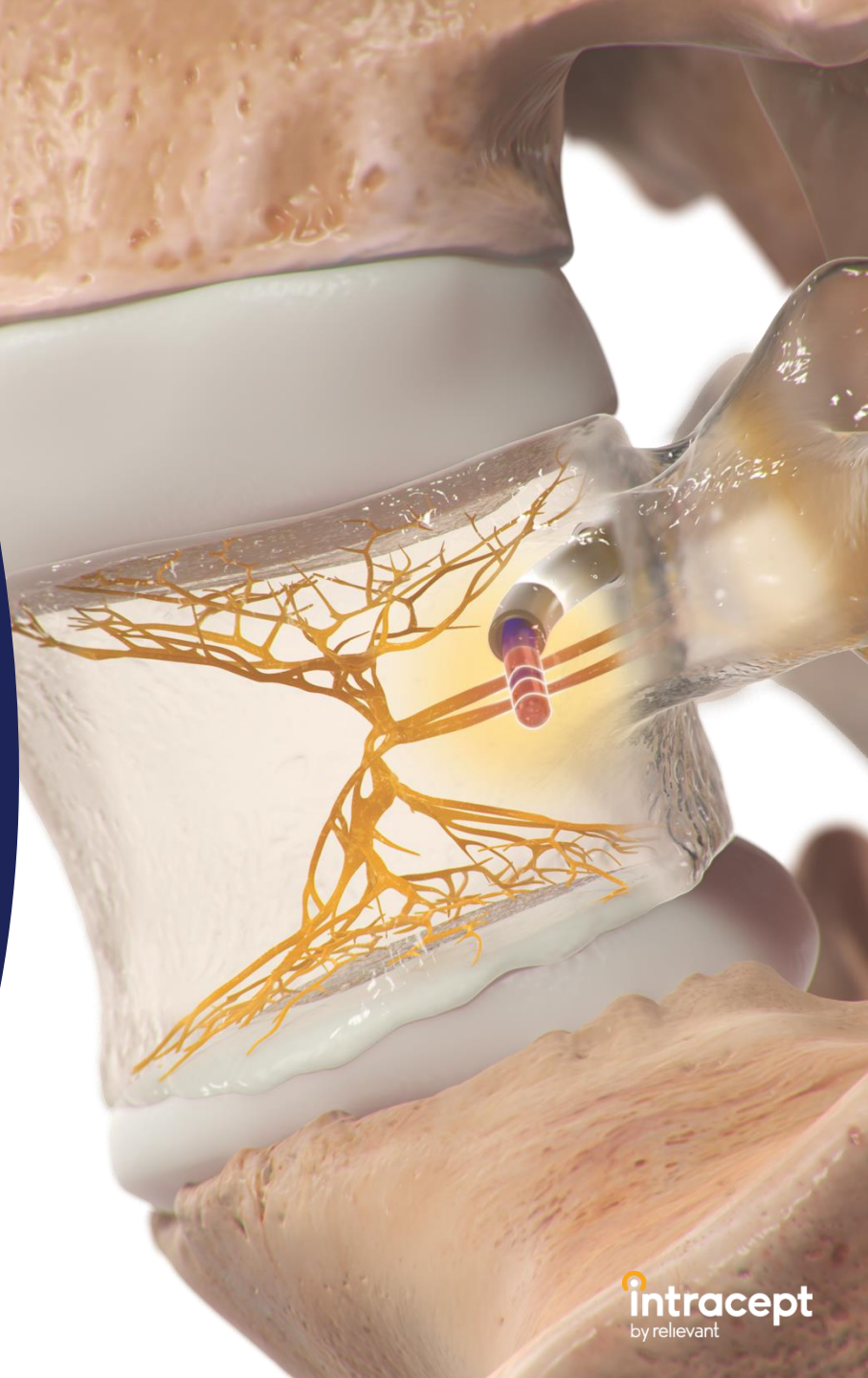


Ablation of the Basivertebral Nerve for Relief of Chronic Vertebroprogenic Low Back Pain: A Paradigm Shift

February 21, 2025

Florida Osteopathic Medical Association 2025



What is a Paradigm?

It is a standard, perspective, or set of ideas. A paradigm is a way of looking at something.



Agenda

- Chronic Low Back Pain Overview
- Science of Vertebrogenic Pain
- Intracept Procedure Overview
- Case Studies
- Clinical Evidence
- Summary & Next Steps



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Interventional Pain Medicine
Kennedy White Orthopaedic Center.

Objectives

1. Learn the significance and pathophysiology of endplate changes (Modic Changes).
2. Understand the different causes of Low Back Pain.
3. Identify patients with low back pain who have not responded to conventional treatment.
4. Identify appropriate patients to refer for Basivertebral Nerve Ablation.
5. Understand the complex, multi-faceted causes and treatments for low back pain.

Chronic Low Back Pain Overview

The Chronic LBP Patient – Epidemiology and Burden

- **10-13% of US Adults (30 million) have Chronic Low Back Pain (CLBP)**
- Lifetime prevalence ~ 60% to 85%¹
- Leading cause of global disability and absenteeism for persons ~ ages of 30 and 64²

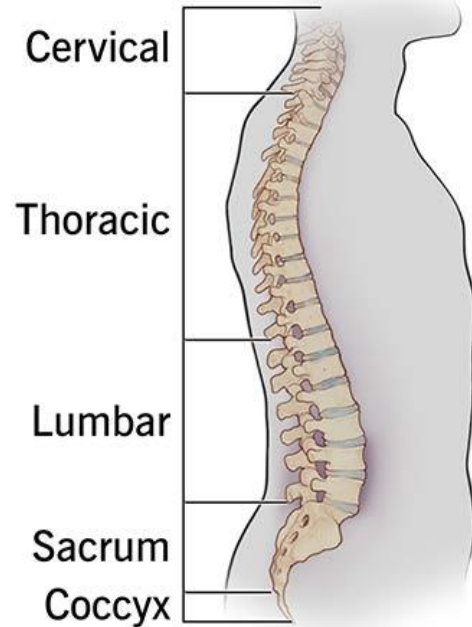


1. Navigant Report of Literature Review for CLBP Incidence Rate, 2019
2. Truven Marketscan 2015-2017 – Navigant Research

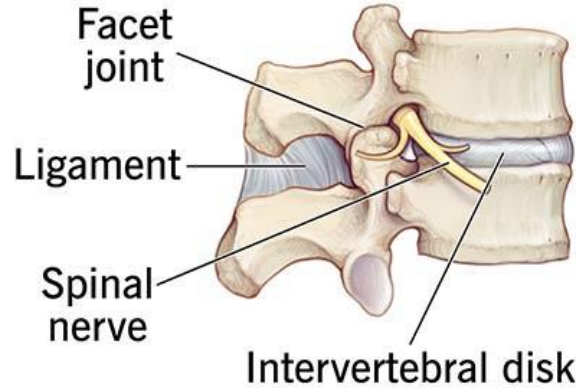
Anatomy of the spine

Spine (backbone)

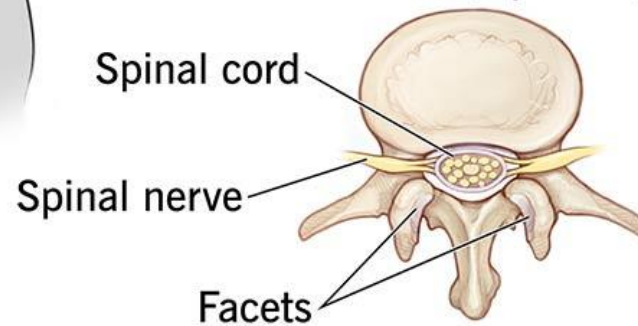
Parts of the spine



Vertebrae (side view)



Vertebra (top view)



Cleveland Clinic ©2023

THE PRIMARY FUNCTION OF THE SPINE INCLUDES:

- Protecting the spinal cord, nerve roots and internal organs
- Providing flexibility of motion
- Providing structural support and balance for upright posture. The spine bears the load of the head, shoulders and arms and upper body. The upper body weight is then distributed to the hips and legs. The spine attempts to keep the body's weight balanced evenly over the pelvis. This reduces the amount of work required by the spinal muscles and can eliminate muscle fatigue and back pain.

BACK PAIN

CAUSE AND EFFECT

Muscle causes of Low Back Pain

Stress and Tension causes...

Stiffness of upper shoulders which causes...



Tightness and pain of upper back (and tightness of its muscle fibers) which causes...



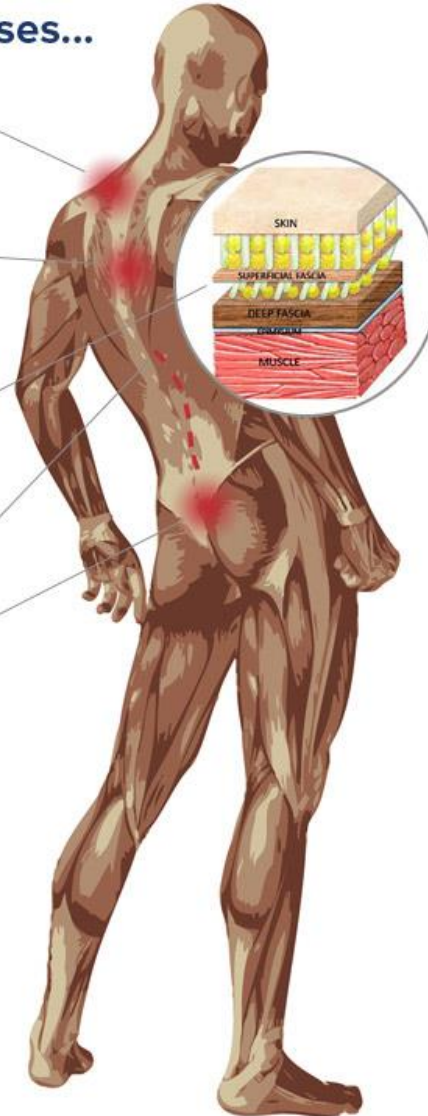
Tension of the fascia (just like the "saran wrap" tight lines are formed) which causes...



