Innovations for Active Healing

Navigating Peripheral Nerve Stimulation:
An Algorithmic Approach to Patient Selection for Orthopedic Surgeons and Pain Specialists

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Faculty Disclosures

- **Vinod Dasa, MD**: Consultant—Bioventus, Curonix
- **Einar Ottestad, MD, FIPP, CIPS**: Consultant—Bioventus, Coloplast, Respera Medical, SPR Therapeutics; Equity—Invicta; Co-founder and Consultant—Altamont Medical

Program Information

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Learning Objectives

- Review the role of peripheral nerve stimulation (PNS) in pain management, highlighting advances in imaging and technology
- Describe an algorithmic approach to patient selection for peripheral nerve stimulation in orthopedic surgery
- Explain key criteria for patient selection in peripheral nerve stimulation (PNS) from the perspective of a pain specialist

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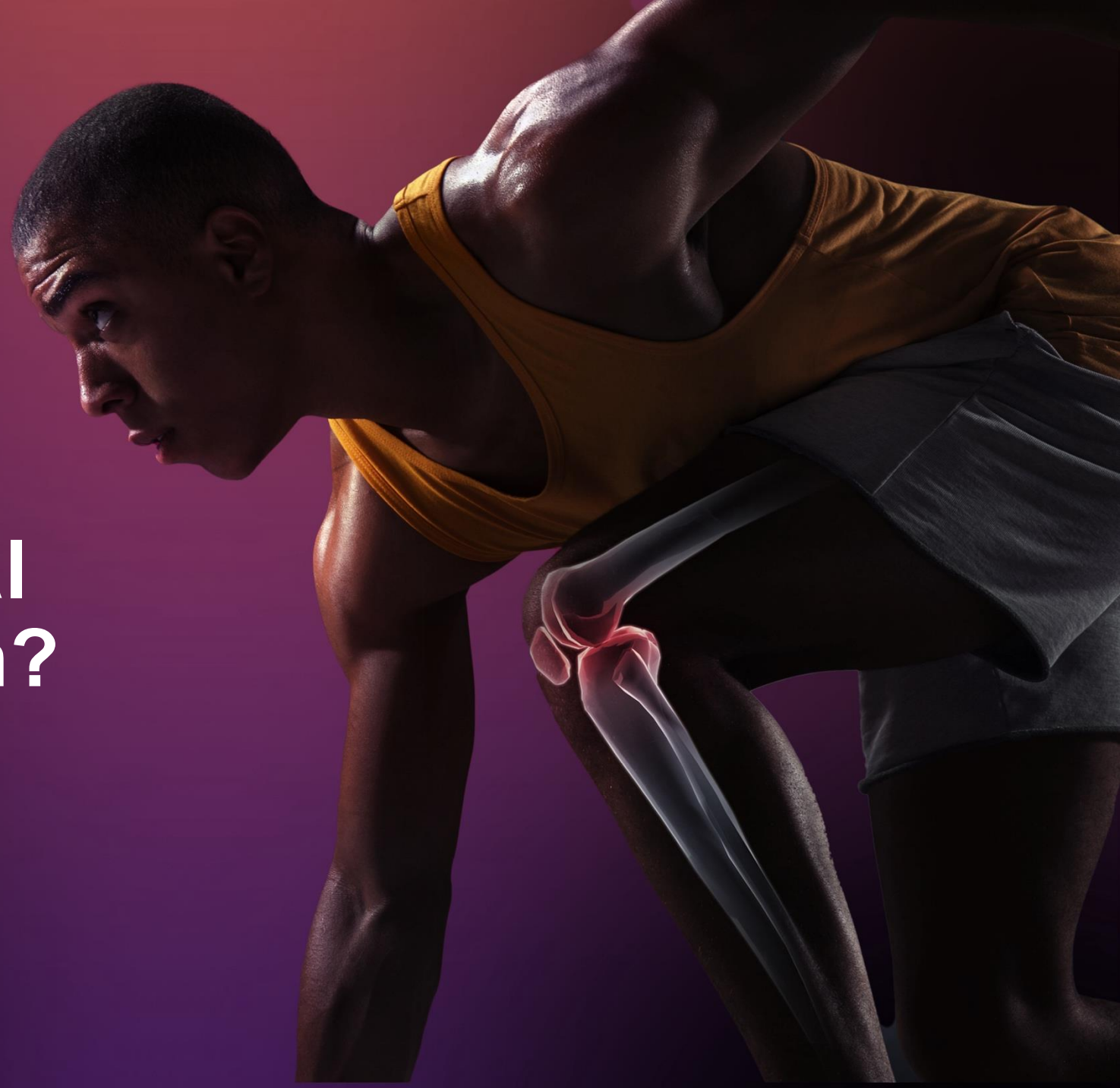
What Is Peripheral Nerve Stimulation?



