RFA OF BVN FOR VERTEBROGENIC PAIN

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29th Annual Gabor Racz
Advanced Interventional Pain Confernceand and Workshop
2023

Disclosure

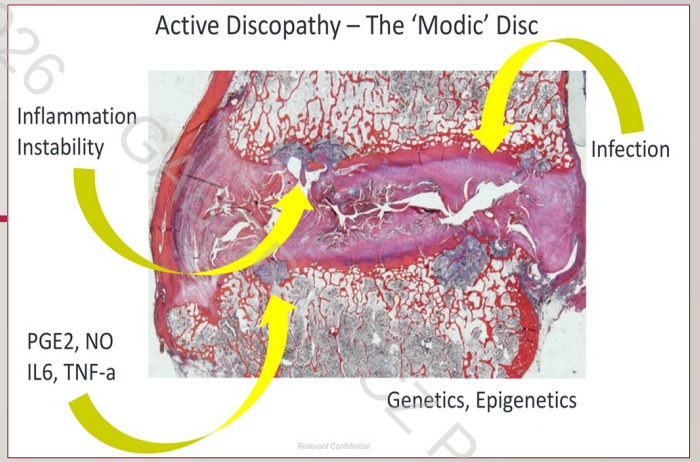
NYNJ Annual Pain Congress

- Founding Governor, World Institute of Regenerative Medicine (WIRM)
- Founder and Co-Chairman, Latin American Pain Society (LAPS)
- Founder and Chairman, NY/NJ Annual Pain Medicine Congress since Nov 2011
- Co-founder and President, Advanced Spine on Park Avenue, New york
- Chair of sections, World Institute of Pain (WIP)
- Past President (2018-2019) and Director Emeritus, ASIPP (2019-Current)
- Former Director, Weill Cornell Pain Medicine Fellowship program and Pain Division
- Section Editor, Regenerative Medicine, Pain Physician, official journal of ASIPP
- Associate editor – Pain Practice, Official journal of WIP
- Section Editor, Regenerative Medicine, Journal of Pain and Neuroscience – Official journal of ASPN

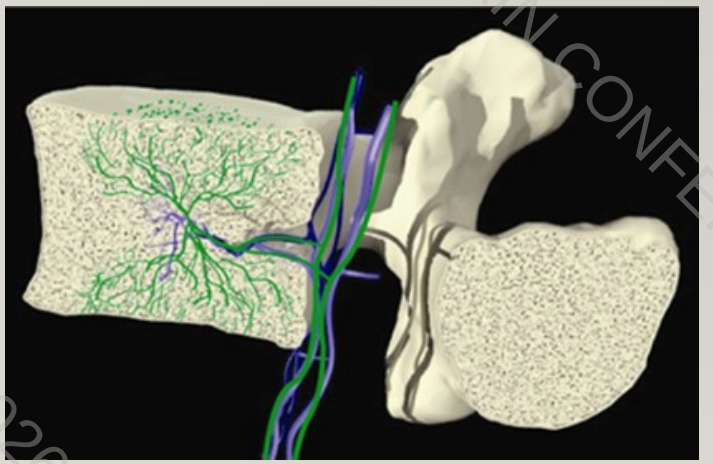
AXIAL LOW BACK PAIN

- Disc degeneration itself does not cause pain!
- Chemical irritation/inflammation
- Disc herniations
- Discs bulging
- Advanced disc degeneration causing radial tears
- Internal disc derangements

PARADIGM SHIFT IN THE CLBP



- The vertebral endplates are the cause of chronic low back pain in many patients
- Endplate defects allow pro-inflammatory disc tissue to leak into the bone marrow, inciting an inflammatory response
- Chronic endplate inflammation leads to Modic changes (MRI) and increases nociceptor density
- The basivertebral nerve innervates the endplates



Stefan Dudli, David C Sing, Serena S Hu et al. Eur Spine J. 2017 May;26(5):1362-1373

Endplate degeneration
inflammatory cascade[4,8]

- Endplate damage results in cellular communication between the inflammatogenic disc nucleus and vertebral bone marrow
- Triggers chronic inflammation and densification of endplate nociceptors
- Results in visible bone marrow changes (Modic changes), visible on MRI
- Leads to endplate nerve proliferation, resulting in pain signals transmitted by the basivertebral nerve (BVN)

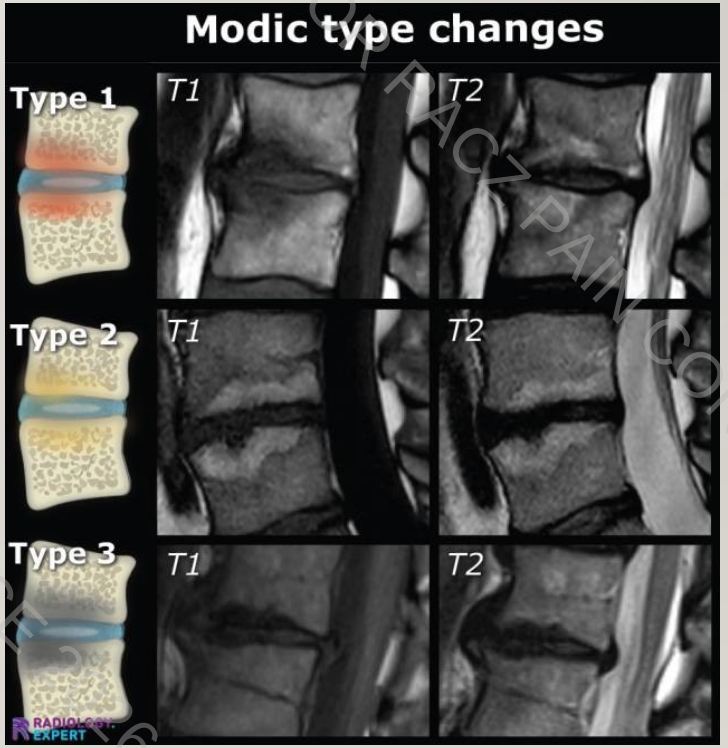
MODIC CHANGES

The Modic changes are **dynamic markers** of the age-related degenerative process in the lumbar spine

Type 1 (Fibrovascular): inflammatory process associated with active low back symptoms and segmental instability
MRI: hypo-intense on T1 and hyper-intense on T2-weighed

Type 2 (Fatty change): are less likely associated with LBP and indicate a more biomechanically stable state
MRI: hyper-intense on T1 and T2-weighed MRI

Type 3 (Sclerotic changes): unclear pathogenic significance



CLINICAL CORRELATION OF DISCOGRAM TO MODIC CHANGES

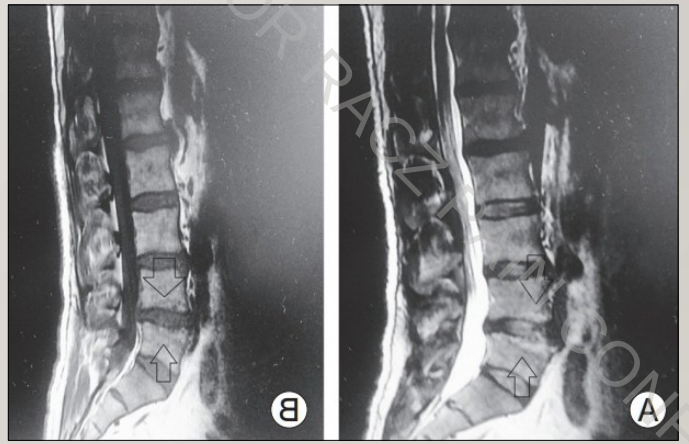
Research Findings:
High correlation between discography and moderate to severe Type 1 and Type 2 Modic changes[7] • 38% sensitivity • 88% specificity with moderate Modic 1 and 2 • 100% specificity with severe Modic 1 and 2
Modic Changes were associated with persistent LBP[6]
These patients seek care more often[10], however, Modic Type 1 with CLBP associated with poor outcomes to conservative treatment[10,11]
Modic Type 1 patients had worse outcomes after discectomy, underscoring the role of the vertebra as a possible pain generator[12]
Modic Changes were associated with historical LBP, and with severity and duration of symptoms ($p<.05$)[9]

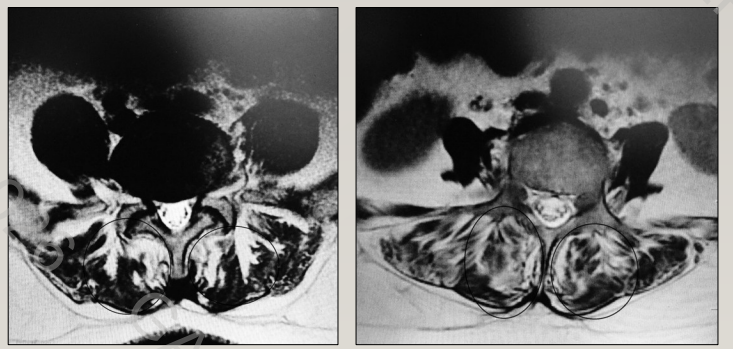
MODIC CHANGES AND PARASPINAL MUSCLES

- **Paraspinal muscle fatty degeneration** directly correlates with the presence of Modic type I and II change in with low back pain

- There is fatty degeneration of the paraspinal muscles in association with Modic changes

- Paravertebral muscles fatty degeneration causes **Functional Instability** of lumbar spine

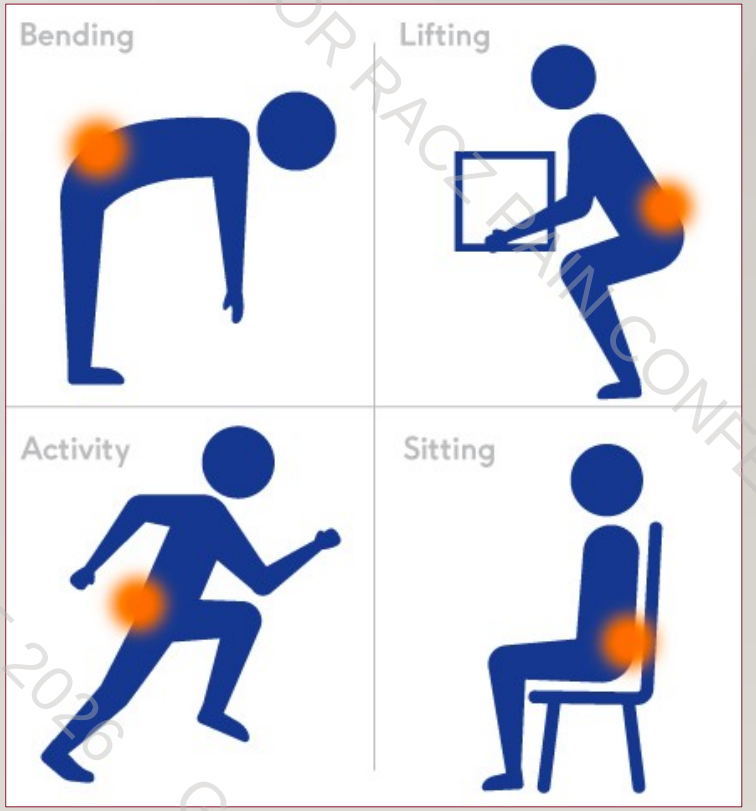




IB Atci, H Yilmaz, MY Samanci, et al. Asian Spine J. 2020 Apr;14(2):185-191

CLINICAL PRESENTATION

- The disc and endplates: ➡ anterior spinal column
- Both produce similar low back pain symptoms
- Constant pain in the middle of the low back
- Aggravated by physical activity
- Prolonged sitting, bending forward, and lifting
- The endplate pain is associated with distinctive changes on MRI - Modic changes



TREATMENT OPTIONS

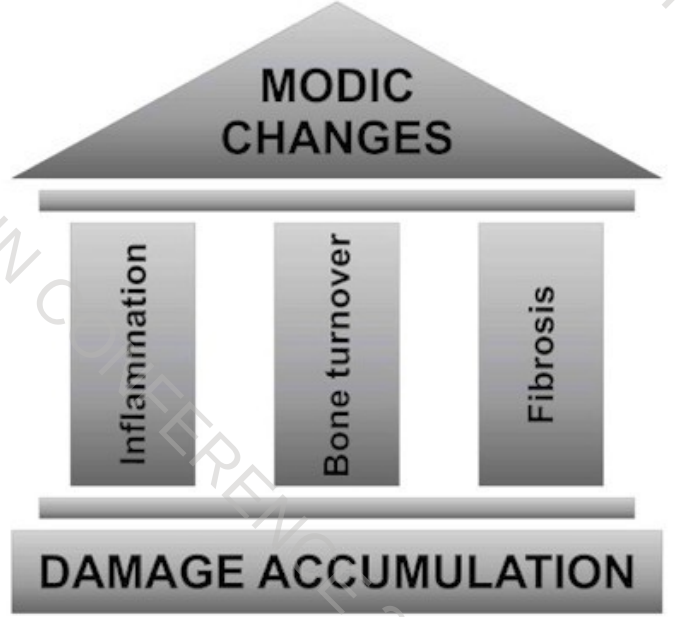
- Conservative therapy: NSAIDs, muscle relaxants, and physical therapy
- Bracing for those with CLBP and MC1 reported short term pain relief
- Oral antibiotics for low grade infection affecting the discovertebral complex
- Intraosseous bipolar RFA of the BVN for vertebrogenic pain with MC1 and/or MC2
- Intraosseous Monopolar RFA of BVN for vertebrogenic pain with MC1 and MC2
- Extraosseous epiduroscopic BVN/SVN laser ablation or bipolar RFA
- Iintraosseous (Subchondral) plasma rich growth factor
- Full endoscopic disc debridement surgery
- Posterior Lumbar Interbody Fusion