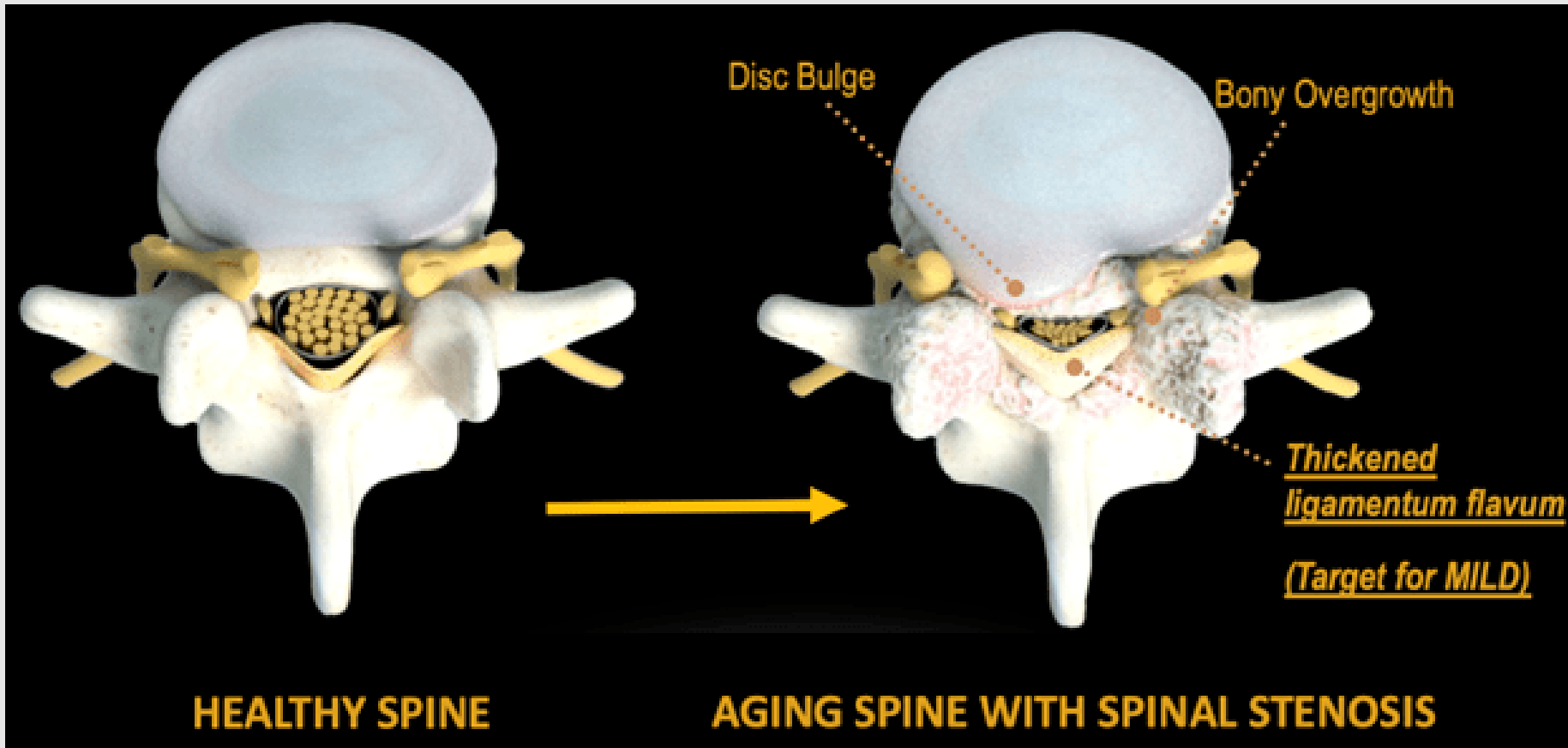
A pulling effect on the lower back fascia which causes...



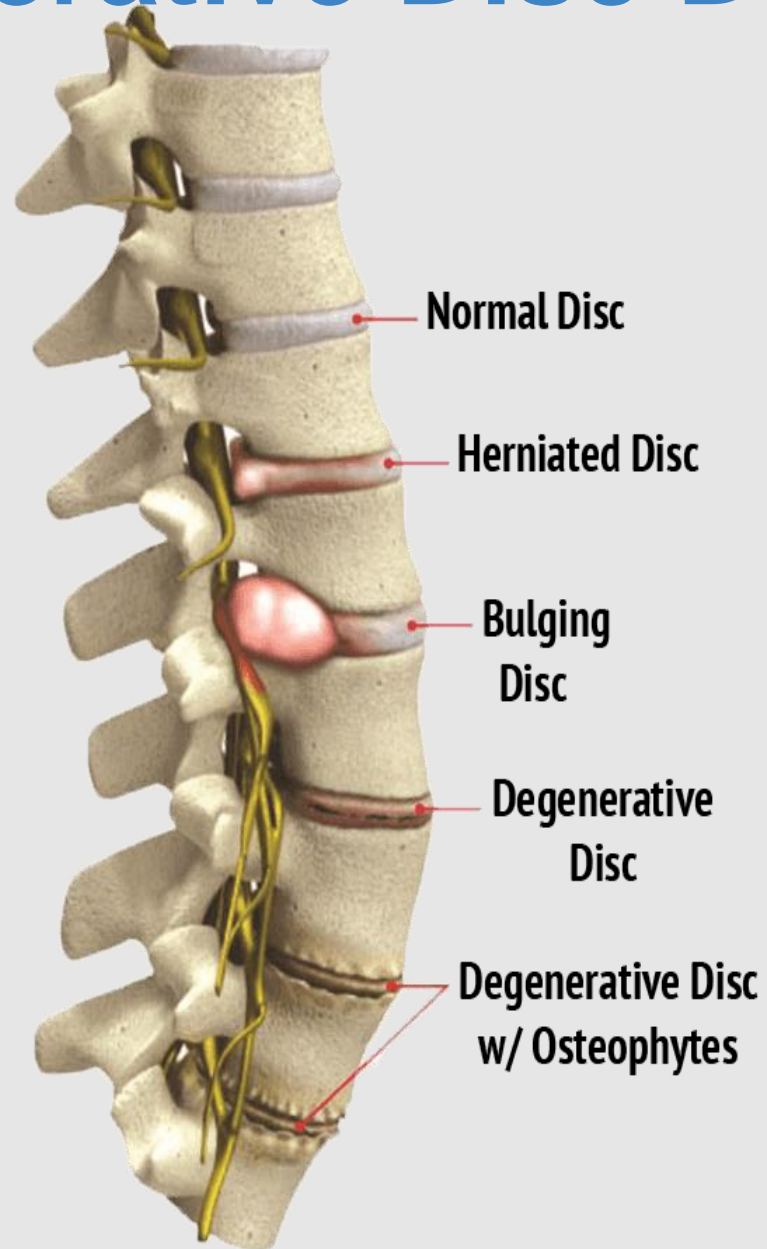
Lower back pain



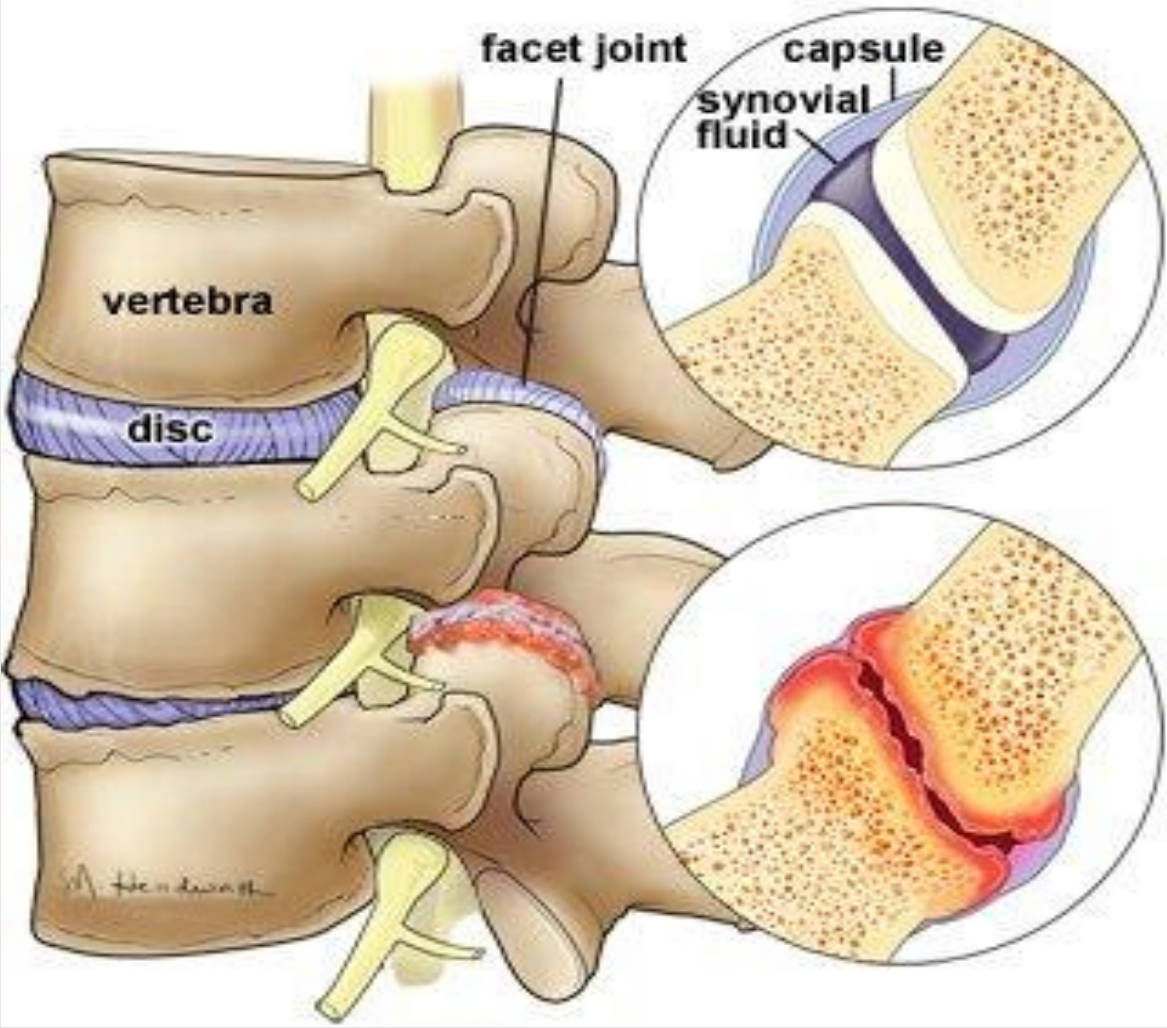
Normal Vertebrae vs Degenerative Vertebrae



Degenerative Disc Disease



Facet Disease (Arthritis)



How do Keep my Spine Healthy?

