Interventional Pain Management: No Longer Just Epidurals and Nerve Blocks

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NIPM
NEUROINTERVENTIONAL
PAIN MANAGEMENT


Beaumont


ProMedica


Wayne State
University

Disclosures

None to report

Objectives

To evaluate most common pain management interventional procedures

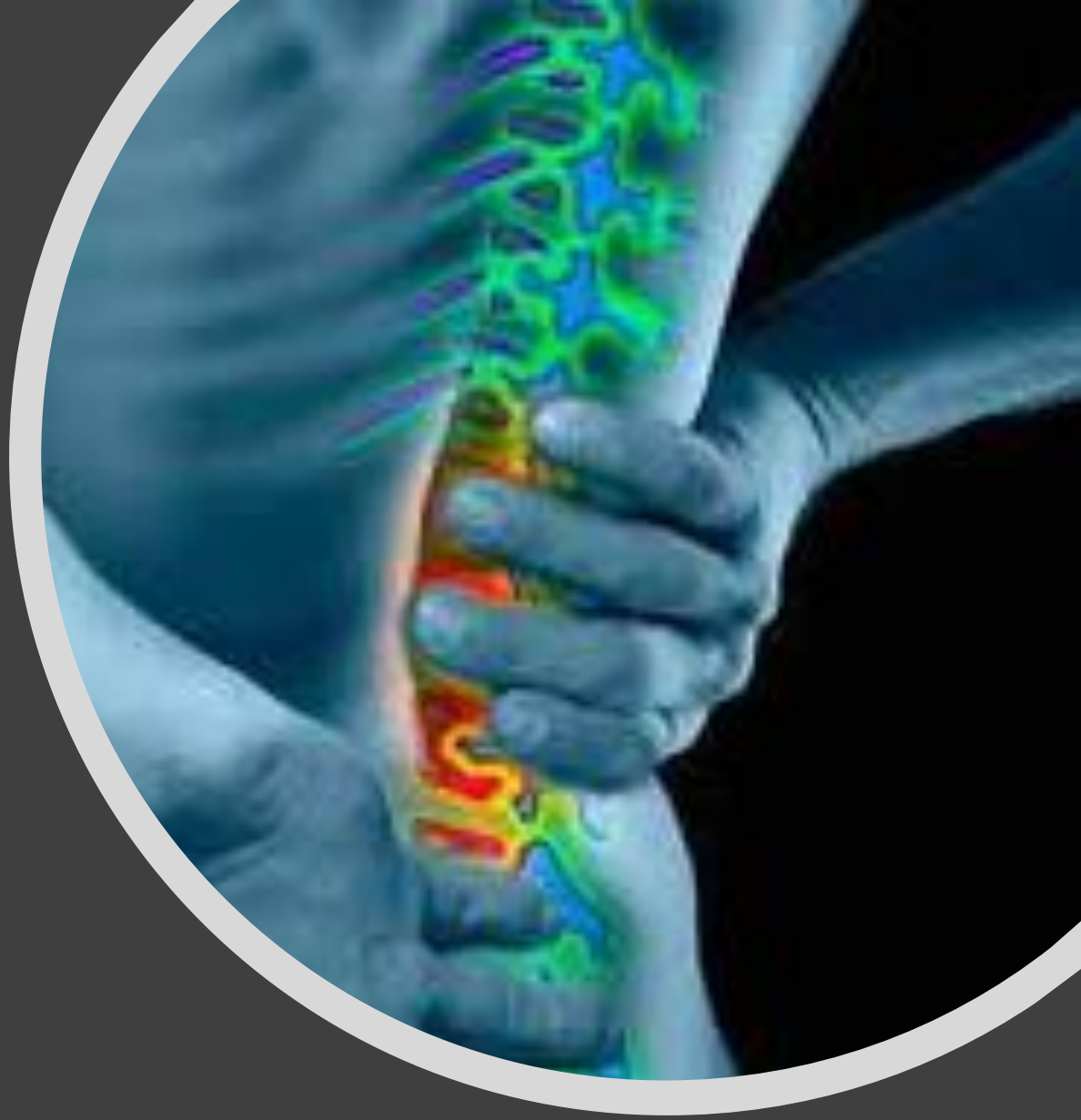
To familiarize yourself with current minimally invasive surgical (MIS) options that pain management can offer

Review efficacy and safety for MIS

Exploring current gap between patients need for advanced procedures treatment and physicians trained in these techniques

Understanding when to refer a patient for MIS

- 84 percent of adults will experience low back pain
- Favorable prognosis
- Nonpharmacologic and pharmacologic treatments
- Nonsurgical and surgical interventional treatments
- Several of these involve the injection of medications, commonly glucocorticoids, into the spinal structures
- Destruction of nerves or other tissues in the back presumed to be the source of pain through the application of various types of energy

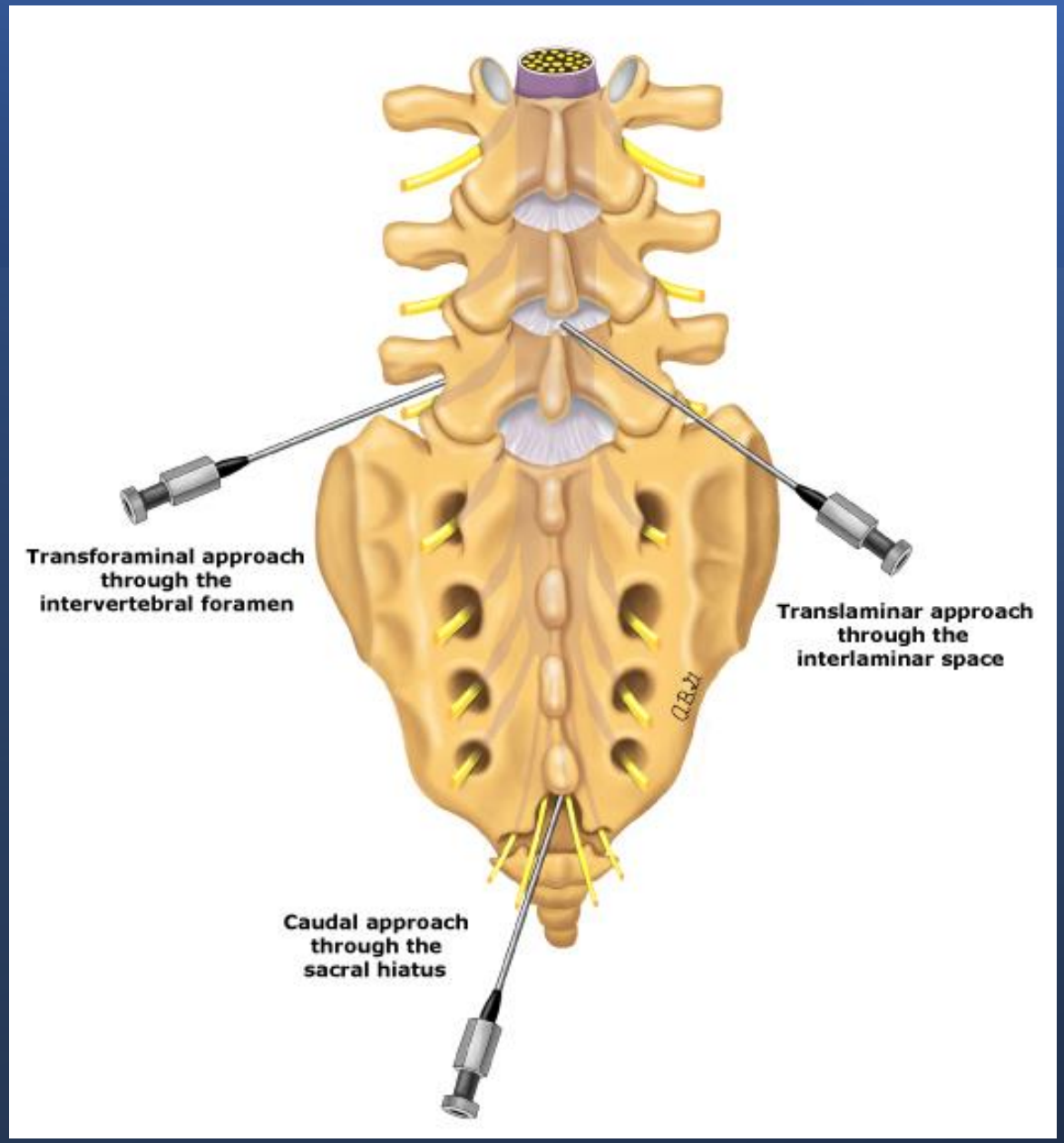


Lumbar Epidurals

Questionable efficacy

Type of steroid, dose, timing, frequency

Adverse effects


Transforaminal approach through the intervertebral foramen
Translaminar approach through the interlaminar space
Caudal approach through the sacral hiatus

In trials of epidural glucocorticoid injection for patients with radiculopathy due to a herniated disc, there is short-term, but not long-term, improvement in pain

In a 2015 systematic review of randomized, placebo-controlled trials, epidural corticosteroid injections was associated with a small improvement in leg pain (mean difference [MD] 7.6 on pain scale 0 to 100; 95% CI 3.7-11.4) and disability (standardized MD 0.33; 95% CI 0.09-0.56) [1]

Decreased risk of surgery at up to three months (relative risk [RR], 0.62, 95% CI 0.41-0.92) but no improvement at longer-term follow-up [1]

One randomized trial of 145 patients with lumbosacral radicular pain secondary to a herniated disc or spinal stenosis compared epidural injection and placebo with sham injection and gabapentin [2]

Among secondary outcomes, one month after treatment those who received epidural steroid injection had greater reductions in worst leg pain (-3.0, SD 2.8) than those treated with gabapentin (-2.0, SD 2.9; P=0.04) and were more likely to experience a positive successful outcome (66% v 46%; number needed to treat=5.0, 95% confidence interval 2.8 to 27.0; P=0.02)

At three months, there were no significant differences between treatments

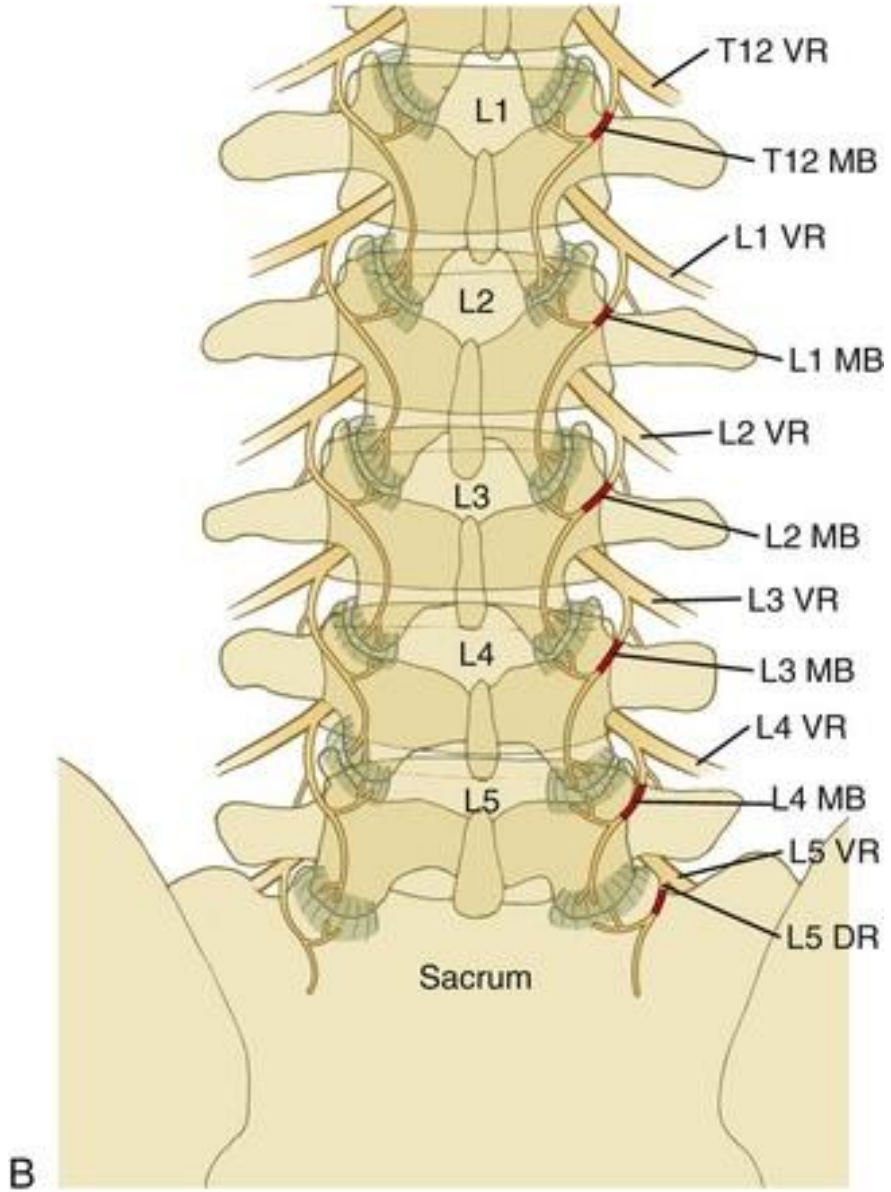
Side Effects

- Large observational studies have found that minor adverse events (eg, bleeding, dural puncture with cerebrospinal fluid leak, transient nerve root irritation) occur in <1 percent of procedures [8]
- Major complications resulting in permanent neurologic sequelae (eg, spine hematoma, infection) were rare with an incidence of 0.01 percent [8]
- Transient systemic glucocorticoid-related effects (eg, blood sugar elevation, gastrointestinal or psychological symptoms, vertigo or dizziness) were observed in 0.1 percent of procedures [9]
- Contaminated medication used in epidural injections have resulted in severe infections

Opinion

- Clinical experience outweighs small benefit seen in studies
- Additional injections are not indicated if the initial injection does not improve symptoms

- Blocks to the medial branch of the primary dorsal ramus
- Used both diagnostically and therapeutically for presumed facet joint pain



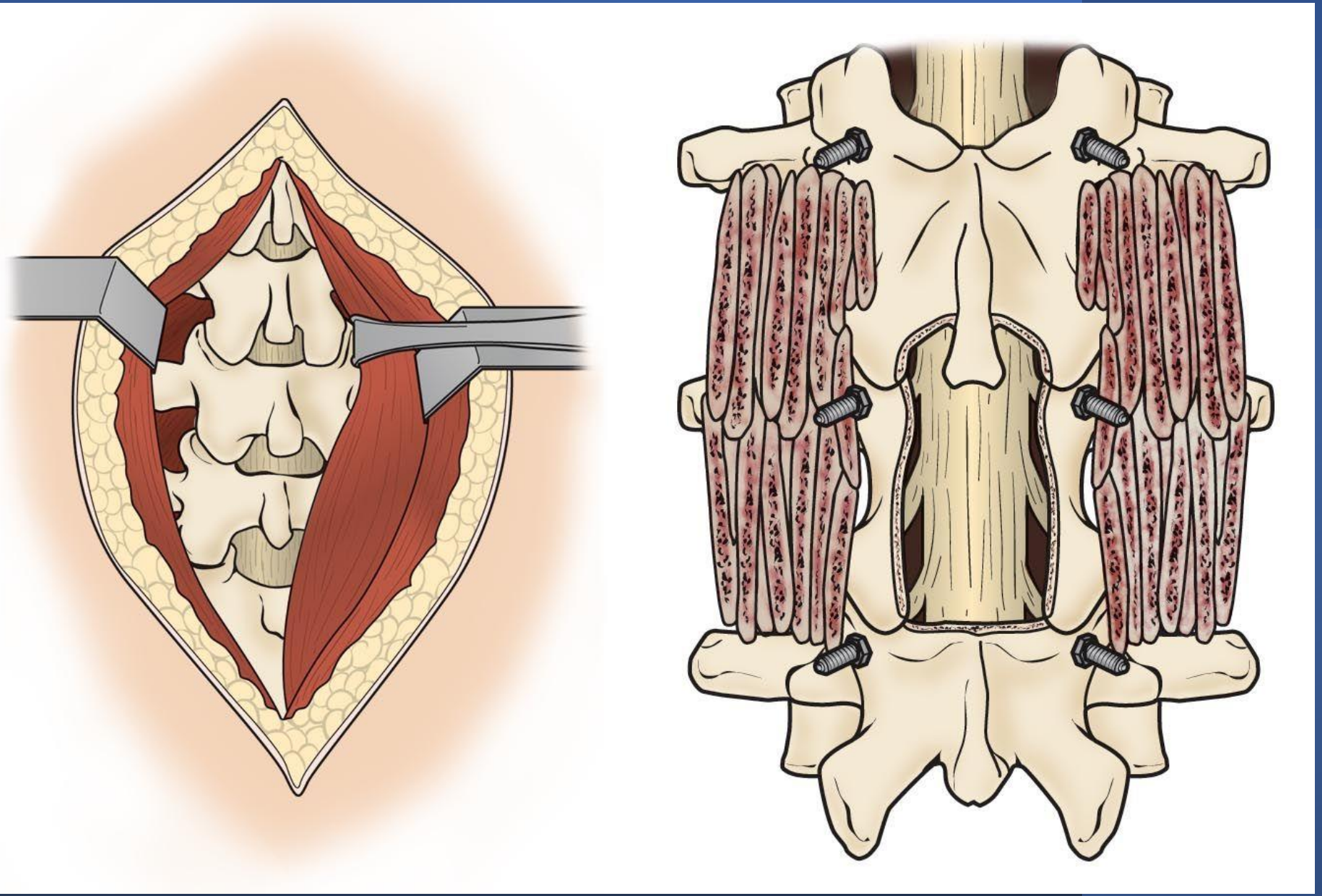
The Effectiveness of Radiofrequency Ablation of Medial Branch Nerves for Chronic Lumbar Facet Joint Syndrome in Patients Selected by Guideline-Concordant Dual Comparative Medial Branch Blocks (2020)