POSTERIOR LUMBAR INTERBODY FUSION IN LUMBAR DISC DISEASES WITH MODIC CHANGES

Young-Min Kwon et al. J Korean Neurosurg Soc. 2009 Oct; 46(4): 322–327

- The clinical outcomes (Bony fusion) in each group were 88% in type 1, 84% in type 2, and 73% in type 3
- The PLIF with TFC has been found to be an effective procedure for lumbar spine fusion
- The authors suggest that PLIF combined with pedicle screw fixation would be the better

POSTSURGICAL INFECTION



Preoperative **Modic changes and severity of endplate damage are independent risk factors for developing postoperative surgical site infection**

The “MC” could be foci of chronic subclinical infection

IA Pradip, SD Chand Raja, S Rajasekaran, et al. Eur Spine J. 2021 Jun;30(6):1732-1743

BEST PRACTICE GUIDELINES 2022

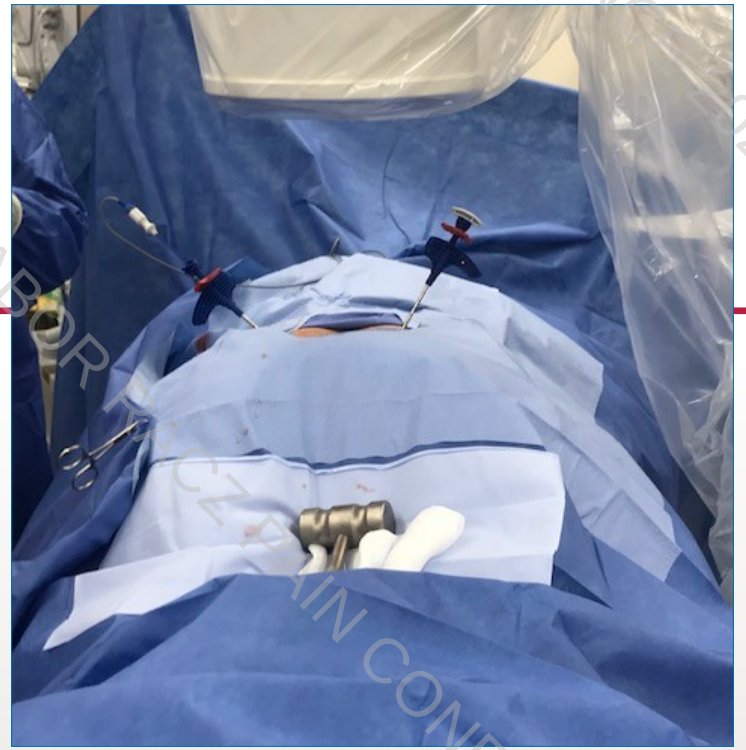
- ASPN multidisciplinary group reviewed the literature to recommend the best practice guidelines
- Based on the United States Preventative Task Force (USPSTF) criteria for grading evidence, **BVN ablation has Level A grade evidence** with high certainty with net benefit is in appropriately selected individuals

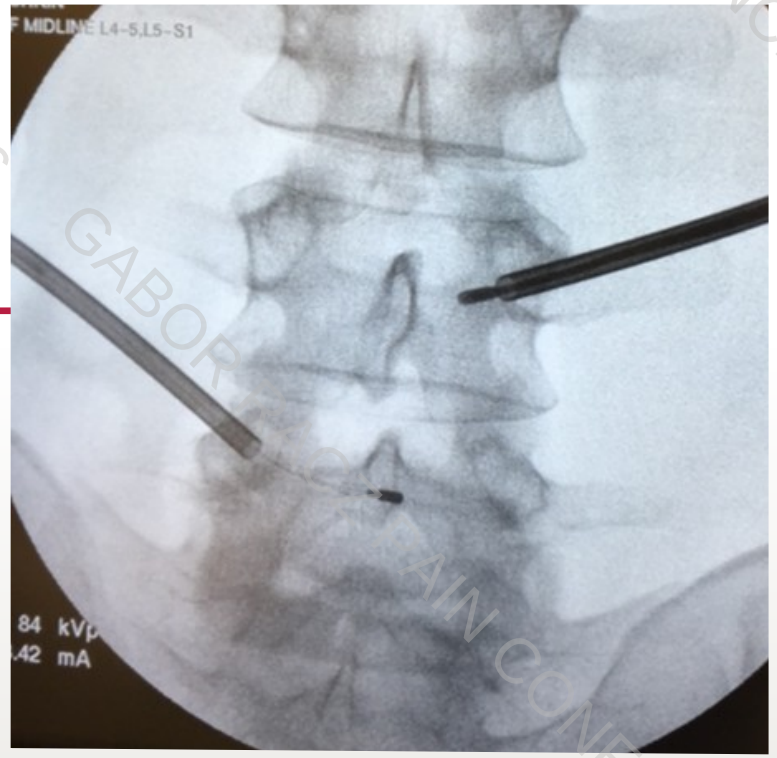
Journal of Pain Research
Dovepress
Journal of Pain Research 2022: 15, 2801-2819
Open Access Full Text Article
REVIEW

Best Practice Guidelines on the Diagnosis and Treatment of Vertebrogenic Pain with Basivertebral Nerve Ablation from the American Society of Pain and Neuroscience

Dawood Sayed[1], Ramana K Naidu[2,3], Kiran V Patel[4], Natalie H Strand[5], Pankaj Mehta[6], Christopher M Lam[1], Vinicius Tieppo Francio[7], Samir Sheth[8], Anthony Giuffrida[9], Brian Durkin[10], Nasir Khatri[11], Shashank Vodapally[12], Christopher O James[13], Benjamin D Westerhaus[9], Adam Rupp[7], Newaj M Abdullah[14], Kasra Amirdelfan[15], Erika A Petersen[16], Douglas P Beall[17], Timothy R Deer[18]

[1]Department of Anesthesiology and Pain Medicine, The University of Kansas Medical Center, Kansas City, KS, USA; [2]Anesthesiology, California Orthopedics & Spine, Marin, CA, USA; [3]Pain Management, MarinHealth Medical Center, Marin, CA, USA; [4]Interventional Pain Management/ Anesthesiology, The Spine & Pain Institute of New York, New York City, NY, USA; [5]Interventional Pain Management, Mayo Clinic, Scottsdale, AZ, USA; [6]Clinical Research, Pain Specialists of Austin, Austin, TX, USA; [7]Department of Rehabilitation Medicine, University of Kansas Medical Center, Kansas City, KS, USA; [8]Interventional Pain Management, Sutter Health, Roseville, CA, USA; [9]Cantor Spine Center, Paley Orthopedic and Spine Institute, Fort Lauderdale, FL, USA; [10]Pain Institute of Long Island, Port Jefferson, NY, USA; [11]Interventional Pain Medicine, Novant Health, Charlotte, NC, USA; [12]Physical Medicine and Rehabilitation, Michigan State University, East Lansing, MI, USA; [13]Department of Physical Medicine and Rehabilitation, University of Kentucky, Lexington, KY, USA; [14]Pain Medicine and Anesthesiology, University of Utah, Salt Lake City, UT, USA; [15]Clinical Research, IPM Medical Group, Inc, Walnut Creek, CA, USA; [16]Department of Neurosurgery, University of Arkansas for Medical Science, Little Rock, AR, USA; [17]Comprehensive Specialty Care, Edmond, OK, USA; [18]The Spine and Nerve Center of the Virginias, Charleston, WV, USA



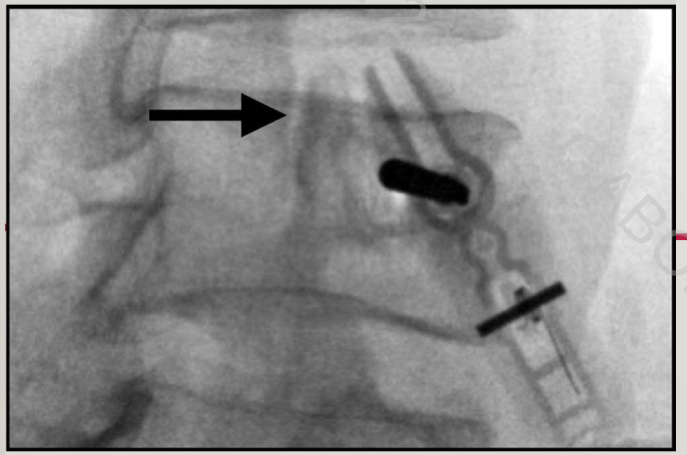


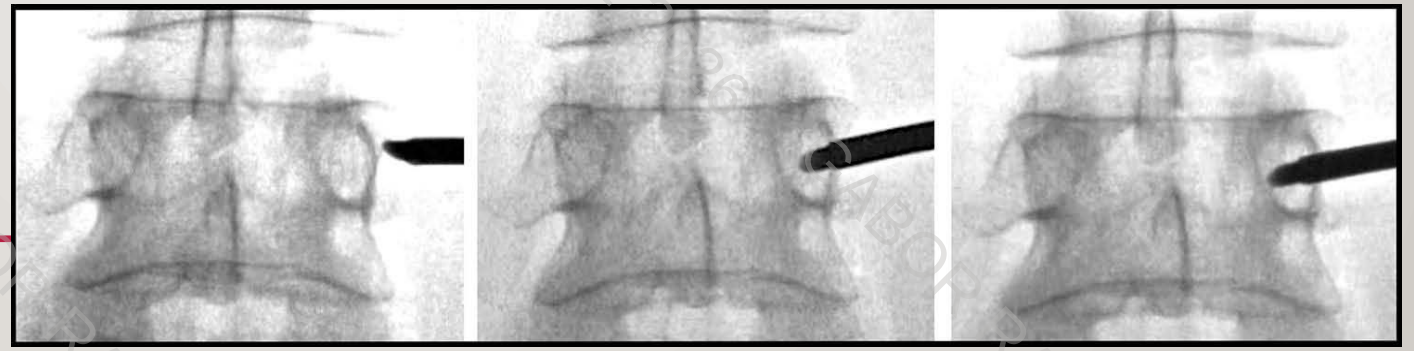
RFA OF BVN

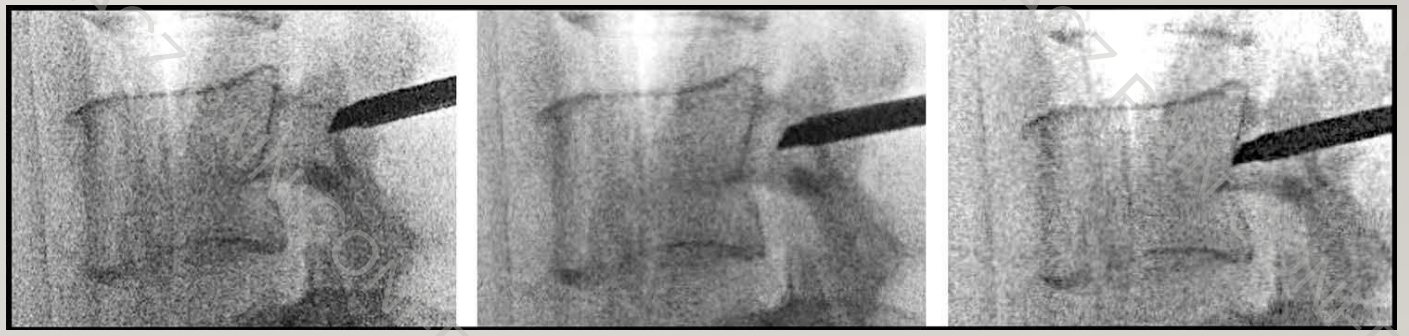
Bipolar lesion at **80º C**

15 mins for S1 lesion or if the placement is not perfect

7 Mins if perfect placement posterior 1/3rd and midway bet' two endplates

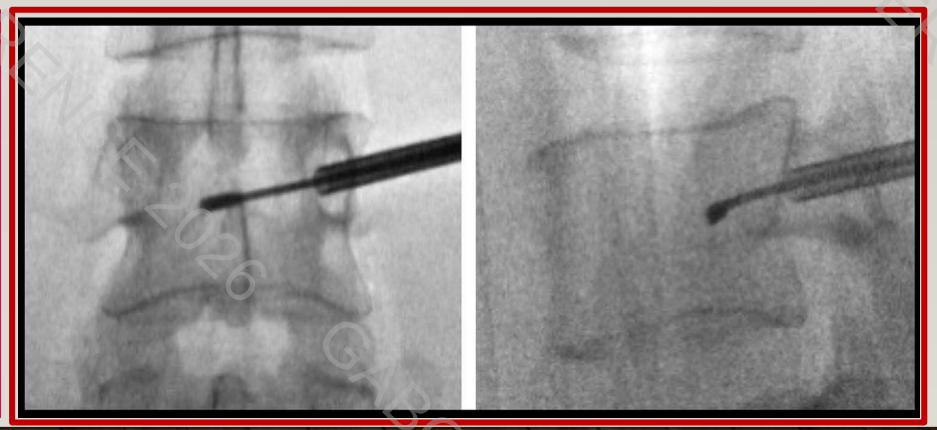






SKIN ENTRY POINT

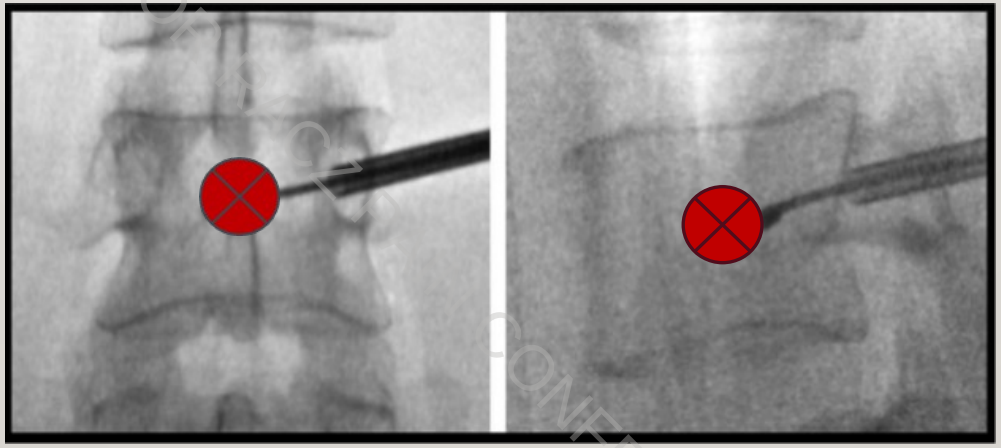
- Square off the superior endplate
- Rotate 35 degrees to obtain an oblique view
- Center the facet joints at the midpoint of v. body
- Superolateral border of pedicle is skin