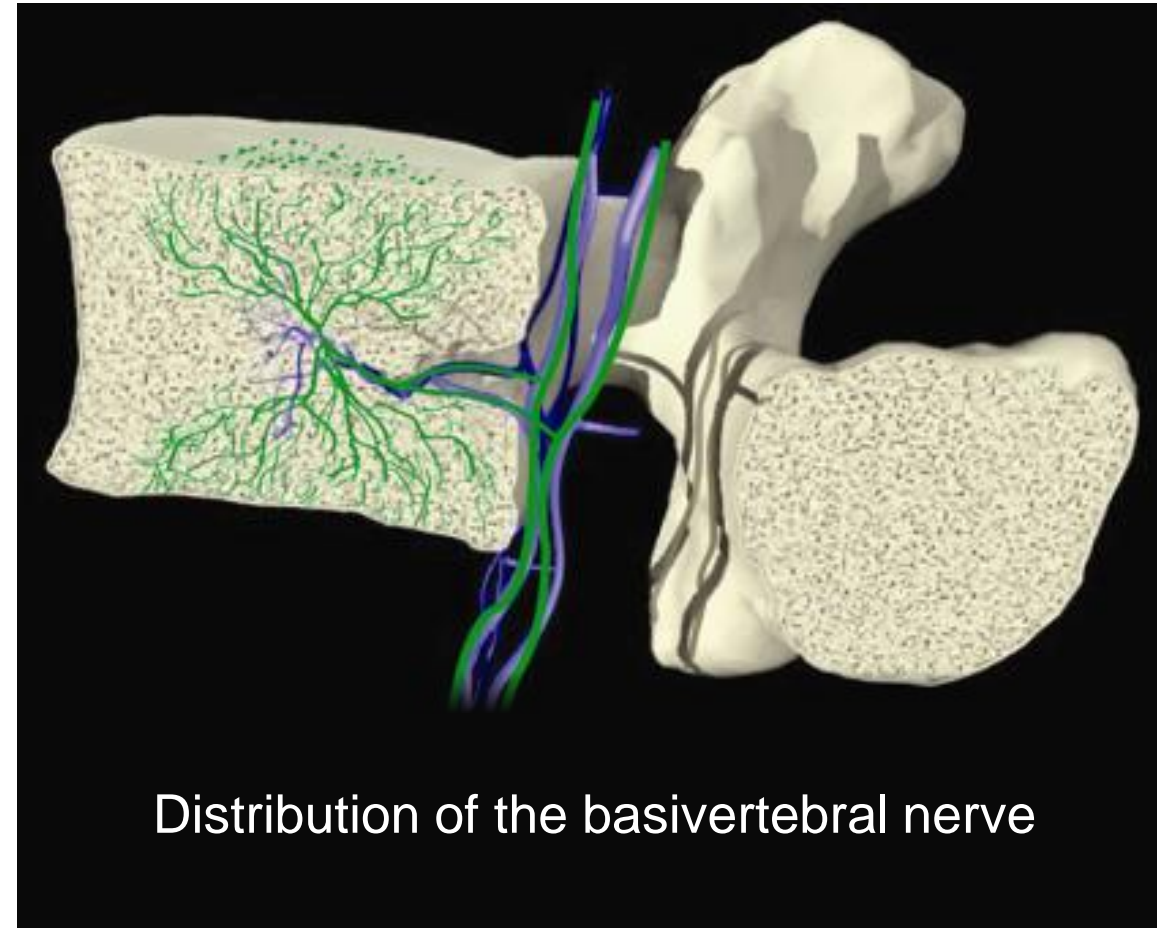
1. Loose Weight ! Loose Weight!! Loose Weight!!!!
2. Exercise!! – Stretch, Build Strength, Maintain Flexibility
3. Eat Healthy! - Change your diet to a Heart Healthy diet. No Industrialized Foods!
4. Reduce Stress!
5. Quit Smoking!!
6. Don't injure your back! – No Falls, No MVAs

The Science of Vertebroprogenic Pain

Vertebrogenic Pain is a Paradigm Shift in the Science of Chronic Low Back Pain (CLBP)

For decades, treatments focused on the disc and ignored the endplates.

- Vertebral endplates are more innervated than intervertebral discs¹
- Basivertebral nerve (BVN) innervates the endplates and transmits pain signals from the vertebral endplates to the CNS²
- September 2021 – CMS designated an ICD-10 diagnosis code specifically for vertebrogenic low back pain (M54.51)



1. Fields AJ, Liebenberg EC, Lotz JC. The Spine Journal 2014;14(3):513-521.

2. Bailey JF, Liebenberg E, Degmetich S, Lotz JC. Innervation patterns of PGP 9.5-positive nerve fibers within the human lumbar vertebra. Journal of Anatomy 2011;218(3):263-70.

Neuroanatomy and innervation of the discs and endplates

The basivertebral nerve originates from the sinuvertebral nerve; it is a branch of the sinuvertebral nerve that enters the vertebral body through the basivertebral foramen to innervate the vertebral endplates.

Key points about the basivertebral nerve:

Origin: Sinuvertebral nerve

Function: Supplies innervation to the vertebral endplates, the superior and inferior surfaces of the vertebral body

Entry point: Enters the vertebral body through the basivertebral foramen

The sinuvertebral nerve is a small sensory nerve that plays a role in innervating the spine.

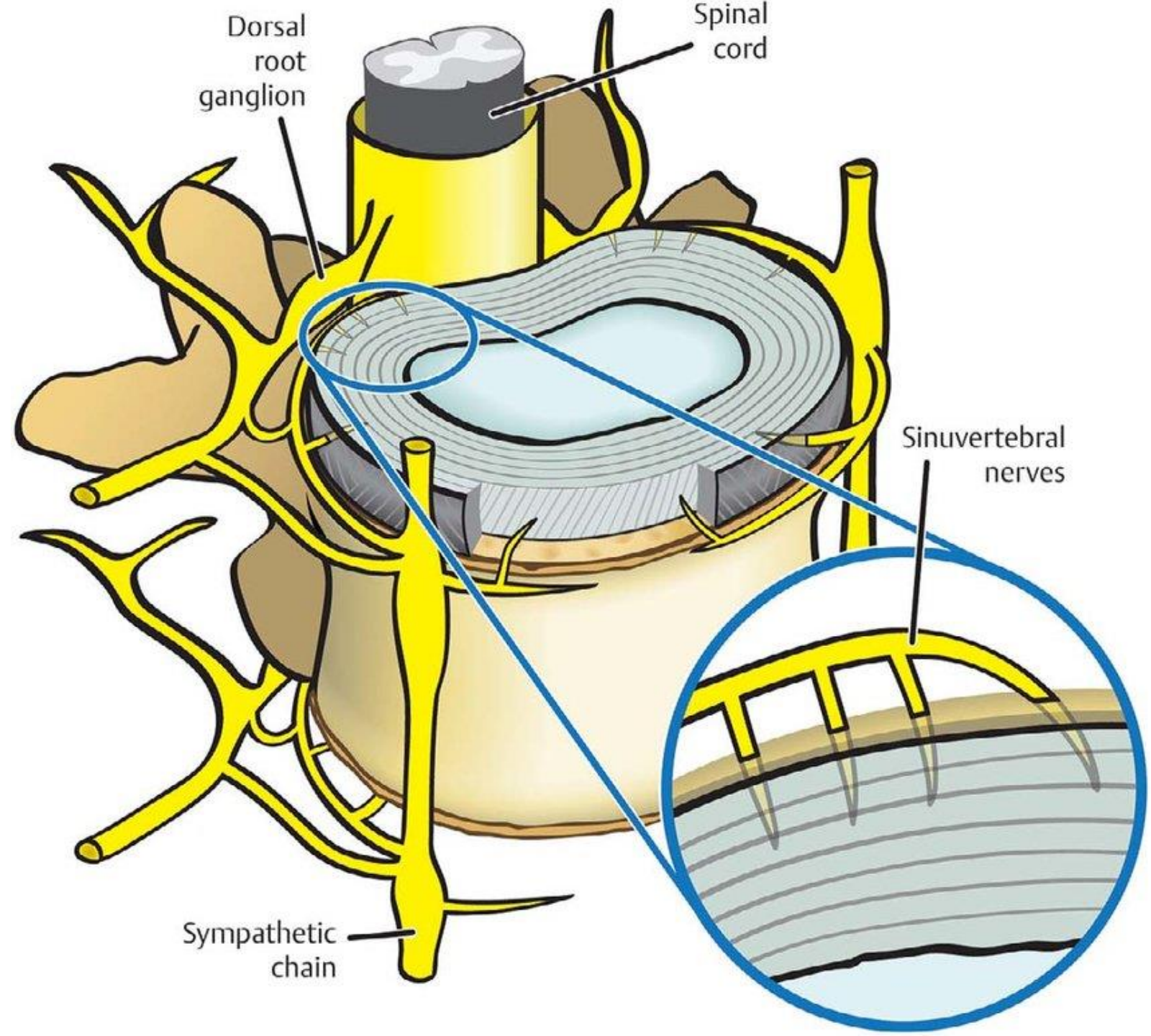
Anatomy:

- Originates from the ventral ramus (front branch) of a spinal nerve.
- Travels through the intervertebral foramen (opening between vertebrae).
- Courses along the posterior border of the intervertebral disc.
- Innervates the posterior longitudinal ligament, annulus fibrosus (outer layer of the disc), and dura mater (tough outer layer of the spinal cord).