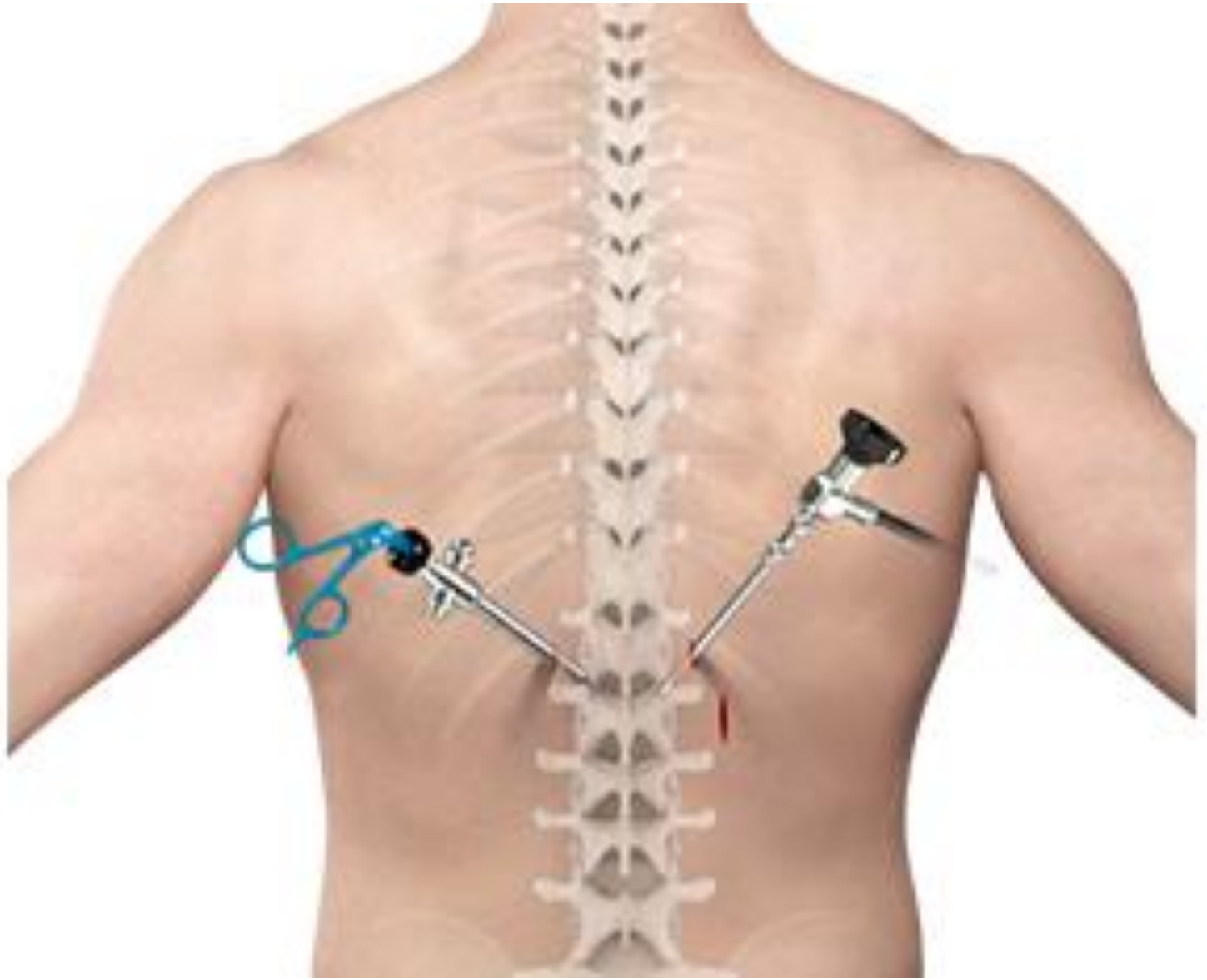
Effectiveness of Lumbar Facet Joint Blocks and Predictive Value before Radiofrequency Denervation: The Facet Treatment Study (FACTS), a Randomized, Controlled Clinical Trial (2018)

Opinion

- Radiofrequency Ablation vs Therapeutic MBBs
- Cost effective modality of treatment, resulting in improvement in pain status, physical status, psychological status, functional status and return to work [11]

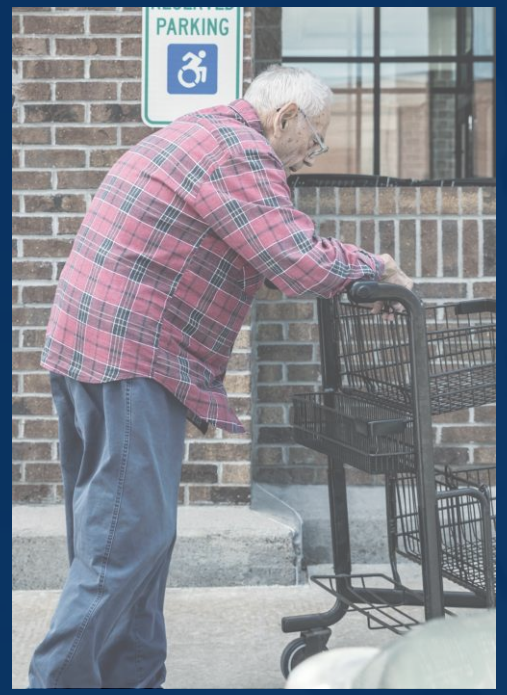
What do we do when injections fail?





Lumbar Spinal Stenosis (LSS)

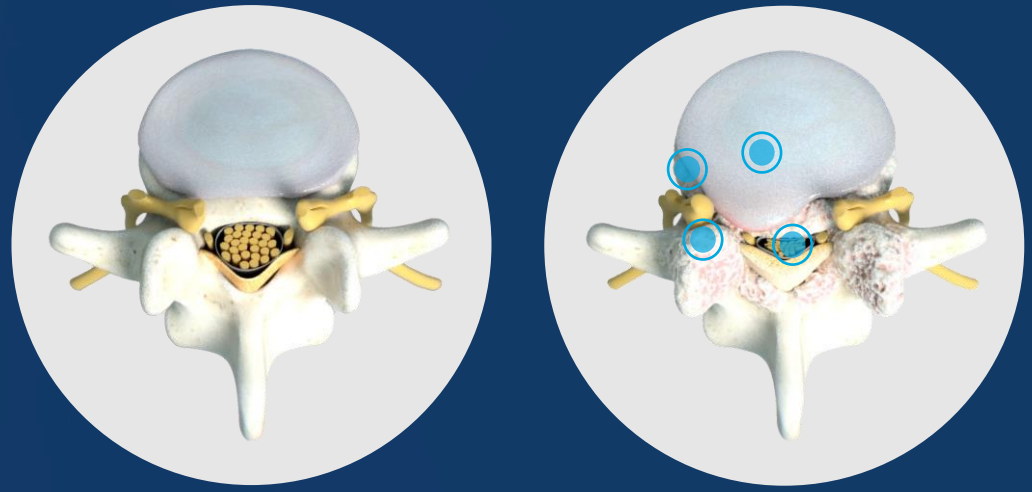
Impacts Millions



2M US patients in active treatment[3]

~20% People over 60 have LSS[3]

Degeneration Requires Treatment



HEALTHY AGING

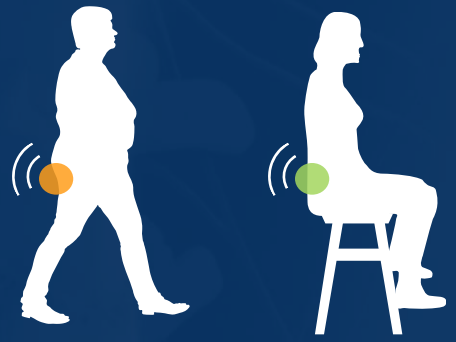
Narrowing & bone overgrowth cause symptoms that require treatment

Typical LSS Patients[3]

Seniors

- Degenerative condition
- Prevalent in patients age 60+

Pain with Mobility & Diminished Quality Of Life



- Pain, numbness, heaviness or tingling in back, legs or buttocks when standing or walking
- Often limited mobility & spend time sitting to avoid pain

Flex for Relief

- Walk in flexed/stooped posture to open canal for temporary relief of symptoms
- Use canes/walking aid
- Sleep in fetal position

Commonly Tried/Failed Conservative Therapies

- Over the counter meds, Opioids
- Physical therapy
- Epidural steroid injections (ESIs)

mild : Patient Identification

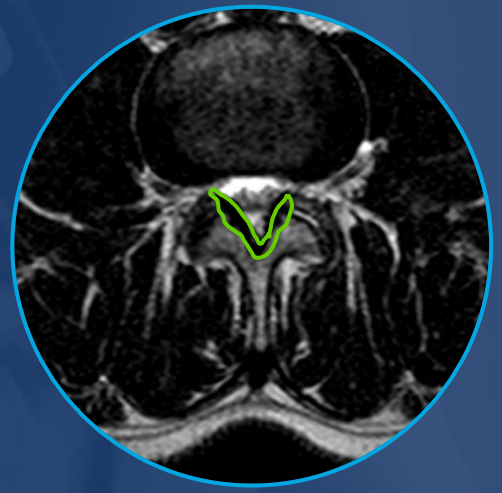
1. Neurogenic claudication (NC)

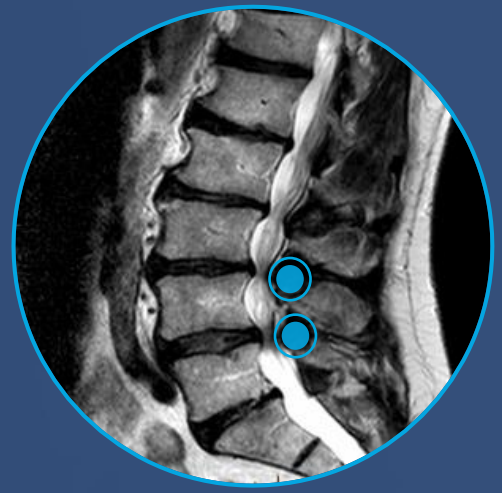
Pain, numbness, heaviness or tingling in back, legs or buttocks when standing or walking

Pain, numbness, heaviness relieved by bending and sitting

2. Look for the Ligament

- Hypertrophic Ligamentum Flavum (HLF) contributes up to 85% of spinal canal narrowing[4]
- 2.5mm is the starting point[5]

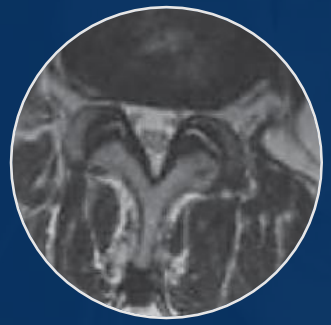




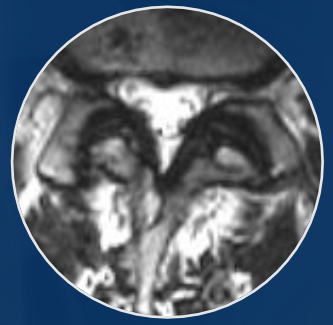
Levels of stenosis with HLF requiring decompression with *mild*

mild treats mild to severe stenosis

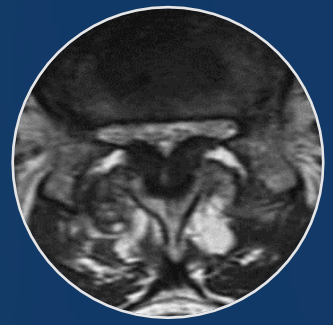
Mild



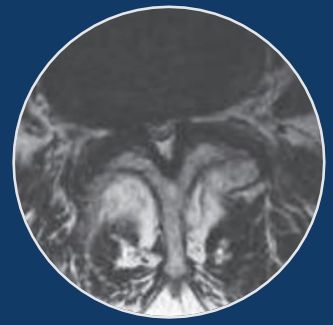
Moderate



Moderate – Severe

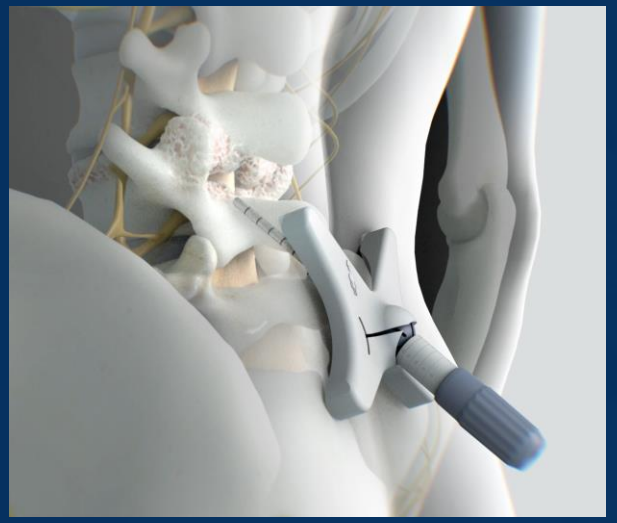


Severe

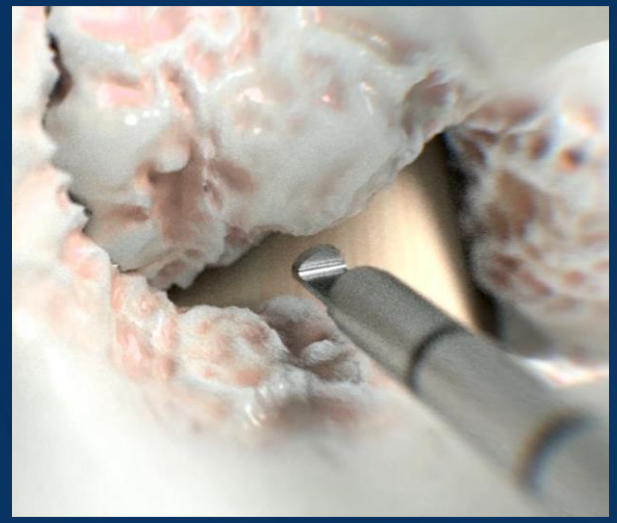


mild Procedure Steps

Outpatient decompression achieved through a tiny incision, smaller than the size of a baby aspirin