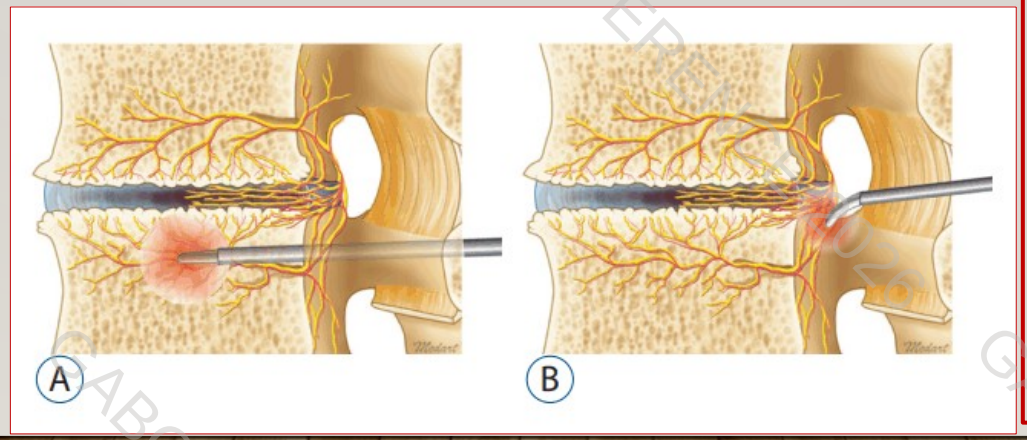


MONOPOLAR VS. BIPOLAR RFA

Monopolar RFA:

- Poorly controlled lesion size
- Final location of the RFA probe in the center
- Same temperature and duration of lesion
- No scientific

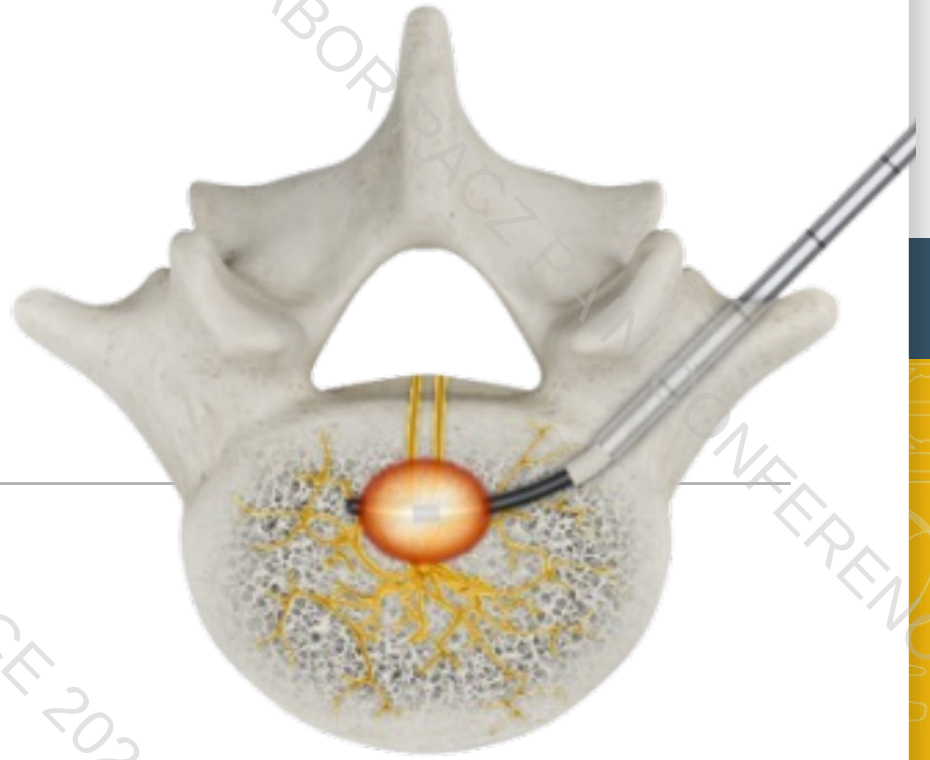




Bipolar RFA

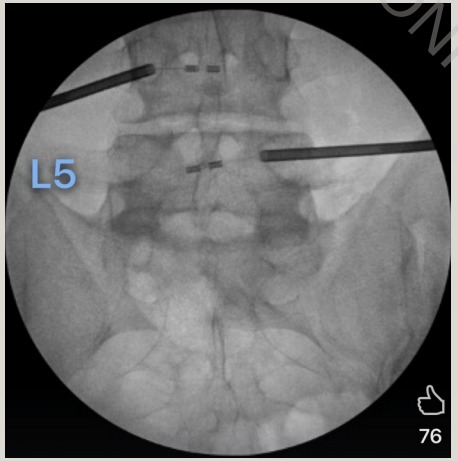
- Lesion size is controlled
- Final position: junction post 1/3rd and middle 1/3rd
- No difference in temp and duration
- Level 1 scientific studies

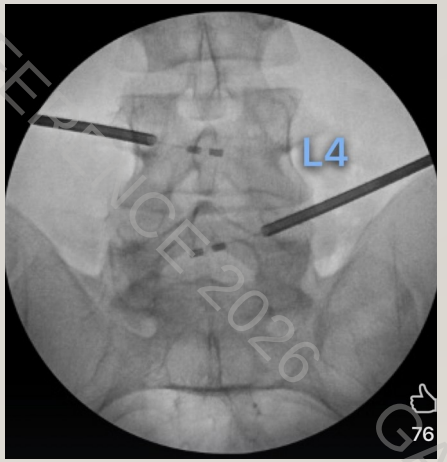
Basivertebral nerve ablation

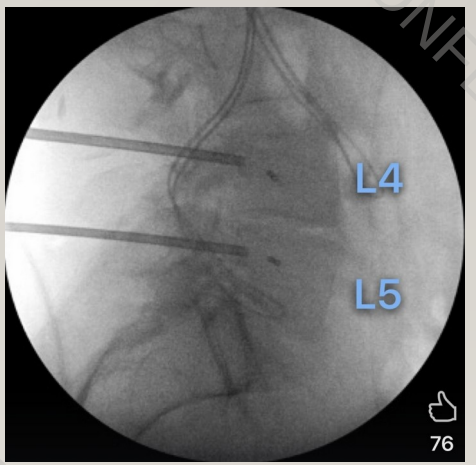


OptaBlate BVN

STRYKER TECHNOLOGY



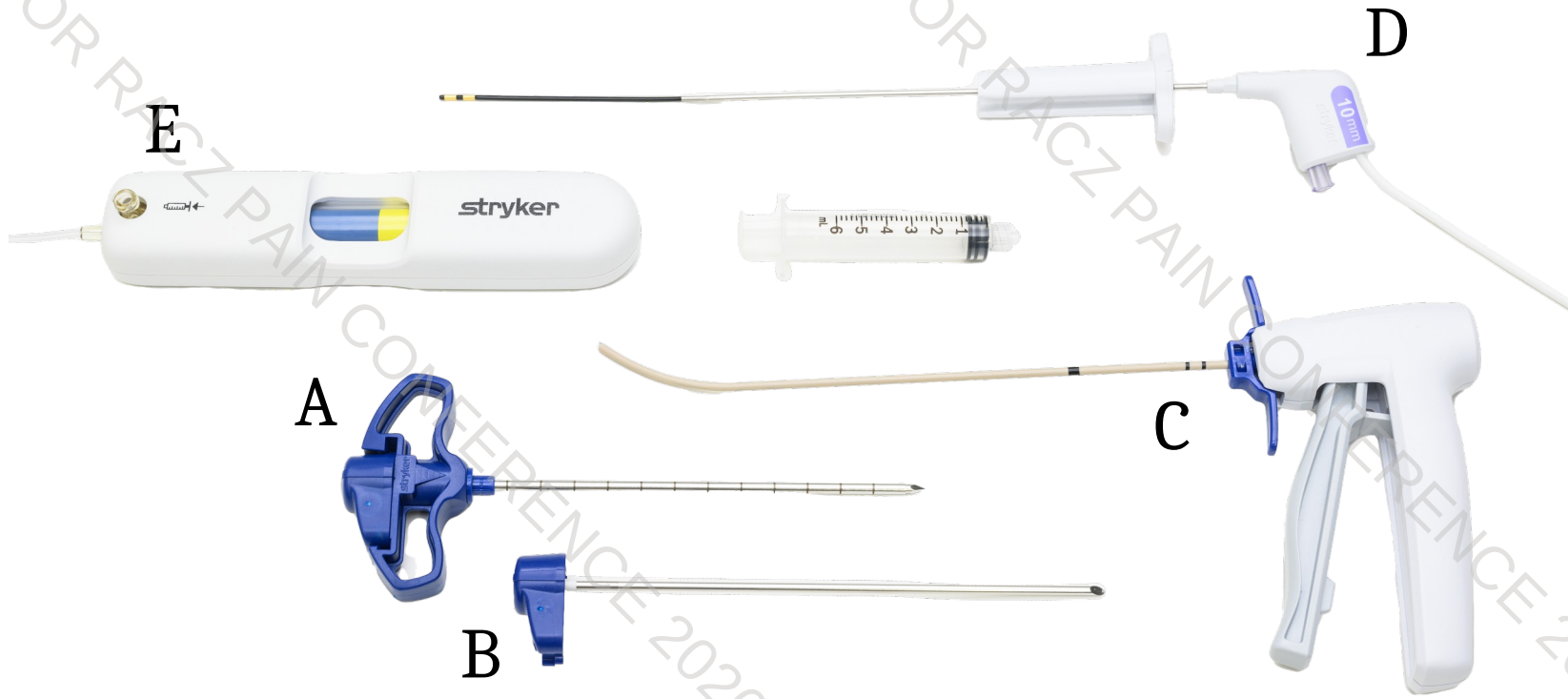




stryker

Optablate BVN 10mm Single Probe Kit

A. 10G access canula
B. 10G bevel stylet
C. 10G Introducer with conduit (PEEK sheath)
D. 10mm OptaBlate BVN probe with spacer
E. Microinfuser and syringe

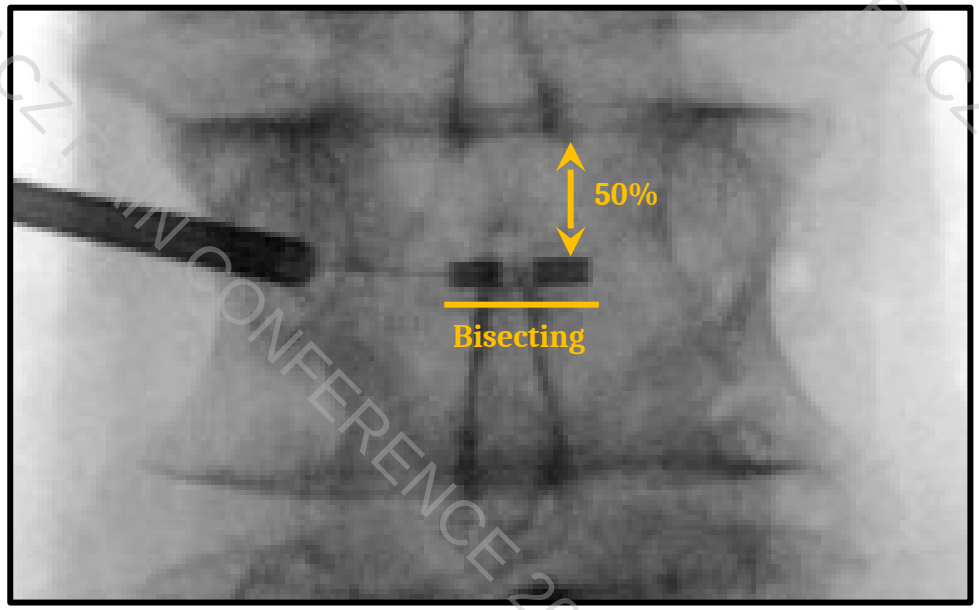


OptaBlate BVN 10mm dual probe kit contain 2 probes with spacers, 1 introducer with 2 conduits, 2 access cannulas, 1 bevel stylet, and 2 Microinfusers.