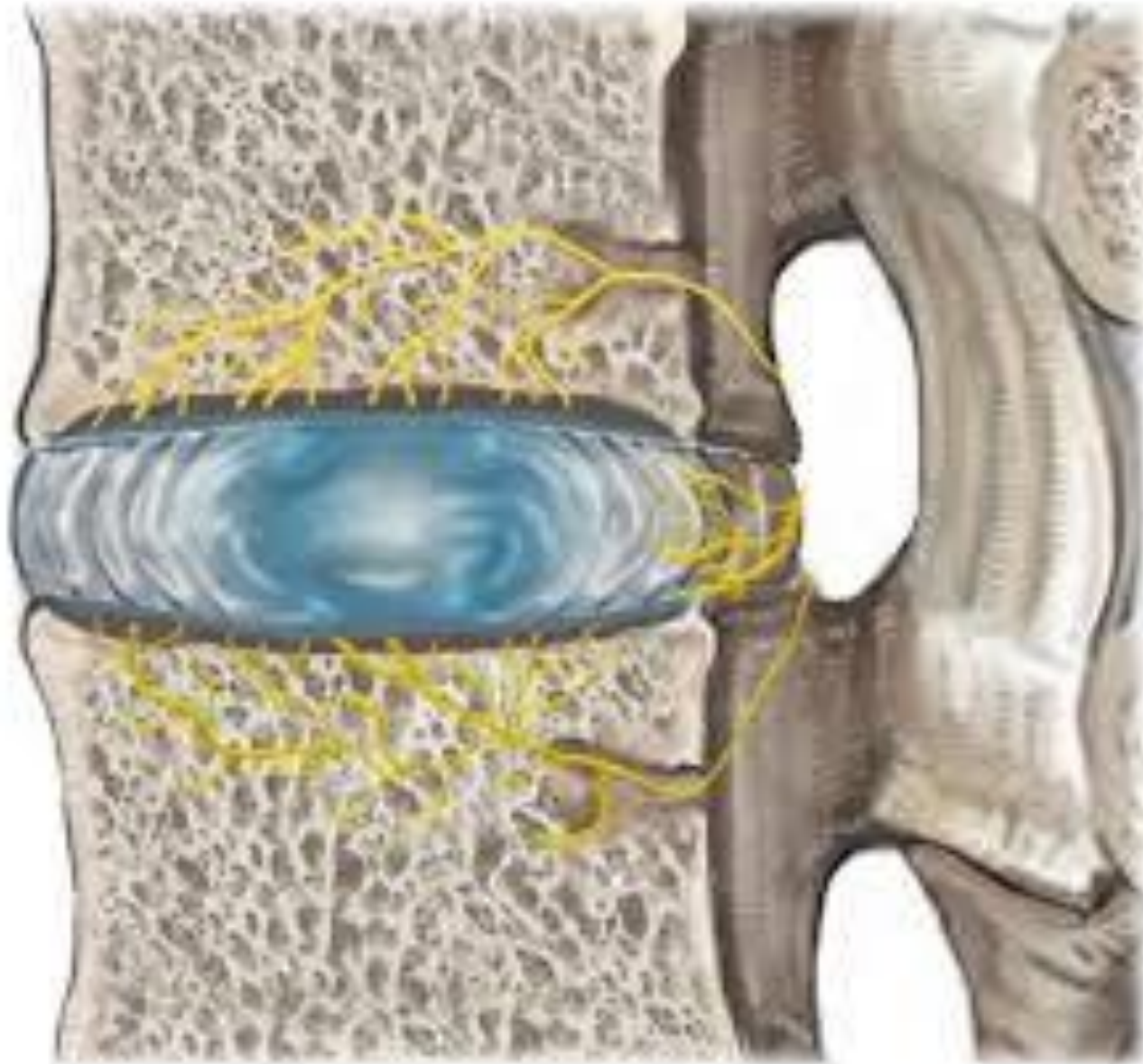
Function:

- Sensory innervation of the spine, particularly the intervertebral discs.
- May contribute to pain perception in conditions such as disc degeneration and herniation.

Sinuvevertebral Nerve

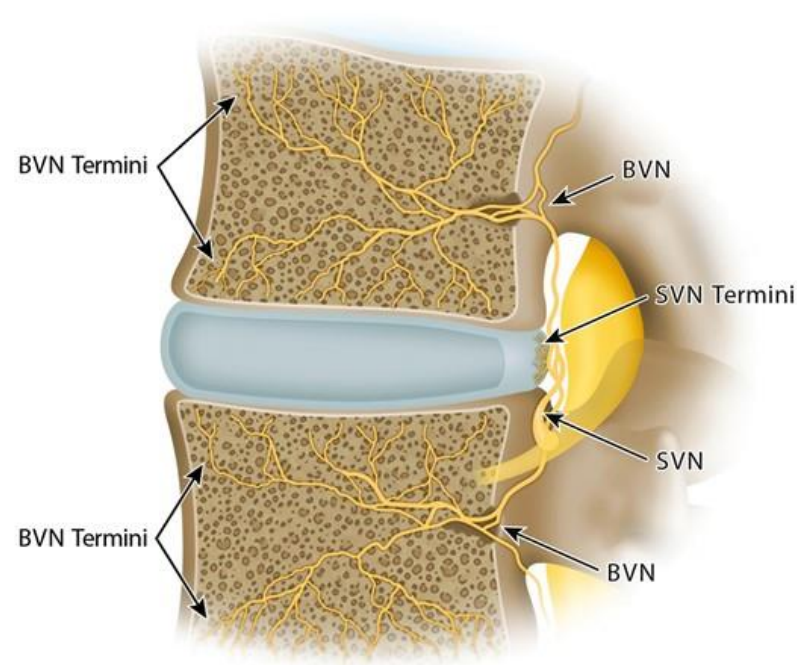


**Sinuvvertebral Nerve
and
Basivertebral Nerve**



Understanding Vertebrogenic Pain¹

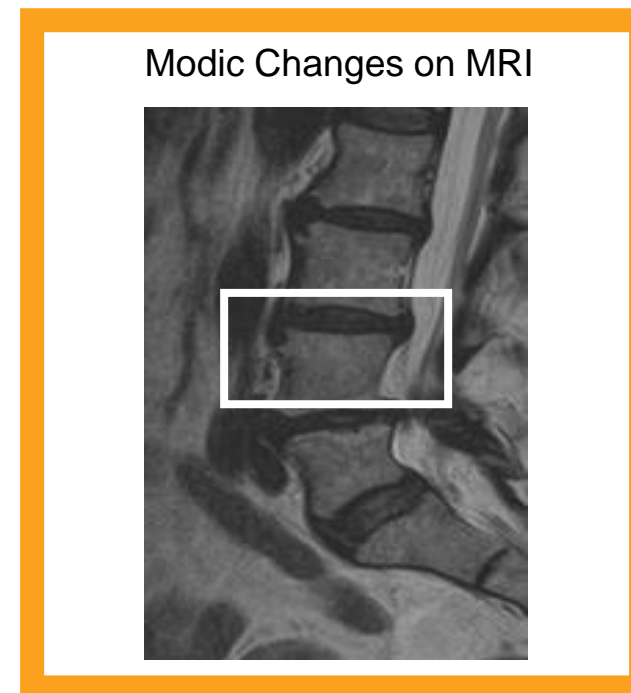
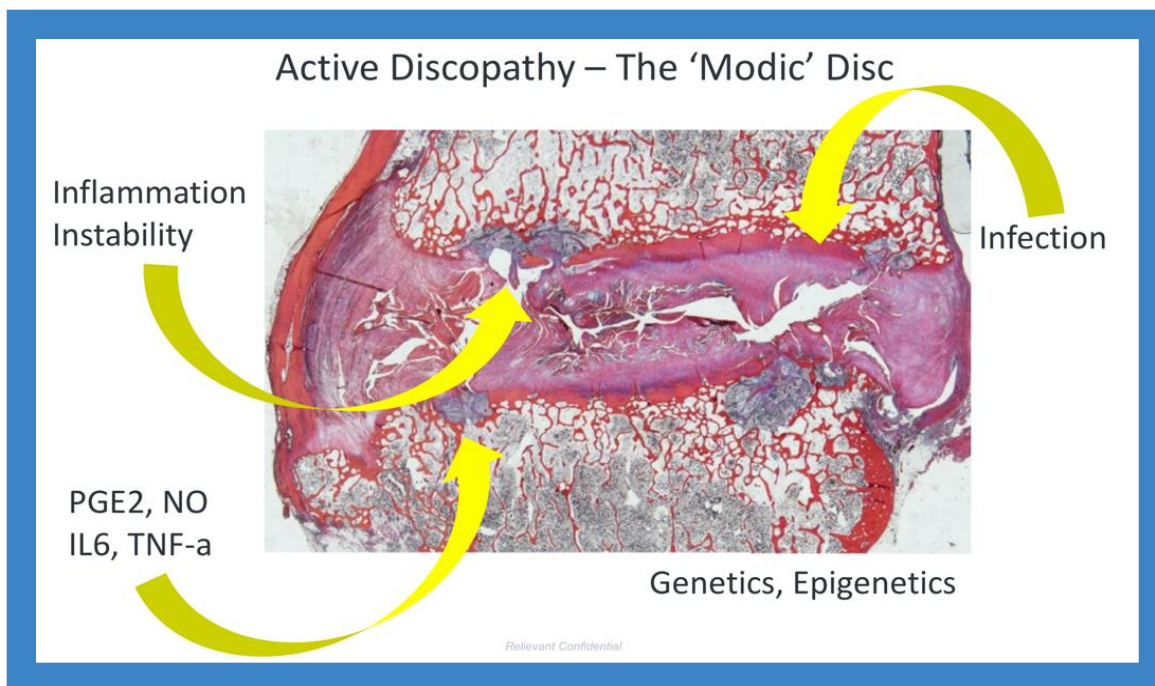
- Accumulated damage to the “discovertebral complex” may result in chemical and mechanical sensitization of endplate nociceptors resulting in chronic vertebrogenic LBP
- Vertebrogenic pain is a distinct cause of CLBP
- Vertebrogenic pain can be the dominant source, and it can be present in conjunction with other LBP etiologies



Neuroanatomy of the lumbar discovertebral complex. SVN = sinuvertebral nerve; BVN = basivertebral nerve.