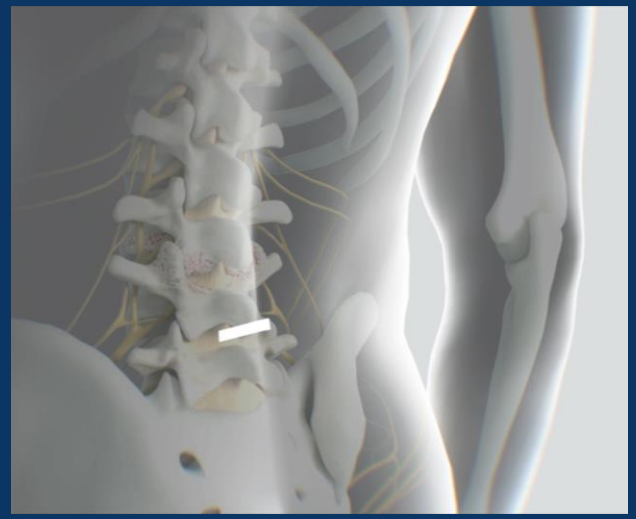


Insert Portal (5.1 mm)



Remove bone to achieve access

Debulk hypertrophic ligament



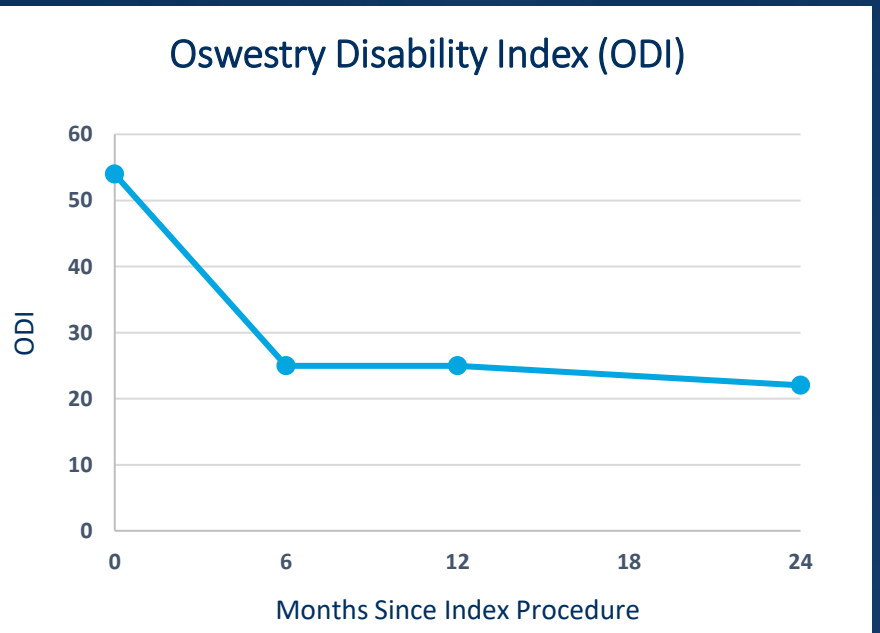
Remove instruments & close w/ Steri-strip

Durable, Significant Improvement in Mobility & Pain

Level 1 RCT: MiDAS ENCORE • 2-Year Follow-up

32-Point
ODI Improvement[1]

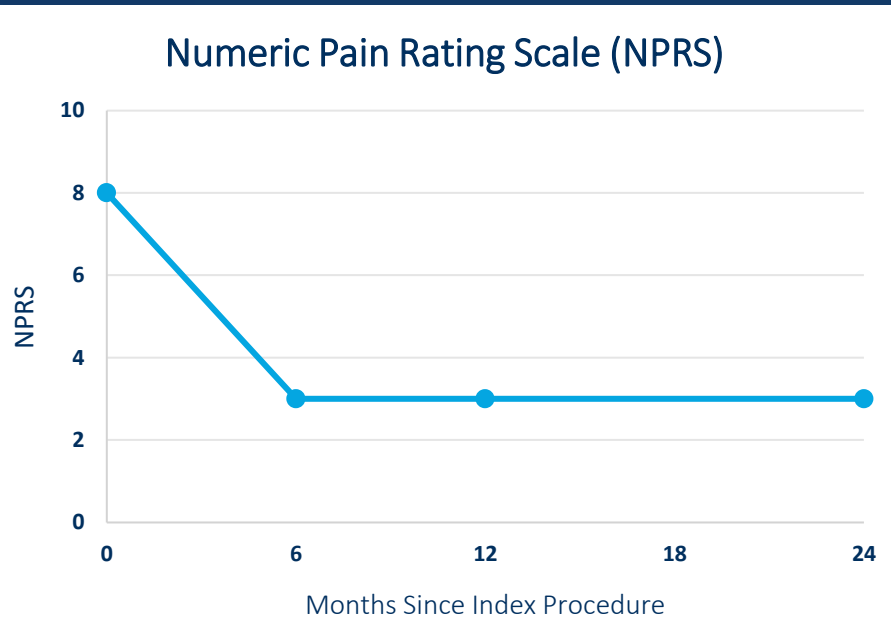
Responders Improved by 32 Points[1]



Mean ODI Responder Improvement
(10-point Improvement is Clinically Significant)

5-Point
NPRS Improvement[2]

Responders Improved by 5 Points[2]



Mean NPRS Responder Improvement
(2-point Improvement is Clinically Significant)

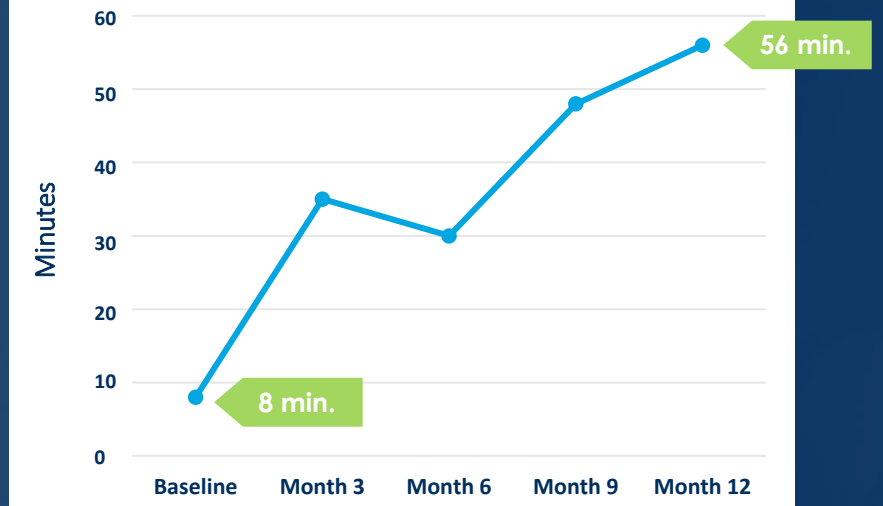
Statistically Significant Functional Improvements

Cleveland Clinic 1-Year Study[6]

"Real-World" Benefit

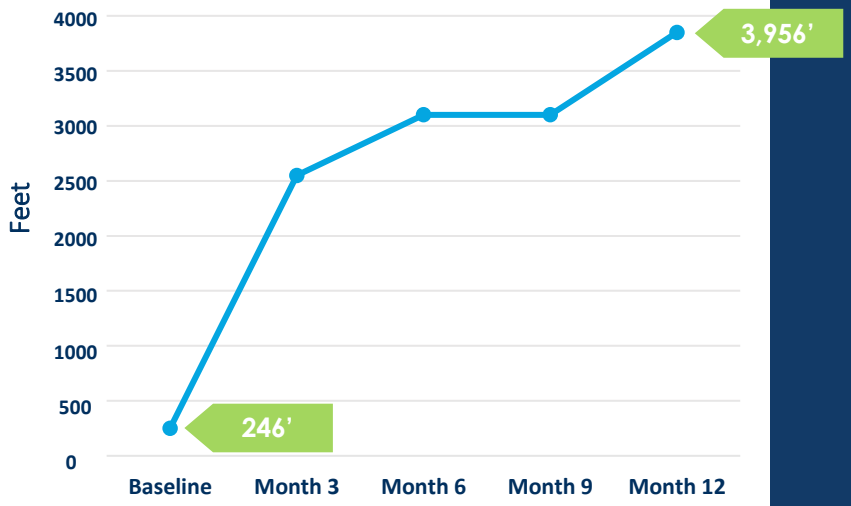
600%
Improvement

7X
Standing Time



Over
1,500%
Improvement

16X
Walking Distance



What is Superion®?

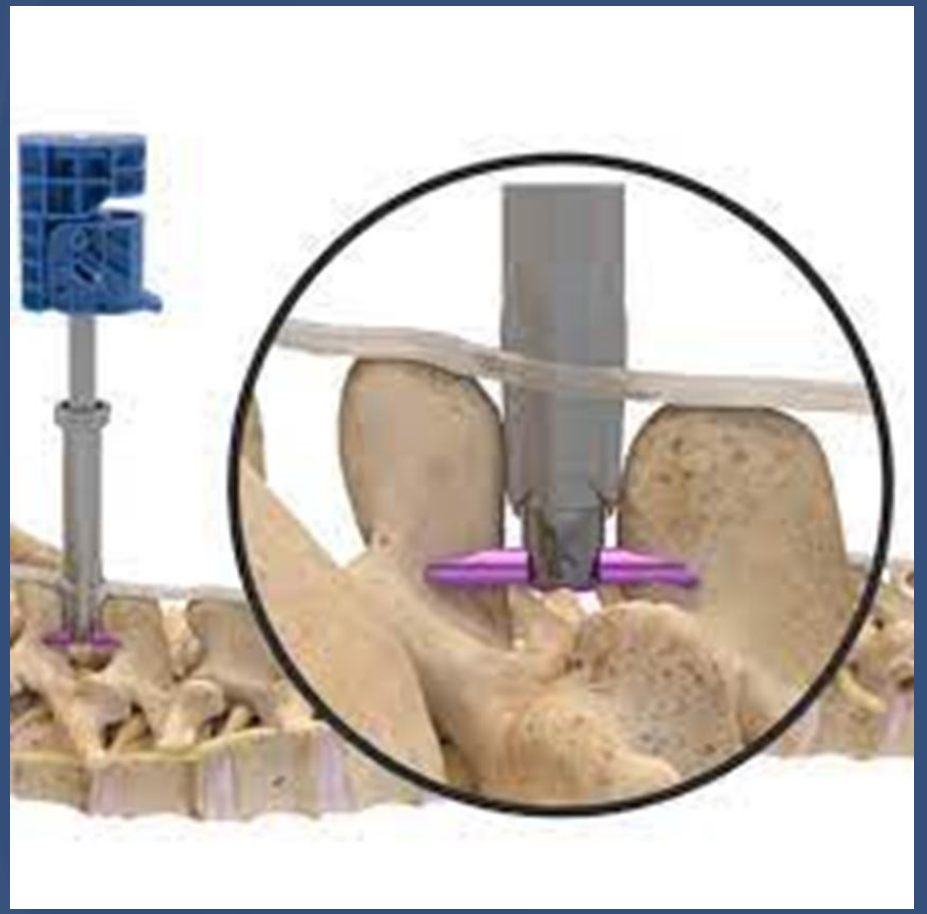
Superion® is an FDA approved spinal implant designed to treat symptoms of lumbar spinal stenosis (LSS).

This device is implanted by minimally invasive methods through a small tube, about the size of a dime.

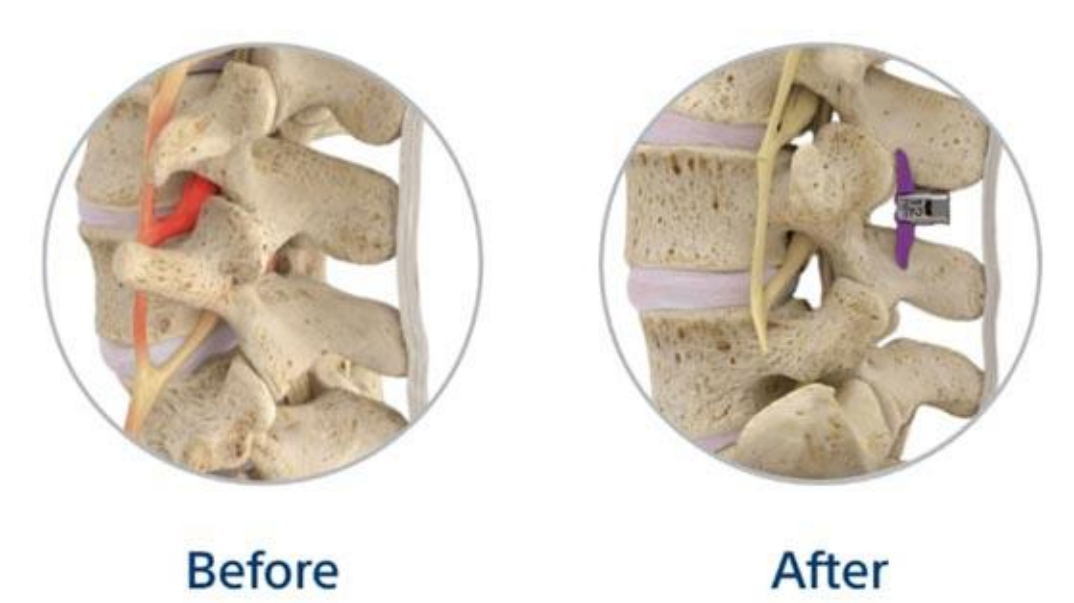
Patients who will benefit the most from the Superion® implant are those whose symptoms are relieved when bending forward, such as when pushing a shopping cart.

The Superion® procedure is reversible and will not remove the structures (bones or tissue) of the spine. All future treatment options will still be available.

- Delivered through a small cannula and deployed in a single step
- Completed in an outpatient setting under local or monitored anesthesia care (MAC)
- Near immediate recovery time
- Requires no resection of anatomical structures
- Completely reversible



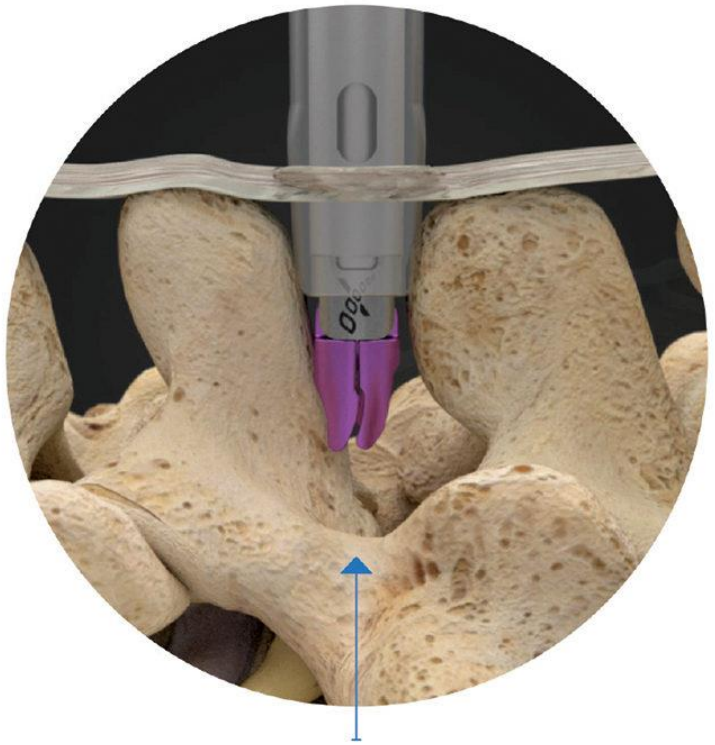
For Patients with Neurogenic Intermittent Claudication Secondary to LSS



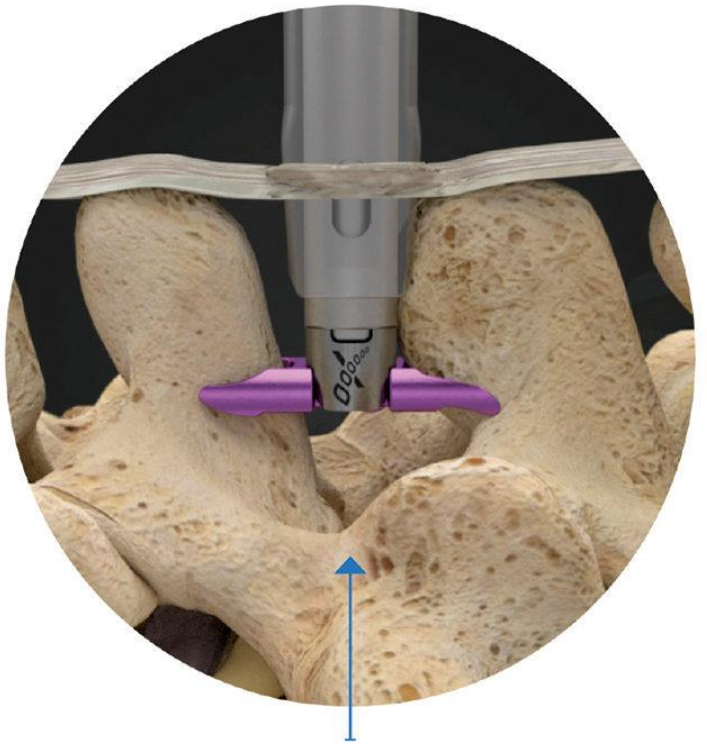
Canal and foraminal space for nerves increase in FLEXION

Canal and foraminal space for nerves decrease in EXTENSION

The Vertiflex Procedure limits EXTENSION



Superion is placed between the vertebrae and holds them open. This relieves the pressure on the nerves in the spinal canal.