Lumbar BVNA targeting[9]

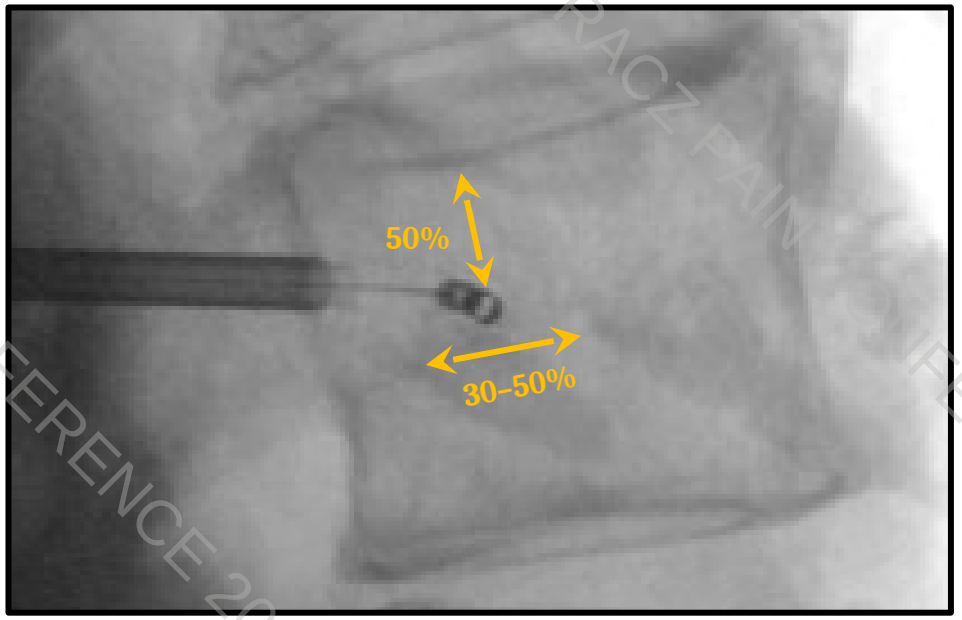
Ideal placement is reached when the tip of the probe is noted to be:

AP



Across **midline** of spinous process, with the spinous process bisecting the emitters

Lateral

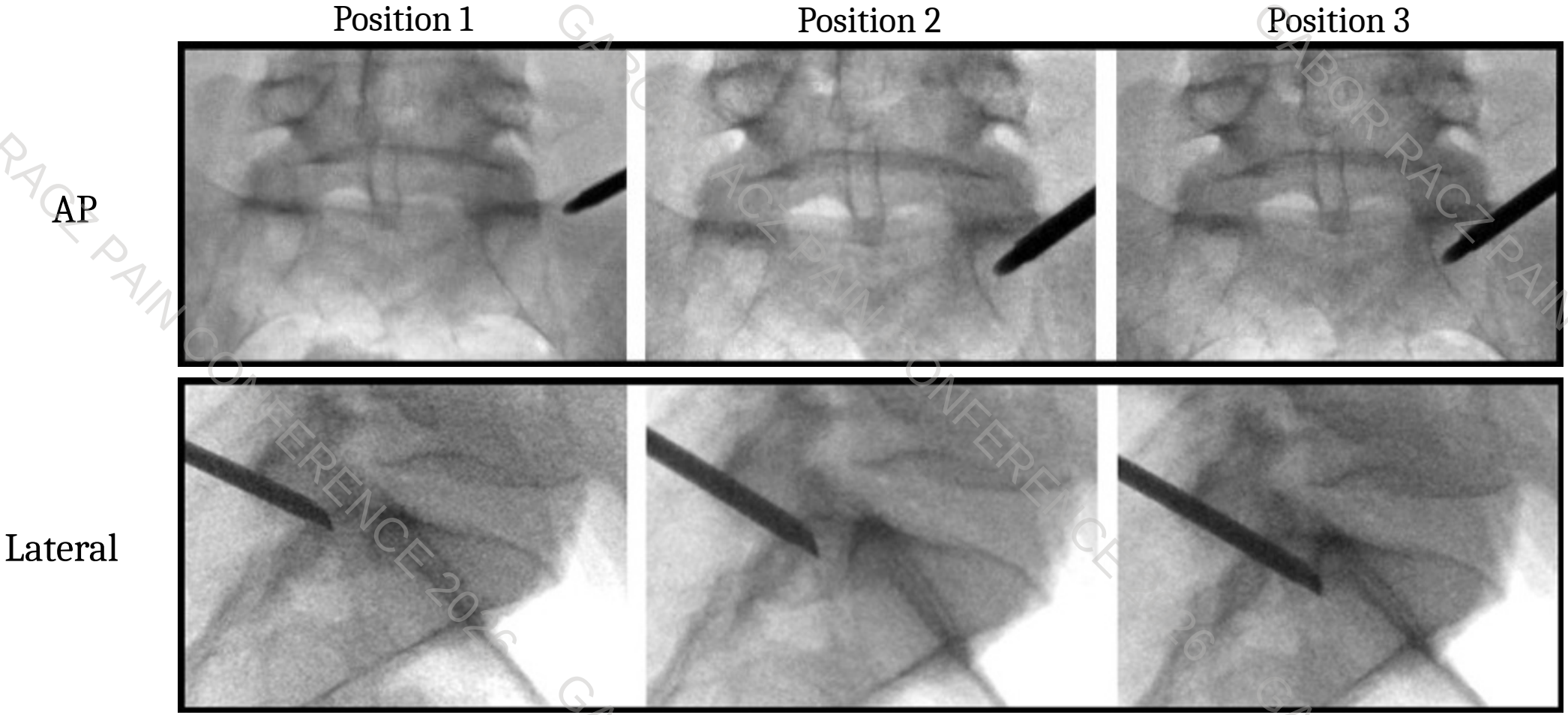


Approximately **30-50%** anterior to the posterior wall, **50%** inferior to the superior endplate

Procedural images taken from a Stryker-owned video.

S1 BVNA

access[9]



Final position should be just inside the vertebral body

Procedural images taken from Sayed et al, 2022.

Step One: Access the Pedicle

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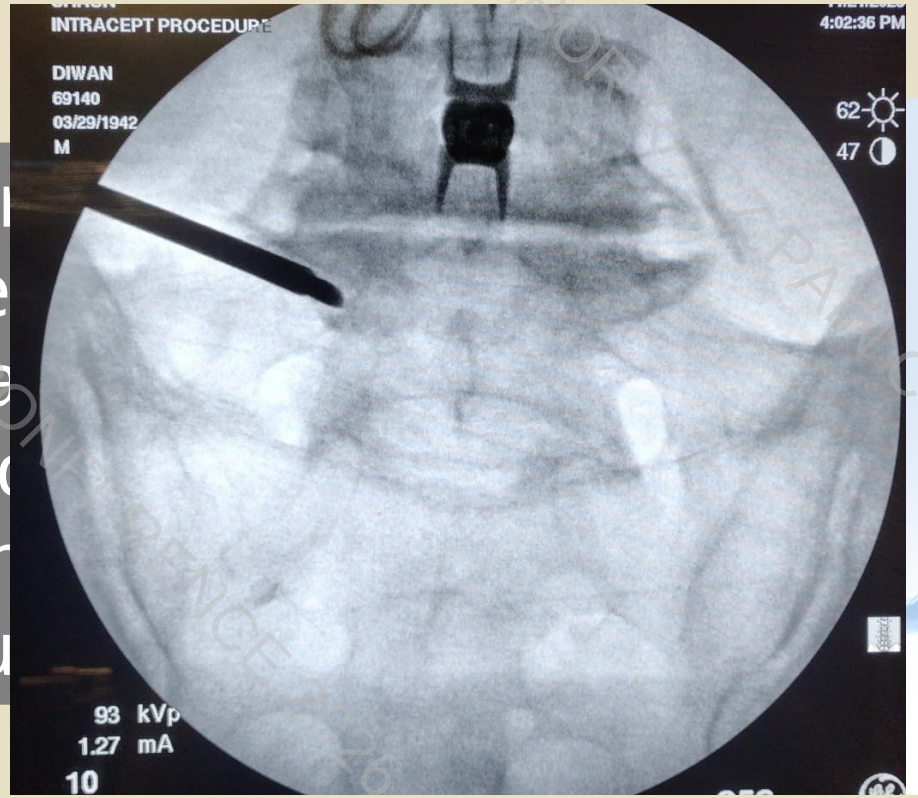
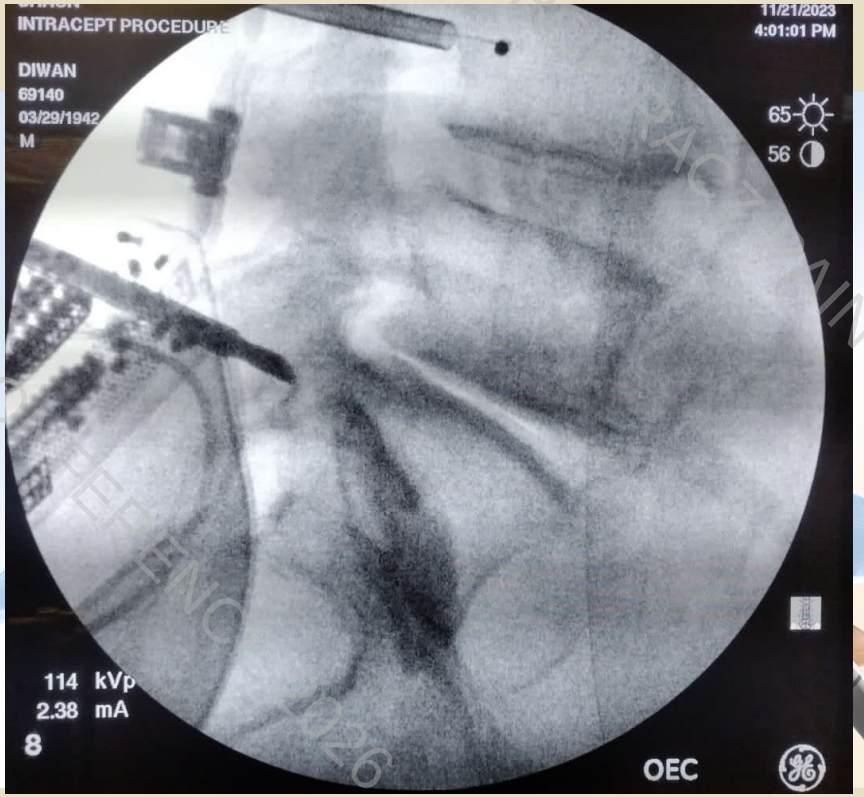


