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Research Article

Two-year Outcomes of Facet-sparing Lumbar Decompression with a Minimally Invasive Flexible Microblade Shaver Device

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Abstract

Background: Surgical decompression in patients with degenerative lumbar spinal stenosis (LSS) may lead to spinal instability. Minimizing inadequate lateral recess decompression is a significant concern for spinal surgeons. Because the world's population is increasing, an increasing number of patients are being treated for symptomatic refractory lumbar spinal stenosis; therefore, the rate of laminectomies will increase. The device in this study was developed to maximize removal of compressing tissues while minimizing loss of structural integrity in ventral-to-dorsal lumbar decompression. We present the two-year safety and effectiveness outcomes of subjects with degenerative LSS who were treated using a minimally invasive flexible microblade shaver device.

Methods: In a prospective multi-center case series conducted over a five-year period (2010-2014), 63 subjects with LSS were treated with the minimally invasive surgical (MIS) guidewire technology system. Subjects were followed for 24 months using the Zurich Claudication Questionnaire (ZCQ), Oswestry Disability Index (ODI), and Visual Analog Scale for Pain (VAS).

Results: The 63 subjects had a total of 86 levels treated. L4-L5 accounted for 54.65% of the levels treated, followed by L5-S1 (23.26%), L3-L4 (18.60%), and L2-L3 (3.49%). Total mean operative time (skin-to-skin) for decompression with the investigational system was 90.84 minutes (SD = 39.51). Decompression was attempted at 113 foraminal openings; 111 attempted (92.79% success) disc-level or above-the-pedicle passes, and 24 attempted (91.67% success) below-the-pedicle passes. At 24 months, the cohort had improved in the ZCQ Symptom Severity Score as compared with the baseline score (mean change 1.08 points, $P < .0001$), as well as improved in the ZCQ Functional Status score (mean change 0.88 points, $P < .0001$), the ODI (mean change 21.93 points, $P < .0001$), and the VAS Back, VAS Leg (Left), and VAS Leg (Right) (mean change 29.69, 25.13, and 43.13, respectively, $P < .0001$). A total of 12 adverse events were reported in 11 subjects. Seven subjects had secondary surgery, two of which occurred during the index hospital stay.

Conclusions: Decompression using the minimally-invasive surgical guidewire technology system in subjects with LSS was associated with improved clinical outcomes and may represent an initial treatment strategy for patients with LSS.

Level of Evidence: III (case series); efficacy.

Keywords: *MicroBlade Shaver®; iO-Flex® System; Lumbar Spine; Spinal Stenosis; Surgical Decompression; Laminectomy; Minimally Invasive*

Clinical Relevance

1. The iO-Flex® MicroBlade Shaver® (MBS) device allows for decompression without causing unnecessary instability secondary to the removal or damage to facet joints, pars interarticularis, and midline structures. The flexible MBS device allows for complete removal of the ligamentum flavum as well as degenerative overgrowth of the superior articulating process without sacrificing facet surface area.
2. Decompression using the iO-Flex® MBS device resulted in clinical and statistical improvement in all measured outcomes in subjects with degenerative lumbar spinal stenosis, including back pain VAS, lower extremity VAS, ZCQ Symptom Severity Score, ZCQ Functional Status Score, and ODI. Improvement was present at six months and was sustained through two years.
3. This study demonstrated successful decompression of lumbar spinal stenosis using the minimally-invasive, facet-sparing iO-Flex® MBS device in subjects suffering from neurogenic claudication and radiculopathy.
4. Decompression with the minimally-invasive iO-Flex® MBS device as an initial treatment strategy for neurogenic claudication refractory to conservative treatment may result in a lower complication rate, lower cost, and better clinical outcome than initial decompression and fusion.

Introduction

Acquired degenerative lumbar spinal stenosis (LSS) is the most frequently observed type of spinal stenosis [1]. LSS typically manifests in the fifth and sixth decades of life and is anatomically defined as a narrowing of the spinal canal or intervertebral foramen at single or multiple levels with compression of neural structures by surrounding bone and soft tissue [2]. Patients typically present with low back pain and neurogenic claudication, and may have unilateral or bilateral radicular leg pain [3].

