

EXPERT  
REVIEWS

# Stand-alone interspinous spacer versus decompressive laminectomy for treatment of lumbar spinal stenosis

Expert Rev. Med. Devices [Early online]

Carl Laurysen<sup>1</sup>,  
Robert J Jackson<sup>2</sup>,  
Jeffrey M Baron<sup>3</sup>,  
Richard A Tallarico<sup>4</sup>,  
William F Lavelle<sup>4</sup>,  
Harel Deutsch<sup>5</sup>,  
Jon E Block<sup>\*6</sup> and  
Fred H Geisler<sup>7</sup>

<sup>1</sup>Neurosurgical Spine Institute,  
Lakeway, TX 78738, USA

<sup>2</sup>Orange County Neurosurgical  
Associates, Laguna Hills, CA 92653,  
USA

<sup>3</sup>Tucson Orthopaedic Institute,  
Tucson, AZ 85712, USA

<sup>4</sup>Upstate Bone and Joint Center, East  
Syracuse, NY 13057, USA

<sup>5</sup>Rush University Medical Center,  
Chicago, IL 60612, USA

<sup>6</sup>Independent Scholar, San Francisco,  
CA 94115, USA

<sup>7</sup>Chicago Back Institute, Chicago, IL  
60625, USA

\*Author for correspondence:  
jb@drjonblock.com

**Objective:** To compare the two-year clinical outcomes of a prospective, randomized controlled trial of an FDA-approved interspinous spacer with the compilation of published findings from 19 studies of decompressive laminectomy for the treatment of lumbar spinal stenosis. **Methods:** Back and leg pain, Oswestry disability index (ODI), and Zurich Claudication Questionnaire (ZCQ) values were compared between spacer- and laminectomy-treated patients preoperatively and at 12 and 24 months. **Results:** Percentage improvements between baseline and 24 months uniformly favored patients treated with the spacer for back pain (65% vs. 52%), leg pain (70% vs. 62%), ODI (51% vs. 47%) and ZCQ symptom severity (37% vs. 29%) and physical function (36% vs. 32%). **Conclusion:** Both treatments provide effective and durable symptom relief of claudicant symptoms. This stand-alone interspinous spacer offers the patient a minimally invasive option with less surgical risk.

**KEYWORDS:** interspinous spacer • lumbar spinal stenosis • Superion • laminectomy

## Introduction

One of the most profound societal ramifications of the increasing proportion of individuals living to advanced age is the impact and burden on the health care system associated with age-related degeneration of the musculoskeletal system. Indeed, the lumbar spine is particularly vulnerable to arthritic deterioration resulting in bony and ligamentous encroachment of the central canal and foramina, commonly referred to as lumbar spinal stenosis.[1] Radiographic stenosis is a common incidental finding in most advanced aged patients. Clinically significant lumbar stenosis that is refractory to nonoperative management is potentially treatable with surgical interventions. In fact, the SPORT trial showed that current nonoperative treatments provide only modest clinical benefit.[2] Stenosis is the most common indication for spine surgery in patients older than 65 with surgical hospitalizations increasing by 30% from 2000 to 2009.[3] Its prevalence is expected to rise 59% to 64 million elderly adults by the year 2025.[4]

The arthritic compression of the neural elements leads to classic intermittent symptoms of neurogenic claudication, leg pain and weakness, which are exacerbated during ambulation, standing and trunk extension. Symptoms are relieved with sitting or forward flexion. Given that the severity of spinal stenosis variably, but insidiously, progresses over time, patients require safe and effective treatment options to manage these symptoms.

Stand-alone interspinous spacers are designed for the treatment of symptoms of intermittent neurogenic claudication secondary to moderate lumbar spinal stenosis, and are implanted by minimally invasive methods through a cannula.[5] In contrast to direct surgical procedures, such as decompressive laminectomy, where the soft and bony tissues compressing the neural elements are surgically removed through an open operative exposure, spacers provide minimally invasive, indirect decompression of spinal nerves, and function by serving as a spinal extension blocker to

prevent compression of neural elements in extension without the removal of tissue adjacent to the nerves.