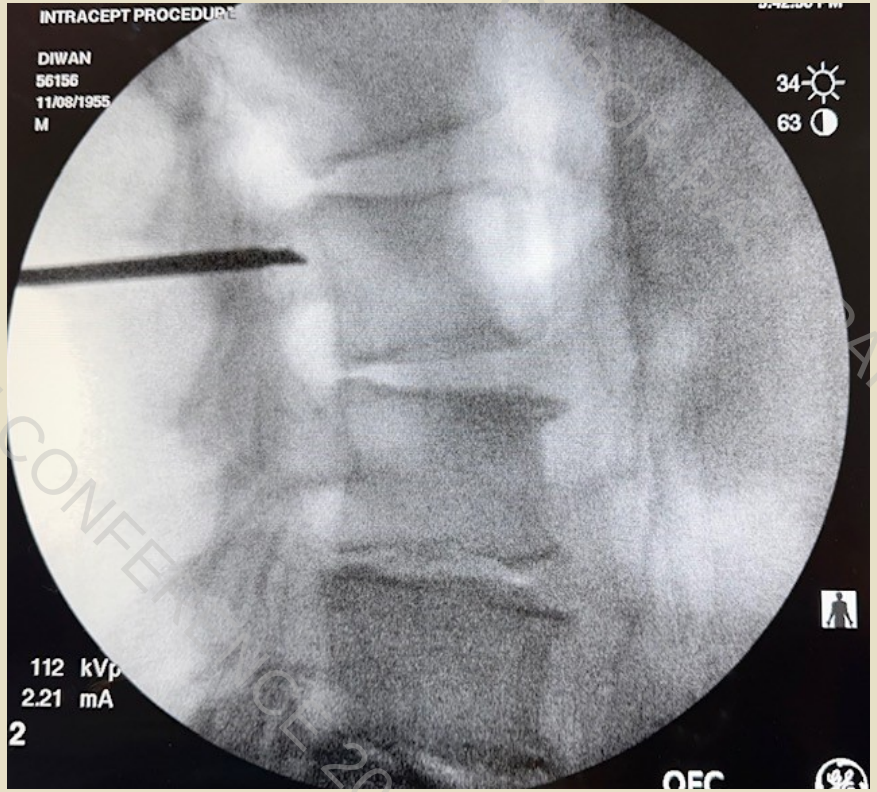


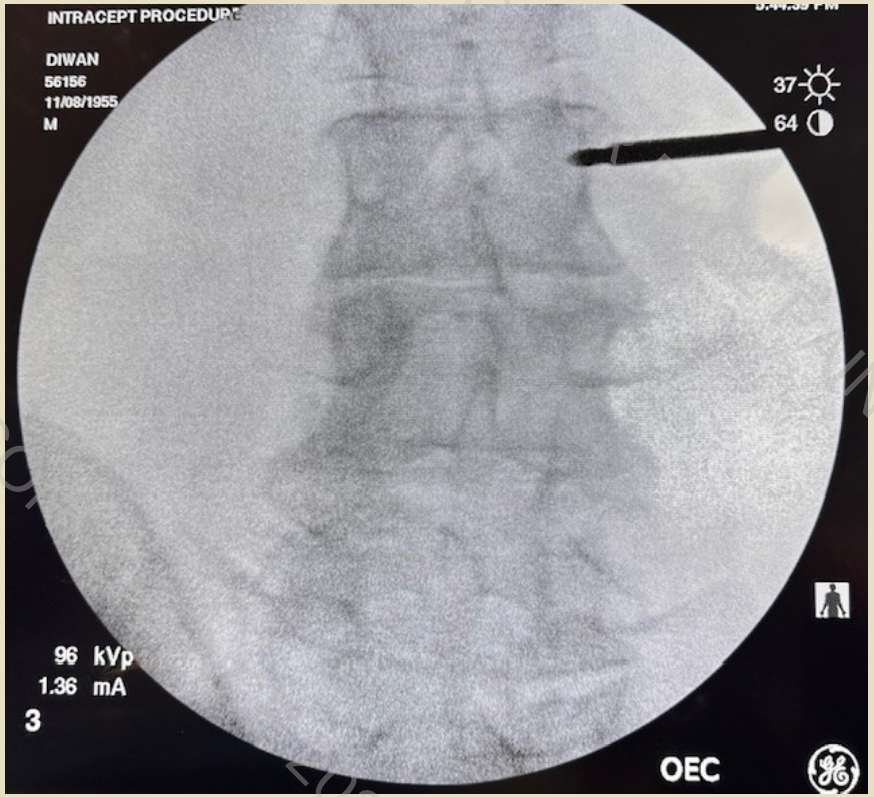
Introducer

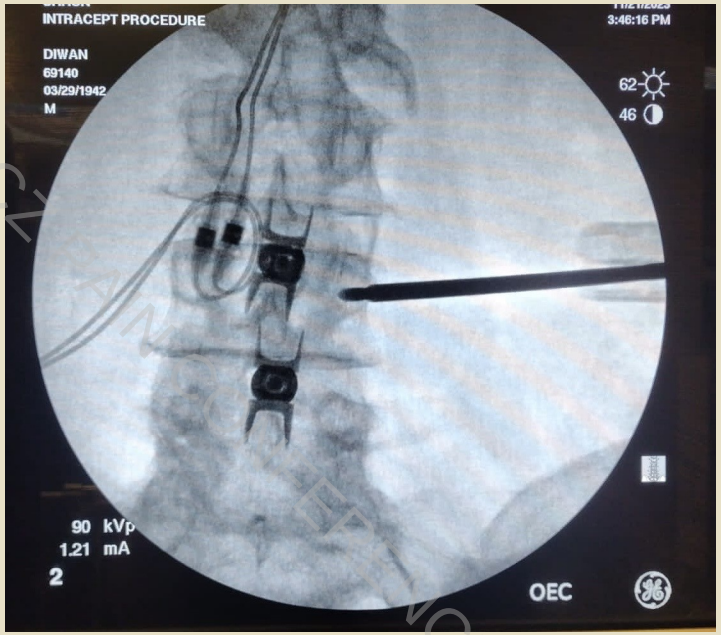
Bevel-Tipped Introducer

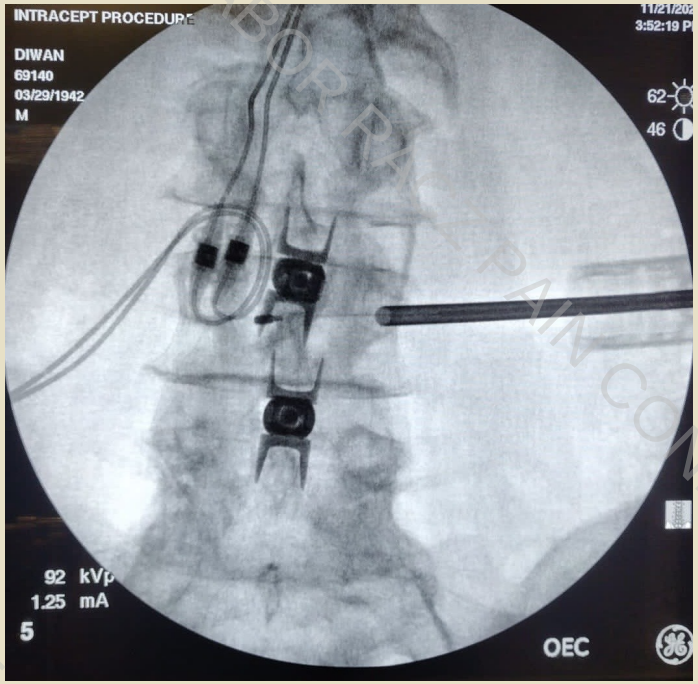
Diamond-Tipped Introducer

L3









Step Two: Create the Channel

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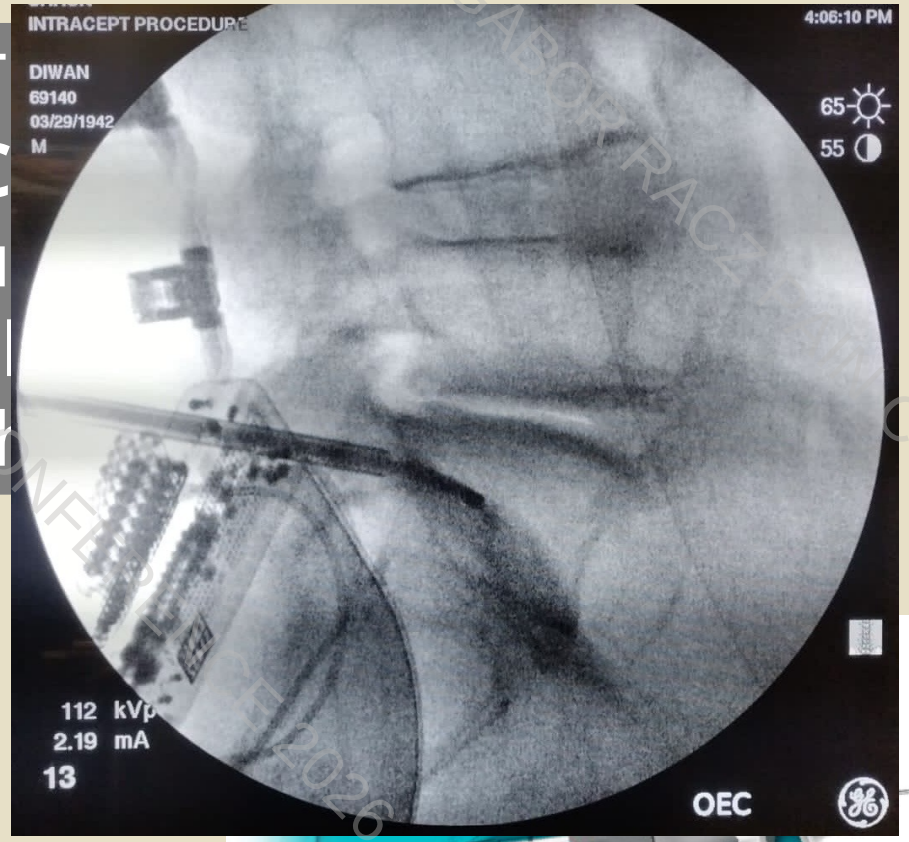
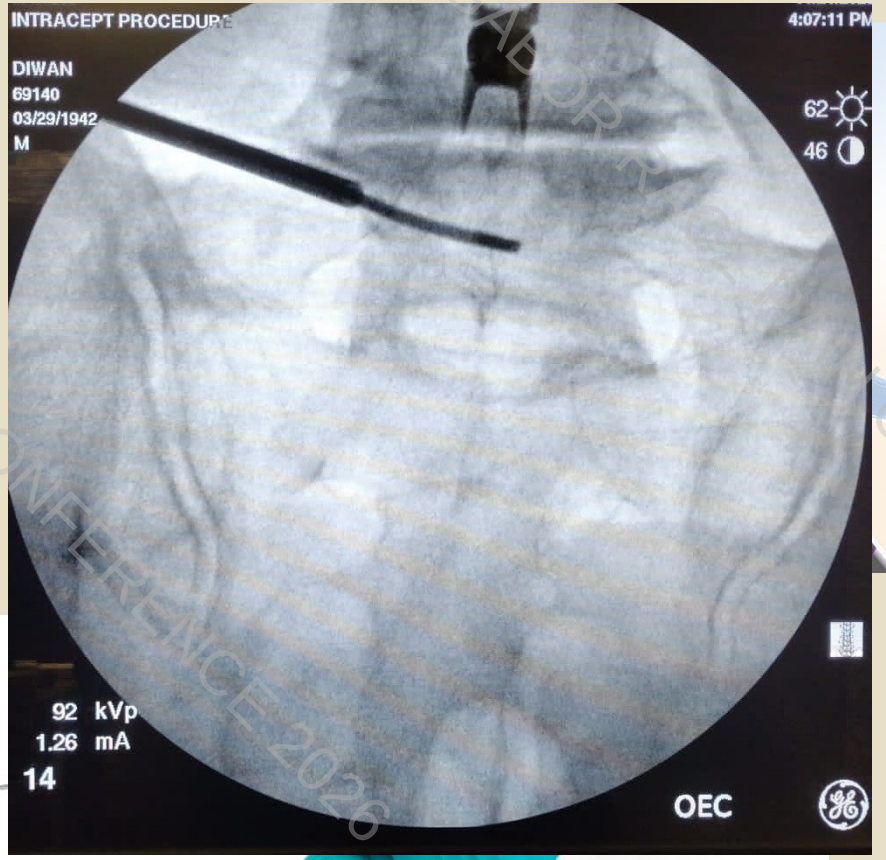
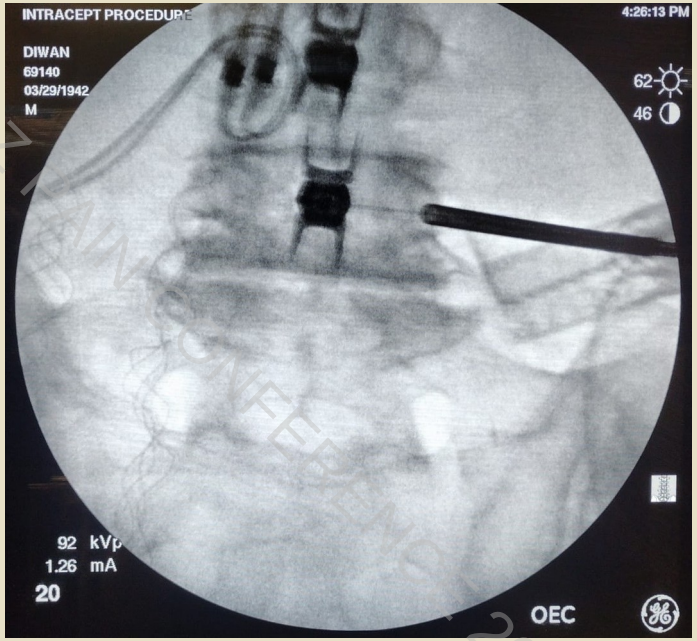
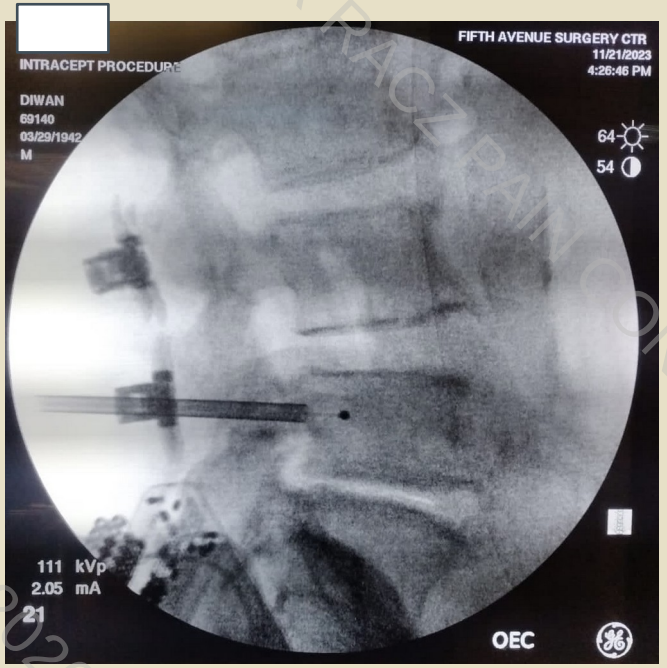