When the Superion is placed, the device arms are opened and surround the spinous process. This ensures that the Superion will not dislodge.

Superion interspinous process spacer for intermittent neurogenic claudication secondary to moderate lumbar spinal stenosis: two-year results from a randomized controlled FDA-IDE pivotal trial

VPeter G Whang, Thomas R Haley, W Daniel Bradley, Pierce D Nunley, Raphael P Davis, Larry E Miller, Jon E Block, Fred H Geisler

Success Backed by Data

- The Superion® system offers a safe and effective alternative to other more invasive surgical options, such as open surgical decompression.
- It is a minimally invasive surgical option. It has been thoroughly tested to ensure it can treat leg pain symptoms associated with moderate spinal stenosis.
- Among those patients in the clinical trial that were followed up through five years, almost all expressed overall satisfaction with the Superion® implant.

	2 years	3 years	4 years	5 years
Physical Function	73%	80%	80%	81%
Symptom Severity	77%	84%	84%	75%
Patient Satisfaction	**84%**	**92%**	**87%**	**90%**

Results

At 5 years, 84% of patients demonstrated clinical success on at least two of three ZCQ domains

Individual ZCQ domain success rates were:

- 75% symptom severity
- 81% physical function
- 90% patient satisfaction

Leg and back pain (VAS) success rates were:

- 80% leg pain improvement
- 65% back pain improvement

ODI success rate was 65%

75% of patients were free from re-operation, revision or supplemental fixation at their index level at 5 years

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

Carl Lauryssen [1], Robert J Jackson [2], Jeffrey M Baron [3], Richard A Tallarico [4], William F Lavelle [4], Harel Deutsch [5], Jon E Block [6], Fred H Geisler [7]

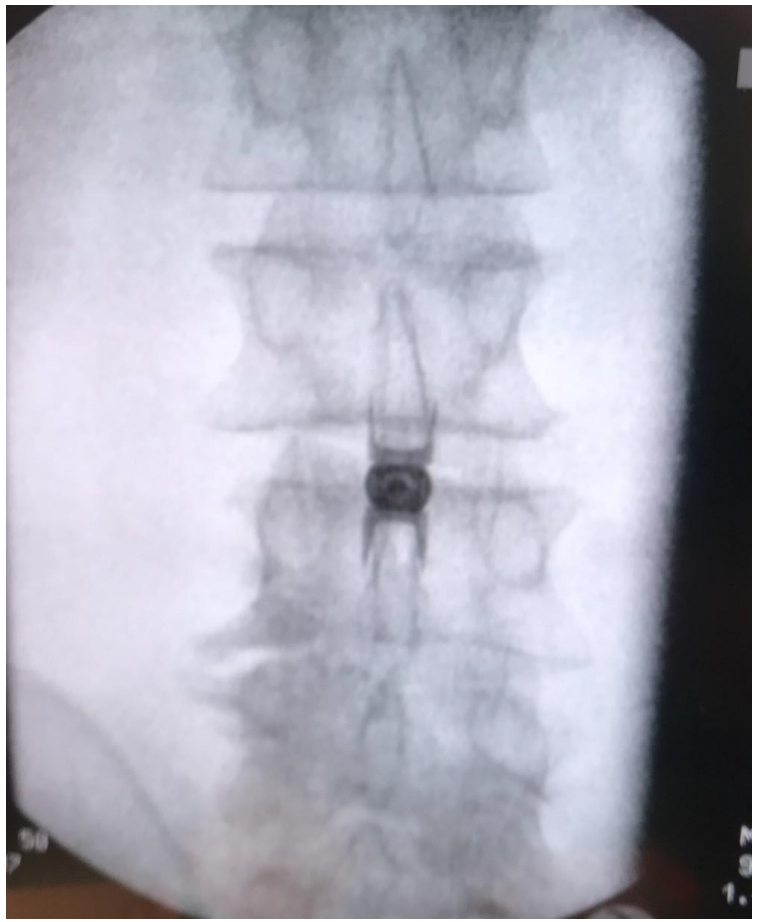
Abstract

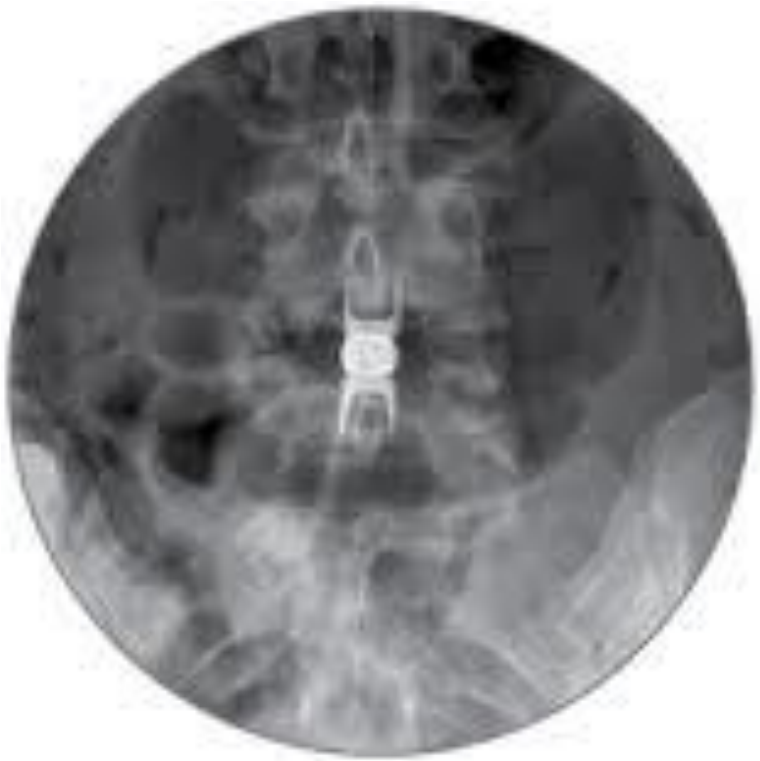
Objective: To compare the two-year clinical outcomes of a prospective, randomized controlled trial of an FDA-approved interspinous spacer with the compilation of published findings from 19 studies of decompressive laminectomy for the treatment of lumbar spinal stenosis.

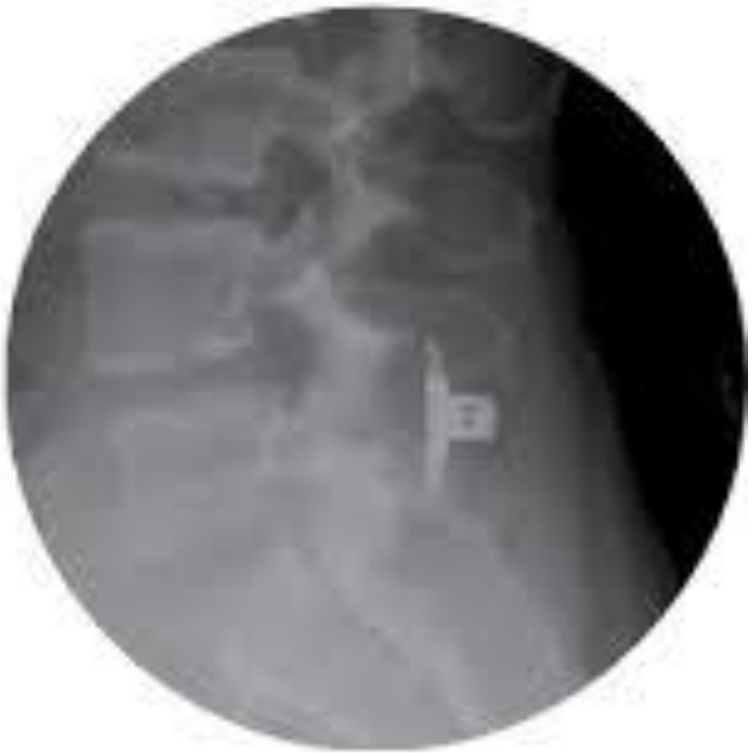
Methods: Back and leg pain, Oswestry disability index (ODI), and Zurich Claudication Questionnaire (ZCQ) values were compared between spacer- and laminectomy-treated patients preoperatively and at 12 and 24 months.

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%).

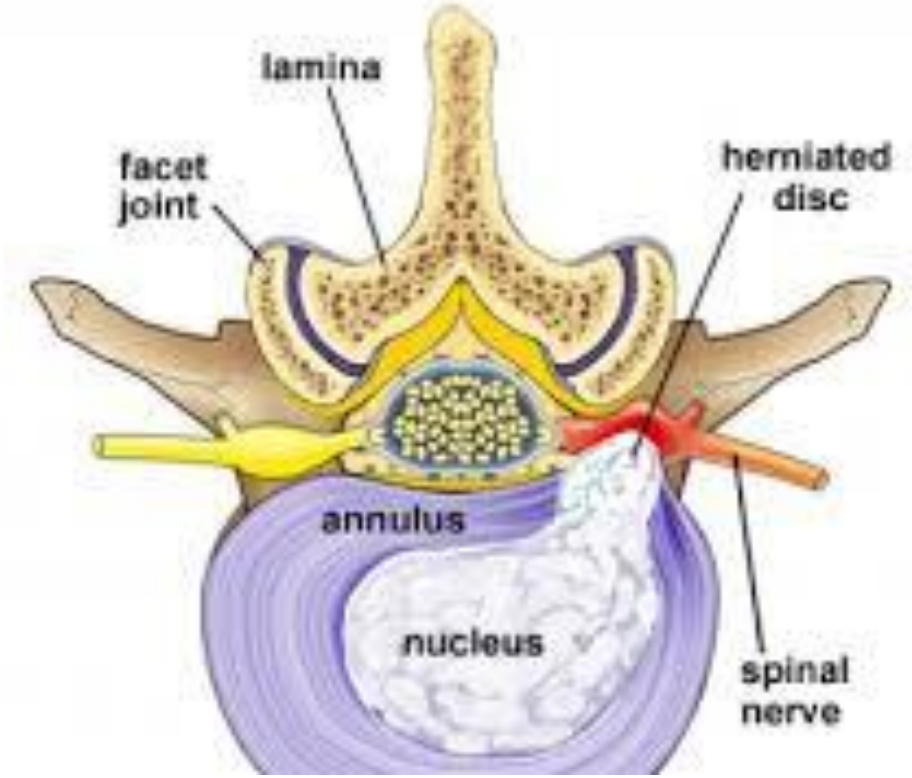
Conclusion: Both treatments provide effective and durable symptom relief of claudicant symptoms. This stand-alone interspinous spacer offers the patient a minimally invasive option with less surgical risk.

