

Case Report

RADIOFREQUENCY FACILITATED MANUAL SEMI-ENDOSCOPIC DISCECTOMY UTILIZING THE DISC FX® SYSTEM IN THE TREATMENT OF DISC-PREDOMINATE LUMBAR SPINAL STENOSIS

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Background: Lumbar spinal stenosis (LSS) occurs with increasing prevalence in the elderly population. The American Academy of Orthopedic Surgeons has estimated that by 2021, 2.4 million adults in the United States (8-11% of the population) will be affected by this condition.

Surgical options for LSS are being performed with increased frequency, high cost, and substantial risk of life-threatening complications. While nonsurgical treatment options for LSS are available, they are limited by patient selection (ligamentum flavum hypertrophy) or high rates of reoperation (Interspinous process spacer devices).

This study is the first to suggest a minimally invasive treatment option for disc-predominate lumbar central canal stenosis.

Objectives: To evaluate the clinical efficacy of radiofrequency facilitated manual semi-endoscopic discectomy utilizing the Disc FX® system in the treatment of disc-predominate lumbar spinal stenosis.

Study Design: Single center, prospective, observational study.

Setting: Multi-specialty private practice clinic. The Medical Group of South Florida, Jupiter, FL.

Methods: This study involved 6 patients with disc-predominant lumbar central spinal stenosis. All patients were treated with the Disc FX® system. Radiographic evidence of central lumbar stenosis was confirmed by measurement of minimum AP canal diameter (mm) performed by 1 board-certified neuroradiologist. Inclusion criteria

included absence of lumbar surgery, physical therapy within the previous 6 months, failure of epidural steroid injections (3) within the previous 8 months, spondylolisthesis limited to Grade I, disc height > 50%, presence of low back axial pain + leg pain exacerbated by walking, and relieved with sitting or forward flexion, absence of dermatomal radicular leg pain, radiographic evidence of disc displacement > 4 mm from disc endplate. Zurich claudication (symptom severity and physical function scale was administered 1 week preoperatively, and again 6 months postoperatively. There were no patients lost to follow up.

Results: All patients in the study demonstrated moderate-severe or severe central canal stenosis, with an average AP canal diameter of 6.63 mm for all treated disc levels and 5.5 mm for the most severe levels. There was a mean improvement of 57% in a symptom severity scale and 56% in the physical function scale at 6 months. This exceeds the improvement reported with interspinous spacer devices.

Limitations: Limitations include very small sample size, observational design, non-randomization, absence of share controls, short follow-up period.

Conclusion: For patients suffering from disc-predominant lumbar spinal stenosis, The Disc FX® System provides an effective, low-cost alternative to surgical intervention.

Key words: Spinal, stenosis, claudication, disc, Disc FX®, operative, minimally invasive, Zürich claudication score

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The syndrome of intermittent claudication resulting from lumbar spinal stenosis was described by Henk Verbiest, MD (1909 to 1979) in 1949 (1). Dr. Verbiest first trained as a neurologist before his appointment as Professor of Neurosurgery at Utrecht University Hospital. His work was not readily accepted, taking 5 years to appear in the *Journal of Bone and Joint Surgery*. The syndrome was also described by Van Gelderen in 1948-50 (2).

It is estimated that 2.4 million adults in the United States, 8–11% of the U.S. population, will be affected by lumbar spinal stenosis by the year 2021. The current overall prevalence of lumbar spinal stenosis is 27.2% in the U.S. population (3).

Three distinct anatomic sites in the spine can be affected by spinal stenosis. The central canal encircling the spinal cord, can be narrowed in the anterior-posterior dimension. This results in compression of neural elements and diminished blood supply to the spinal cord and cauda equina. Lumbar spinal stenosis can affect the neural foramen and lateral recess. While lumbar spinal stenosis is the most common indication for lumbar spine surgery in the United States, there remains no standardized paradigm for the non-operative treatment of this condition (4).

Narrowing of the spinal canal has been attributed to short pedicles, tumors, osteoporosis, spondylolisthesis, epidural lipomatosis, fractures, infection and systemic bone diseases (3-7).

Lumbar spinal stenosis occurs with increasing prevalence in the elderly population, a demographic associated with significant comorbidities. Often, there is an associated impairment in self-care and quality of life (4-7).