Modic Changes – A Binary Biomarker for Vertebroprogenic Pain⁶

- Endplate defects allow proinflammatory disc tissue to leak into the bone marrow, inciting inflammation¹⁻³
- Recent analysis showed the mere presence of Modic changes impacts treatment outcomes, not the volume of Modic or Type⁴



1. Dudli S, Sing DC, Hu SS, et al. ISSLS PRIZE IN BASIC SCIENCE 2017: Intervertebral disc/bone marrow cross-talk with Modic changes. *Eur Spine J.* 2017;26(5):1362-1373. doi:10.1007/s00586-017-4955-4
2. Fields AJ, Liebenberg EC, Lotz JC. Innervation of pathologies in the lumbar vertebral end plate and intervertebral disc. *Spine J.* 2014;14(3):513-521. doi:10.1016/j.spinee.2013.06.075
3. Lotz JC, Fields AJ, Liebenberg EC. The role of the vertebral end plate in low back pain. *Global Spine J.* 2013;3(3):153-164. doi:10.1055/s-0033-1347298
4. McCormick ZL, Conger A, Smuck M, et al. Magnetic Resonance Imaging Characteristics Associated with Treatment Success from Basivertebral Nerve Ablation: An Aggregated Cohort Study of Multicenter Prospective Clinical Trials Data. *Pain Med.* 2022;23(Suppl 2):S34-S49. doi:10.1093/pm/pnac093

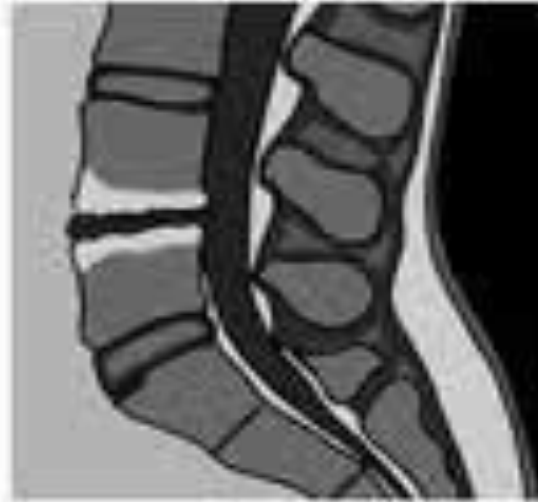
Modic changes

Modic 1

Modic 2

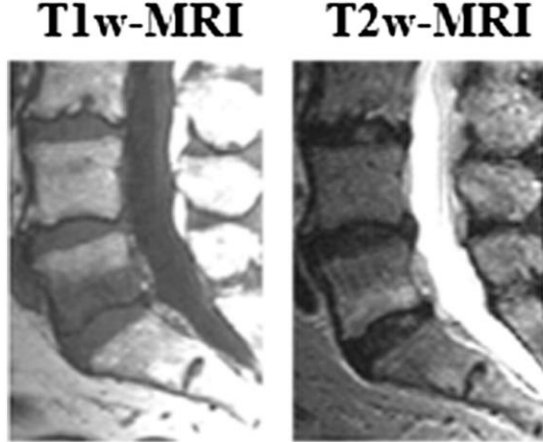
Modic 3

T1



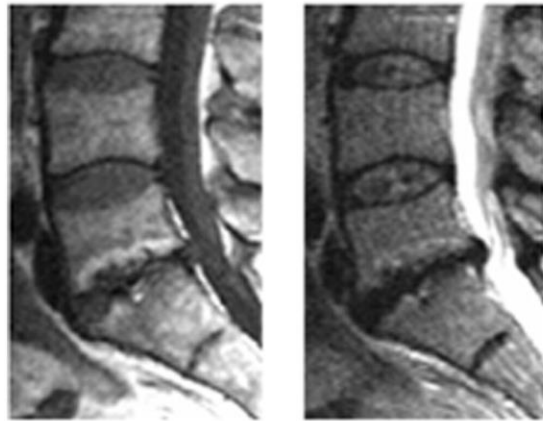
T2





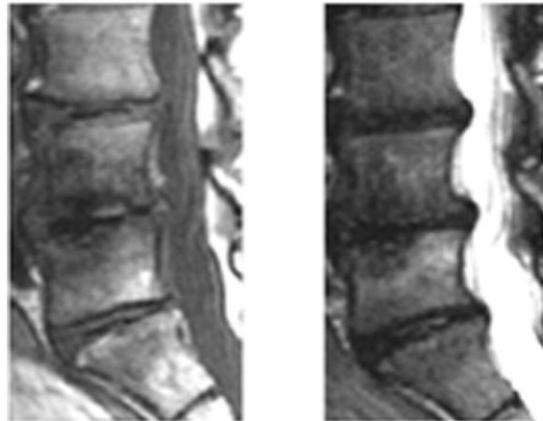
MC type 1

Hypointense on T1w and hyperintense on T2w.
 Characterized by reactive or inflammatory changes.



MC type 2

Hyperintense on T1w and hyper- or isointense on T2w.
 Characterized by lipid marrow replacement.



MC type 3

Hypointense on T1w and T2w.
 Characterized by calcification of the endplate
 and subchondral vertebral marrow.

T1-weighted (T1w)
 T2-weighted (T2w)

What symptoms Describe Vertebrogenic Pain?



KNOWN SYMPTOMS:

Pain during activity;
bending; lifting; sitting¹

OVER

5

MILLION PATIENTS

suffer from vertebrogenic pain²



SITTING



BENDING



ACTIVITY

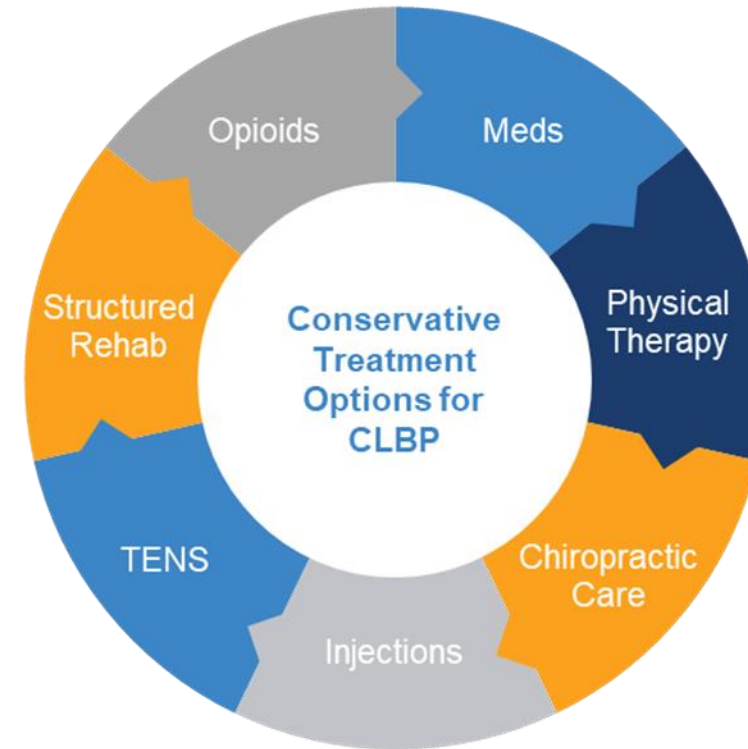


LIFTING

1. McCormick ZL, Sperry BP, Boody BS, et al. Pain Location and Exacerbating Activities Associated with Treatment Success Following Basivertebral Nerve Ablation: An Aggregated Cohort Study of Multicenter Prospective Clinical Trial Data. Pain Med. 2022;23(Suppl 2):S14-S33. doi:10.1093/pm/pnac069
2. Navigant Report of Literature Review for CLBP Incidence Rate, 2019

Historical Approaches for Treating Vertebroprogenic Pain

- Family Practice approach
- Chiropractor approach
- Physical Therapy approach
- Pain Interventionalist approach
- Surgical approach



PROS

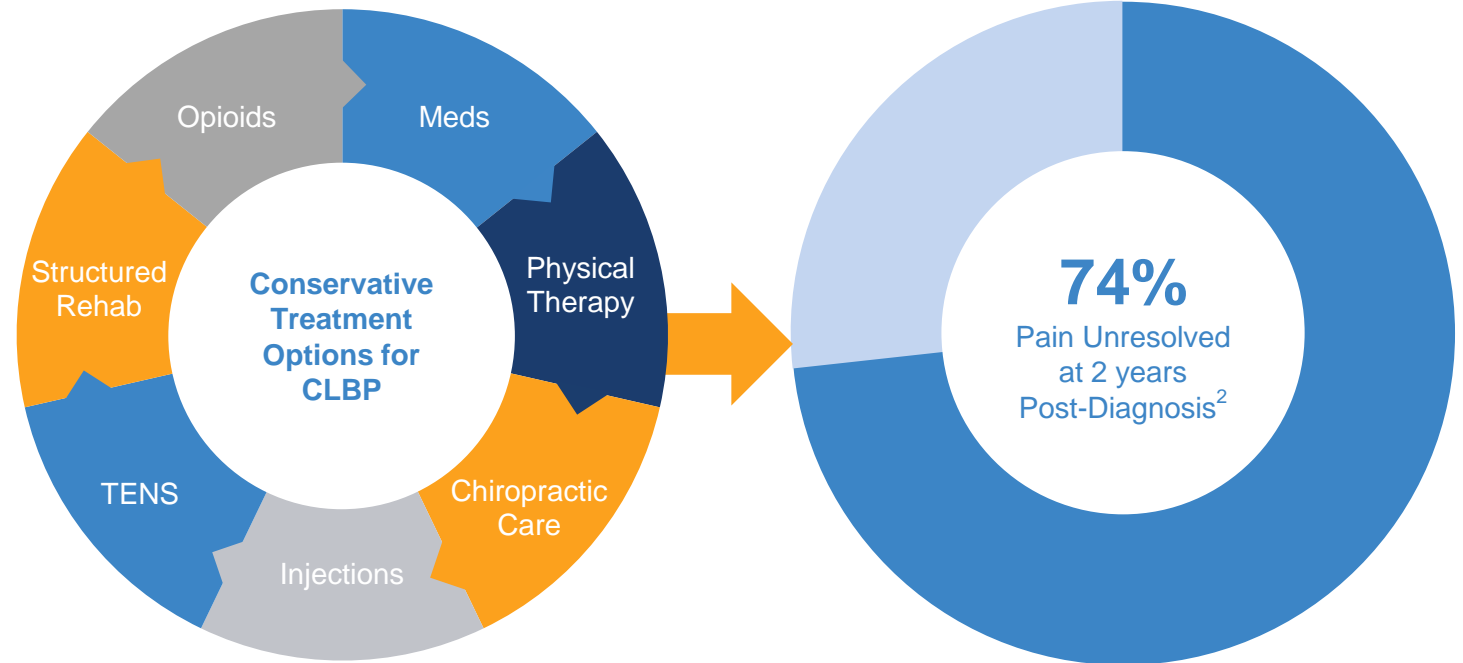
CONS

Vertebrogenic Pain Is Common & Most Chronic Low Back Pain Patients Do Not Achieve Adequate Pain Relief From Conservative Treatment Options

Intracapt Indicated Patients*



Historical Treatment Approaches



* Net Addressable Market Prevalence - primary etiology vertebrogenic pain after clinical exclusions

Intracept[®] Procedure Overview

The Intracept Procedure

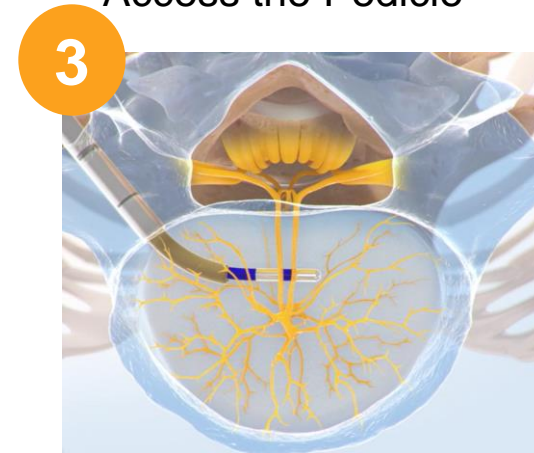
- Same-day surgery, brief recovery
- Implant free
- Preserves overall spine structure
- Long-term pain relief after single treatment¹⁻³
- Reduced utilization of injections²
- Proven safety profile⁴