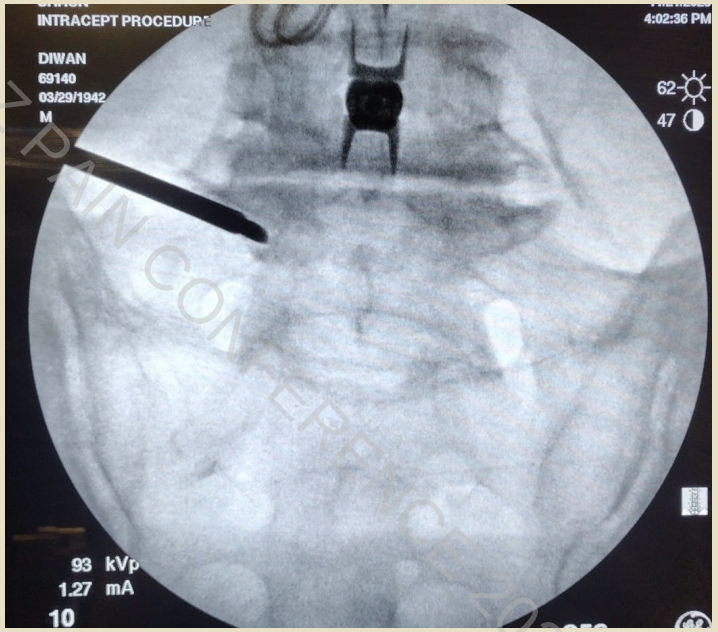


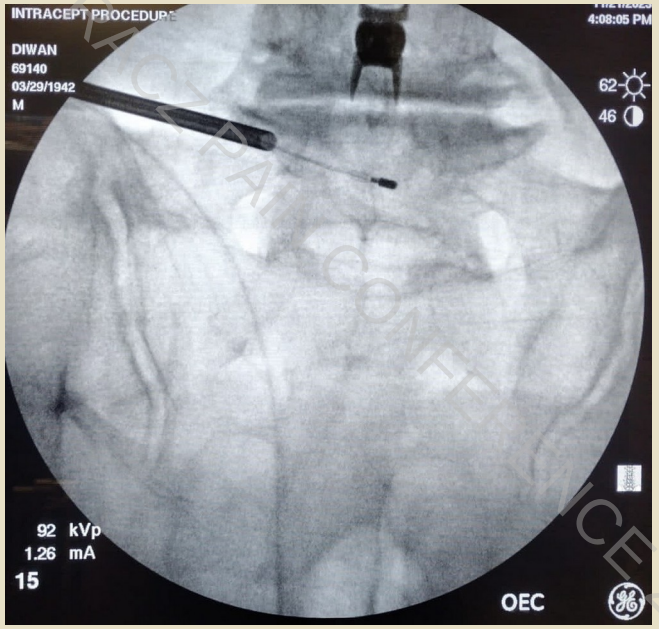
RFA of L5 BVN

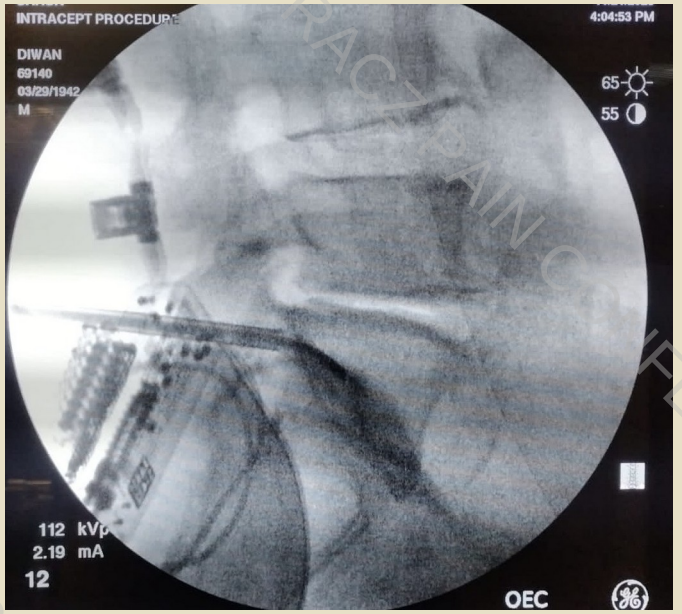




S1 Placement







Step Three: Place the RF Probe

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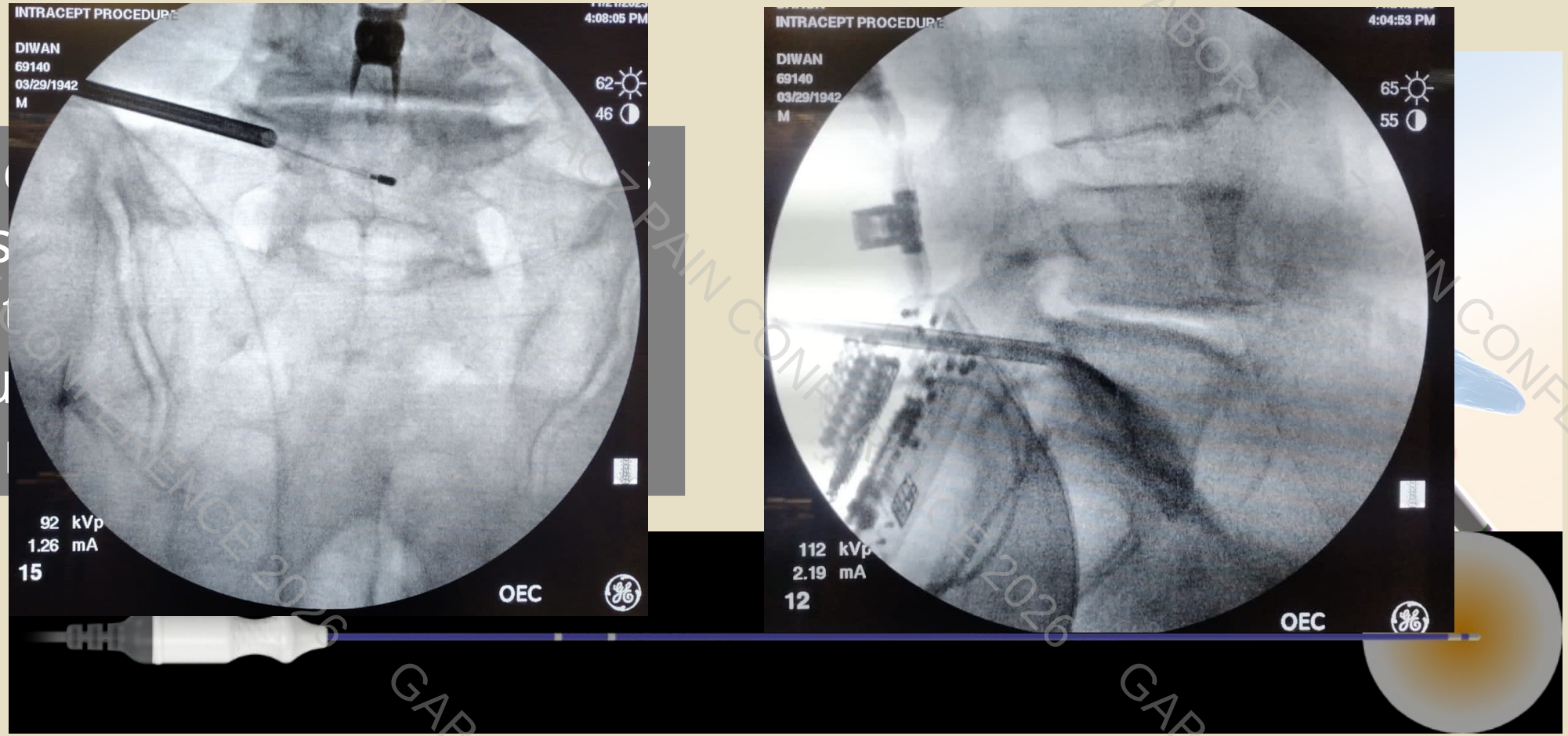
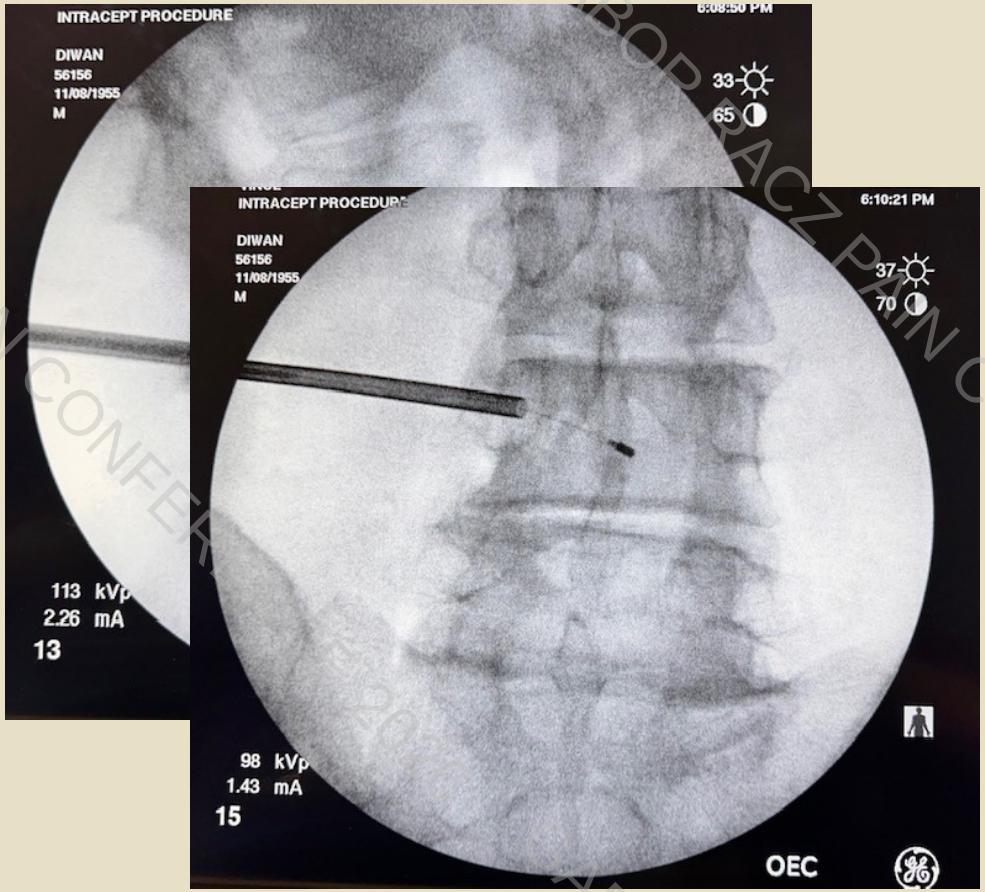
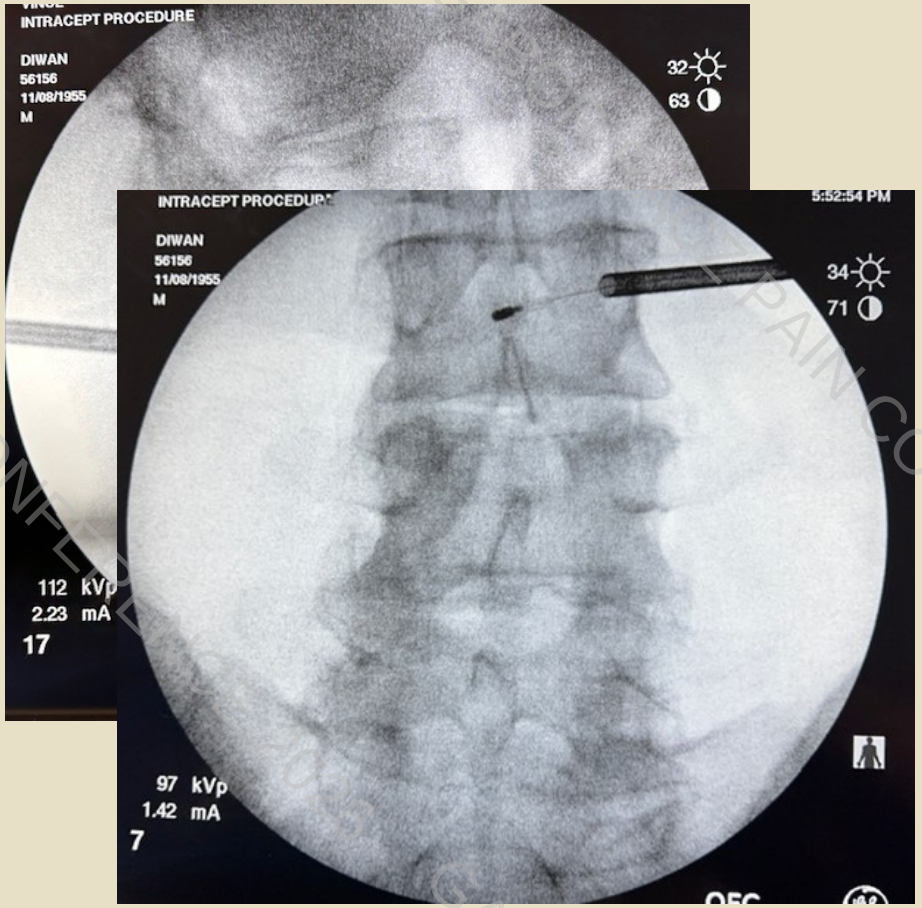


Step Four: Ablate the BVN

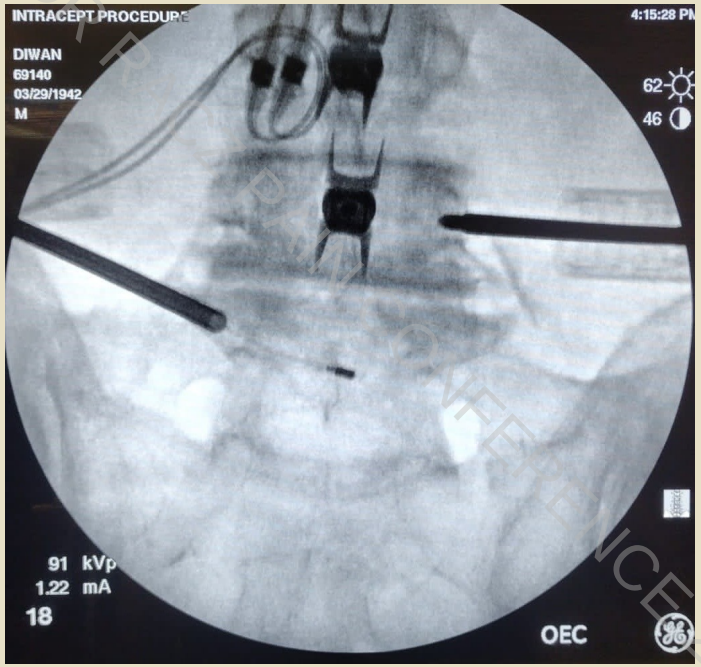
The Intracept RF Generator is used to deliver RF energy that ablates the basivertebral nerve.

