in the ASC setting which avoids the expenditures and complications associated with a hospital admission, and offers a significant reduction in health-care costs to the insurer and patient.

The approximate 4% frequency of revision or reoperation captured in our phone survey within the initial 6–12 months following IPD is somewhat lower than the 6-month revision rate of 7% (13 of 190) reported in the regulated clinical trial of Superion.⁷ The low rate of revision estimated in this survey may be related to a tendency for more compliant patients with better outcomes to participate in post-market surveillance. Additionally, we speculate that improvement in patient selection by controlled and well-selected physician training in the IPD procedure during the post-market period may have contributed to a reduction in the risk of subsequent revision.

Registries are playing an increasingly important role in monitoring the quality of care, providing technical feedback, and for supplying a platform for the ongoing conduct of research.^{4,10} This medical device registry was initiated to capture real-world, pragmatic experience regarding the clinical utilization and performance of IPD for patients with symptoms of neurogenic claudication secondary to LSS. This initial report of the PRESS registry and a direct-to-patient phone survey corroborates, expands and complements previously published studies of this device.

Conclusions

Pragmatic experience with stand-alone IPD using the Superion spacer in the real-world, clinical practice environment confirms the success achieved with this treatment in the controlled clinical trial setting. These registry findings further support the continued clinical adoption of this beneficial treatment in patients considering minimally invasive options to manage neurogenic claudication symptoms due to LSS.

Data Sharing

Requests for data sharing can be made by contacting the corresponding author. Individual participant data that underlie the results reported in this article will be made available (after deidentification) from 9 to 36 months after article publication. Data sharing will be limited to investigators whose proposed use of the data has been approved by an independent review committee identified for this purpose.

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Author Contributions

All authors contributed to data analysis, drafting and revising the article, gave final approval of the version to be published, and agree to be accountable for all aspects of the work.

Disclosure

GT reports grants from Vertiflex, during the conduct of the study. DS reports personal fees from Vertiflex, outside the submitted work. KC was paid for time to enroll patients and track data in PRESS registry from Vertiflex, during the conduct of the study. He also received personal fees from Boston Scientific and Vertiflex, outside the submitted work. LJR serves as consultant/instructor for Vertiflex and Boston Scientific. JEB is an independent advisor to Vertiflex and was remunerated for assistance in manuscript development. The authors report no other conflicts of interest in this work.

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