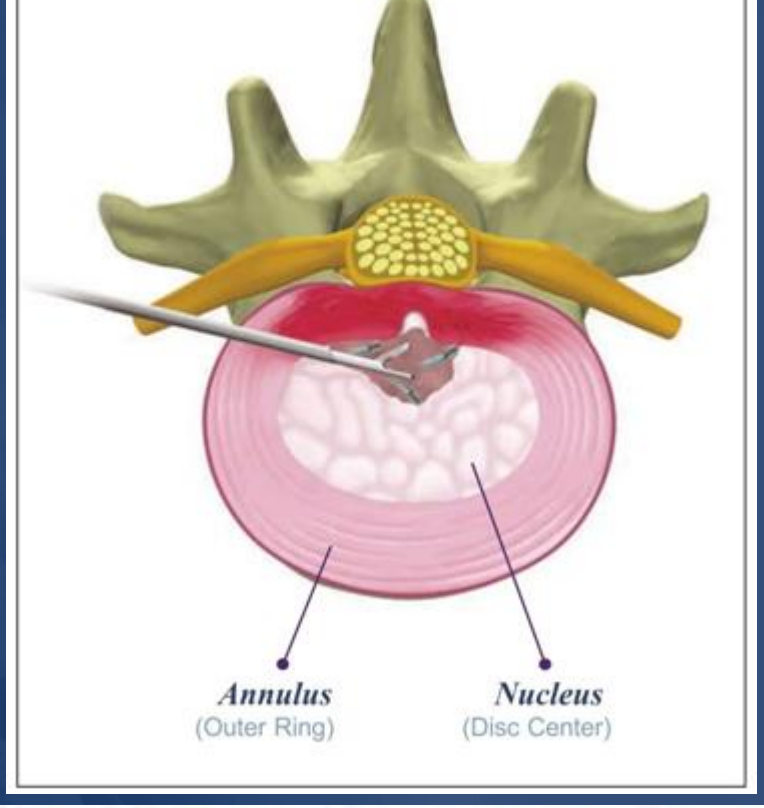


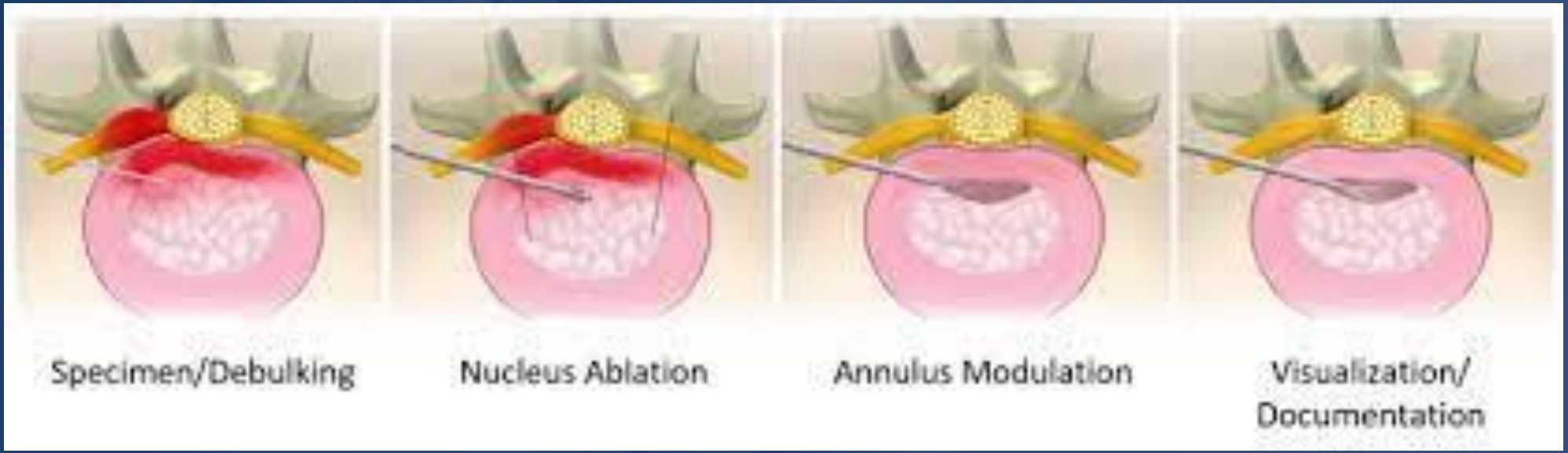


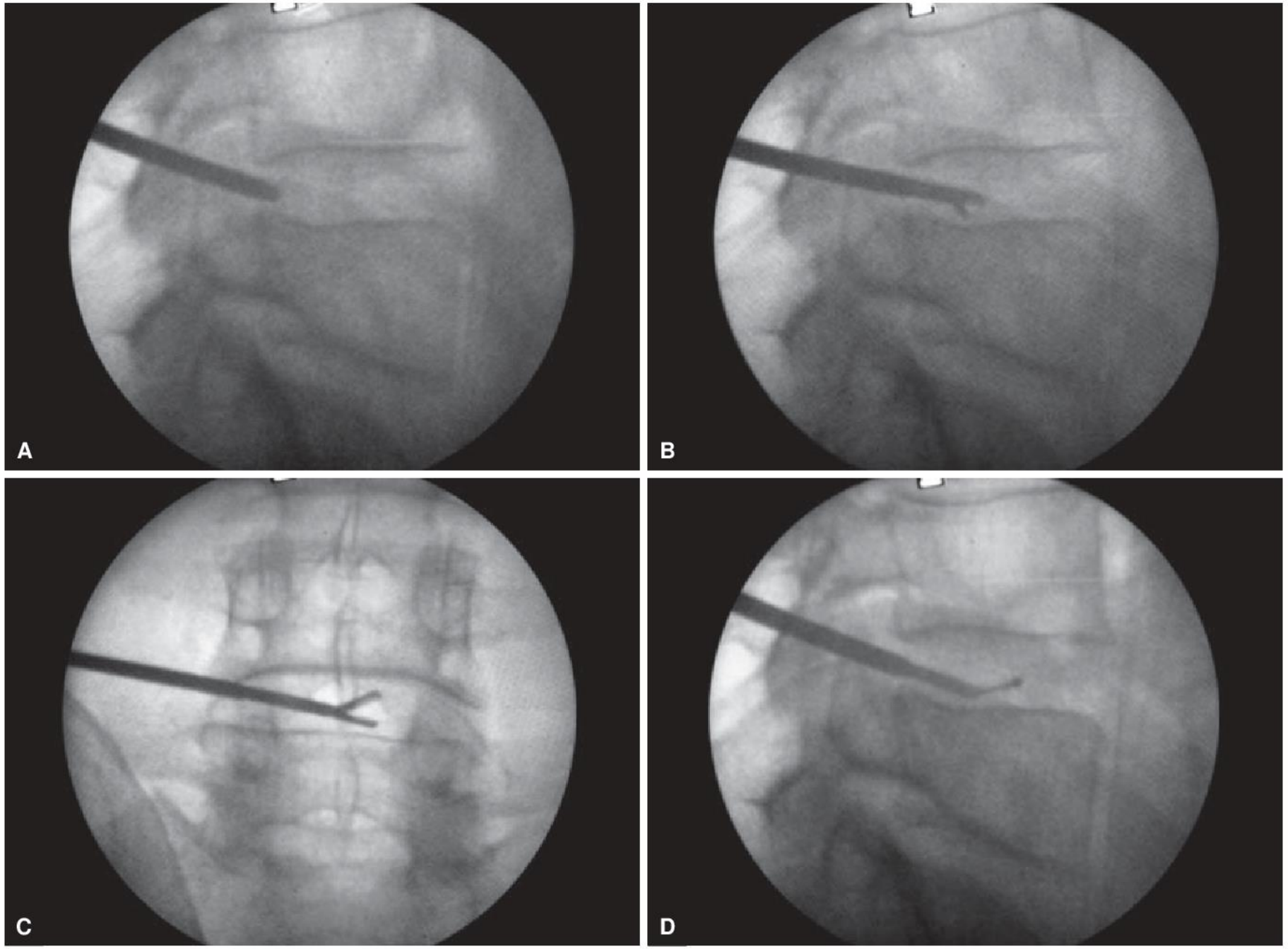


Microdisectomy




Annulus
(Outer Ring)
Nucleus
(Disc Center)


Specimen/Debulking
Nucleus Ablation
Annulus Modulation
Visualization/
Documentation


A
B
C
D

Compatible for Patients with Existing Risk Factors

Early to Late Disease State

- Degenerative condition
- Prevalent in patients age 60+

All Lumbar Levels

- Including L5-S1

Medical & Spinal Comorbidities Not Contradicted

- Often compatible for those who are unable to tolerate surgery (eg high BMI, anesthesia intolerance)

Often Not Candidates for Other Therapies

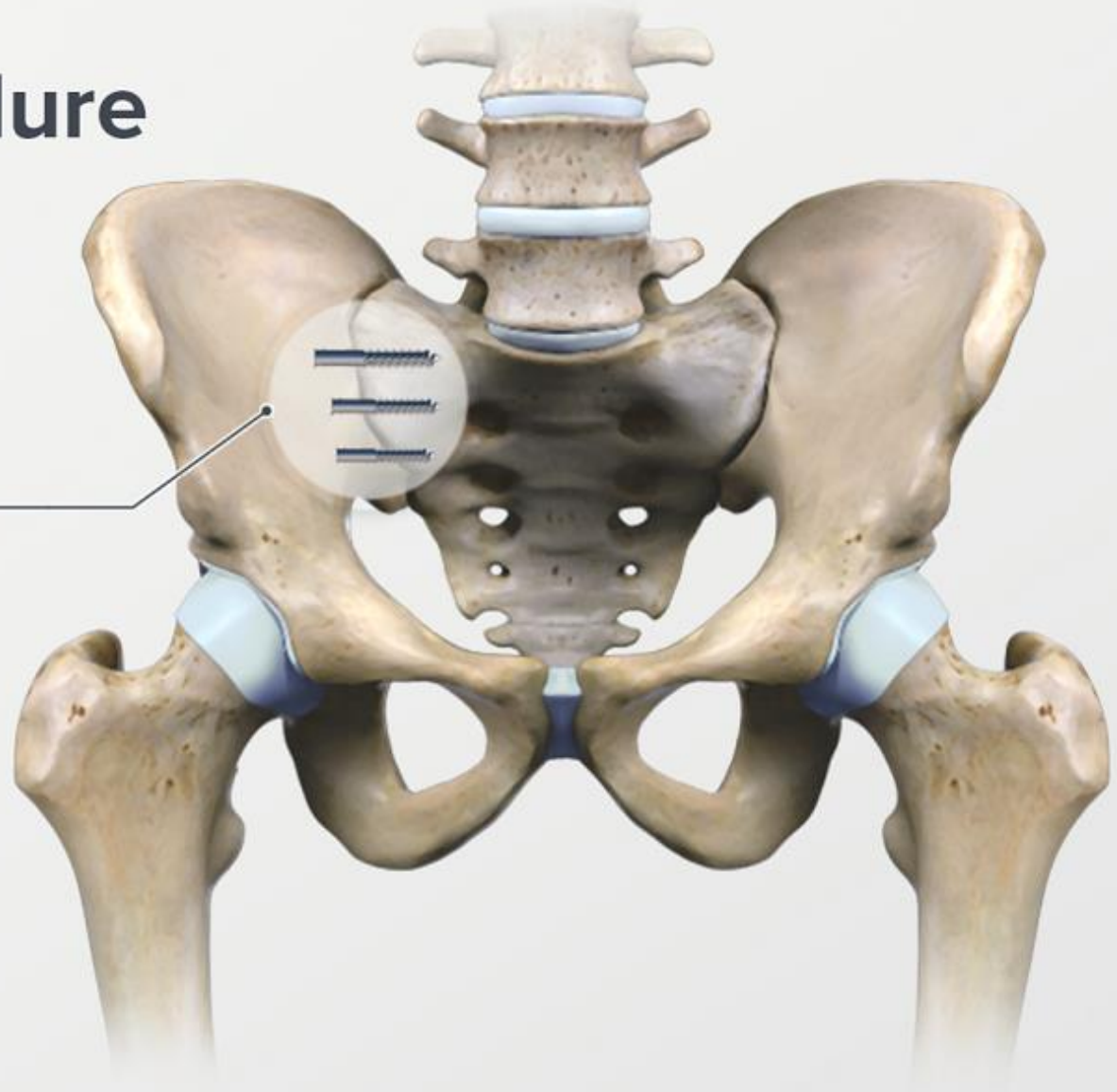
Usually an option for patients with:

- Hardware at adjacent level
- Grade ≤2 spondylolisthesis
- Bone integrity/osteoporosis

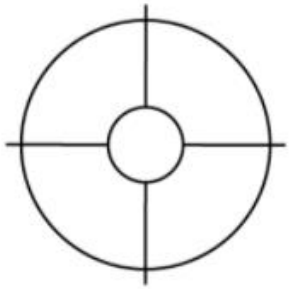
- The sacroiliac (SI) joint accounts for 10-27% of all low back pain [7]
- Treatment options for SI joint dysfunction include physical therapy, bracing, and interventions including injections and radiofrequency ablation
- SI fusion is an alternative for long term pain relief
- Minimally Invasive SI fusion (MI-SIF) is a newer procedure which allows for less operating time, recovery time, and morbidity while still achieving the same end result of traditional open SI fusion
- Minimally invasion SI fusion (MI-SIF) requires minimal operating time, recovery time, and has low complication rates

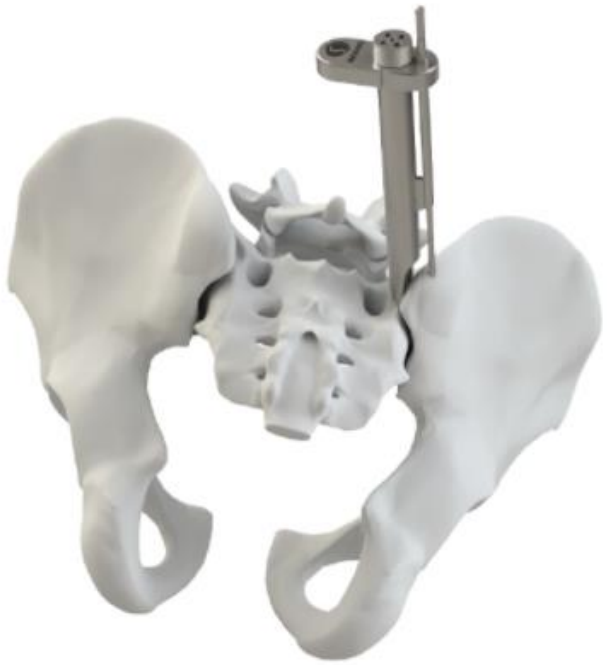
Minimally-Invasive SI Joint Fusion Procedure

multiple implants are typically used to better stabilize and prevent movement at the joint

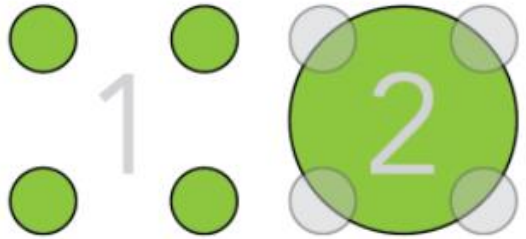


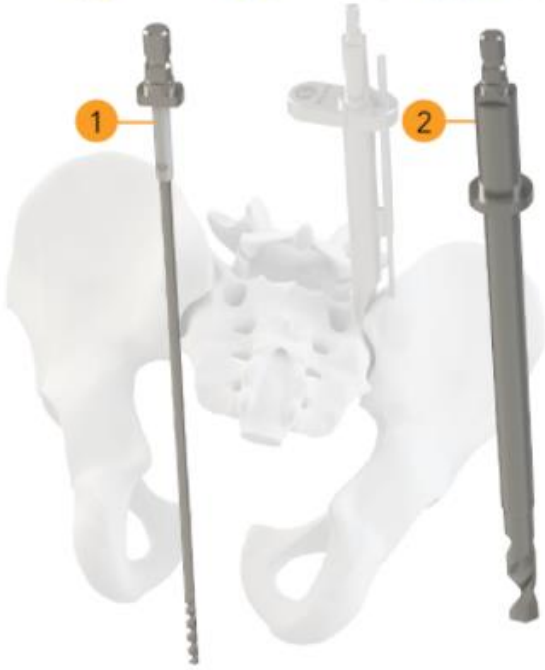
Dock.



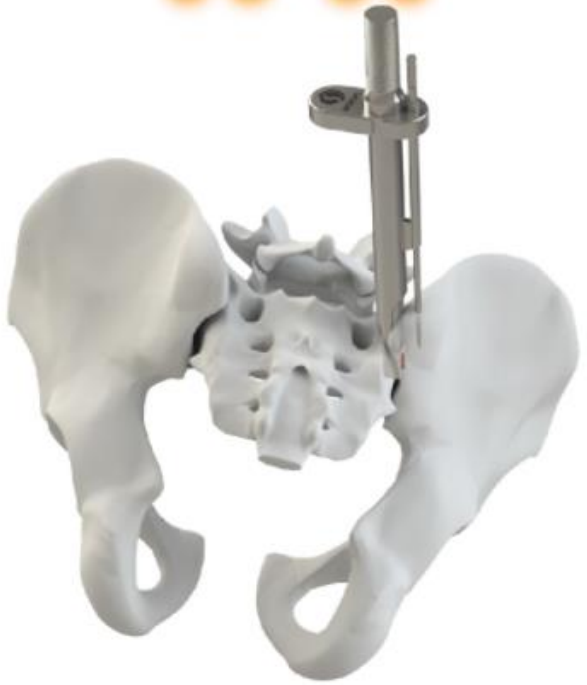


Ream.

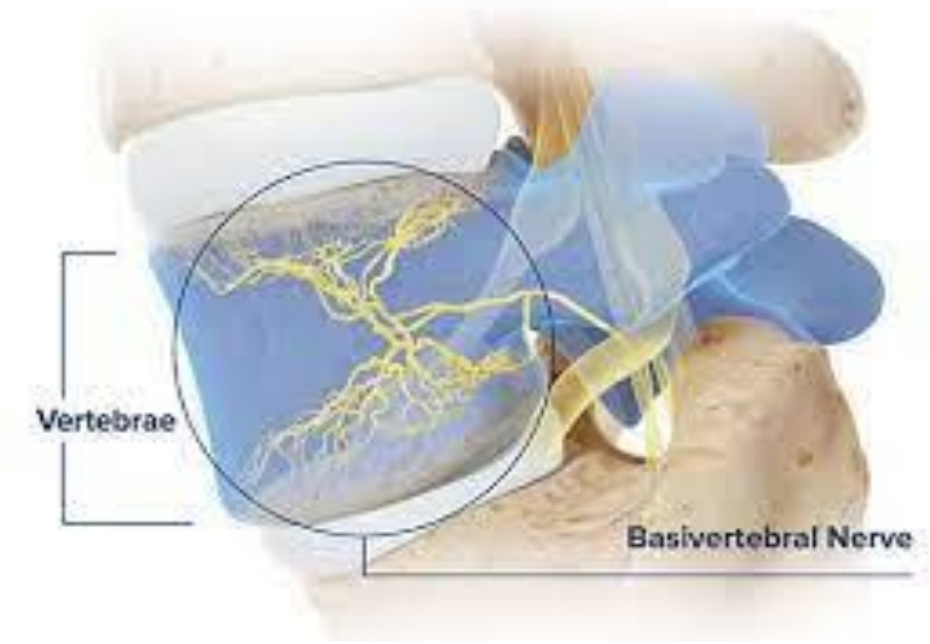




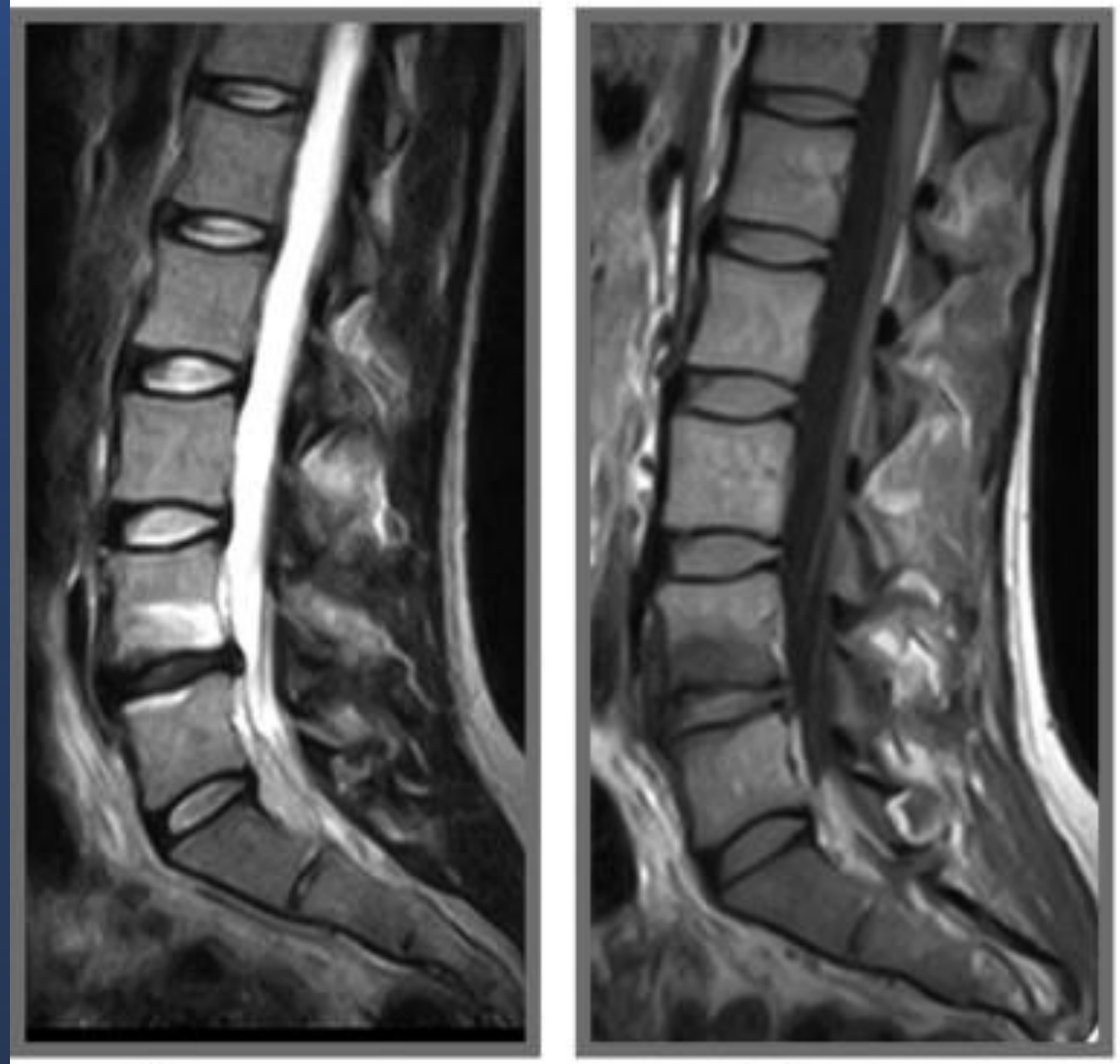
Implant.