RFA of L3 and L4 BVN





Contralateral approach



Bi-Polar RF Probe RFA system

- Bipolar lesion at **80° C**
- **15 mins** for S1 lesion or if the placement is not perfect
- **7 Mins** if perfect placement posterior 1/3rd and midway between two endplates

Intracept Post Procedure Images

6 weeks post-treatment
(T2 Weighted)

6 months post-treatment
(T2 Weighted)

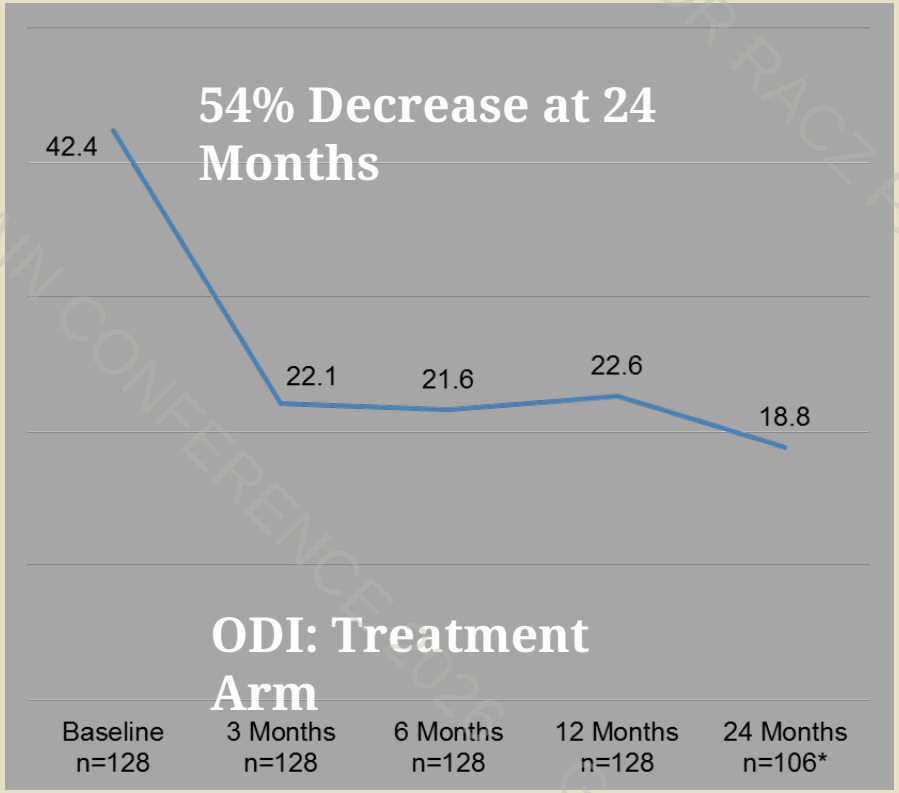
SMART Trial Design

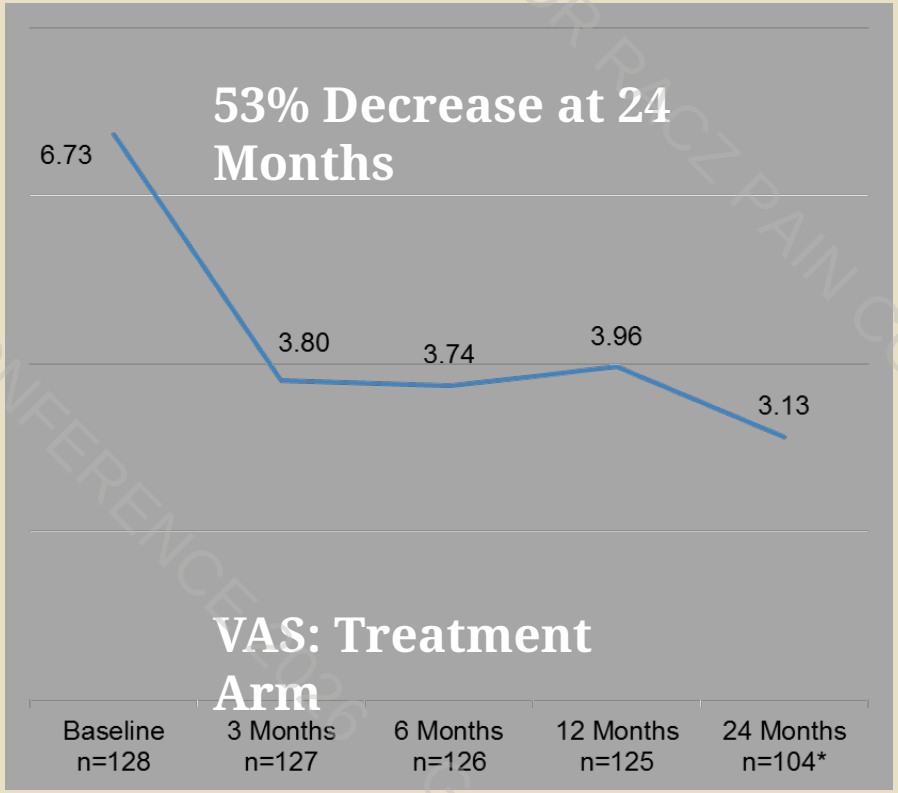
- Randomized, double-blind, **sham-controlled**, Multi-Center study
- 225 Patients: 147 – **treatment arm** and 78 - **sham intervention**
- F/U at 2 wks. and 6 wks., and 3, 6, 12 and **24 mos**. postoperatively
- Chronic pain for ≥ 6 months, not responded to at least 6 mos.
- All patients had Type 1 or Type 2 Modic changes
- Outcome Measures: ODI, SF-36, and VAS
- Sham patients offered cross-over Intracept Procedure at **12 mos.**

Fischgrund JS, Rhyne A, Franke J, et al. International Journal of Spine Surgery, Vol. 13, No. 2, 2019, pp. 1–10

Improvement at 24 Mo. F/U

Fischgrund JS, Rhyne A, Franke J, et al. International Journal of Spine Surgery, Vol. 13, No. 2, 2019, pp. 1–10





INTRACEPT Study

Prospective, Multi-center**, Open label RCT: BVN vs. Standard care**

- 140 pts, randomized to **BVN ablation** vs. **standard care** (PT, injections, medications)
- F/U at 3, 6, 9, and 12 Months **and 24 Month** F/U after BVN - RF ablation
- 67% had back pain for >5 years,
- 36% were taking opioids,
- 50% had prior ESIs, and 12% had prior low back surgery

Primary Inclusion criteria

- LBP > 6 months; Minimum of 6 months conservative care
- Modic endplate changes (Type 1 or 2) of L3 to S1 vertebral bodies

Outcome Measures: ODI (primary), VAS, SF-36, EQ-5D-5L, patient satisfaction

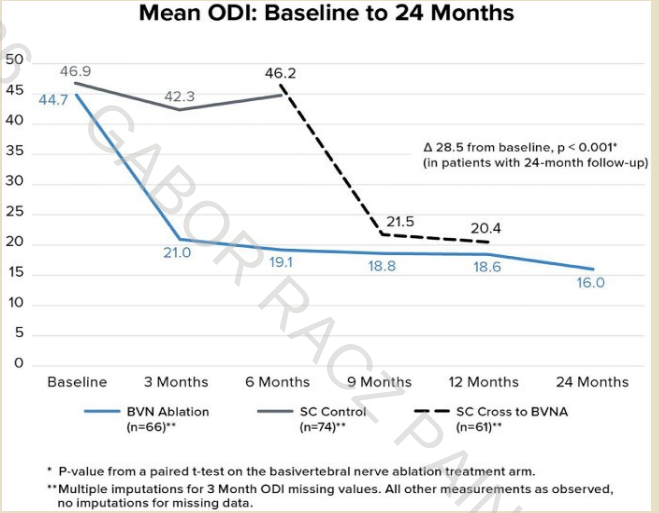
Theodore Koreckij et al. N Am Spine Soc J. 2021 Oct 26;8:100089. doi: 10.1016/j.xnsj.2021.100089

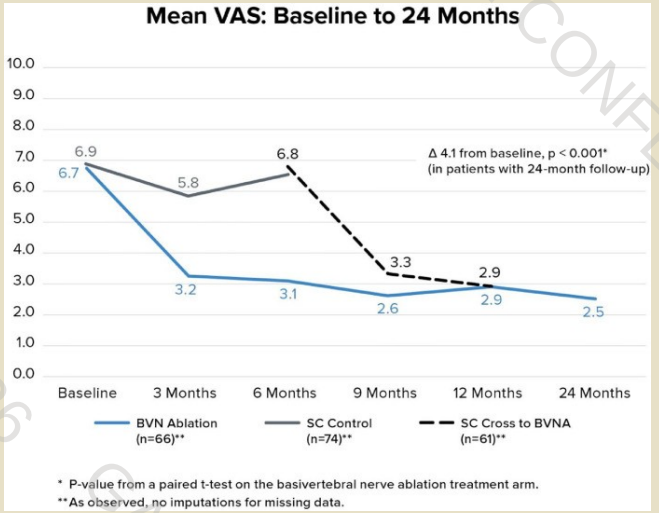
INTRACEPT Study Interim Analysis

- Pre-specified Interim Analysis at ≥ 60% of patients at 3 month primary endpoint
- Primary endpoint and all secondary endpoints demonstrated statistical significance in favor of the RF ablation arm ($p < 0.001$)
- Independent data management committee (DMC) recommended to halt randomization and allow **early cross-over** of SC arm pts.
- Study population at time of interim analysis: 104/140 patients randomized
- 104 patients at 3 month primary endpoint (51 RF ablation; 53 SC) included in ITT analysis

INTRACEPT Trial
24 Months F/U

- 140 pts, 66 pts had BVNA, 58 pts completed f/u at 24 months
- ODI improved by 28.5 points (baseline 44.5)
- VAS improved by 4.1 points (baseline 6.6)
- Responder rate (ODI≥15 and VAS≥2) was 73.7%
- Excellent safety profile
- Significant improvements in pain, function, and QOL



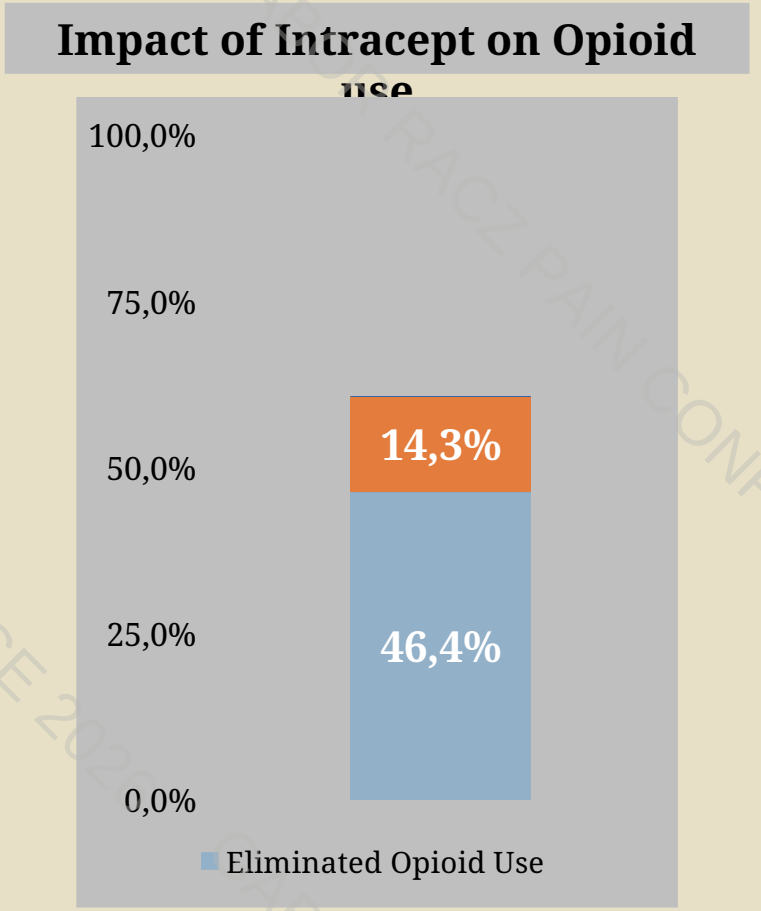


Theodore Koreckij et al. N Am Spine Soc J. 2021 Oct 26;8:100089. doi: 10.1016/j.xnsj.2021.100089

Opioid Results: Per Protocol Treatment Arm

- Baseline opioids use in 28/106 patients (26%)

- At 12 months
  - **46.4%** of the patients who were taking opioids at the time of enrollment **completely eliminated** the use of opioids
  - **14.3%** of the patients who were taking opioids at the time of enrollment had **reduced opioid medication**



SMART vs. INTRACEPT Trial

SMART

- Mean age 47 yrs.
- CLBP more than 3 years: 78%
- CLBP for more than 5 years: 67%
- At least one type of conservative treatment for CLBP: 100%