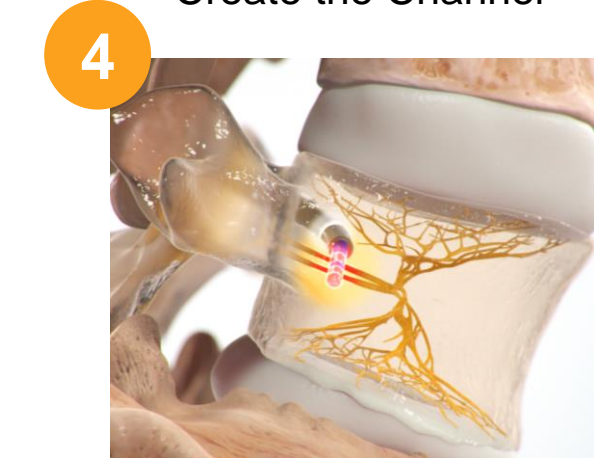
Access the Pedicle



Create the Channel



Place the Radiofrequency Probe

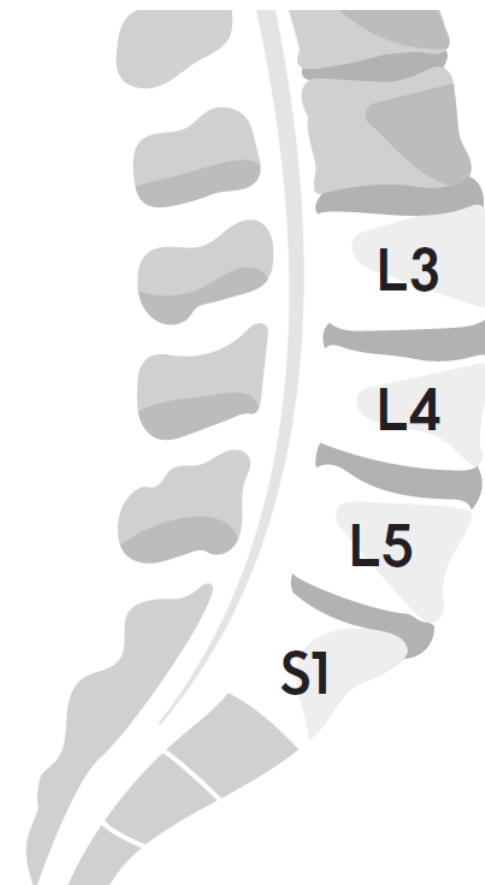


Ablate the BVN

1. Koreckij T, Kreiner S, Khalil JG, Smuck M, Markman J, Garfin S. Prospective, randomized, multicenter study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 24-month treatment arm results. NASSJ. Published online October 26, 2021. DOI: <https://doi.org/10.1016/j.xnsj.2021.100089>
2. Fischgrund J, Rhyne A, Macadaeg K, et al. Long-term outcomes following intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 5-year treatment arm results from a prospective randomized double-blind sham-controlled multi-center study. Eur Spine J. 2020;29(8):1925-34. doi.org/10.1007/s00586-020-06448-x
3. Fischgrund JS, Rhyne A, Franke J, et al. Intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 2-year results from a prospective randomized double-blind sham-controlled multicenter study. Int J Spine Surg. 2019;13(2):110-9. doi:10.14444/6015
4. Relevant data on file as of July 2023.

Patient Indications for the Intracept Procedure

- Chronic Low Back Pain of at least 6 months duration; and
- Failure to respond to at least 6 months of conservative care; and
- MRI changes consistent with Modic Type 1 or Type 2 at one or more levels from L3 to S1
- Features consistent with Type 1 or Type 2 Modic changes (MC) on an MRI:
 - Type 1 MC: Inflammation, edema, vertebral endplate changes, disruption and fissuring of fibrous tissues within the adjacent marrow, hypointensive signals
 - Type 2 MC: Changes to the vertebral body marrow including replacement of normal bone marrow fat and hyperintensive signals



Indications for Use: The Intracept Intraosseous Nerve Ablation System is intended to be used in conjunction with radiofrequency (RF) generators for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least six months duration that has not responded to at least six months of conservative care, and is also accompanied by features consistent with Type 1 or Type 2 Modic changes on an MRI such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypointensive signals (Type 1 Modic change), and changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyperintensive signals (Type 2 Modic change)

Renata MRI 8/10/2022



Renata MRI 12/04/2024 (2 years 4 months)



Case Study #1

Baseline Characteristics:

- 33-year-old female with CLBP >2 years
- History of fibromyalgia, anxiety, headaches, allergies
- Baseline ODI – 56
- Baseline VAS – 8

Baseline Imaging Characteristics:

- L5/S1 Pfirrmann Grade 5, severe narrowing (50% loss) of disc height
- Modic Changes - L5, S1 (25% to 50% of VB height & >50% of endplate area)
- Mild facet arthrosis, irregular endplate >2/3 of endplate area at L5, S1

Lumbar Treatment History:

- Right L5-S1 hemilaminectomy
- Medial facetectomy foraminotomy and microdiscectomy
- Right L5-S1 hemilaminectomy, medial facetectomy, discectomy
- L5-S1 laminectomy, medial facetectomy and discectomy
- Multiple epidural injections



1. Smuck M, Khalil JG, Barrett K, Hirsch JA, Kreiner S, Koreckij T, et al. A prospective, randomized, multi-center study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 12-month results. Reg Anesth Pain Med. 2021;rapm-2020-102259. doi:10.1136/rapm-2020-102259.
2. Macadaeg K, Truumees E, Boody B, Pena E, Arbuckle A., Gentile, J, et al. A prospective, open-label, single-arm, multi-center study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 12-month results. NASSJ 2020;3(100030). E-pub 18 Sept 2020. <https://doi.org/10.1016/j.xnsj.2020.100030>.

Case Study #1

- Levels treated L5, S1
- 12-Months Post Ablation:
 - ODI – 26 (30-point improvement)
 - VAS – 2 (75% reduction)
- 36-Months Post Ablation:
 - ODI – 14 (42-point improvement)
 - VAS – 3 (63% reduction)
- No additional pain interventions or surgeries post BVNA through 3 years of follow-up



Case Study #2

Baseline Characteristics:

- 48-year-old male with CLBP >5 years
- Baseline ODI – 38
- Baseline VAS - 7

Baseline Imaging Characteristics:

- L5/S1 Pfirrmann Grade 5
- Modic Changes - L5, S1 (<25% of VB height and >50% of endplate area)
- Mild facet joint arthropathy
- L5 with mild diffuse disc bulge, anterior thecal sac flattening without distinct descending nerve root encroachment
- S1 moderate bilateral foraminal narrowing, slightly worse on right

Lumbar Treatment History:

- L5/S1 micro lumbar discectomies
- Right hemilaminectomy and median facetectomy
- Multiple epidural injections



1. Smuck M, Khalil JG, Barrett K, Hirsch JA, Kreiner S, Koreckij T, et al. A prospective, randomized, multi-center study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 12-month results. Reg Anesth Pain Med. 2021;rapm-2020-102259. doi:10.1136/rapm-2020-102259.
2. Macadaeg K, Truumees E, Boody B, Pena E, Arbuckle A., Gentile, J, et al. A prospective, open-label, single-arm, multi-center study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 12-month results. NASSJ 2020;3(100030). E-pub 18 Sept 2020. <https://doi.org/10.1016/j.xnsj.2020.100030>.

MKT 0071 Rev. G

Case Study #2

- Levels treated L5, S1
- 12-Months Post Ablation:
 - ODI – 14 (24-point improvement)
 - VAS – 2.5 (64% reduction)
- 36-Months Post Ablation:
 - ODI – 10 (28-point improvement)
 - VAS – 3 (71% reduction)
- No additional pain interventions or surgeries post BVNA through 3 years of follow-up



1. Smuck M, Khalil JG, Barrett K, Hirsch JA, Kreiner S, Koreckij T, et al. A prospective, randomized, multi-center study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 12-month results. *Reg Anesth Pain Med.* 2021;rapm-2020-102259. doi:10.1136/rapm-2020-102259.

2. Macadaeg K, Truumees E, Boody B, Pena E, Arbuckle A., Gentile, J, et al. A prospective, open-label, single-arm, multi-center study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 12-month results. *NASSJ* 2020;3(100030). E-pub 18 Sept 2020. <https://doi.org/10.1016/j.xnsj.2020.100030>.

Case Study #3

Baseline Characteristics:

- 50-year-old female with CLBP >5 years
- Baseline ODI – 52
- Baseline VAS - 7

Baseline Imaging Characteristics:

- Modic Changes - L5, S1 (<25% of VB height and 25-50% of endplate area)
- L3/L4, L4/L5, L5/S1 - bulge, circumferential, symmetrical disc extension, narrowing of the FJ space (<2 mm) and/or small osteophytes

Lumbar Treatment History:

- History of two laminotomies with discectomies at L5/S1



1. Smuck M, Khalil JG, Barrett K, Hirsch JA, Kreiner S, Koreckij T, et al. A prospective, randomized, multi-center study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 12-month results. Reg Anesth Pain Med. 2021;rapm-2020-102259. doi:10.1136/rapm-2020-102259.
2. Macadaeg K, Truumees E, Boody B, Pena E, Arbuckle A., Gentile, J, et al. A prospective, open-label, single-arm, multi-center study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 12-month results. NASSJ 2020;3(100030). E-pub 18 Sept 2020. <https://doi.org/10.1016/j.xnsj.2020.100030>.