Vertebrogenic Pain

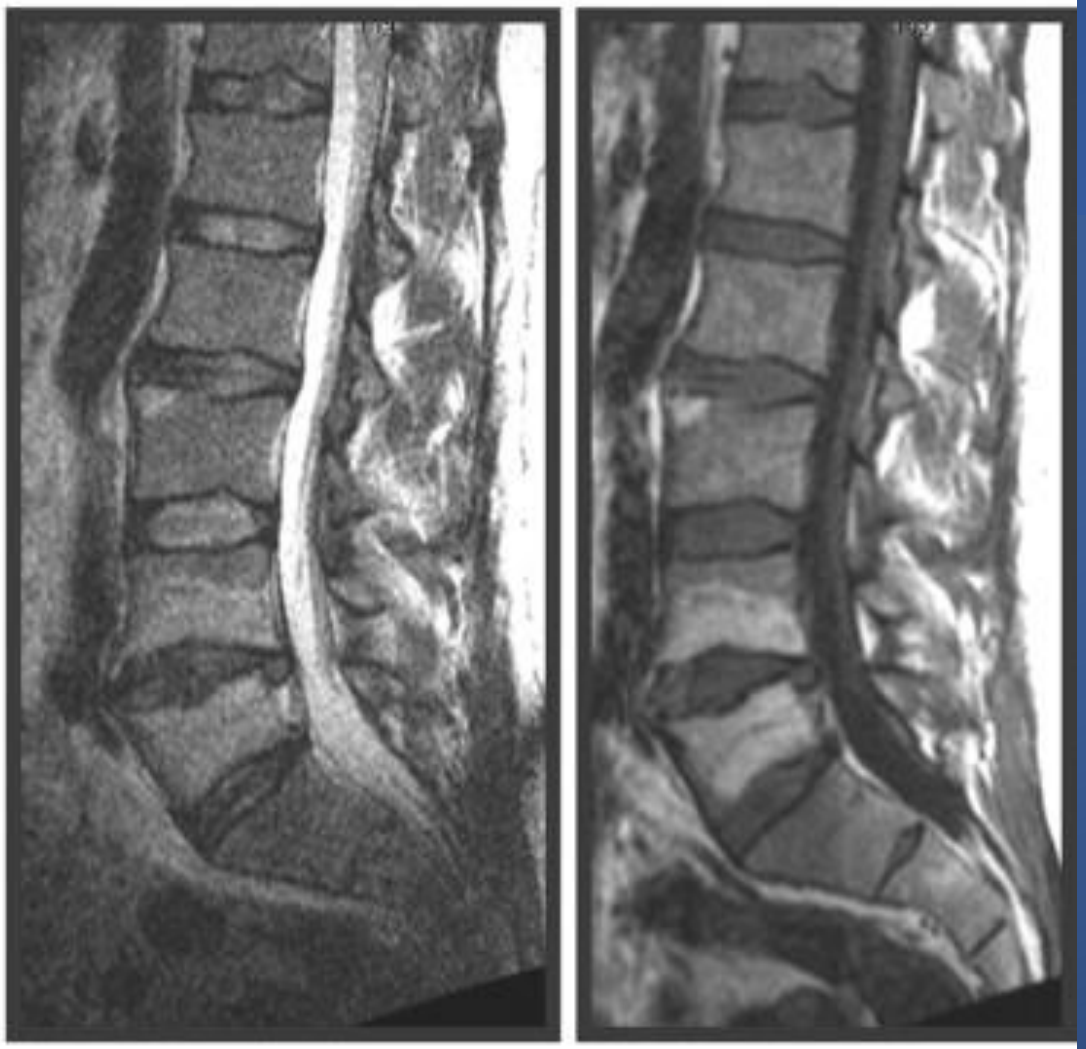


Modic type 1



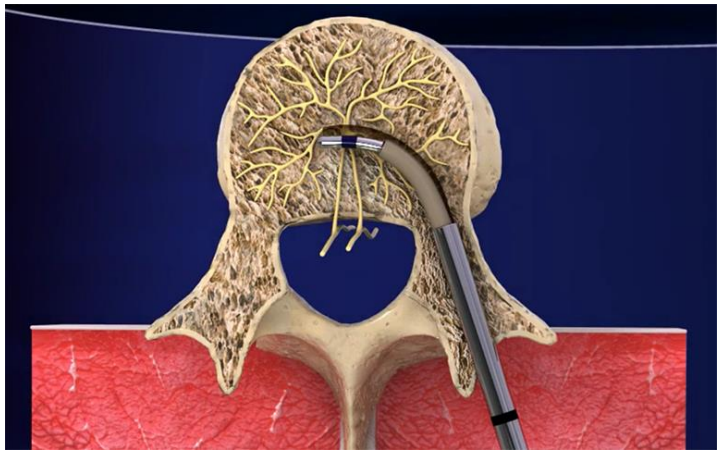
T2-weigthed T1-weigthed

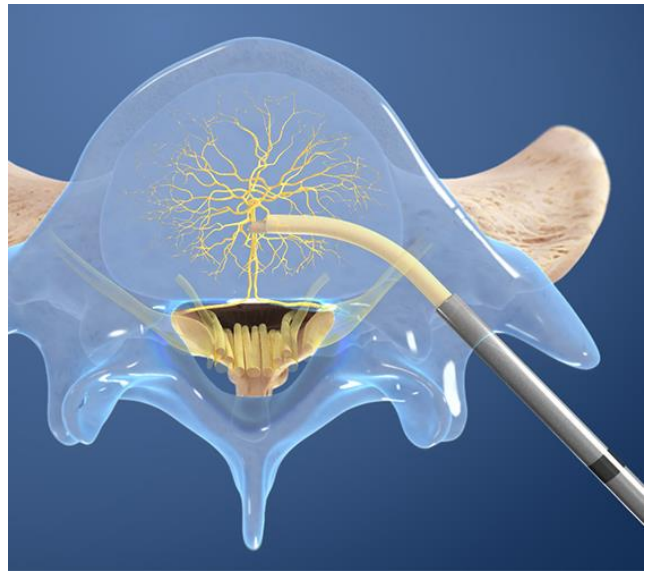
Modic type 2

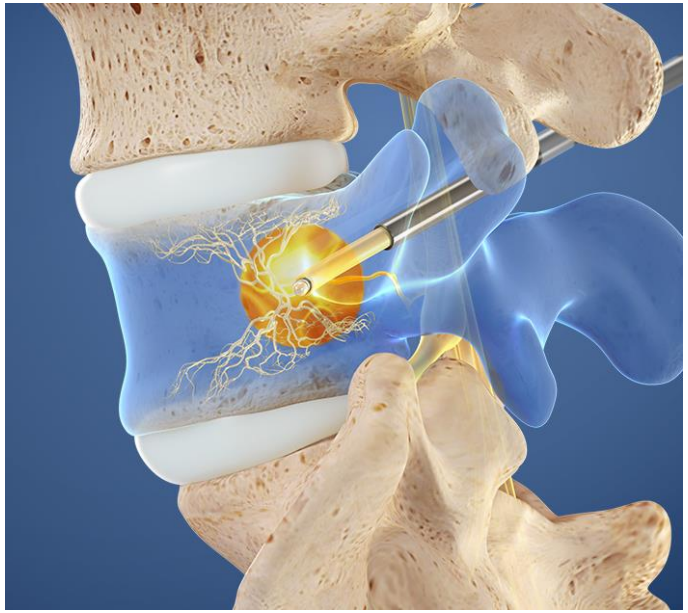


T2-weigthed T1-weigthed

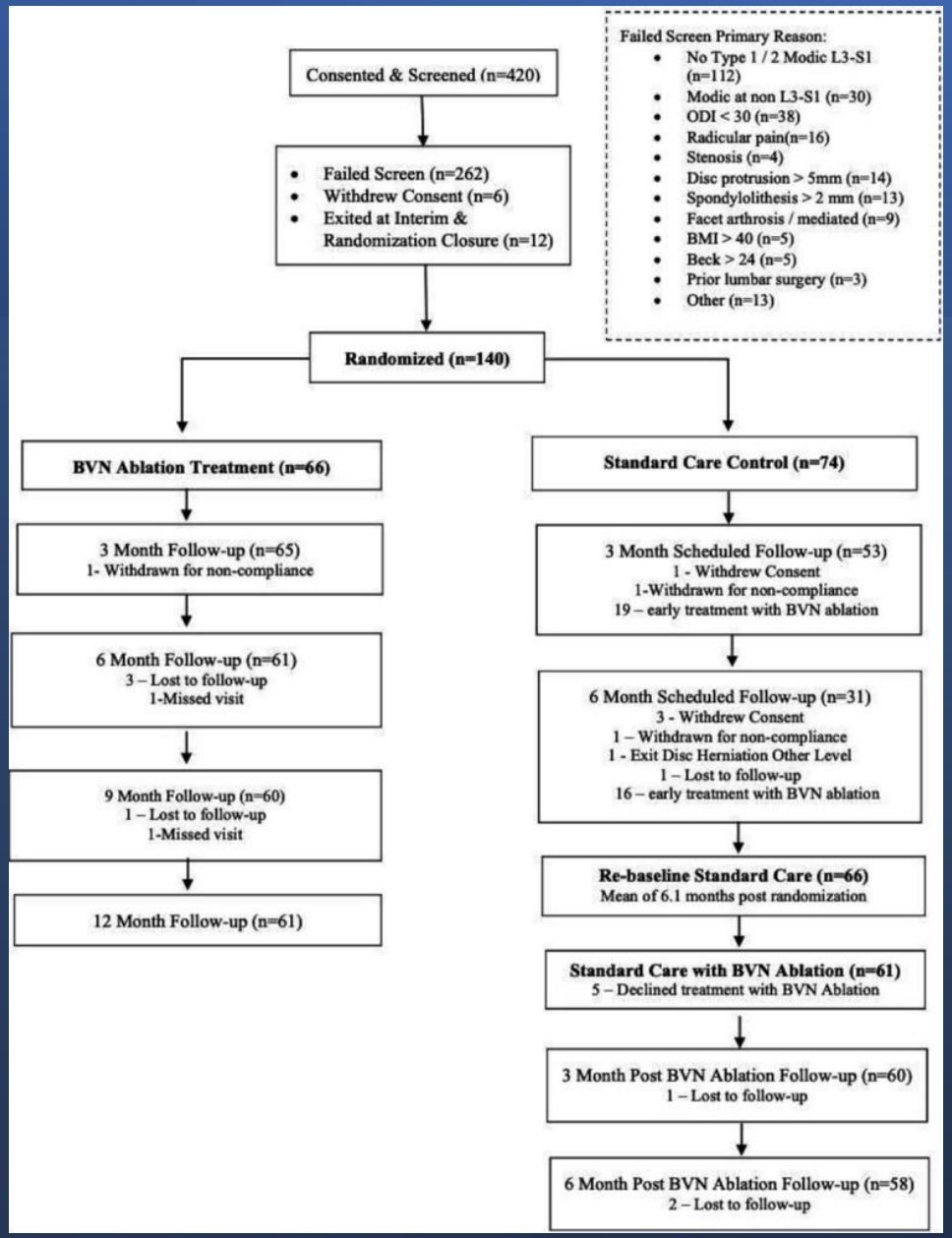
Intracept Procedure



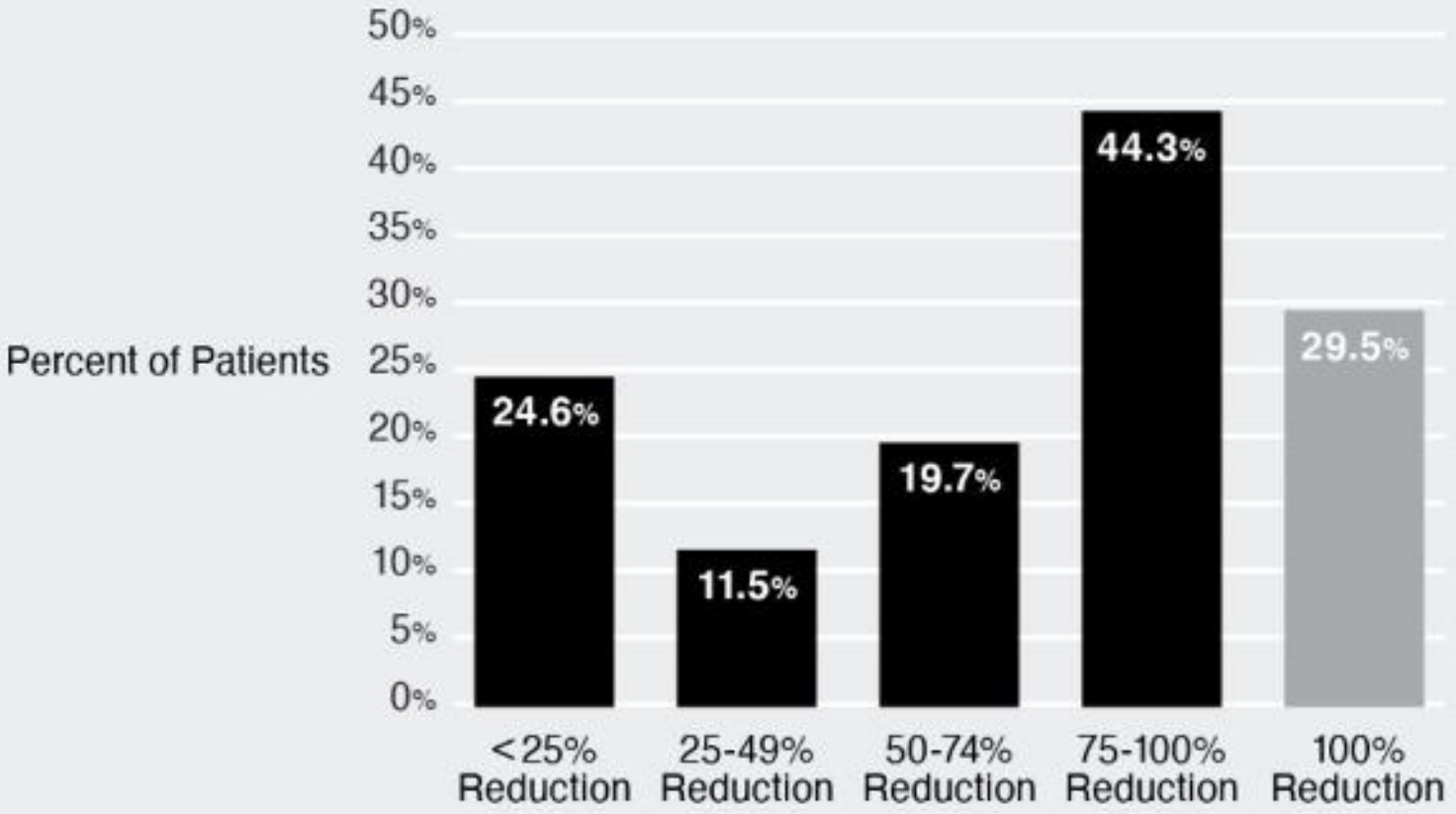




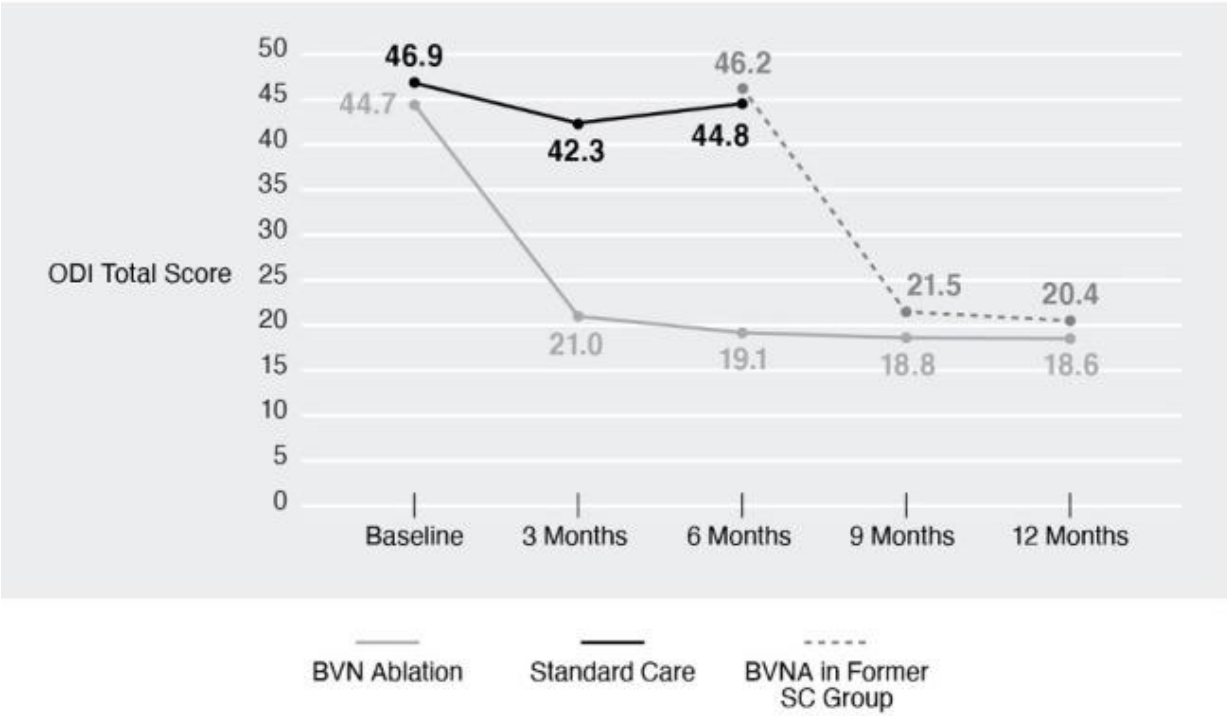
Prospective, randomized, multicenter study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 12-month results (2021)


Failed Screen Primary Reason:
No Type 1 / 2 Modic L3-S1 (n=112)
Modic at non L3-S1 (n=30)
ODI < 30 (n=38)
Radicular pain(n=16)
Stenosis (n=4)
Disc protrusion > 5mm (n=14)
Spondylolithesis > 2 mm (n=13)
Facet arthrosis / mediated (n=9)
BMI > 40 (n=5)
Beck > 24 (n=5)
Prior lumbar surgery (n=3)
Other (n=13)
Consented & Screened (n=420)
Failed Screen (n=262)
Withdrew Consent (n=6)
Exited at Interim & Randomization Closure (n=12)
Randomized (n=140)
BVN Ablation Treatment (n=66)
3 Month Follow-up (n=65)
1- Withdrawn for non-compliance
6 Month Follow-up (n=61)
3 – Lost to follow-up
1-Missed visit
9 Month Follow-up (n=60)
1 – Lost to follow-up
1-Missed visit
12 Month Follow-up (n=61)
Standard Care Control (n=74)
3 Month Scheduled Follow-up (n=53)
1 - Withdrew Consent
1-Withdrawn for non-compliance
19 – early treatment with BVN ablation
6 Month Scheduled Follow-up (n=31)
3 - Withdrew Consent
1 – Withdrawn for non-compliance
1 - Exit Disc Herniation Other Level
1 – Lost to follow-up
16 – early treatment with BVN ablation
Re-baseline Standard Care (n=66)
Mean of 6.1 months post randomization
Standard Care with BVN Ablation (n=61)
5 – Declined treatment with BVN Ablation
3 Month Post BVN Ablation Follow-up (n=60)
1 – Lost to follow-up
6 Month Post BVN Ablation Follow-up (n=58)
2 – Lost to follow-up

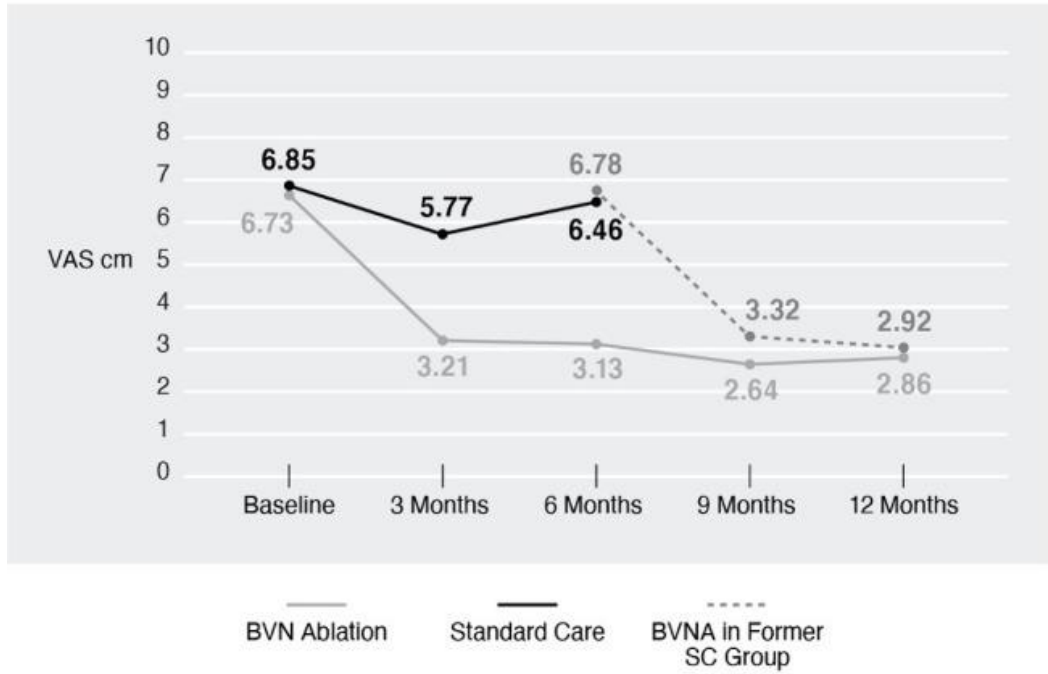
Percent Visual Analog Scale (VAS) Pain Score Reduction: Baseline to 12 Months in the Basivertebral Ablation Treatment Arm



Mean Oswestry Disability Index (ODI) Over Time

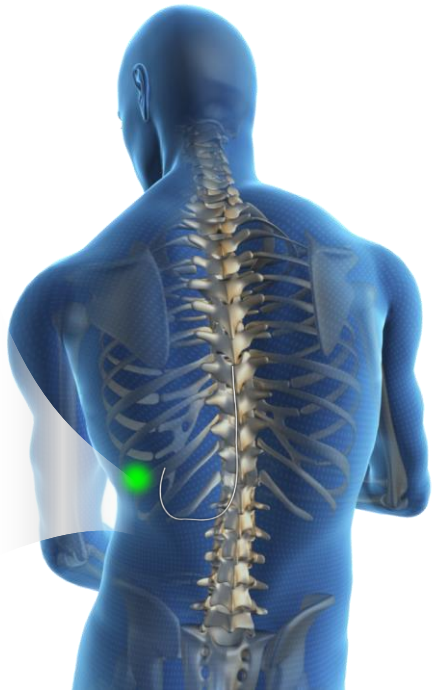


Mean Visual Analogue Scale (VAS) Pain Score Over Time



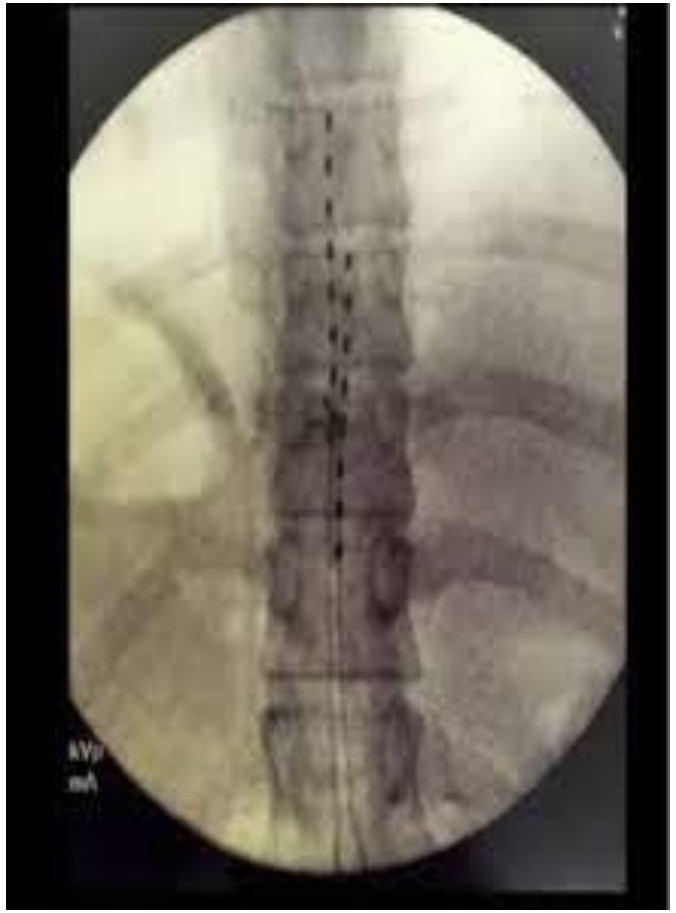
What is Spinal Cord Stimulation?

Spinal Cord Stimulation (SCS) is an implanted neuromodulation solution that provides relief to chronic pain sufferers by disrupting pain signals traveling between the spinal cord and the brain



- SCS is a non-pharmacologic therapy that works by delivering small electrical pulses to the pain sensing pathways of the spinal cord, effectively altering the pain signals traveling to the brain
- Conventional stimulation operating between 2 – 1,200 Hz has been safely used for over 40 years, primarily to treat leg pain
- Typically prescribed for the treatment of pain of the back, trunk, or limbs after failed conventional medical management
- Minimally invasive procedure and reversible therapy
- **Success is defined as achieving 50% pain relief as measured by patient's VAS score**

*Kapural L, et al. Comparison of 10-kHz High-Frequency and Traditional Low-Frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: 24-month Results from a Multicenter, Randomized, Controlled Pivotal Trial. Neurosurgery. Published 09 2016