For patients without gross instability, the mainstay of treatment after medical management has failed is surgical decompression. Two randomized trials and one high-quality observational study have shown the benefits of direct decompression over conservative care [2,4,5]; however, concerns remain. The removal or damage of supporting anatomical structures may create an iatrogenic instability and accelerate the degenerative process [6], while removal of as little as 30% of the facet joint can lead to spinal instability [7,8]. Failed back surgery syndrome (FBSS) associated with LSS is largely due to inadequate diagnosis and/or inadequate surgical decompression of lateral recess stenosis and/or post-surgical induced altered biomechanics [9-11]. Several minimally-invasive techniques have been introduced with more limited lamina and facet joint removal to preserve the integrity of the posterior column [12,13].

The surgical dilemma is finding the correct balance of thorough decompression without causing unnecessary instability secondary to the removal or damage of supporting structures, such as facet joints, pars interarticularis, and midline structures. A flexible decompression system which allows for ventral-to-dorsal decompression of foraminal areas would theoretically maximize removal of the compressing tissues while minimizing the loss of structural integrity. The iO-Flex® flexible MicroBlade Shaver® (MBS) device (Spinal Elements, Inc., Marietta, GA, formerly Baxano Surgical, Inc.) was designed to allow for ventral-to-dorsal decompression of impinged neural elements in the lumbar spine.

The potential value of a novel ventral-to-dorsal lumbar decompression technique via familiar mini-open or tube system approach is investigated in a prospective case series. In this report we present two-year safety and effectiveness outcomes of subjects with degenerative LSS who underwent surgical decompression using the iO-Flex® MBS device.

Materials and Methods

Study design

The study was a prospective multi-center series of patients with degenerative LSS who underwent surgical decompression with the iO-Flex® MBS device (Spinal Elements, Inc., Marietta, GA) (Clinicaltrials.gov NCT01067014). Subjects were followed at six weeks and 3, 6, 12, and 24 months using the Zurich Claudication Questionnaire (ZCQ) [14], Oswestry Disability Index v2.1a [15], Visual Analog Scale for Pain

(0-100 mm), and neurological evaluation. Adverse events were collected at each follow-up and during the unscheduled visits. Adverse events were reviewed and classified by a senior author as treatment complications or unrelated events. Data were collected using an eCRF system. Professional external monitors performed on-site visits to assure that data were true, accurate, and reliable.

Subjects

The study protocol was approved by a central Institutional Review Board (Western IRB, Washington State) for five sites and locally at 11 sites. Between March 2010 and May 2012, 73 patients were screened and 63 were enrolled at 16 investigational sites in the United States.

Diagnosis of LSS was determined by the testing surgeon using clinical signs and symptoms and radiographic findings; either an MRI or myelogram with post-CT was required.

Patient selection criteria targeted subjects with symptomatic and refractory LSS (claudication and/or radiculopathic process). Lateral recess stenosis, specifically foraminal stenosis, was an independent factor for inclusion as assessed by radiographic findings. Central and lateral recess stenosis symptoms were not differentiated because they typically occur together; moreover, central stenosis may be less contributory to presenting symptoms despite prominent scan features. Laminotomy, by definition, addresses central stenosis and is required for the introduction of the shaver device.

Patients were deemed eligible for this study if they were 18 years or older, had leg or buttock pain of at least 4 on the 10-point Visual Analog Scale (VAS), had failed non-operative medical treatment, and had one or two contiguous levels of symptomatic LSS between L2 and S1.

Failed non-operative treatment was defined as 24 weeks of conservative treatment including non-steroidal anti-inflammatory drugs (NSAIDs) if appropriate, rest or restriction of activities, physical therapy, or steroid injections.

Patients with back pain only, central stenosis only, or significant instability (defined as greater than 4 mm translation on flexion/extension radiographs) were excluded from participation.

Operative technique

A minimally-invasive surgical (MIS) technique was used in all subjects using either a mini-open or tube system approach per surgeon preference. Surgeon familiarity with the laminotomy approach provided a twofold balance: (1) there was no expected difference in outcome relative to the central MIS decompression technique utilized; and (2) familiarity with laminotomy minimized or limited the potential impact of the learning curve on the actual introduction of the shaver device. Central stenosis was surgically addressed first before addressing foraminal stenosis in order to avoid neural compromise within the foramen. The lateral recess or doorway was defined by the medial borders of the superior facet and the pedicle, respectively.