This report provides a qualitative comparison of the published two-year clinical findings from the prospective, randomized controlled trial of a recently FDA-approved interspinous spacer [6] with the body of evidence for similar outcome measurements associated with the “gold standard” surgical treatment for lumbar spinal stenosis, decompressive laminectomy.[7]

## Methods

This study was undertaken to compare the 2-year clinical outcomes of a randomized controlled investigational device exemption (IDE) trial of a stand-alone interspinous spacer (Superior®, Vertiflex, Inc. San Clemente, CA, USA) with the compilation of published findings on decompressive laminectomy for the treatment of claudicant symptoms associated with spinal stenosis. The IDE study methodology including eligibility criteria, randomization methods, sample size estimates, outcome measures and statistical analyses have been detailed earlier.[6,8] The findings of this trial supported the May 2015 regulatory approval of this device by the US Food and Drug Administration (FDA) and have been published previously.[6]

Articles were selected for inclusion in the laminectomy literature control group if they met the following criteria: inclusion of at least one patient-reported clinical outcome measurement consisting of back pain severity, leg pain severity, Oswestry disability index (ODI) or Zurich Claudication Questionnaire (ZCQ); outcome(s) measured preoperatively with at least one follow-up measurement at a minimum of 12 months, and surgical procedure consisted of complete ligamentous and bony decompression performed via open or endoscopic access. Articles reporting the outcomes of minimal decompression procedures (e.g., *mild*® procedure) and spinal fusion were excluded. Literature controls were identified from single-arm studies of laminectomy as well as from trials where laminectomy served as a “gold standard” comparator. Articles eligible for inclusion were identified through electronic key word searches of the PubMed database as well as through review of bibliographies of two recently published meta-analyses on the safety and effectiveness of decompressive laminectomy for spinal stenosis.[9,10]

For each clinical outcome, the median value (range) was computed from the contributing laminectomy study groups and compared graphically to the corresponding spacer mean value preoperatively as well as at 12 and 24 months. Additionally, the percentage improvement over baseline was estimated as the preoperative value compared to the final follow-up value for all outcomes. Back and leg pain scores were adjusted as necessary to correspond to a 100-mm visual analog scale. Only two of three ZCQ domains, symptom severity and physical function, were included in this comparative analysis as the patient satisfaction domain does not involve a baseline measurement. All data are presented as descriptive statistics.

## Results

In all, 19 articles were identified that included a laminectomy study arm reporting at least one clinical outcome with a minimum 12 months of follow-up, representing 1045 patients (Table 1).[2,11–28] Fourteen laminectomy articles reported back pain severity (n = 618), 12 reported leg pain severity (n = 537), 12 reported ODI (n = 753) and 3 reported ZCQ values (n = 129). In the Superior® trial, 190 patients were randomly allocated to receive the device.[6]

Preoperatively, patients consistently presented with moderate to severe symptoms of neurogenic claudication irrespective of treatment, with laminectomy patients showing somewhat greater levels of chronic pain, functional impairment and condition-specific dysfunction (Figures 1–5). For example, prior to surgery, the average leg pain severity in the spacer group was 67 mm compared to a median value of 74 mm among laminectomy patients (range: 58–91 mm) (Figure 2).

Following treatment with either spacer or laminectomy, patients attained clinically substantial gains across all outcome measures at 12 months with durable improvement through 24 months, postoperatively (Figures 1–5). For back pain severity, patients realized an approximate 35-mm improvement following implantation with the spacer, reflecting an average percentage improvement of 65% (Figures 1 & 6). In comparison, laminectomy patients achieved an approximate 52% (range: 30–68%) improvement from a preoperative median score of 60 mm (range: 50–83 mm) to 27 mm (range: 21–39 mm) at 24 months, postoperatively (Figures 1 & 6).

For leg pain severity, the average percentage change with the spacer was 70%, exhibiting an improvement of approximately 47 mm over baseline (Figures 2 & 6). This improvement was slightly higher than the 62% median percentage improvement realized with laminectomy (range: 43–79%), reflecting a change from 74 mm (range: 58–91 mm) preoperatively to 29 mm (range: 19–37 mm) at 24 months, postoperatively (Figures 2 & 6).