Patients with neurogenic claudication associated with lumbar spinal stenosis demonstrate marked sedentary behavior. According to prevailing physical activity guidelines “there is an urgent need for interventions aimed at reducing sedentary behavior and increasing the overall level of physical activity in lumbar spinal stenosis, not only to improve function but also to prevent diseases of inactivity” (8).

The foundational elements of the lumbar spinal

stenosis have historically focused upon the thickening of the ligamentum flavum, degenerative facet arthropathy (hypertrophic posterior elements) and herniation of the intervertebral discs.

While ligamentum flavum hypertrophy can be treated with percutaneous image-guided lumbar decompression (PILD) (9), facet encroachment requires open operative techniques. Open lumbar decompression surgery has been associated with a 12-29% postoperative complication rate (6). In addition, up to 33% of patients who undergo open surgical decompression for lumbar spinal stenosis are not satisfied with their postoperative clinical outcomes (10).

In response to these concerns, less invasive treatment strategies are being investigated to manage patients with lumbar spinal stenosis (4). Displacement of the intervertebral disc can narrow the central canal, lateral recess, or neuro foramina individually, or in combination. There remains a paucity of literature describing minimally invasive, non-operative treatments for disc-related lumbar central canal stenosis. Wu et al (11) describe a transforaminal endoscopic discectomy technique in a patient with lumbar fusion (no spinal stenosis). The described procedure is technically challenging and requires expensive capital equipment expenditures.

In this observational study, I describe 6 patients with lumbar central spinal stenosis secondary to contained intervertebral disc displacement treated with a minimally invasive, low-cost, disposable device (Disc FX® Elliquence Medical, 2455 Grand Ave., Baldwin, NY 11510). All patients demonstrated primary clinical symptoms of neurogenic claudication, including increasing low back/leg pain while walking, and relief of symptoms with sitting and/or forward flexion.

METHODS

A total of 6 patients (5 male, 1 female), age range 52–85 years (median 66 years) were enrolled for this study. Inclusion criteria included: absence of prior lumbar surgery, physical therapy completed within the previous 6 months, failure of epidural steroid injections (3) within the past 8 months, spondylolisthesis limited to grade I (neutral on flexion–extension imaging), disc height > 50%, diagnosis of central lumbar

spinal stenosis by MRI, presence of low back axial pain + leg pain exacerbated by walking, and relieved with sitting or forward flexion.

Patients with primary lumbar radicular pain including dermatomal/myotomal weakness or those with positive dural root signs were excluded. Magnetic resonance imaging (MRI) was performed at 1 institution and interpreted by a neuroradiologist, as well as the author. Imaging utilized a 3T Excite System; STIR Sagittal T1 – flair sequences; T2 weighted fast recovery spin echo sequence (sagittal); axial T2-weighted fast recovery fast spin echo sequence, and axial T1-weighted fast spin echo sequence. Ligamentum flavum thickness (L/R) in millimeters, minimum A–P canal diameters (mm), and disc displacement (contained) from the endplate (mm) were measured and recorded at each lumbar level in every patient (Table I).

The Zürich claudication questionnaire was administered 1 week preoperatively and again 6 months postoperatively (symptom severity scale and physical function scale) (Table 2). Based upon the MRI findings, 1 patient received single level endoscopic-assisted manual disc decompression (Disc FX®), 3 patients received 2-level treatment, and 1 patient received a 3-level decompression discectomy.

All operative procedures were performed by the same surgeon (author), at 1 institution. Operative levels were determined by minimum AP canal diameters, degree of disc displacement, including laterality, and physical examination.

Perioperative laboratory evaluation included PT, PTT, INR, CBC with differential, urinalysis and MRSA screen-

ing. All patients were provided with Hibiclens® (4% chlorhexidine gluconate) solution and instructed to bathe with this product the evening prior and morning of surgical procedure. Postoperatively, all patients were placed in a pre-fitted brace (Aspen Quickdraw®) for 2 weeks. Activity guidelines were provided in written form for weeks 1-6 postoperatively.

PROCEDURE

Each patient received 2 grams of intravenous Cephazolin 30 minutes prior to surgery. Patients were placed in a prone position on the operating table, with 2-3 pillows placed to flatten the

Table 1. Study population demographics and analytics.