Subjects underwent operative decompression with the iO-Flex® flexible over-the-wire MBS device. This device allows ventral-to-dorsal decompression of impinged neural elements in the lumbar spine with controlled alternating manual reciprocations while sparing anatomy uninvolved in neural compression. A small ipsilateral laminotomy was performed to create an interlaminar window to allow the removal of the ligamentum flavum and to directly visualize the dura. A cannulated probe was inserted through the laminotomy and passed through the lateral recess and out the foramen, just superior to the inferior pedicle (Figure 1A). The probe position was confirmed using lateral fluoroscopy and the inner catheter was then deployed. A nitinol guidewire was passed through the probe and out dorsally through the skin where it was locked into the distal handle. The catheter was then retracted and the probe removed, leaving the guidewire in place within the foramen to facilitate the next step of localizing the nerve root.

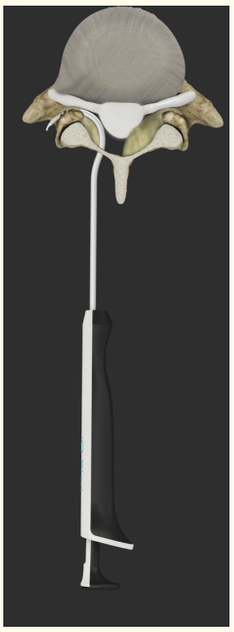

Figure 1A: *A cannulated probe is inserted through the laminotomy and passed through the lateral recess and out the foramen just superior to the inferior pedicle.*

To confirm the nerve root was located safely ventral to the guidewire, and ultimately to the MBS device, the iO-Flex® Neuro Check® device was attached to the wire via a proximal exchange tip and pulled into the lateral recess and foramen using the distal handle (Figure 1B). Low energy electrical stimulation was applied separately and sequentially through electrodes located on the anterior (ventral) and posterior (dorsal) surfaces of the device. Electrical current passed from the Neuro Check® device and was propagated down the nerve root, where it was assessed by electromyography (EMG) surface electrodes. To produce activity at the surface electrodes, a threshold amount of current was applied from the Neuro Check® device to the nerve itself. Generation of an adequate top/bottom differential ratio confirmed the nerve root was localized and the pass was safely dorsal to the nerve root. The Neuro Check® device was then removed.

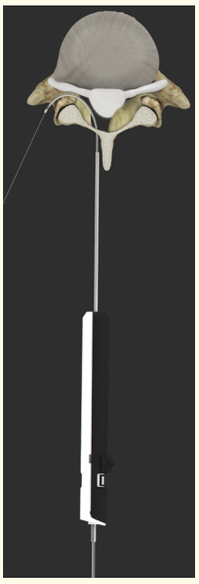

Figure 1B: *To confirm the nerve root is located safely ventral to the guidewire, and ultimately to the MicroBlade Shaver® device, the iO-Flex® Neuro Check® device is attached to the wire via a proximal exchange tip and pulled into the lateral recess and foramen using the distal handle.*

An appropriately-sized iO-Flex® MBS device (5.5, 7.5, 10.0, and 12.0 mm widths) was selected and passed into the lateral recess and foramen via the guidewire in the same manner (Figure 1C).

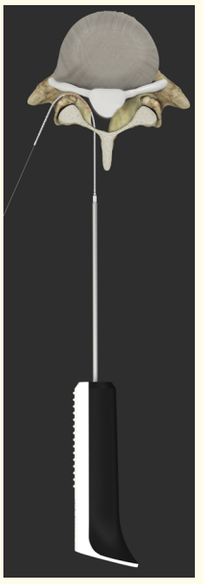

Figure 1C: *An appropriately sized MicroBlade Shaver® device is selected and passed into the lateral recess and foramen via the guidewire.*

The dorsal side of the device has cutting teeth designed to excise bone and ligament, while the ventral side is smooth to protect the neural structures. Decompression of the lateral recess and foramen was achieved with gentle upward tension and short bimanual reciprocations with the MBS and a distal handle. Tissue removal, thoroughness of decompression, and the structural change effected with the iO-Flex® MBS was assessed by intraoperative sagittal fluoroscopic review. The increase in foraminal height and width (with the MBS in the foramen), was compared to the preprocedural baseline (with the MBS in the foramen). Foraminal volume change was further assessed with standard palpatory probes (Figure 1D) [16]. When the surgeon deemed thorough decompression was achieved, all instruments were removed, the decompressed area was irrigated, and a hemostatic agent was applied as necessary.