With respect to back functional impairment as measured by ODI, overall percentage improvements were somewhat smaller for both spacer (51%) and laminectomy (47%, range: 36–83%) (Figure 6). Spacer patients showed an approximate 19 percentage point improvement through 24 months, whereas laminectomy patients improved from 43% (range: 31–74%) preoperatively to 20% (range: 12–25%) at 24 months, postoperatively (Figure 3).

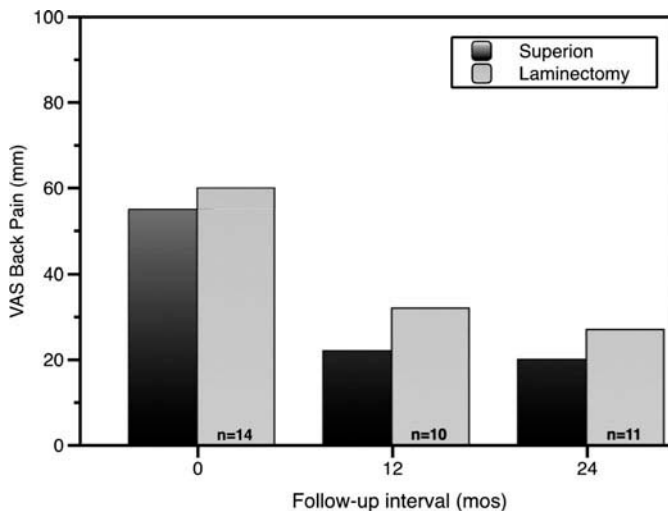
Condition-specific dysfunction as measured by the ZCQ showed modest improvements for both treatments. For spacer, the symptom severity and physical function domains improved from 3.3 and 2.6 preoperatively to 2.1 and 1.6 at 24 months, reflecting gains of 37% and 36%, respectively (Figures 4–6). For laminectomy, the median preoperative scores for the symptom severity and physical function domains were 3.5 (range: 3.4–3.8) and 2.7 (range: 2.5–3.3) compared to 24-month median postoperative scores of 2.4 (range: 2.3–3.0) and 1.8 (range: 1.7–2.6), reflecting improvements of 29% (range: 21–34%) and 32% (range: 21–33%), respectively (Figures 4–6).

**Table 1. Summary of studies of decompressive laminectomy.**

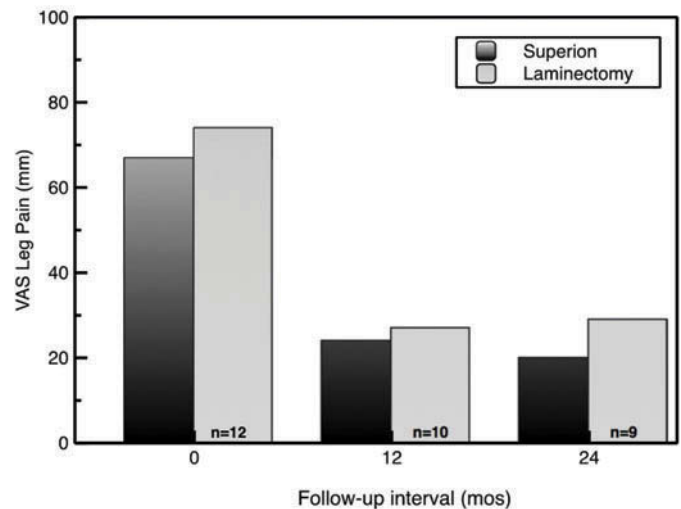
Reference	Study design*	Sample size (n)	Procedure	Outcomes <sup>†</sup>
Fokter and Yerby (2006) [14]	Retrospective	38	Open decompression	ZCQ
Cavusoglu et al (2007) [12]	One-group pretest-posttest	50	Open decompression	BP, ODI
Malmivaara et al. (2007) [21]	RCT	50	Open decompression	BP, LP, ODI
Kim et al. [2007] [18]	Retrospective	31	Open decompression	BP, LP
Weinstein et al. (2008) [2]	RCT	278	Open decompression	ODI
Haro et al. (2008) [16]	One-group pretest-posttest	42	Open decompression	BP, LP
Pao et al. (2009) [23]	One-group pretest-posttest	50	Microendoscopic decompression	ODI
Celik et al. (2010) [13]	Retrospective	34	Open decompression	BP, LP, ODI
Jakola et al. (2010) [17]	Retrospective	101	Open decompression	BP, LP, ODI
Postacchini et al. (2011) [24]	Retrospective	35	Open decompression	ODI
Gurelik et al. (2012) [15]	RCT	26	Open decompression	ODI
Beyer et al. (2013) [11]	Two-group pretest-posttest	26	Microsurgical decompression	BP, LP, ODI
Son et al. (2013) [27]	Retrospective	31	Open decompression	BP, LP, ODI
Rajasekaran et al. (2013) [25]	RCT	23	Open decompression	BP, LP
Stromqvist et al. (2013) [28]	RCT	50	Open decompression	BP, LP, ZCQ
Liu et al. (2013) [19]	RCT	29	Open decompression	BP, LP
Richter et al. (2014) [26]	Two-group pretest-posttest	31	Microsurgical decompression	BP, ODI
Lonne et al. (2015) [20]	RCT	41	Microsurgical decompression	BP, LP, ODI, ZCQ
Moojen et al. (2015) [22]	RCT	79	Open decompression	BP, LP