Gender/Age	Disc Level	AP Canal Diameter	Procedure Date/Level
Male/85	L4-5: 5 mm Right foraminal protrusion	L4-5: 7 mm	L4-5 (R) 01/25/2017
Male/67	L4-5: 5 mm Left protrusion	L4-5: 6 mm	L4-5 (L) 03/22/2017
Male/66	L3-4: 5 mm left protrusion	L3-4: 2 mm	L2-3 (L) 03/22/2017
	L4-5: Concentric bulge w/ protrusion	L4-5: 4 mm	L3-4 (L) 03/22/2017
	L2-3: Central disc protrusion	L2-3: 6 mm	L4-5 (L) 03/22/2017
Male/53	L3-4: Central protrusion	L3-4: 5 mm	L3-4 (L) 05/17/2017
	L4-5: 5 mm left protrusion	L4-5: 7.9 mm	L4-5 (L) 05/17/2017
Male/52	L3-4: Left protrusion	L3-4: 11 mm	L3-4 (L)
	L4-5: Central left protrusion	L4-5: 10 mm	L4-5 (L)
Female/74	L3-4: Central protrusion	L3-4: 10 mm	L3-4 (L)
	L4-5: 7 mm left protrusion	L4-5: 3 mm	L4-5 (L) 06/13/2017
Average Age 66			

Table 2. Symptom and functional improvement.

2CQ	SSS Pre	SSS Post	Percentage Improvement	PFS Pre	PFS Post	Percentage
Patient 1	26	8	69%	17	6	64%
Patient 2	20	10	50%	15	7	53%
Patient 3	24	11	54%	15	8	46%
Patient 4	20	9	55%	15	7	53%
Patient 5	24	14	42%	17	8	53%
Patent 6	27	8	70%	14	5	64%

MEAN: SSS: 57%, PFS: 56%

lumbar lordosis. All procedures were performed under conscious sedation with midazolam and fentanyl intravenously. Wide sterile prep was performed covering the lower thoracic and lumbar regions using chlorhexidine-alcohol (Chloraprep®). At each targeted disc level, the sterile-draped fluoroscopic beam was rotated to a 45° ipsilateral oblique view. A point was marked on the skin approximately 1.5 cm lateral to the superior articular process, corresponding to a point 10–12 cm lateral to the spinous process. Infiltration was performed with a 1:1 mixture of 1% lidocaine and 0.25% bupivacaine with 1:200,000 (au unit) epinephrine using a 5-inch 22-gauge spinal needle to contact the superior articular process.

Skin perforation was performed at the previously marked site using an 18-gauge needle. Then a 16-gauge spine needle (DFX.NG) was advanced under fluoroscopic guidance to the annular border, using anterior–posterior, oblique, and lateral fluoroscopic views. A ventral-medial trajectory into the triangular safe working zone was used. This corresponds to the transforaminal zone lateral to the traversing nerve root and medial to the exiting nerve root. A significantly shallower approach is employed compared to the standard discogram approach in order to target the dorsal part of the disc space, and dorsal annulus. The needle was advanced to the mid-nuclear disc position. Intranuclear injection was performed with 2.0 mL of the following solution: 1:1:1 mixture and sterile normal saline, Omnipaque 240 mg/mL, and IC-Green® (12). Intraoperative discography may be performed, if desired. Visualization of the intranuclear disc pattern revealed contained disc structure without Grade 5 tears. A sterile guidewire was advanced through the spinal needle, into the mid-nuclear position, and then the spine needle was removed.

Then, the Disc FX cannula system was advanced over the guidewire. This system is comprised of a 3.3 mm beveled cannula secured over a soft tissue dilator. The entire system was advanced through the subcutaneous tissue and muscle fascia into the foraminal target zone, to the dorsal surface of the annulus fibrosis. Using a twisting motion, the cannula was advanced into the dorsal disc space. After confirmation of cannula position on the AP lateral fluoroscopic views, the guidewire and soft tissue dilator were removed. The endoscope was placed

through the 3.0 mm portal with excellent intradiscal visualization. Intradiscal decompression (dorsal nucleotomy) was performed using a 2.5 mm surgical micro forceps (DFX G). Dorsal disc material was excised manually in multiple planes, to a volume of 2-3 grams. The 2.5 mm endoscope was again utilized to verify intradiscal cannula position as well as intradiscal decompression. Disc material was stained green so as to be easily differentiated from annular or scar tissue.