Case Study #3

- Levels treated L5, S1
- 12-Months Post Ablation:
 - ODI – 18 (34-point improvement)
 - VAS – 0 (100% reduction)
- 36-Months Post Ablation:
 - ODI – 0 (52-point improvement)
 - VAS – 0 (100% reduction)
- Additional interventions
 - S1 Joint block 762 days post BVNA

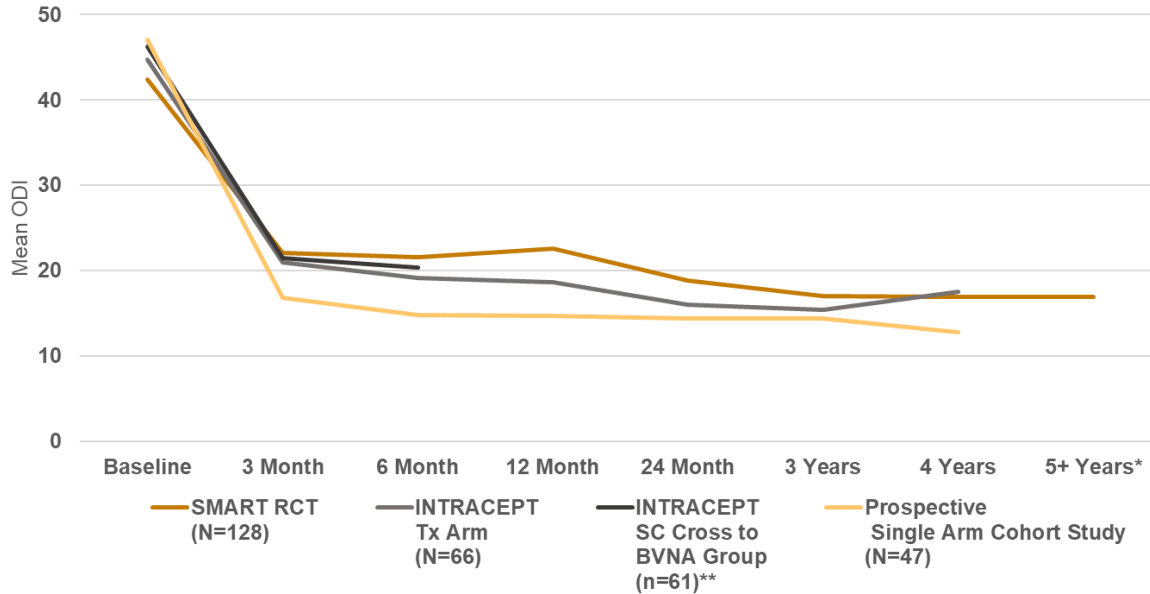


1. Smuck M, Khalil JG, Barrett K, Hirsch JA, Kreiner S, Koreckij T, et al. A prospective, randomized, multi-center study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 12-month results. *Reg Anesth Pain Med.* 2021;rapm-2020-102259. doi:10.1136/rapm-2020-102259.
2. Macadaeg K, Truumees E, Boody B, Pena E, Arbuckle A., Gentile, J, et al. A prospective, open-label, single-arm, multi-center study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 12-month results. *NASSJ* 2020;3(100030). E-pub 18 Sept 2020. <https://doi.org/10.1016/j.xnsj.2020.100030>.

Clinical Evidence

Improvements in Pain and Function Across Studies

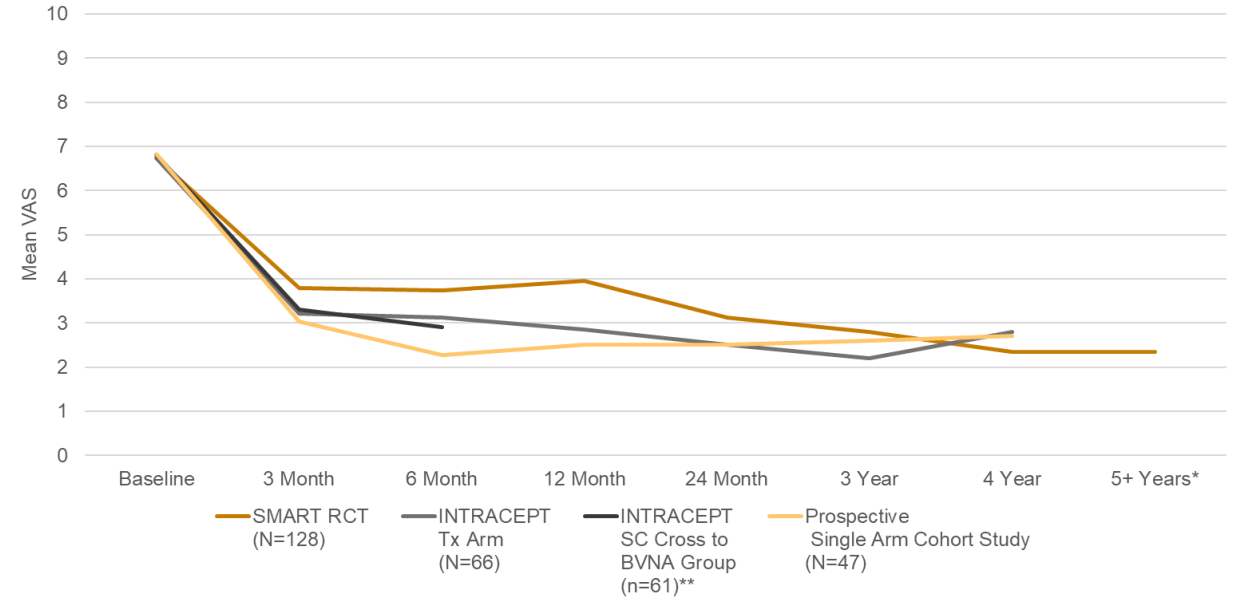
**BVN Ablation Treatment in Multiple Studies:
Mean Oswestry Disability Index (ODI) Overtime**



*SMART RCT US per protocol treatment arm at mean of 6.4 years

** Standard arm re-baselined and offered active treatment at a median of 5.8 months

**BVN Ablation Treatment in Multiple Studies:
Mean Visual Analog Scale (VAS) Overtime**



*SMART RCT US per protocol treatment arm at mean of 6.4 years

** Standard arm re-baselined and offered active treatment at a median of 5.8 months

Clinically meaningful and statistically significant reductions in mean ODI and mean VAS that are durable to 4+ years and reproducible across three clinical studies

Fischgrund JS, Rhyne A, Macadaeg K, Moore G, Kamrava E, Yeung C, et al. Long-term outcomes following intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 5-year treatment arm results from a prospective randomized double-blind sham-controlled multi-center study. *Eur Spine J.* 2020 Aug;29(8):1925-1934. DOI: 10.1007/s00586-020-06448-x.

Smuck M, Khalil JG, Barrett K, Hirsch JA, Kreiner S, Koreckij T, et al. A prospective, randomized, multi-center study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 12-month results. *Reg Anesth Pain Med.* 2021;rapm-2020-102259. doi:10.1136/rapm-2020-102259.

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Macadaeg K, Truumees E, Boody B, Pena E, Ar buckle A., Gentile, J, et al. A prospective, open-label, single-arm, multi-center study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 12-month results. *NASSJ* 2020;3(100030). E-pub 18 Sept 2020. <https://doi.org/10.1016/j.xnsj.2020.100030>.

Smuck M, Truumees E, Macadaeg K, Jaini AM, Chatterjee S, Levin J. Intraosseous basivertebral nerve ablation: pooled long-term outcomes from two prospective clinical trials. *Interventional Pain Medicine.* 2023; 2(2). <https://doi.org/10.1016/j.inpm.2023.100256>.

Khalil J. Pooled Intraosseous Basivertebral Nerve Ablation: 4-Year Effectiveness and Safety Results from Two Long-Term Follow-up Studies. Lecture ASPN annual meeting; July 13-16, 2023. Miami, FL

Basivertebral Nerve Radiofrequency Ablation: Potential Benefits at Initial Follow-up Appointment

Dr. Jessica Beetham, DO and Dr. Donald Erb, DO



Interactive!
Click on any of
these bubbles to
jump to each
section

Introducti
on

Methods

Results

Discussio
n

Background:

Chronic low back pain affects 30 million people in the United States and costs the healthcare system 90 billion dollars yearly.¹ Defined as low back pain lasting more than six months, there are various potential causes of this pain including intervertebral discs, zygapophyseal facet joints, ligaments, sacroiliac joints, muscles, and vertebral endplates.¹⁻² Determining the etiology of the main source of the pain consists of localization of the pain, diagnostic imaging, and understanding which movements exacerbate the pain to determine the anatomical structure involved.³

Pain from a vertebrogenic etiology occurs with standing, sitting, or with spinal flexion, is non-radiating, and located in the midline of the spine.¹ In addition to these findings, diagnostically physiological changes must be seen in the vertebral endplates, the superior and inferior edges of the vertebral body, on magnetic resonance images (MRI).¹ The vertebral endplates function to separate the intervertebral discs from the adjoining vertebrae and transmit pain signals by the basivertebral nerve (BVN).³ These endplates can be damaged from physiological aging, strains from disc degeneration, and excessive load from activities of daily living.³ Once injured, the endplates demonstrate Modic changes on MRI.¹⁻³ The combination of the aforementioned symptoms plus the Modic changes are needed for the diagnosis of vertebrogenic low back pain.

Three types of Modic changes can be seen on MRI.¹ Modic type 1 changes show as decreased signal intensity on longitudinal relaxation time (T1)-weighted MRI sequence and increased signal intensity of transverse relaxation time (T2)-weighted MRI sequence which represent vertebral endplate disruption, fissuring, degeneration and inflammation.¹⁻² Modic Type 2 changes appear as increased signal intensity on T1-weighted and T2-weighted MRI sequences which represents fatty infiltration of the bone marrow.¹⁻² The Modic type 3 changes manifest as decreased signal intensity on T1-weighted and T2-weighted MRI sequences.¹

In 2016, the Food and Drug Administration (FDA) approved ablation of the BVN (BVNA) as a treatment for the vertebrogenic type of low back pain in patients that have failed conservative treatment for at least six months and have Modic changes in the L3-S1 region of the spine.^{1,4} Contraindications for this procedure include pregnancy, spinal infections, systemic infections, implantable pulse generators like pacemakers or defibrillators.¹ Potential reasons to consider as possible exclusions to the procedure are: osteoporosis, coagulopathy, or metastatic diseases.¹ Currently, the only FDA approved device for this procedure is the INTRACEPT® device (Relieva Medsystems, Inc).⁴

Basivertebral Nerve Radiofrequency Ablation: Potential Benefits at Initial Follow-up Appointment

Dr. Jessica Beetham, DO and Dr. Donald Erb, DO



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Methods:

A retrospective chart review was performed and a total of 53 patients were involved in this study. A set of inclusion and exclusion criteria was utilized for each patient. The following inclusion criteria was used: the patient must be greater than 18 years old, have experienced chronic low back pain for at least six months or more, have not responded to at least six months of conservative care, and patient must have Modic type 1 or type 2 changes. Conservative care was defined as physical therapy, massage therapy, osteopathic and chiropractic adjustments, and use of over-the-counter medications. The exclusion criteria included the presence of severe cardiac or pulmonary disease, active infection that is systemic or localized, and the patient must be at least 18 years old.