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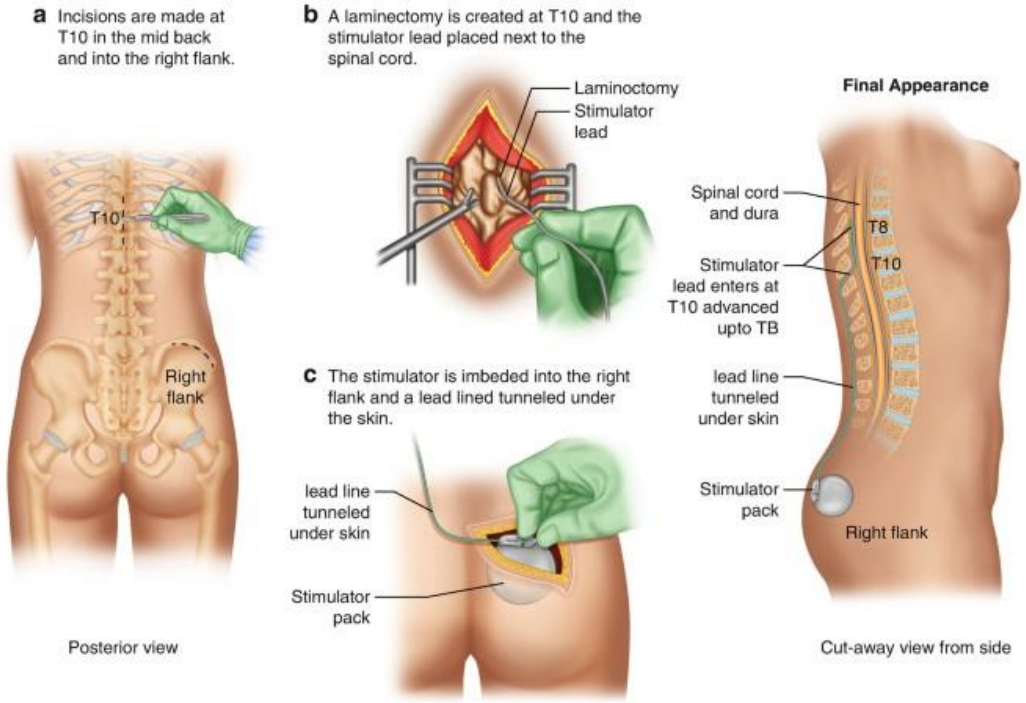
Types of Pain

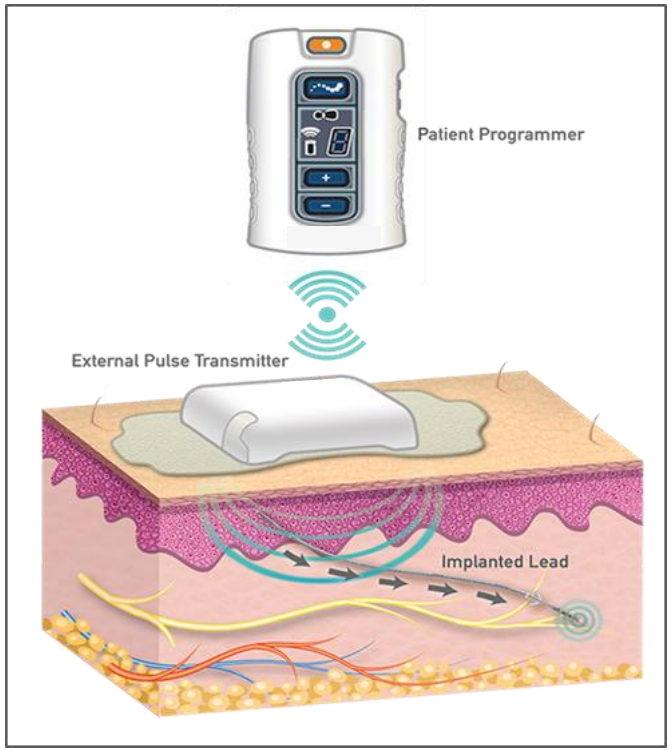
Spinal Cord Stimulation (SCS)

Neuropathic Pain



Peripheral Nerve Stimulation (PNS)

Nociceptive Pain



SISMED. Accessed August 5, 2025. https://www.sismed-it.com/neurostimolazione-elettrica-e-breakthrough-cancer-pain. Guzman-Negron JM, et al. *Curr Urol Rep*. 2017;18(12):94.

How Do We Block Peripheral Sensory Nerves?