The Trigger-Flex® Bipolar System coupled with the SurgiMax® High Frequency Energy Source was then employed to facilitate further disc decompression. With the generator set to the Bipolar Turbo Mode, 6 separate 1-second sweeps were performed across the dorsal disc space in variable quadrants. This was performed under PA and lateral fluoroscopic views. Intermittent saline irrigation was utilized after manual disc extraction to remove any remaining disc material. After endoscopic confirmation of successful removal of disc herniation, the working cannula was withdrawn to the annular border (dorsal annular fibers visualized with endoscope). The Trigger-Flex® probe was then configured in the Bipolar-Hemo Mode to perform dorsal annular modulation. Six, 1-second sweeps were performed across the dorsal annulus to contract annular fibers. The angulation of the Trigger-Flex® Probe allows coagulation of dorsal annular tears, if present.

At the conclusion of the procedure, the working cannula was withdrawn to visualize the annulotomy entry region and the Bipolar-Hemo is utilized to create a thermal annuloplasty of the 2.7 mm annulotomy site. The identical procedure was performed at subsequent disc levels as necessary.

Disc Procedures

The Disc FX system is a new, multi-dimensional procedure for minimally invasive disc surgery. The disposable system is cost-effective, and reusable at multiple levels. Percutaneous disc decompression (PDD) encompasses several minimally invasive disc procedures, including chymopapain chemonucleolysis, laser vaporization, and manual or automatic tissue resection with or without endoscopic assistance (13-15).

Disk Nucleoplasty™, a type of PDD using coblation technology, was approved by the U.S. Food and Drug Administration in July 2000. A systematic review (15) described level 1-C strong recommendations supporting the therapeutic efficacy of this procedure. Radiofrequency energy delivered by a bipolar device intradiscally has been shown to excite electrolytes in the disc nucleus, with excitation – fracture of molecular bonds, resulting in soft tissue dissolution of the disc nucleus (15,16). In contained disc structures, there is a disproportionate reduction in intradiscal pressure with small reductions of nucleus pulposus volume. Removal of 1 millimeter of disc tissue corresponds to a 10–20% reduction of discal volume (15,17).

Systematic reviews and meta-analysis of disc nucleoplasty have demonstrated long-term pain reduction (24 months) as well as functional improvements (18).

There are significant differences between the energy source used in Nucleoplasty™ (Arthrocare) and that used in the Disc FX (Elliquence) procedure. The low-frequency (100k Hz) nucleoplasty energy may require saline administration in order to provide a reduced temperature environment intradiscally. The Disc FX system employs a patented high frequency (1.7 MHz), low temperature radio wave energy (Table 3). The dual-mode system allows for high frequency disc ablation, annular modulation, volume reduction (tissue shrinkage), and coagulation (annular tears/annuloplasty). The Bipolar-Turbo Mode consists of a 1.7 MHz sinusoidal waveform, while the Bipolar-Hemo Mode is characterized by a 1.7 MHz sinusoidal partially rectified waveform with a 50% duty cycle.

Surgical Options for Lumbar Spinal Stenosis

From 2001–2010 an estimated 3.6 million spinal fusions were performed in the United States with total charges exceeding \$287 billion. There are approximately 650,000 to 750,000 spinal surgical procedures performed annually in the United States at a cost exceeding \$20 billion, the majority for treatment of lumbar spinal stenosis (19-22). Concerning the surgical treatment of lumbar spinal stenosis, the rate of one-two level lumbar fusion surgery increased significantly between 2004 and 2009 (19).

A retrospective analysis of Medicare claims from

2002 to 2007 found a 15-fold increase in the rate of complex fusion surgery (more than two-disc levels or combined anterior and posterior approach). The study population was associated with an increased risk of life-threatening complications (5.6%), increased 30–day mortality, and increased hospital charges (20).

The (SPORT) Spine Patient Outcomes Research Trial was the first to track healthcare expenditures along with outcomes (21-24). Given the continued escalation of healthcare expenditures in the U.S., the economic value of surgical interventions must be closely examined. XTosteson calculated the cost of lumbar laminectomy at \$77,000 per QALY gained, while spinal fusion surgery was estimated to be \$115,000 per QALY gained (21-24). The direct costs of lumbar fusion surgery may approach \$169,000 per case. At this time, no trials have compared surgery with no treatment, placebo, or sham surgery.