INTRACEPT

- INTRACEPT Study was 50
- CLBP more than 3 years: 80%
- CLBP for more than 5 years: 67%
- At least one type of conservative treatment for CLBP: 100%

Long-term Outcomes Following Intraosseous BVN Ablation for CLBP: 5-Year follow up after Treatment

Fischgrund JS, Rhyne A, Macadaeg K et al. Long-term outcomes following intraosseous basivertebral nerve ablation for the treatment of chronic low back pain. Eur Spine J. epub May 25, 2020

Baseline

- ODI – 42.81
- VAS – 6.73
- 69% > 5 years of pain at baseline

Sample US vs Global Assessment:

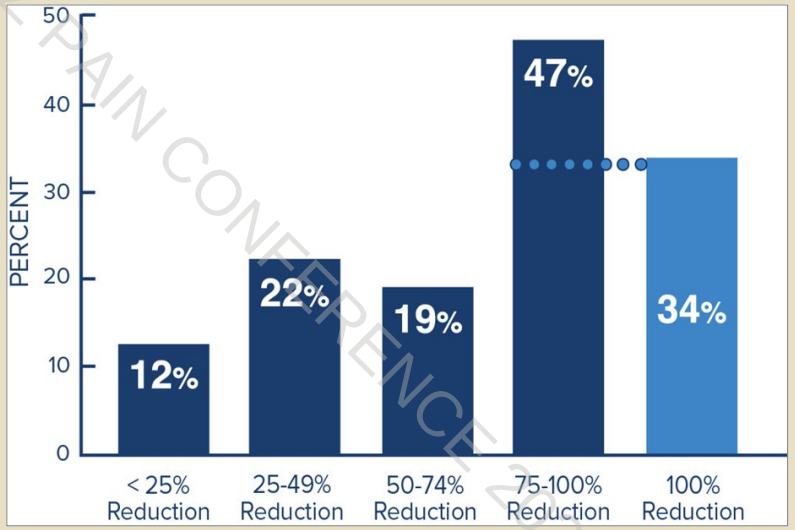
- No statistical differences in Baseline or 3-month primary endpoint outcomes for SMART Global PP (N=128) and the 5-year US PP cohort (N=100)

LTFU Bias Assessment:

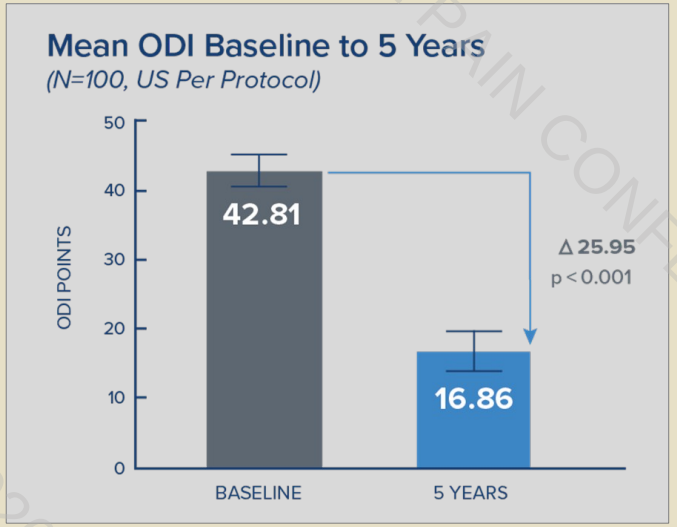
- No statistical differences between the 100 patients that participated at 5 years and the 17 who did not in 3-month primary endpoint outcomes

SMART 5 Year - Primary Endpoint

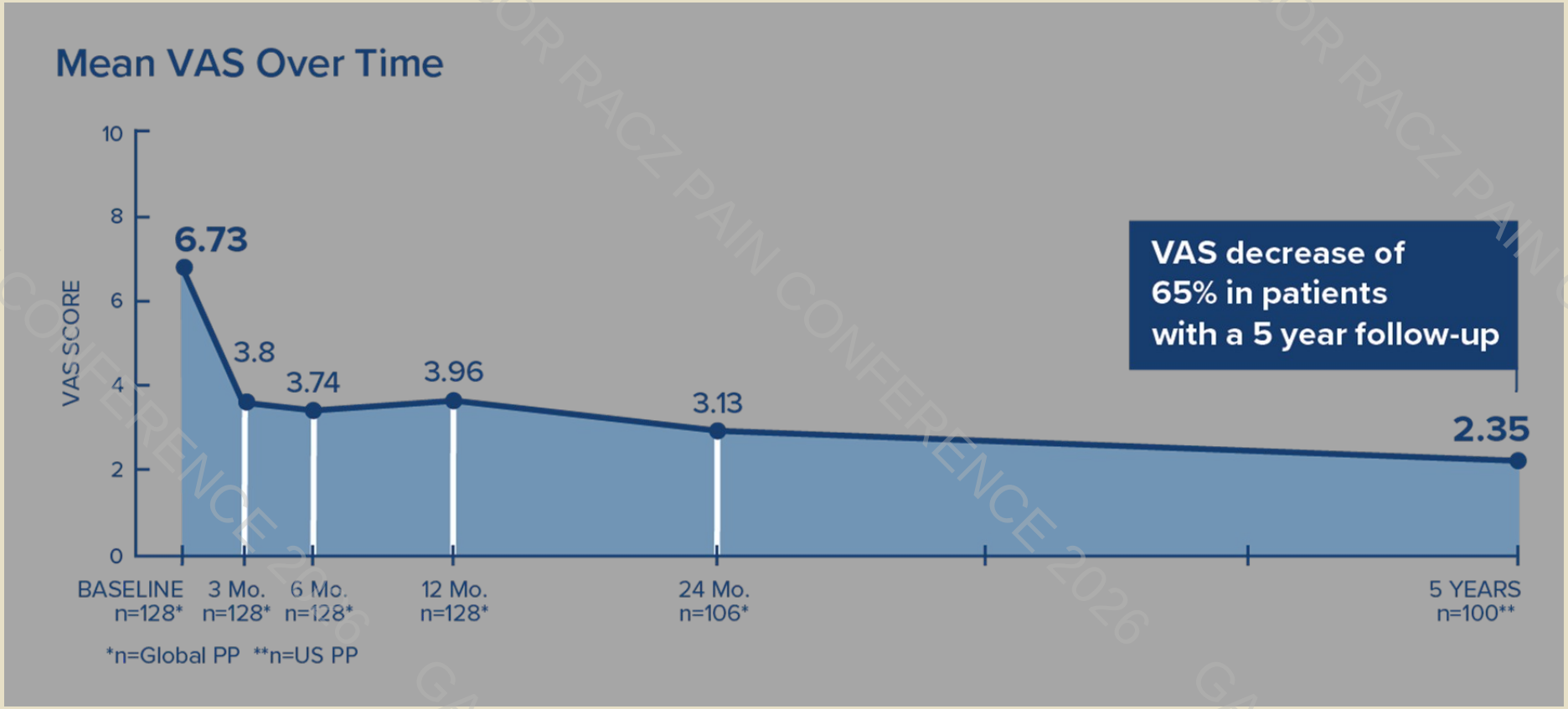
Mean ODI and Mean VAS Improvement



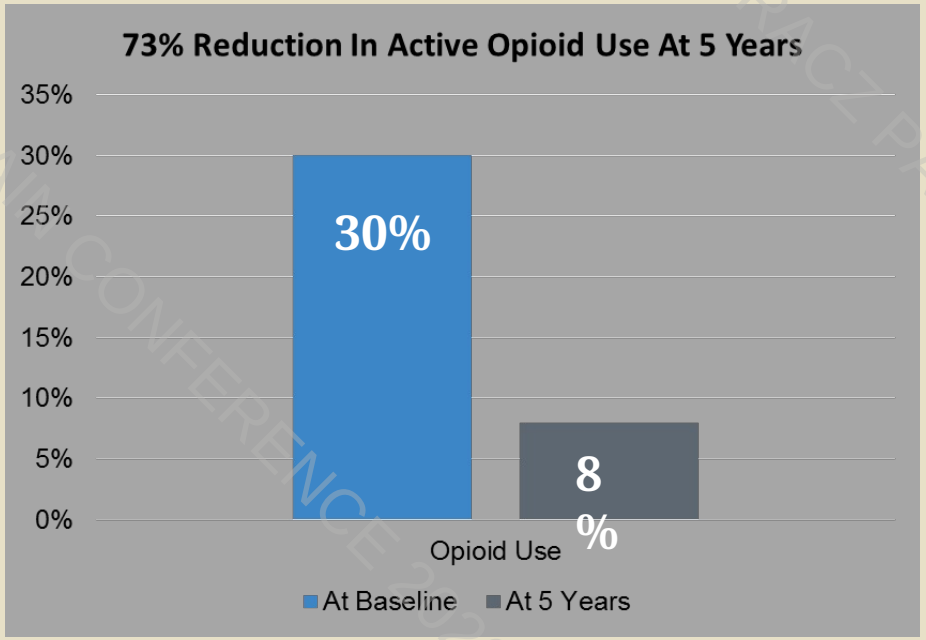
- Mean reduction in VAS of 4.38 points
- 66% of pts had ≥ 50% improvement
- 47% of pts. had ≥ 75% improvement in pain
- **34% of pts. were pain free at 5**

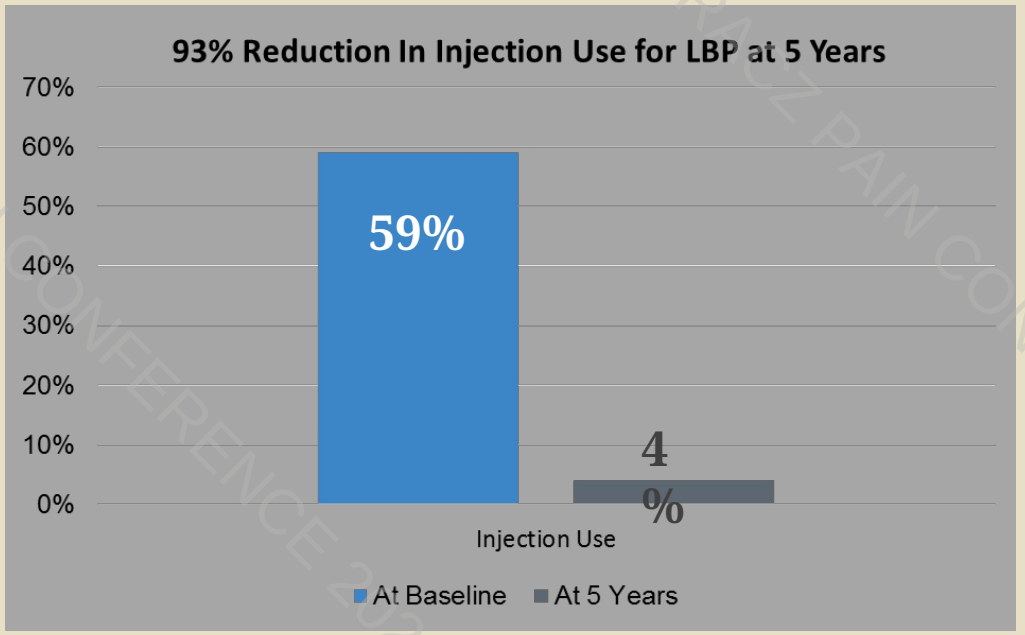


SMART 5 Year - Durability of VAS reduction



SMART 5 - Opioids & Injection Utilization

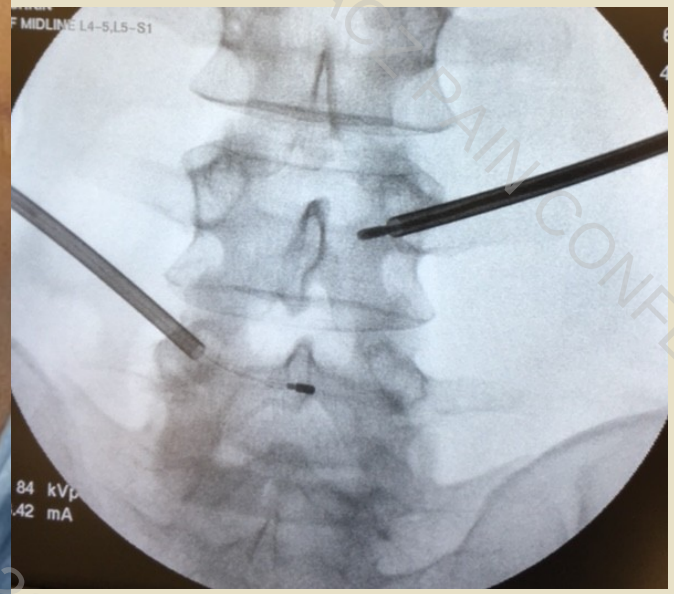




Summary

Evidence Based	• 10+ years of research, 2 RCTs with Level 1 evidence • Vertebral body endplates are a significant source of CLBP • Modic 1 & 2 changes are consistent with vertebrogenic pain
Outcomes	• 75% combined responder rate of ODI (≥15 points) and VAS (≥ 2 points) • 66% reported > 50% reduction in pain • 34% of patients were pain free (VAS - 0) at 5 years
Patient Satisfaction	• 79% pts. indicated they would have the BVN ablation again if needed • 65% reported resumption of activity level similar to before they had low back pain • Evidence of durable outcomes following BVN Ablation

Int ure



Thank you for your attention!!