The basivertebral nerve ablation was performed by a single physician (Dr. Donald Erb, D. O.) utilizing the INTRACEPT device (Reliant Medsystems, Inc.). These procedures were completed between January 2022 and April 2024. For each patient an assessment of the level of pain was performed at baseline and next approximately 10 days after the procedure using the visual analog score (VAS). This score was determined on a 10-point scale with no pain equating to zero and the highest score of ten equating to the greatest level of pain.

For the procedure, the patient was placed in a prone position and was given conscious sedation. Fluoroscopic guidance was utilized to find the pedicle of the vertebra to be treated and an introducer cannula was advanced through the pedicle into the vertebral body. The introducer trocar was exchanged with a smaller stylet which creates a curved path to the from the posterior wall of the vertebral body to the center of the vertebral body, where the basivertebral nerve is located. The curved stylet was removed and a radiofrequency probe was placed, activated to a temperature of 85°C for seven minutes. Lastly, the stylet and introducers were removed.

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There was a total of 26 females and 26 males who received the INTRACEPT procedure during the time of the retrospective chart review. Two of the male patients and one of the female patients did not document a number for the VAS at the follow up appointment, so they were not included in the analysis of the VAS for the patients that received the INTRACEPT procedure. The average VAS for patients at baseline was 5.61 and the average at the initial follow up appointment was 4.30. The table lists the age, sex, spinal levels treated, if spinal stenosis was present, if therapeutic interventions were performed before or after the procedure plus the VAS before and after the procedure.

Patient #	Sex	Age	Spinal Stenosis	Levels Treated	Therapeutic Interventions Before BVN RFA	Therapeutic Interventions After BVN RFA	Benefit	VAS score before	VAS Score after
					Replacement of spinal cord stimulator (SCS)				
	1M	75Y		L3, L4	Bilateral L4, L5, S1 RFA	None	Y	6	4
	2M	80Y		L2,L3,L4	None	None	Y	5	2
	3M	74Y		L5,S1	None	None	N	5	4
	4F	70N		L2-3 and L5-S1	None	Right L3 TFESI	N	8	7
	5F	69Y		S1	Fusion at L4-5 Laminectomy L3-5	Bilateral S1, S2, and sacral ala RFA	N	7	8
	6F	84Y		L4, L5	Left L3-5 RFA	None	Y	6	3
	7F	70N		L3, L4	None	Right L4 TFESI	N	6	5
	8M	76Y		L3-5, S1	Bilateral L3-L5 RFA	None	N	5	4
	9M	77N		L3-5, S1	Bilateral L3-L5 RFA	None	Y	7	4
	10M	72Y		L3-5, S1	Caudal ESI	None	N	2	3
	11M	79Y		L5-S1	Left L5 TFESI	None	N	8	8
	12M	85N		L3-5, S1	Bilateral L3-L5 RFA	Right L4 TFESI	Y	8	4
	13F	77N		L4-5	Bilateral L3-L5 RFA Caudal ESI	None	N	8	8
	14F	87Y		L4-5, S1	Left L4 TFESI	None	N	6	5
	15F	69N		L3-5, S1	None	None	N	4	3
	16F	75N		L4, L5, S1	None	None	N	3	4
	17M	77N		L4, L5, S1	None	None	N	3	2
	18F	69Y		L4, L5, S1	None	None	Y	9	3
	19F	67N		L3, L4	None	None	Y	5	2
	20F	83Y		L3, L4	Bilateral SI Joint injection Bilateral S1-S3 RFA	None	N	2	4
	21F	73N		L3-5, S1	Bilateral L1-3 RFA	None	N	3	3
	22F	83N		L3-5	Bilateral L3-5 RFA	None	N	2	1
	23F	70Y		L5, S1	Right L5 TFESI Left S1TFESI	None	N	8	8
	24M	70Y		L3-5	Left S1 TFESI	None	N	1	1
	25F	70N		L4, L5	None	None	N	8	8
	26F	80N		L5, S1	None	None	N	5	6
	27M	75N		L3, L4	Bilateral L3-5 RFA	None	N	3	3
	28M	72N		L4-S1	Bilateral L3-5 RFA	None	N	6	5
	29M	76Y		L3-5	Bilateral L3 TFESI Bilateral L3-5 RFA	None	Y	7	2
	30M	76N		S1	Bilateral L3-5 RFA	Left L5 and S1 TFESI	N	3	4
	31F	69N		L3-L5	Bilateral SI joint injection	None	Y	5	5
	32F	80Y		L3-S1	Left L3-5 RFA	None	Y	9	5
	33F	66N		L5, S1	None	None	N	8	4
	34F	73N		L3-S1	Bilateral SI joint injection TFESI	None	Y	8	5
	35M	67Y		L3-S1	Caudal ESI	None	Y	3	1

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For this retrospective chart review, the minimal clinically important difference (MCID) was utilized. The American Society of Pain and Neuroscience guidelines considers a VAS difference of two as an improvement of pain for the basivertebral nerve radiofrequency ablation.⁴⁻⁵ This guideline aided to determine if the patients received benefit from the procedure.

Upon further examination of recent research performed on the basivertebral nerve ablation, it was determined that several limitations exist for this study.^{3,4,6} Since it was a retrospective observational study, there were three patients whose change in VAS were undetermined because they did not state a score for either before or after the procedure. Also, this was a small population and there were no controls for this study. Furthermore, there is a need to create a consistent follow-up protocol for patients to better delineate how much this procedure is improving pain since it can take time to receive the full benefit of it. For example, the short duration of follow-up revealed that only 15 patients (9 males and 6 females) initially received benefit. Thus, a prospective research study would be a more ideal method to analyze how the basivertebral nerve ablation impacts patient's pain.

Some patients such as #4, #7 and #12 actually experienced increased pain after the BVNA. For each of these patients, their pain was treated with a transforaminal epidural steroid injection that correlated with the location of the radicular pain. The VAS surprisingly was decreased for patient #4 when compared to the score before the procedure even though she had increased pain indicating the VAS may not be the most ideal tool to interpret pain improvement. Therefore, using a different tool such as the Oswestry Disability Index (ODI) in addition to the VAS may make it easier to determine if benefit was achieved through this procedure.

Conclusion:

Based on previous research studies, basivertebral nerve radiofrequency ablation is a method to decrease chronic vertebrogenic low back pain. This study showed the need to expand examination of patient's analysis of pain before and after the procedure by using different outcome measures plus increase the follow-up protocol to better determine the degree of benefit of this procedure in an outpatient setting. Limitations of this study included the small sample size and a lack of a control. Thus, further research over a longer period of time and with the use of a more descriptive tool like the Oswestry Disability Index will help physicians to know the degree of pain improvement from basivertebral nerve radiofrequency ablation.

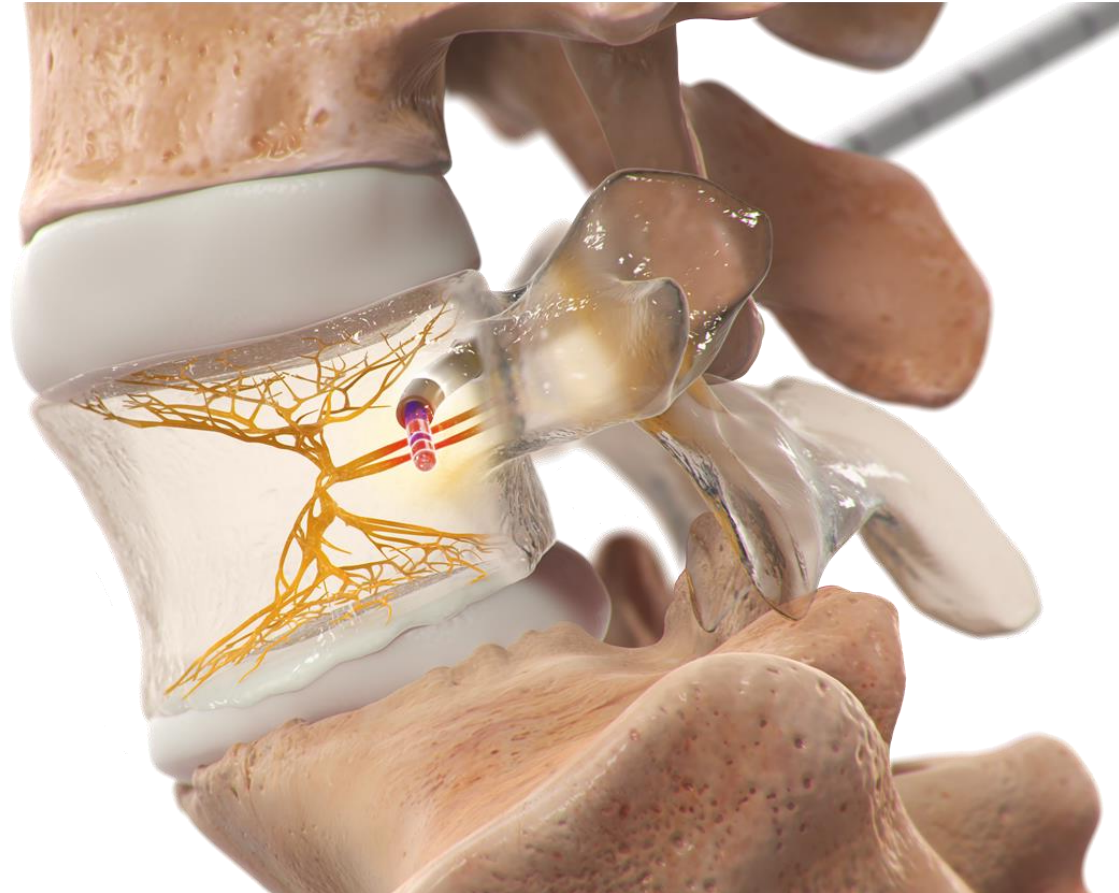
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Summary

Summary

- Vertebrogenic Pain is common
- Strong scientific foundation
- Straightforward procedure
- Highly quality clinical evidence and growing society support
- Patient Indications
 - Chronic Low Back Pain of at Least 6 Months Duration
 - Failure to Respond to at Least 6 Months of Conservative Care
 - MRI Demonstrated Modic Type 1 or Type 2 Changes at One or More Levels From L3 to S1



Thank You

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