Machado and colleagues (25) performed a Cochrane review of 24 randomized controlled trials, representing 2,352 patients with lumbar spinal stenosis (25). The authors conclude that there is a paucity of evidence regarding the efficacy of surgery for lumbar spinal stenosis. A similar Cochrane review compared surgical versus non-operative treatments for lumbar spinal stenosis (26,27). The authors reported a 10 to 24% rate of side effects in surgical cases compared to no side effects reported for any conservative treatment. Conservative modalities included minimally invasive therapies. Ma and colleagues (28) reported higher complication rates in surgical versus conservative treatment for lumbar spinal stenosis (randomized controlled trials) at 2 years post-treatment .

Table 3. Energy profile Nucleoplasty* vs. Disc FX system.

Output Power	COBLATOR II	SurgiMax PLUS
Fundamental frequency	100 kHz	1.7 MHz
Max output power	400 W @ 250 Ohms	120W @ 200 Ohms
Bipolar Cut Mode	100 kHz	1.7 MHz
Bipolar Coagulation Mode	?	1.7 MHz (Half Wave Rectification)
Operation temperature	10* C to 40* C	10* C to 40* C

The nature of data collection, inconsistencies with the clinical definition of lumbar spinal stenosis, and a lack of standardized treatment guidelines have impaired conclusive evidence of the benefits of surgical versus non-surgical treatment of lumbar spinal stenosis. The only study to compare lumbar decompression alone and spinal fusion for the treatment of lumbar spinal stenosis demonstrated limited evidence that additional fusion surgery results in better outcomes, an associated increase in risk and cost with lumbar fusion in the treatment of lumbar spinal stenosis (29).

Current research does, however, demonstrate a positive role and favorable results for minimally invasive modalities in the treatment of lumbar spinal stenosis (30).

Nonsurgical Treatment Options for Lumbar Spinal Stenosis

Several studies have compared interspinous process spacer devices to lumbar spinal decompression alone, or with fusion (25-27). The results suggest a longer operative time and higher risk of re-operation with the spacer devices. A recent long-term study (7 years) of interspinous process devices revealed a reoperation rate of 66.6%, as well as poor or average results in 80% of study patients (31).

Other novel non-operative treatments have been recommended in the treatment of lumbar spinal stenosis. Calcitonin (50 IU) added to laminar epidural steroid injection led to increased walking distance and diminished pain intensity at 1-year follow-up (32). However, the lowest minimum AP canal diameter in this study was 10.8 mm. Therefore, this study did not examine the efficacy of epidural calcitonin in moderate or severe spinal canal stenosis.

Minimally invasive lumbar decompression (MILD/PILD) continues to show beneficial results in pain and function (9,30). Most studies to date have compared MILD to epidural steroid injections (9,33-36). Other studies show mixed results, with epidural steroid injection providing better Zurich claudication (ZCQ) results, and MILD providing greater improvement in visual analog scale (VAS) (26,27). Although the ligamentum flavum becomes thicker with age, there remains little data on the prevalence of ligamentum flavum hypertrophy (LVH) in the general popula-

tion (37). Finally, there are errors associated with measuring the ligamentum flavum thickness by MRI. Variations in cutting angle, individual anatomic variations, and T1 weighted MR axial slice thickness can all influence ligamentum flavum measurements (38).

DISCUSSION

Patients with symptomatic lumbar spinal stenosis and neurologic claudication are extremely sedentary and are not meeting the 2008 United States Physical Activity Guidelines (8,39,40).

In the case of lumbar stenosis, the decision to pursue surgical versus non-surgical treatment must be carefully considered. It remains incontestable that patients who demonstrate progressive myelopathy, neurologic deficits, or spinal instability require a surgical approach.

As previously discussed, open lumbar laminectomy (decompression) has been correlated with a 12-29% postoperative complication rate, substantial direct and indirect cost, and a paucity of evidence regarding efficiency (4,21,26,27).

Recent research reviews demonstrate a positive role for conservative therapies as well as favorable results for minimally invasive approaches (26,27,30).