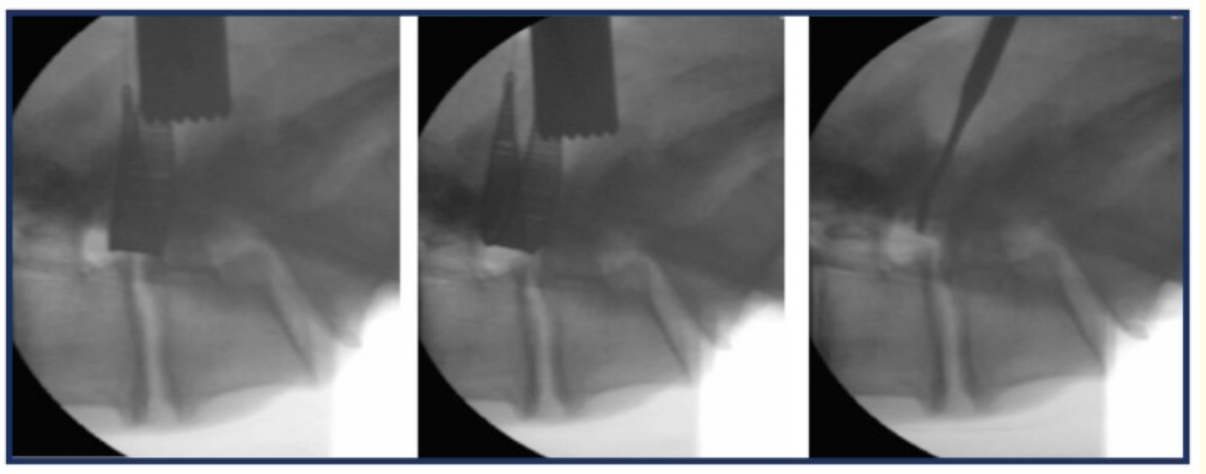

Figure 1D: *Lateral images of pre-procedural and post-procedural assessment of decompression using fluoroscopy and a Woodson probe (left to right: pretreatment with MicroBlade Shaver® instrument, post-treatment with MicroBlade Shaver® instrument, and post-treatment assessment with Woodson probe).*

The surgical technique described here is the one most commonly used with the device and is referred to as an "above-the-pedicle" or "disc-level" pass, because the instruments are passed and decompression is performed at the level of the disc which is also the level of the exposure. The ipsilateral and contralateral sides may be decompressed through the original laminotomy, with the contralateral instruments being slightly less angulated. Likewise, both the ipsilateral and contralateral foramina of the inferior adjacent disc space may be decompressed through the original laminotomy. This technique is termed a "below-the-pedicle" pass, because the instruments are passed below the lower pedicle of the vertebral body at the level of the exposure. Using all of these approaches, four foramina may be decompressed through a single laminotomy (Figure 2). Additional incisions and approaches can be made per the treating surgeon's preference. Further details about the technique may be found in Lauryssen [16] and Lauryssen., *et al* [17].