OPEN

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Comparison of 10-kHz High-Frequency and Traditional Low-Frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: 24-Month Results From a Multicenter, Randomized, Controlled Pivotal Trial

BACKGROUND: Pain relief with spinal cord stimulation (SCS) has focused historically on paresthesias overlapping chronically painful areas. A higher level evidence supports the use of SCS in treating leg pain than supports back pain, as it is difficult to achieve adequate paresthesia coverage, and then pain relief, in the low back region. In comparison, 10-kHz high-frequency (HF10) SCS therapy does not rely on intraoperative paresthesia mapping and remains paresthesia-free during therapy.

OBJECTIVE: To compare long-term results of HF10 therapy and traditional low-frequency SCS.

METHODS: A pragmatic randomized, controlled, pivotal trial with 24-month follow-up was conducted across 11 comprehensive pain treatment centers. Subjects had Visual Analog Scale scores of ≥5.0/10.0 cm for both back and leg pain, and were assigned randomly (1:1) to receive HF10 therapy or low-frequency SCS. The primary end point was a responder rate, defined as ≥50% back pain reduction from baseline at 3 months with a secondary end point at 12 months (previously reported). In this article, 24-month secondary results are presented. Non-inferiority was first assessed, and if demonstrated the results were tested for superiority.

RESULTS: In the study, 198 subjects were randomized (101 HF10 therapy, 97 traditional SCS). One hundred seventy-one subjects (90 HF10 therapy, 81 traditional SCS) successfully completed a short-term trial and were implanted. Subjects averaged 54.9 ± 12.9 years old, 13.6 ± 11.3 years since diagnosis, 86.6% had back surgery, 88.3% were taking opioid analgesics. At 3 months, 84.5% of implanted HF10 therapy subjects were responders for back pain and 83.1% for leg pain, and 43.8% of traditional SCS subjects were responders for back pain and 55.5% for leg pain ($P < .001$ for both back and leg pain comparisons, non-inferiority and superiority). At 24 months, more subjects were responders to HF10 therapy than traditional SCS (back pain: 76.5% vs 49.3%; 27.2% difference, 95% CI, 10.1%-41.8%; $P < .001$ for non-inferiority and superiority; leg pain: 72.9% vs 49.3%; 23.6% difference, 95% CI, 5.9%-38.6%; $P < .001$ for non-inferiority and $P = .003$ for superiority). Also at 24 months, back pain decreased to a greater degree with HF10 therapy (66.9% ± 31.8%) than traditional SCS (41.1% ± 36.8%, $P < .001$ for non-inferiority and superiority). Leg pain also decreased to a greater degree with HF10 therapy (65.1% ± 36.0%) than traditional SCS (46.0% ± 40.4%, $P < .001$ for non-inferiority and $P = .002$ for superiority).

CONCLUSION: This study demonstrates long-term superiority of HF10 therapy compared with traditional SCS in treating both back and leg pain. The advantages of HF10 therapy are anticipated to impact the management of chronic pain patients substantially.

