Lumbar Spinal Stenosis Treatment with an Interspinous Spacer: Preliminary Results of a Multi-Center, Randomized, Controlled FDA-IDE Trial

Reginald J. Davis MD; Jon Block PhD; Larry Miller PhD
Greater Baltimore Medical Center
Towson, MD, USA

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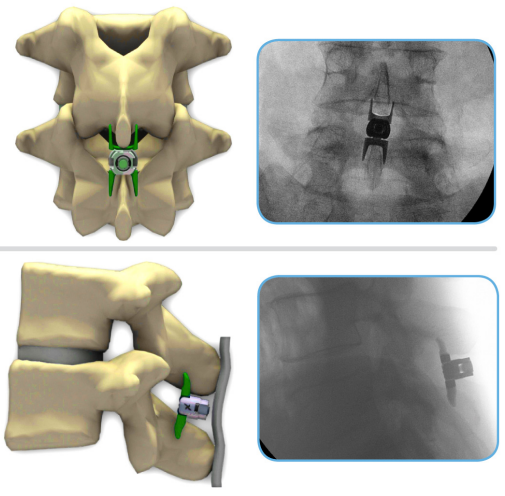
Introduction

A therapeutic void exists for patients with moderate LSS and increasingly recalcitrant symptoms. The purpose of this clinical trial was to evaluate the preliminary safety and effectiveness of the Superion Interspinous Spacer *(Vertiflex, Inc., San Clemente, CA)* in patients with intermittent neurogenic claudication secondary to radiographically confirmed moderate LSS

Methods

This multicenter, prospective, randomized, controlled, investigational device exemption trial enrolled 166 patients with intermittent neurogenic claudication secondary to moderate LSS and unresponsive to conservative care. Patients were randomized to implant with the Superion (n=80) or X-STOP (n=86) interspinous spacer. Outcomes included Condition-specific Zurich Claudication Questionnaire (ZCQ), back function with Oswestry Disability Index (ODI), back and leg pain severity with visual analogue scale (VAS), and adverse events through 6 months post-treatment.



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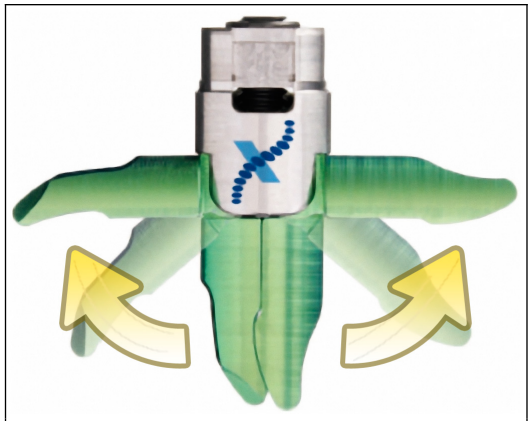


Superion Interspinous Spacer

Results

The proportions of patients that reported ZCQ improvements of >=0.5 points were 64% and 63% for Physical Function and 75% and 53% for Symptom Severity with Superion and X-STOP, respectively. Mean Patient Satisfaction scores ranged from 1.7 to 2.0 at all follow-up visits in both groups. Median back function scores improved 48% with Superion and 38% with X-STOP (both p<0.001). ODI clinical success, defined as a >=15-point improvement, was 47% with Superion and 37% with X-STOP.

Both groups experienced improvements in median back (Superion 70%, X-STOP 64%) and leg (Superion 93%, X-STOP 81%) pain scores (all p<0.001). Pain clinical success, defined as a >=20-point improvement on the VAS, was 60% and 50%, respectively, for back pain and 74% and 60%, respectively, for leg pain. Clinical failure, defined as reoperation, major implant- or procedure-related complication, spinal cord stimulation, rhizotomy, epidural steroid injection, or nerve block, was identified in 15% of Superion and 21% of X-STOP patients.

Baseline Patient Characteristics

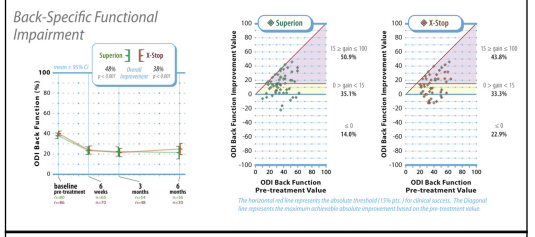
Baseline Patient Characteristics	Superion (n=80)	X-Stop (n=86)
Age, *mean ± SD, y*	67 ± 9	67 ± 11
Male, *n (%)*	**48** (60)	**57** (66)
Body Mass Index, *mean ± SD, kg/m²*	30 ± 5	30 ± 5
Tobacco Use, *n (%)*		
None	**34** (43)	**41** (48)
Previous use	**35** (44)	**34** (40)
Current use	**11** (14)	**11** (13)
Axial Pain Severity Score, *mean ± SD, mm*	55 ± 27	54 ± 29
Extremity Pain Severity Score, *mean ± SD, mm*	61 ± 26	64 ± 26
Oswestry Disability Index, *mean ± SD, %*	38 ± 13	40 ± 13

Procedural Data

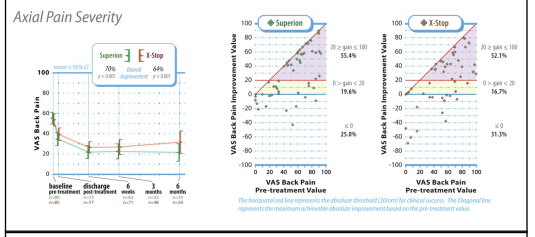
Procedural Data	Superion (n=80)	X-Stop (n=86)
Anesthesia, *n (%)**		
General	**68** (85)	**79** (92)
Conscious Sedation	**12** (15)	**7** (8)
Local	**7** (9)	**4** (5)
Number of Devices, *n (%)*		
One	**40** (50)	**38** (44)
Two	**40** (50)	**48** (56)
Procedure Time, *median, mins*	55	45
Procedural Blood Loss, *median, cc*	10	25

* The sum of percentages is greater than 100% because more than one anesthesia type was used in some patients.

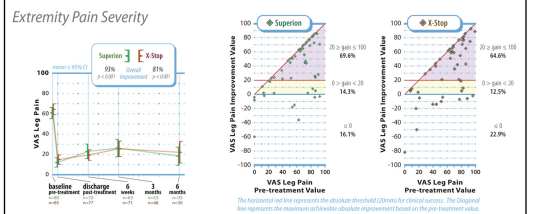
Back Function Scores



Back Pain Scores



Leg Pain Scores



Conclusions

Treatment with the Superion Interspinous Spacer results in promising early outcomes in patients with intermittent neurogenic claudication secondary to moderate LSS.

Learning Objectives

To understand the rationale for and efficacy of interspinous spacers in patients with lumbar spinal stenosis.