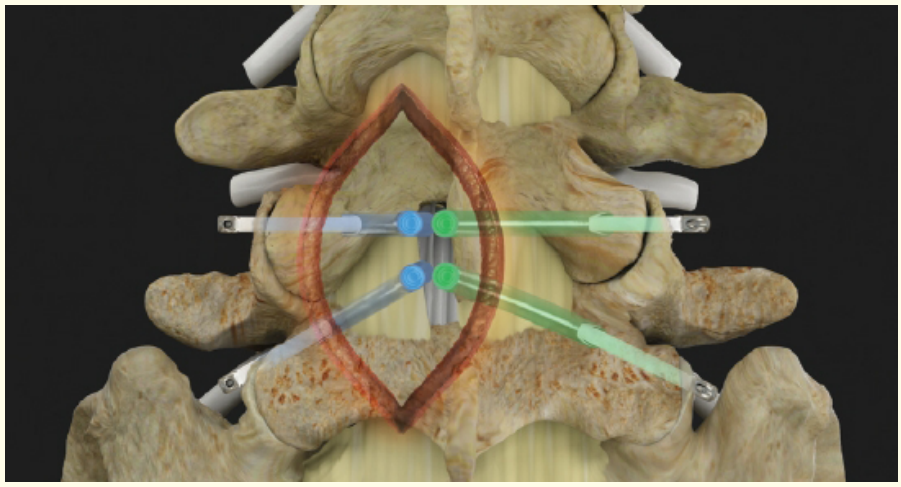

Figure 2: *Four foramina may be decompressed through a single laminotomy.*

Statistical methods

As a single-arm observational evaluation, all variables were tabulated, and appropriate descriptive summary statistics were presented. Baseline and post-operative assessment data for individual subjects were compared and summarized. Analyses of continuous variables employed asymptotic methods based on multivariate normality (paired T-test was used to test the difference between paired observations, analysis of variance, and linear regression). P values less than 0.05 were considered statistically significant.

Missing 12- and 24-month values were documented using last value carry-forward approach starting with six-month values. After imputation, data were available for 56 (94.92%) subjects at all follow-ups.

Changes in ZCQ Symptom Severity Score, ZCQ Physical Function Score, ODI score, and VAS pain scores at 6, 12, and 24 months were evaluated using one-way analysis of variance. All analyses were performed on imputed data. For sensitivity purposes, analyses were performed on non-imputed data sets. All statistical analyses were performed using SAS/STAT version 9.4 (SAS Institute Inc. Cary, NC).

Results

Demographics and pathology

The mean age of the patient sample was 64.73 years (SD = 11.96); 30 (47.62%) were females (Table 1).

Characteristics		Measurement
Gender, n (%)	Female	30 (47.62)
Tobacco smoking, n (%)		8 (12.9)
Race, n (%)	White	58 (92.06)
	African American	2 (3.17)
	American Indian	2 (3.17)
	Other	1 (1.59)
Age, years (SD)*		64.73 (± 11.96)
BMI** (SD)		29.02 (± 5.12)
Duration of surgery, minutes (SD)		90.84 (± 39.51)
Hospital stay, days (SD)		1.41 (± 1.42)
Number of treated spinal levels, n (%)	One level	40 (63.49)
	Two levels	23 (36.51)
ZCQ (SD)	Symptom severity	3.27 (± 0.56)
	Functional status	2.62 (± 0.56)
ODI (SD)		43.06 (± 16.24)
Pain (SD)	Lower back	49.05 (± 33.42)
	Left side	43.98 (± 33.25)
	Right side	55.22 (± 35.66)
Radiology, mm (SD)	Translation (F to E) (mm)	0.55 (± 0.61)

Table 1: *Patient demographics.*

**Plus–minus values are means ±SD (Standard Deviation).*

***The body-mass index is the weight in kilograms divided by the square of the height in meters,*

Mean body mass index was 29.02 (SD = 5.12). All subjects were diagnosed with symptomatic degenerative LSS at one (N = 40, 63.49%) or two (N = 23, 36.51) contiguous levels between L2 and S1. The 63 subjects had a total of 86 levels treated. L4-L5 accounted for 54.65% of the levels treated, followed by L5-S1 (23.26%), L3-L4 (18.60%), and L2-L3 (3.49%).

Operative parameters

Total mean operative time (skin-to-skin) for decompression with the iO-Flex® MBS device was 90.84 minutes (SD = 39.51). Operative time for subjects with one level treated was significantly shorter than those with two levels treated (76.70 minutes ± 28.8 SD vs 115.40 minutes ± 42.7 SD, p = 0.0103). Mean estimated blood loss was 163.17 cc (±153.31 SD). The mean length of hospital stay was 1.41 days (±1.42 SD).

Preoperative characteristics and surgery details were summarized using tables of frequencies and means and standard deviations. Two subjects required re-operation during the initial hospital stay and were excluded from further follow-up. Two additional subjects withdrew before six months. Six-month follow-up was available for 56/59 (94.92%). One patient withdrew by 12 months. Twelve-month follow-up was available for 46/58 (79.31%). Six more subjects withdrew by 24 months; the 24-month follow-up was available for 37/52 (71.15%).