\* RCT indicates randomized controlled trial

† ZCQ, Zurich Claudication Questionnaire; BP, back pain; ODI, Oswestry disability index; LP, leg pain



**Figure 1. Back pain severity.** Preoperative, 12- and 24-month scores for spacer (mean) and laminectomy (median); n refers to number of included studies.

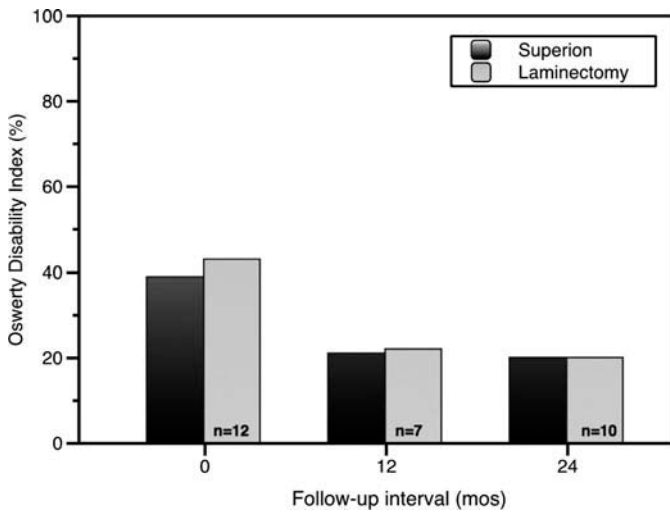


**Figure 2. Leg pain severity.** Preoperative, 12- and 24-month scores for spacer (mean) and laminectomy (median); n refers to number of included studies.

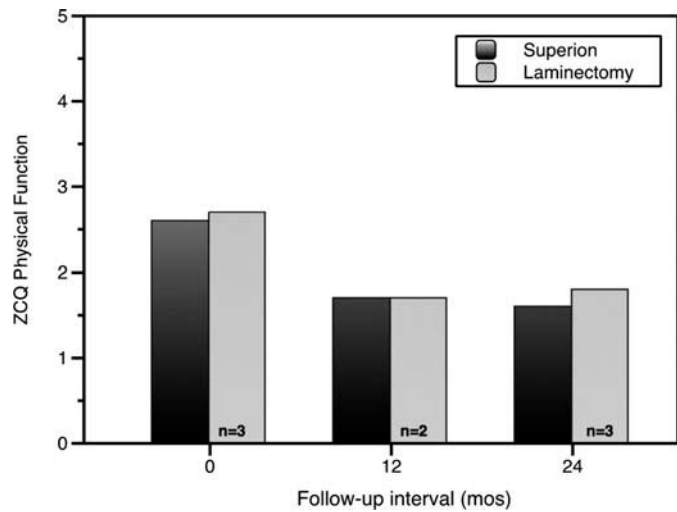
## Discussion

Lumbar stenosis is an increasingly common disorder affecting our aging population with patients suffering from reduced mobility as well as chronic back and leg pain. Decompressive