In this observational report, 6 patients with disc-predominant central lumbar spinal stenosis were treated with an endoscopically--assisted, minimally invasive percutaneous manual disc decompression utilizing a low-cost, disposable system (Disc FX). All patients in this study demonstrated moderate to severe or severe central canal stenosis, with mean anterior-posterior canal diameter of 6.63 mm for all treated disc levels 1-month post-treatment with significant increase in the AP canal diameter (same MRI instrument and neuro radiologist). The Zurich Claudication Questionnaire (ZCQ) is a disease-specific self-report outcome instrument commonly used in trials to measure treatment outcomes in patients with lumbar spinal stenosis (41). It has been reported that, using the disc FX system, modulation of the dorsal annulus and cauterization of inflamed structures, combine to shrink the annulus by 30% and expand the epidural space by up to 9%. Ablation of

annular nerve fibers (C-fibers), may contribute to a reduction of pain (44).

Using the standard criteria for an improvement of 0.5 points or greater to define clinical success, 100% (6/6) patients in this study achieved symptom severity and physical function success.

Table 2 demonstrates a mean improvement of symptoms severity of 57% (42–70%) and physical function of 56% (46–64%). This improvement exceeds that previously reported with minimally invasive interspinous process spacer devices (43). Disc-related lumbar central stenosis is commonly encountered in clinical practice. The Disc FX disposable system, compared to alternatives for lumbar spinal stenosis, is an effective, low complication, low-cost, minimally invasive option. Previous studies have established Disc FX system as a valuable modality in the treatment of lumbar disc pathology (29,43,44). The high frequency, low temperature patented radiowave energy source has demonstrated clinical success in orthopedic, intradiscal, and neurosurgical (separation of conjoined

twins) environments. The Trigger-Flex Bipolar System is utilized globally in minimally invasive spine and orthopedic procedures. The surgical micro forceps allow for physician-directed, multi-spatial, manual nucleotomy and decompression, while the Trigger-Flex System provides for nuclear tissue ablation, tissue shrinkage, and annular modulation.

Limitations of the study include a very small sample size, non-randomization, absence of sham controls, and a short follow-up period. High-quality research is necessary to compare surgical versus minimally invasive options for these patients affected with lumbar spinal stenosis.

This is the first case series to report significant improvement in claudication scores (ZCG) in patients with disc-predominant lumbar central spinal stenosis using a Disc FX system. Larger study populations randomized to include other minimally invasive modalities, as well as lumbar laminectomy with and without fusion is recommended.