Procedural details

Access was achieved 50 times (79.37%) via an open method and 13 times (20.63%) via a tube system.

Forty-seven (74.60%) subjects underwent laminotomies and 16 (20.93%) underwent laminectomies. Decompression with the MBS device was attempted at 86 levels, 70 (71.6%) of which were unilateral while 16 (18.60%) were bilateral. Flexible MBS decompression was attempted at a total of 113 foraminal openings. There were 111 attempted disc-level or above-the-pedicle passes and 24 attempted below-the-pedicle passes. The success rate of above-the-pedicle passes was 103/111 (92.79%), and the success rate of below-the-pedicle passes was 22/24 (91.67%).

Patient outcomes

By six months postoperative, there was improvement in all patient-reported outcome measures (Table 2).

	Baseline	6 months	12 months	24 months	P-value
ZCQ Symptom Severity, mean (CI)*	3.27 (3.08, 3.45)	2.12 (1.92, 2.31)	2.12 (1.93, 2.32)	2.19 (2.00, 2.39)	< .0001
ZCQ Functional Status, mean (CI)*	2.62 (2.45, 2.78)	1.66 (1.49, 1.83)	1.71 (1.54, 1.88)	1.74 (1.57, 1.91)	< .0001
ODI, mean (CI)*	43.06 (38.65, 47.48)	19.31 (14.72, 23.90)	21.72 (17.13, 26.31)	21.13 (16.54, 25.72)	< .0001
VAS Back, mean (CI)*	49.05 (42.20, 55.90)	20.79 (13.60, 27.97)	19.11 (11.93, 26.29)	19.36 (12.18, 26.54)	< .0001
VAS Leg (Left), mean (CI)*	43.98 (37.09, 50.88)	14.66 (7.40, 21.91)	16.41 (9.15, 23.66)	18.85 (11.60, 26.11)	< .0001
VAS Leg (Right), mean (CI)*	55.22 (48.42, 62.02)	16.87 (9.73, 24.02)	12.07 (4.93, 19.21)	12.09 (4.95, 19.23)	< .0001

Table 2: *Outcomes of Patients Treated with the iO-Flex® System (N = 56).*
**Numbers in parentheses are 95% confidence intervals (CI).*

Specifically, at 24 months compared with baseline, the ZCQ Symptom Severity Score improved for 1.08 mean change (P < .0001); the ZCQ Functional Status score improved for 0.88 mean change (P < .0001); the ODI improved for 21.93 mean change (P < .0001), and the VAS Back, VAS Leg (Left), and VAS Leg (Right) improved 29.69, 25.13, and 43.13 millimeters, respectively (P < .0001), for improvements of 57.6%, 66.7%, and 69.4%, respectively. There were no significant changes at 12 months and 24 months follow-up compared with six months follow-up.

Reoperations and subsequent surgeries

Of 63 subjects who underwent the procedure, two had secondary surgery during the index hospital stay and five had subsequent surgery following discharge for the index procedure, for a total of seven subjects who underwent reoperations and subsequent surgeries. Subject 1 had a disc herniation and underwent discectomy during the index hospital stay. Subject 2 was found to have a pars defect at the time of the index surgery. The planned iO-Flex® System procedure was aborted and the patient was returned to the operating room for interbody fusion and instrumentation during the index hospital stay. These two reoperations were secondary to patient selection error with pathologies that were identified as exclusion criteria. The index surgery did not compromise either patient's ultimately good recovery from their definitive treatment. Of the five subjects who underwent additional surgery after index surgery discharge, three had subsequent surgery at the index level and two had surgery at additional levels due to the development of pathology. Subject 3 underwent L3-L4 laminotomy with synovial cyst resection at six months postoperative. Subject 4 underwent L3-L4 decompression and L4-L5 posterolat-

eral interbody fusion at 12 months postoperative. Subject 5 underwent discectomy at three months postoperative. Subject 6 underwent fusion at six weeks postoperative. Finally, Subject 7 underwent third-level decompression at three months postoperative.

Adverse events

All adverse events were unrelated to the iO-Flex® MBS device and procedure. Twelve adverse events were reported in 11 (17.46%) subjects. Decompression is performed within a more confined spinal canal geometry with laminectomy (or laminotomy) as compared to Transforaminal Interbody Fusion (TLIF); laminectomy is therefore a risk factor for dural tear or durotomy [18]. Four subjects sustained a dural tear during the procedure. All dural tears occurred during exposure before the introduction of the iO-Flex® MBS device.