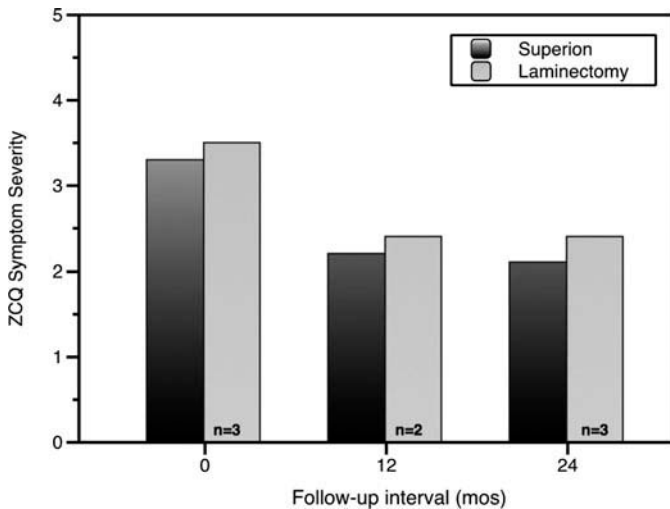
laminectomy is considered the “gold standard” surgical treatment when conservative options are exhausted.[7,29] The long-term results of the SPORT trial reported superiority of



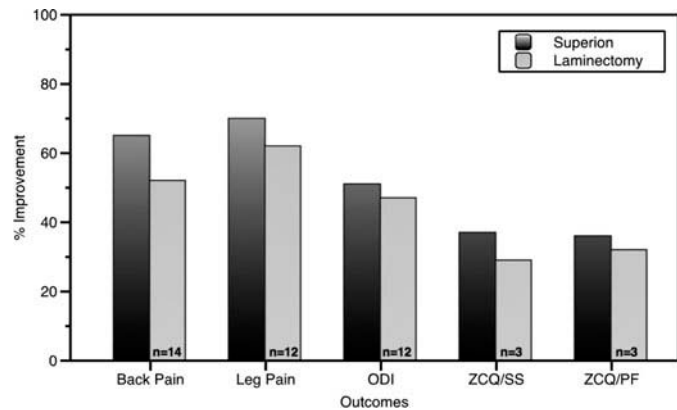
**Figure 3. Oswestry disability index.** Preoperative, 12- and 24-month scores for spacer (mean) and laminectomy (median); n refers to number of included studies.



**Figure 5. ZCQ physical function.** Preoperative, 12 and 24 month scores for spacer (mean) and laminectomy (median); n refers to number of included studies.



**Figure 4. ZCQ symptom severity.** Preoperative, 12- and 24-month scores for spacer (mean) and laminectomy (median); n refers to number of included studies.



**Figure 6. Percentage improvement by outcome measurement.** ODI, Oswestry disability index; ZCQ/SS, Zurich Claudication Questionnaire Symptom Severity domain; ZCQ/PF, Zurich Claudication Questionnaire Physical Function domain. n refers to number of included studies.

laminectomy over continued nonoperative management.[2] Interspinous spacer devices offer a less invasive approach with the potential for decreased morbidity in the treatment of moderate lumbar stenosis.

This study demonstrated that intractable symptoms of neurogenic claudication are effectively ameliorated by treatment with an interspinous spacer or traditional decompressive surgery. Robust improvements were realized uniformly across all patient-reported outcomes through 24 months of follow-up for both treatments. These reported gains translate to tangible health benefits for the patient. In fact, in the spacer IDE study group, the percentage of patients that achieved the

minimal clinically important level of improvement was 67% for back pain, 76% for leg pain, 63% for ODI and 82% for ZCQ.[6]

Not requiring concomitant surgical decompression, the Superior® is the second “stand-alone” interspinous spacer approved by the FDA and the only one currently available on the US market. Importantly, the implantation procedure does not cause substantial alterations or disruptions to the spinal anatomy which likely reduces the complexity of future surgical options in the event that revision becomes necessary to address progressive degenerative changes and/or reemergence of symptoms. Specifically, the epidural space is not surgically exposed during spacer insertion, whereas a laminectomy decompression

directly opens the epidural space. The surgical exposure of the epidural space is known to routinely produce epidural adhesions around the dural sac and exiting nerve roots, which can cause symptomatic problems.[30,31] Additional treatment and modification of subsequent surgical procedures may be necessary. If device removal is required, the implant can be explanted via the same minimally invasive access as the original implantation procedure. This suggests that interspinous spacers may be considered a reasonable “first-line” option in the continuum of care for the treatment of moderate lumbar spinal stenosis.