REFERENCES

1. Evans JG. Neurogenic intermittent claudication. *Br Med J* 1964; 2:985-987.
2. Verbiest H. Primary stenosis of the lumbar spinal canal in adults, a new syndrome. *Ned Tijdschr Geneesk* 1950; 94:2415-2433.
3. Kalichman L, Cole R, Kim DH, Li L, Suri P, Guermazi A, Hunter DJ. Spinal stenosis prevalence and association with symptoms: The Framingham study. *Spine J* 2009; 9:545-550.
4. Parker SL, Anderson LH, Nelson T, Patel VV. Cost-effectiveness of three treatment strategies for lumbar spinal stenosis: Conservative care, laminectomy, and the superior interspinous spacer. *Int J Spine Surg* 2015; 9:28
5. Benz RJ, Ibrahim ZG, Afshar P, Garfin SR. Predicting complications in elderly patients undergoing lumbar decompression. *Clin Orthop* 2001; 384:116-121.
6. Reindl R, Steffen T, Cohen L, Aebi M. Elective lumbar spinal decompression in the elderly: Is it a high-risk operation? *Can J Surg* 2003; 46:43-46.
7. Skidmore G, Ackerman SJ, Bergin C, Ross D, Butler J, Suthar M, Rittenberg J. Cost-effectiveness of the X-STOP® interspinous spacer for lumbar spinal stenosis. *Spine* 2011; 36:E345-E356.
8. Nordon J, Smuck M, Sinha A, Hu R, Tomkins-Lane, C. Objective measurement of free-living physical activity (performance) in lumbar spinal stenosis: Are physical activity guidelines being met? *Spine J* 2017; 17:26-33.
9. Benyamin RM, Staats PS, MiDAS Encore I. MILD® is an effective treatment for lumbar spinal stenosis with neurogenic claudication: MiDAS ENCORE randomized control trial. *Pain Physician* 2016; 19:229-242
10. Parker SL, Anderson LH, Nelson T, Patel VV. Cost-effectiveness of three treatment strategies for lumbar spinal stenosis: Conservative care, laminectomy, and the superior interspinous spacer. *Int J Spine Surg* 2015; 9:28.
11. Wu JJ, Chen HZ, Zheng C. Transforaminal percutaneous endoscopic discectomy and foraminoplasty after lumbar spinal fusion surgery. *Pain Physician* 2017; 20:E647-E651.
12. IC-Green®. Indocyanine green for injection lyophilized green powder containing 25 mg of triarboyaninedye. Pub Chem ID 5282412. Formula C43H47N2NaO6S2. McKesson 32738532 Cardinal: 2311801.
13. Singh V, Manchikanti L, Benyamin RM, Helm S, Hirsch JA. Percutaneous lumbar laser disc decompression: A systematic review of current evidence. *Pain Physician* 2009; 12:573-588.
14. Hirsch JA, Singh V, Falco FJ, Benyamin RM, Manchikanti L. Automated percutaneous lumbar discectomy for the contained herniated lumbar disc: A systematic assessment of evidence. *Pain Physician* 2009; 12:601-620.
15. Gerges FJ, Lipsitz SR, Nedeljkovic SS. A systematic review on the effectiveness of the nucleoplasty™ procedure for discogenic pain. *Pain Physician* 2010; 13:117-132.
16. Manchikanti L, Derby R, Benyamin RM, Helms, Hirsch, JA. A systematic review of mechanical lumbar disc decompression with nucleoplasty. *Pain Physician* 2009; 12:561-572.
17. Chev YC, Lee SH, Saenz Y, Lehman NL. Histologic findings of disc, end plate and neural elements after coblation of nucleus pulposus: An experimental nucleoplasty study. *Spine J* 2003; 3:466-470.
18. Eichen PM, Achilles N, Konig V, Mosges R, Hellmich M, Himpe B, Kirchner R. Nucleoplasty, a minimally invasive procedure for disc decompression: A systematic review and meta-analysis of published clinical studies. *Pain Physician* 2014; 17:E149-E173.
19. Bae HW, Rajae SS, Kanim LE. Nationwide trends in the surgical management of lumbar spinal stenosis. *Spine* 2013; 38:916-26.
20. Deyo RA, Mirza SK, Martin BI, Kreuter W, Goodman DC, Jarvik JG. Trends, major medical complications, and charges associated with surgery for lumbar spinal stenosis in older adults. *JAMA* 2010; 303:1259-1265.
21. Tosteson AN, Lurie JD, Tosteson TD, Skinner JS, Herkowitz H, Albert T, Boden SD, Bridwell K, Longley M, Andersson GB, Blood EA, Grove MR, Weinstein JN. Surgical treatment of spinal stenosis with and without degenerative spondylolisthesis: Cost-effectiveness after 2 years. *Ann Intern Med* 2008; 149:845-853.
22. Deyo RH, Mirza SK. Trends and variations in the use of spine surgery. *Clin Orthop Relat Res* 2006; 443:139-146.
23. Kuntz KM, Snider RK, Weinstein JN, Pope MH, Katz JN. Cost-effectiveness of fusion with and without instrumentation for patients with degenerative spondylolisthesis and spinal stenosis. *Spine* 2000; 25:1132-1139.
24. Weinstein JN, Tosteson TD, Lurie JD, Tosteson AN, Blood E, Hanscom B, Herkowitz H, Cammisia F, Albert T, Boden SD, Hilibrand A, Goldberg H, Berven S, An H; SPORT Investigators. Surgical versus nonsurgical therapy for lumbar spinal stenosis. *N Engl J Med* 2008; 358:794-810.
25. Machado GC, Ferreira PH, Yoo RI, Harris IA, Pinheiro MB, Koes BW, van Tulder MW, Rzewuska M, Maher CG, Ferreira ML. Surgical options for lumbar spinal stenosis. *Cochrane Database Syst Rev* 2016; Nov 1; 11.
26. Zaina F, Tomkins-Lane C, Carragee E, Negrini S. Surgical versus non-surgical treatment for lumbar spinal stenosis. *Cochrane Database Syst Rev* 2016; Jan 29; 1.
27. Shen J, Xu S, Xu S, Ye S, Hao J. Fusion or not for degenerative lumbar spinal stenosis: A Meta-analysis and systematic review. *Pain Physician* 2018; 21:1-8.
28. Ma XL, Zhao XW, Ma JX, Li F, Wang Y, Lu B. Effectiveness of surgery versus conservative treatment for lumbar spinal stenosis: A system review and meta-analysis of randomized controlled trials. *Int J Surg* 2017; 44:329-338.
29. Zhang WWH, Jiao JX, Wang YX, Yang DL, Ding WY. Preliminary results of the 3 in 1 technique of Disc FX System for the discogenic low back pain. *Chin J Orthop* 2011; 31:1049-1055.
30. Patel J, Osburn I, Wanaselja A, Nobles R. Optimal treatment for lumbar spinal stenosis: an update. *Curr Opin Anaesthesiol* 2017; 30:598-603.
31. Fransen P. Long-term results with percutaneous interspinous process devices in the treatment of neurogenic intermittent claudication. *J Spine Surg* 2017; 3:620-623.
32. Elsheikh NA, Amr YM. Effect of adding calcitonin to translaminal epidural steroid in degenerative lumbar spinal canal stenosis. *Pain Physician* 2016; 19:139-146.
33. Benyamin RM, Staats PS, MiDAS Encore I. MILD® is an effective treatment for lumbar spinal stenosis with neurogenic claudication: MIDAS ENCORE randomized controlled Trial. *Pain Physician* 2016; 19:229-242.
34. Brown LL. A double-blind, randomized, prospective study of epidural steroid injection vs. the MILD® procedure in patients with symptomatic lumbar spinal stenosis. *Pain Pract* 2012; 12:333-341.
35. Chen H, Kelling J. Mild procedure for lumbar decompression: a review. *Pain Pract* 2013; 13:146-153.