Electrical Methods

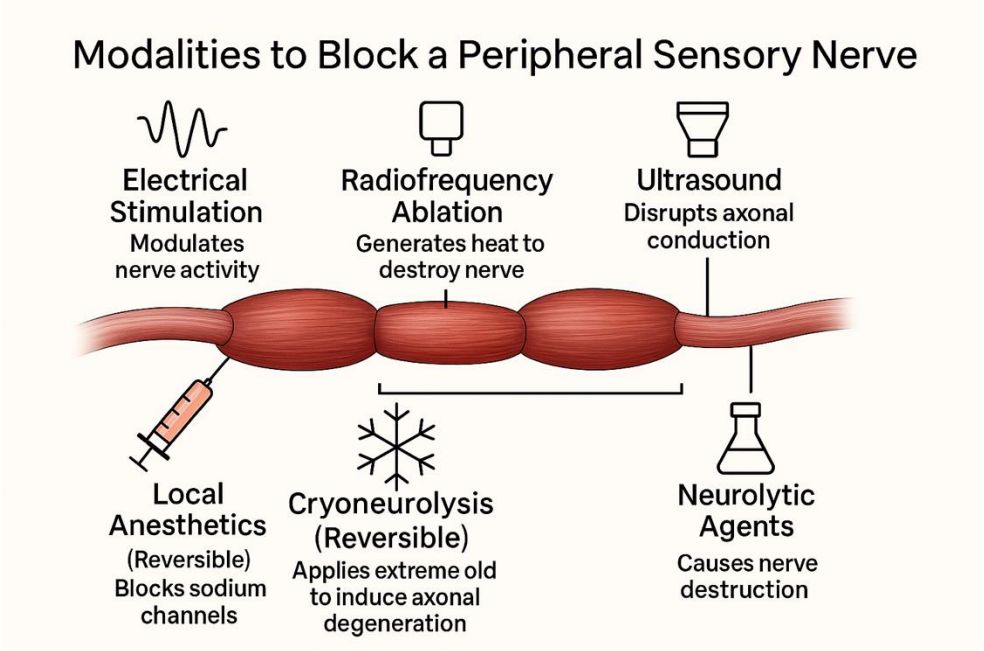
- **Transcutaneous Electrical Nerve Stimulation (TENS)**
  - Non-invasive; uses surface electrodes to modulate nerve activity
- **Peripheral Nerve Stimulation (PNS)**
  - Implantable device delivers pulses near the nerve to block pain signals
- **Kilohertz Frequency Alternating Current (KHFAC)**
  - Delivers high-frequency current to **reversibly block** Aδ and C fibers

Chemical Methods

- **Local Anesthetics (eg, lidocaine, bupivacaine)**
  - Block sodium channels; reversible nerve conduction block
- **Neurotoxins (eg, botulinum toxin, capsaicin)**
  - Temporarily or permanently impair neurotransmission
- **Alcohol or Phenol Neurolysis**
  - Cause irreversible nerve destruction—used in severe chronic pain

Thermal Methods

- **Cryoneurolysis**
  - Uses extreme cold to disrupt axonal conduction; can be temporary or long-lasting



Verrills P, et al. *J Pain Res.* 2016;9:481-492. Neuroaxis. Accessed August 21, 2025. https://neuroaxis.com.au/procedures/pain-procedures/spinal-cord-stimulators.

What Is PNS?

- Use of electricity to treat pain
- Neuromodulation is the direct application of electrical current to alter neural activity, in this case, specific to an affected peripheral nerve
- Goal is to deliver selective stimulation of pain-relieving large sensory fibers while avoiding the induction excitation of unwanted muscle contractions, muscle weakness, and reduced proprioception pain and motor fibers

Lin T, et al. *Pain Med.* 2020;21(Suppl 1):S6-S12.

Mechanism of Action

Nerve Fiber Type	Diameter	Conduction Velocity	Myelination	Sensation Carried
Aα (Alpha)	Largest	Fastest (~80–120 m/s)	Yes	Proprioception (not pain-related)
Aβ (Beta)	Large	Fast (~35–90 m/s)	Yes	Touch, pressure (can modulate pain)
Aδ (Delta)	Small	Medium (~5–35 m/s)	Lightly myelinated	Sharp, acute, localized pain; cold
C Fibers	Smallest	Slowest (~0.5–2 m/s)	No	Dull, burning, diffuse pain; warm/hot; itch