The minimization of iatrogenic insult associated with implantation of interspinous spacers significantly reduces the risk of operative adverse events. In a recent review of spinal devices in the Medicare population, higher perioperative complication rates were found in decompression surgeries compared to interspinous spacers.[32] Because of the minimally invasive nature of the surgery, implantation of spacers can be accomplished under local anesthesia or with sedation.

Despite similar levels of clinical effectiveness, two meta-analyses of treatments for spinal stenosis reported that reoperation rates were higher with interspinous spacers than with decompressive laminectomy.[9,10] However, these two interventions are not directly comparable in terms of their indications for use, target population or sequence in the continuum of care. Laminectomy is best reserved for more severely stenotic patients and, indeed, inspection of preoperative outcome scores in the current study consistently showed that patients treated with laminectomy presented with a higher degree of pain and functional impairment at baseline (Figures 1–5). Additionally, the revision procedure itself is notably different between these treatments with laminectomy requiring wide surgical exposure, dissection of extensive scar tissue with significant blood loss and operative risks, and conversion to fusion necessitating bone grafting and insertion of hardware. Alternatively, removal of the spacer can be accomplished with minimal tissue disruption and low surgical risk prior to conversion to a laminectomy. Thus, the spacer device, with its avoidance of epidural scarring, allows the patient to consider a wider choice of potential reoperations and their timing. The differences noted in reoperation rates may, in large part, reflect the ease of conversion (or lack thereof) to the next option in the continuum of care.

In conclusion, this recently FDA-approved stand-alone interspinous spacer offers an effective and safe treatment option for patients suffering from intermittent neurogenic claudication associated with moderate spinal stenosis. It is noteworthy that

this review of the historical laminectomy literature failed to show that direct decompression provided superior clinical benefit compared to the indirect decompression provided by the spacer. Treatment with the spacer offers robust and durable symptom relief for at least two years postoperatively. It should be considered in the continuum of care prior to decompressive laminectomy, thereby minimizing the attendant surgical risks while allowing for multiple future options as the degenerative disease progresses.

### Expert commentary

Interspinous spacers fill a distinct treatment gap in the continuum of care for patients with moderate degenerative lumbar spinal stenosis. These patients have exhausted conservative care but may be inappropriate candidates for or unwilling to undergo surgical decompressive laminectomy. Because spacers are implanted in a minimally invasive fashion without anatomical disruption, they can be easily removed and converted to laminectomy if symptoms reemerge. This study corroborates previous meta-analyses that found similar clinical benefit provided by both spacers and laminectomy, providing the patient with a minimally invasive option without compromising symptom relief.

### Five-year view

Current projections indicate a marked increase in the number of patients afflicted with spinal stenosis. Consequently, there remains a keen interest in minimally invasive treatment options that delay or obviate the need for invasive surgical procedures, such as decompressive laminectomy or fusion. Stand-alone interspinous spacers will likely fill a currently unmet treatment gap in the continuum of care and help to reduce the burden of this chronic degenerative condition on the health care system.

### Acknowledgement

We thank Terry Meredith for graphical assistance.

### Financial & competing interests disclosure

*The authors were supported by Vertiflex Inc (San Clemente, Ca, USA). JE Block receives consultancy fees from Vertiflex, Inc. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.*

### Key issues

- Lumbar spinal stenosis is a progressively disabling condition that represents the leading cause for spinal surgery in older adults.
- Interspinous spacers offer a minimally invasive treatment option for patients with intermittent neurogenic claudication due to moderate spinal stenosis who have failed conservative care but where surgery is unwarranted or unwanted.
- Both spacer and laminectomy offer similarly robust and durable clinical improvements in claudicant symptoms.
- Use of the spacer may obviate the need for decompressive laminectomy in the majority of patients carefully selected in accordance with the approved indications for use.



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