KEY WORDS: Back pain, Chronic pain, Leg pain, Paresthesia, Spinal cord stimulation

Neurosurgery 0:1–10, 2016 DOI: 10.1227/NEU.0000000000001418 www.neurosurgery-online.com

ABBREVIATIONS: HF10, 10-kHz high-frequency therapy; **IPG,** implantable pulse generator; **MCID,** minimal clinically important difference; **PI,** permanent implant; **ODI,** Oswestry Disability Index; **SCS,** spinal cord stimulation; **VAS,** Visual Analog Scale

Effective pain relief with spinal cord stimulation (SCS) has historically been critically dependent on overlapping stimulation-induced paresthesias with chronically painful areas. Although efficacy of SCS for the treatment

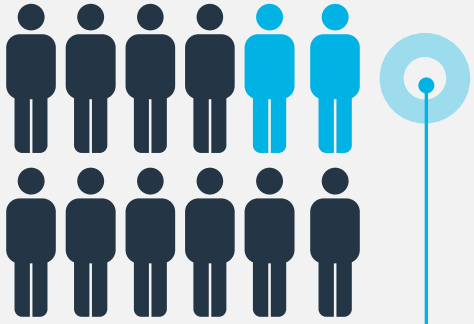
Painful Diabetic Neuropathy (PDN): Large patient population with limited treatment options

Prevalence

Diagnosed PWD

26.8 MM PATIENTS

20% with PDN



5.3 MM PATIENTS

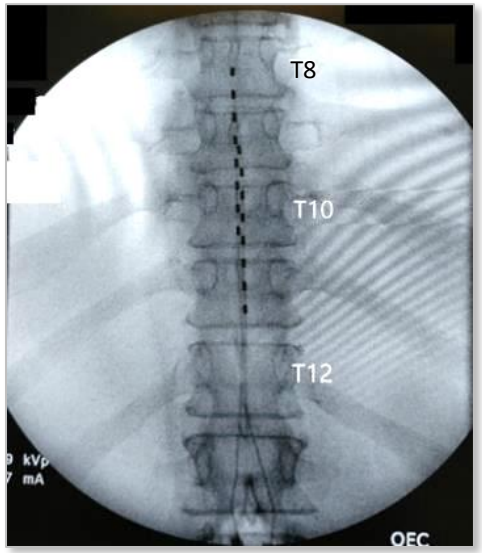
45% Refractory to CMM

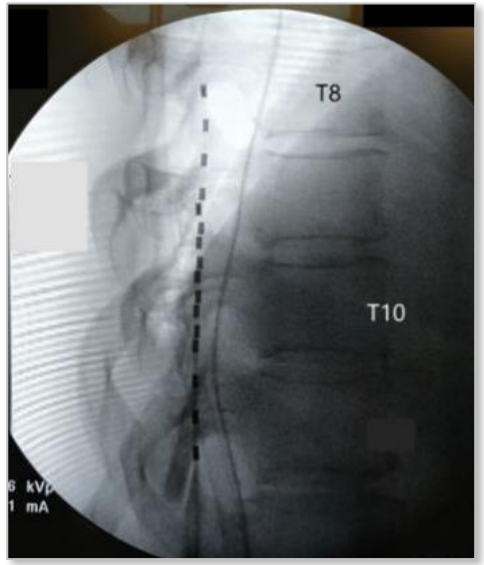
2.3 MM PATIENTS

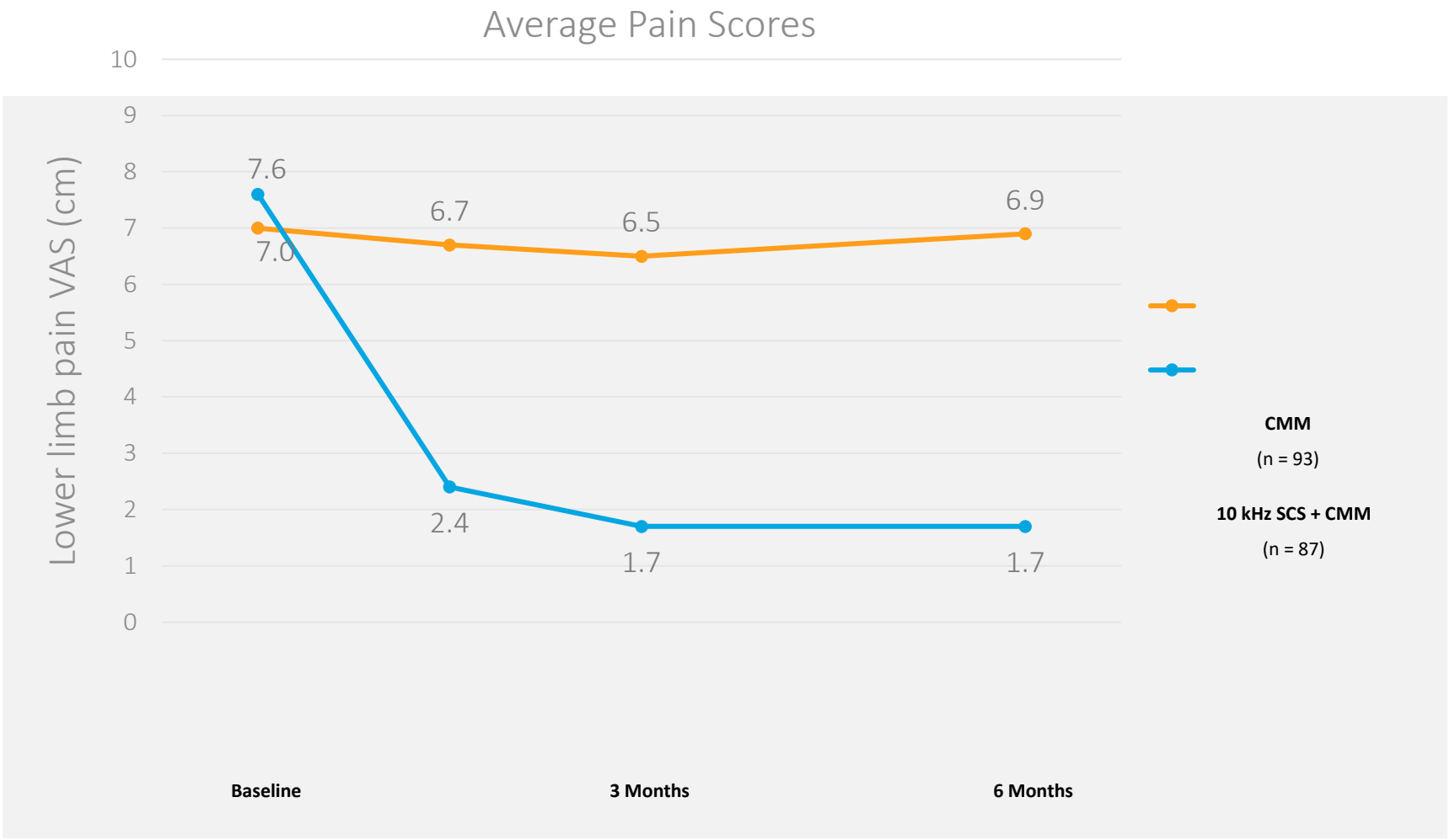
Current Treatment Options Demonstrate Mild Efficacy and Low Adherence

Safety and Efficacy Demonstrated in a Level 1 Randomized Controlled Trial SENZA-PDN RCT

- Painful diabetic neuropathy (PDN) in patients with symptoms refractory to evidence-based treatments
- HbA1c < 10%, BMI < 45
- 18 US centers randomized 216 subjects 1:1
- Independent Medical Monitors reviewed all subjects
- Independent data collection with independent bio- statistician review
- Crossover at 6 months with 24-month follow-up
- Treatments: Conventional medical management (CMM) alone vs
  10 kHz SCS (Nevro Corp.) + CMM
- 6-month follow-up published in JAMA Neurology April 2021.
  - Pain
  - Quality of life
  - Detailed Neurological Examination

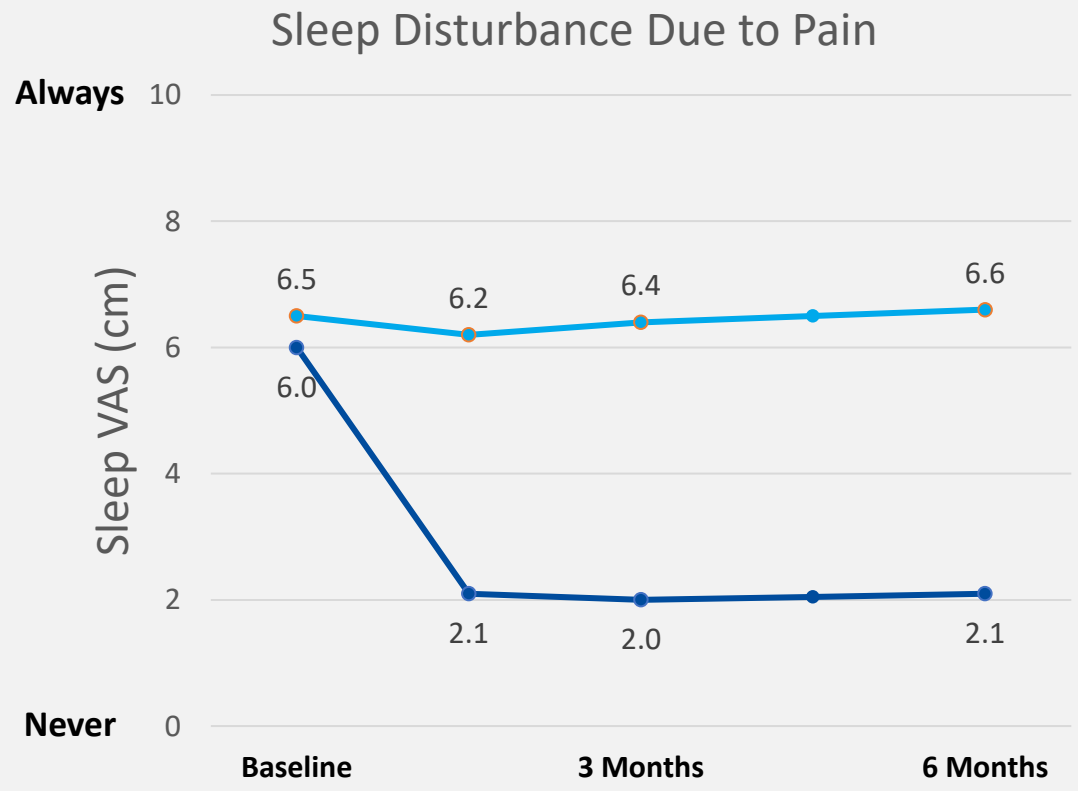


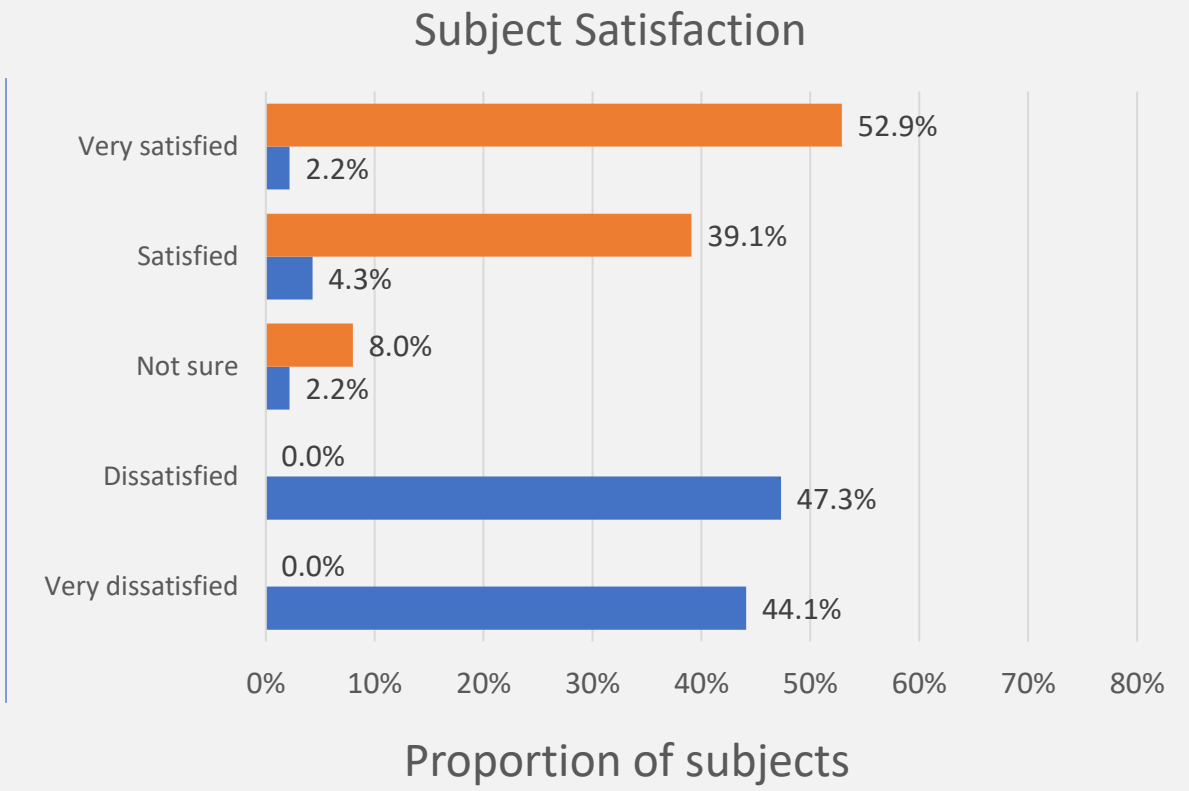




Petersen, E, et. al. Effect of High-frequency (10-kHz) Spinal Cord Stimulation in Patients With Painful Diabetic Neuropathy A Randomized Clinical Trial. JAMA Neurology, April 2021.

SENZA-PDN RCT: Quality of Life Improvements at 6 Months



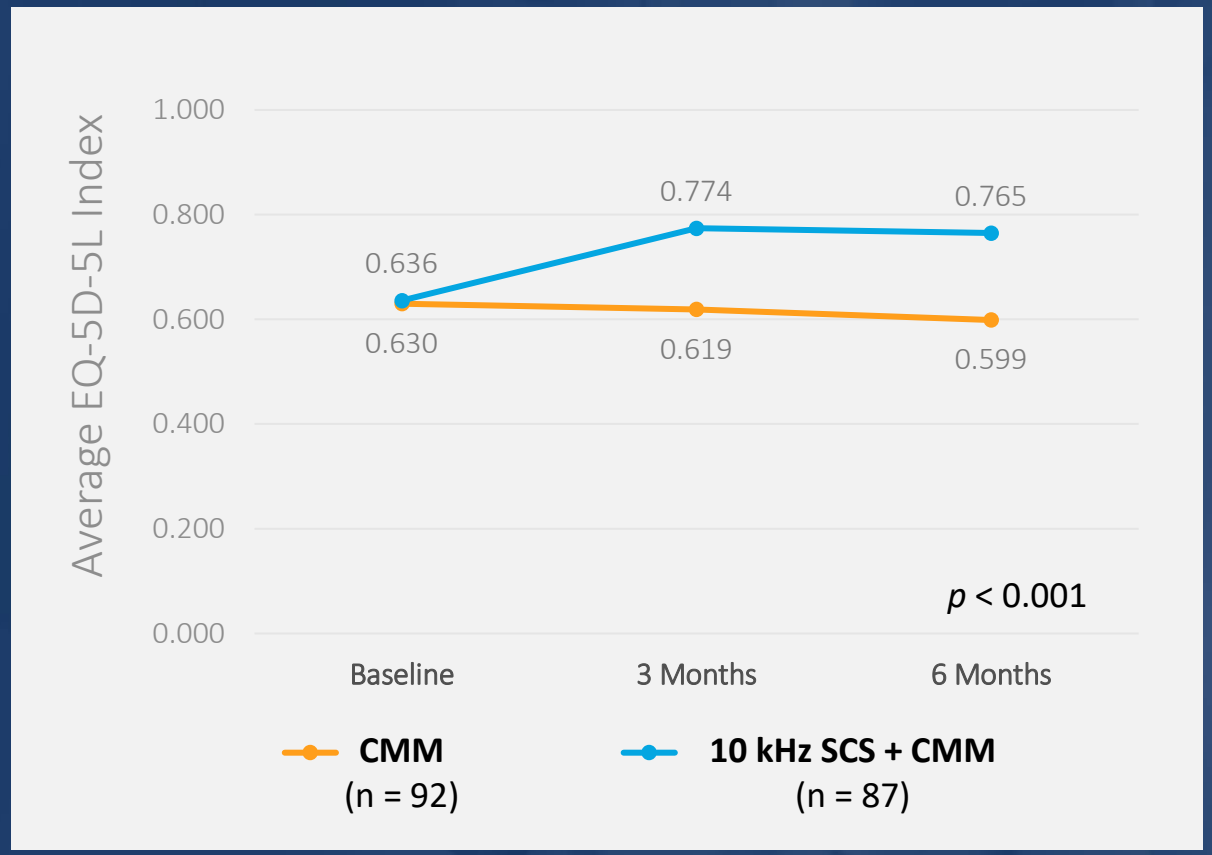


CMM (n = 93)

10 kHz SCS + CMM (n = 87)

SENZA-PDN RCT: Health Economic Trends

Health-related QoL improvement



Opioid reduction

- Decreased or eliminated: 23% of 10 kHz Therapy subjects vs 8% of CMM subjects
- Increased: 2% of 10 kHz Therapy subjects vs 11% of CMM subjects

Reduced hospital & ED visits

- Over 6 months, there were 7 fewer visits per 100 patients in the 10 kHz SCS group
  - 1.35 visits/CMM subject vs 1.27 visits/10 kHz SCS subject, difference = 0.07 visits/subject

The Gap

Training level

ASC vs Office

Future

Cervical and Thoracic

SCS

Intrathecal Pain Pump

Stem Cells

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The End