Four subjects had transient worsening of their extremity pain, one subject developed a procedure-related synovial cyst, one subject developed a urinary tract infection, and one subject developed radiculopathy following a failed attempted procedure. Transient dysesthesia was managed conservatively when present and resolved by six weeks.

This case series presents moderate to severe degenerative pathology that may have been considered for TLIF so as to facilitate access to the lateral recess including the foramen had this shaver device technology not been available for use. The reported incidence of unintended durotomy during lumbar surgery is common and varies widely, ranging up to 35% and averaging 17% across all indications. Prospective studies have reported a higher incidence than retrospective studies for dural tear or durotomy [19,20].

Discussion

This study demonstrated successful decompression of degenerative lumbar spinal stenosis (LSS) using a minimally-invasive, facet-sparing device in patients suffering from neurogenic claudication.

Surgical decompression with the iO-Flex® MBS device improved all measured outcomes in subjects with degenerative LSS, including back pain VAS, lower extremity VAS, ZCQ Symptom Severity Score, ZCQ Functional Status Score, and ODI compared with the baseline scores.

Improvement was present at six months and was sustained through two years. Although some have argued that decompression will not adequately address severe back pain complaints in this population, we found excellent resolution of lumbago with decompression, supporting a neurogenic etiology for this complaint. Preserving facet anatomy creates the potential to limit the development of postoperative back pain complaints that are frequently observed following standard decompression techniques. The findings of this study provide evidence for a viable alternative to fusion in the degenerative LSS population.

Reported rates of patients requiring a subsequent fusion procedure following decompression range from 5% to as high as 17%, due to complications secondary to iatrogenic destabilization [21,22]. Clinically, some surgeons believe that fusion will be a more definitive procedure than decompression alone, with a lower re-treatment rate. This has resulted in an increase in spinal fusions for LSS patients without initial spinal instability [23]. Other studies suggest that decompression with fusion in patients without instability may not actually be necessary [24,25]. The iO-Flex® MBS device allows for decompression without causing unnecessary instability secondary to the removal or damage to facet joints, pars interarticularis, and midline structures. The flexible MBS device allows for complete removal of ligamentum flavum as well as degenerative overgrowth of the superior articulating process without sacrificing facet surface area. By limiting damage to the facet joint and allowing for preservation of midline anatomy, the iO-Flex® MBS device has the potential of attenuating the development of segmental instability in spinal decompression procedures. Because of this, the iO-Flex® MBS should be able to limit the need for fusion procedures in patients with LSS.

In this study, two subjects (3%) developed instability during follow-up. Of these two subjects, one demonstrated no improvement following the index procedure, subsequently returning at six weeks for fusion at that level. The second patient had initial improvement;

however, with the progression of spondylolisthesis at the treated level and return of symptoms, the patient underwent fusion one year after the index procedure. The two reoperations were secondary to patient selection error; the first patient had a pars defect and the second patient had disc herniation. Both fusions were accomplished by facetectomy and interbody arthrodesis with instrumentation. The index surgery did not compromise either patient's ultimately good recovery, nor were the subsequent fusion procedures made more difficult by the index procedure. One additional operation was performed at an index level during the study period, for the treatment of a synovial cyst that had developed contralateral to the iO-Flex® system side.

This study had some limitations. The lack of a control group limited the ability of the study to compare the efficacy of the device to the current standard of care. The follow-up rate at 24 months was somewhat low. Some information was missing but was handled using standard statistical methodology.

Conclusion

In conclusion, subjects treated with the minimally-invasive iO-Flex® MicroBlade Shaver® device for neurogenic claudication experienced clinically and statistically significant improvements at the two-year follow-up in all outcome measures compared with baseline. This study successfully demonstrated the feasibility of decompression using the iO-Flex® MBS device in resolving neurogenic claudication and radiculopathic symptoms in subjects with degenerative LSS. These encouraging results warrant further exploration in a large, prospective, randomized clinical trial.

Funding Statement

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Study Approval

The study protocol was approved by a central Institutional Review Board (Western IRB, Washington State) for five sites and locally at 11 sites.

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