36. Mekhail N, Vallejo R, Coleman MH, Benyamin RM. Long-term results of percutaneous lumbar decompression MILD® for spinal stenosis. *Pain Pract* 2012; 12:184-193.
37. Abbas J, Hamoud K, Masharawi YM, May H, Hay O, Medlej B, Peled N, Hershkovitz I. Ligamentum flavum thickness in normal and stenotic lumbar spines. *Spine* 2010; 35:1225-1230.
38. Kim YU, Park JY, Kim DH, Karm MH, Lee JY, Yoo JI, Chon SW, Suh JH. the role of the ligamentum flavum area as a morphological parameter of lumbar central spinal stenosis. *Pain Physician* 2017; 20:E419-E424.
39. Lee SI, Campion A, Huang A, Park E, Garst JH, Jahanforouz N, Espinal M, Siero T, Pollack S, Afridi M, Daneshvar M, Ghias S, Sarrafzadeh, M, Lu DC. Identifying predictors for postoperative clinical outcome in lumbar spinal stenosis patients using smart-shoe technology. *J Neuroeng Rehabil* 2017; 14:77.
40. Norden J, Smuck M, Sinha A, Hu R, Tomkins-Lane C. Objective measurement of free-living physical activity (performance) in lumbar spinal stenosis: Are physical activity guidelines being met? *Spine J* 2017; 17:26-33.
41. Stucki G, Daltroy L, Liang MH, Lipson SJ, Fossel AH, Katz JN. Measurement properties of a self-administered outcome measure in lumbar spinal stenosis. *Spine* 1996; 21:796-803.
42. Nunley PD, Patel VV, Orndorff DG, Lavelle WF, Block JE, Geisler FH. Superior Interspinous Spacer Treatment of Moderate Spinal Stenosis: 4-Year Results. *World Neurosurg* 2017; 104:279-283.
43. Kumar N, Kumar A, Siddharth, MS, Sambhav PS, Tan J. Annuloplasty using Disc-FX in the management of lumbar disc pathology; early results. *Int J Spine Surg* 2014; 1:8.
44. Hellinger S. Radiofrequency-assisted lumbar semi-endoscopic manual discectomy using the Disc-FX System - preliminary results of various ongoing clinical outcome studies worldwide. *Eur Musculoskel Rev* 2011; 31:1049-1055.