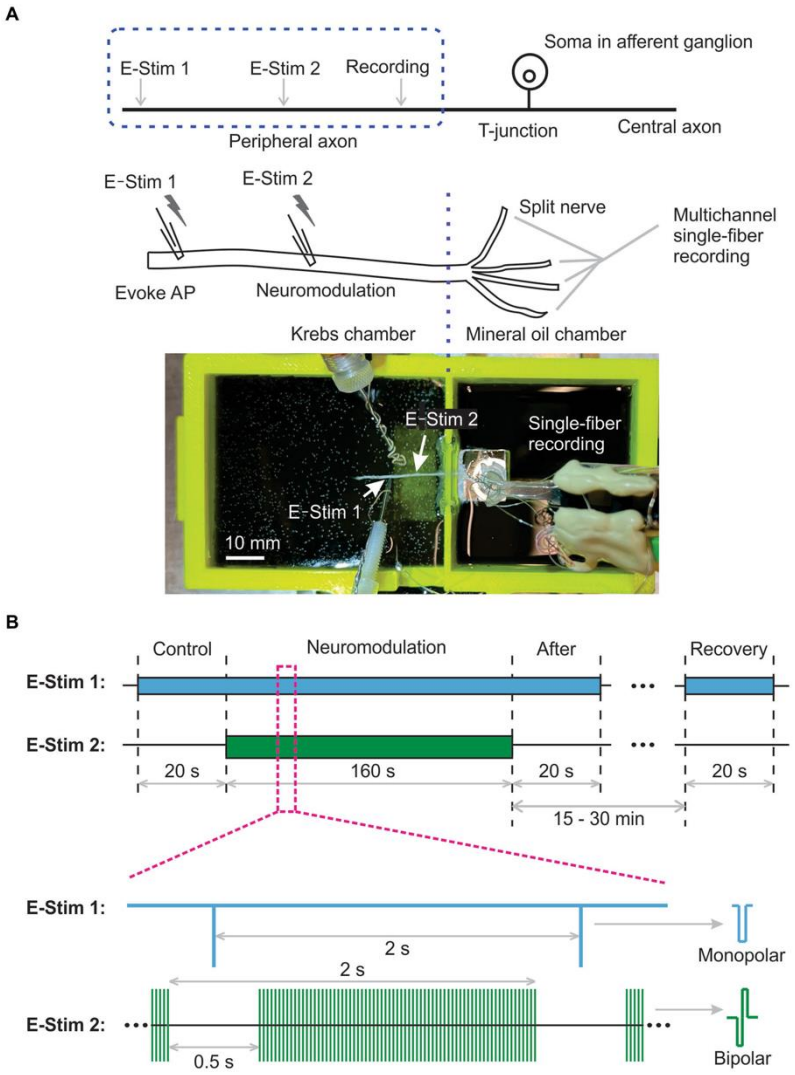
Grace Brandhurst…Vasa D, et al. Presented at: 9th Annual Interdisciplinary Conference on Orthopedic Value-Based Care; April 3, 2025; Dana Point, California.

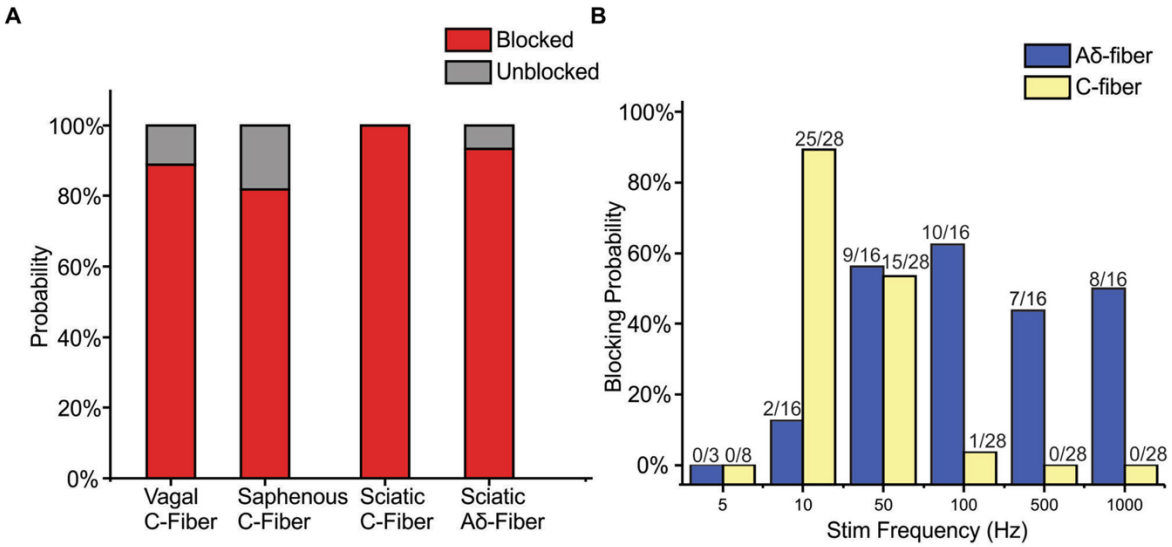
Mechanism of Action

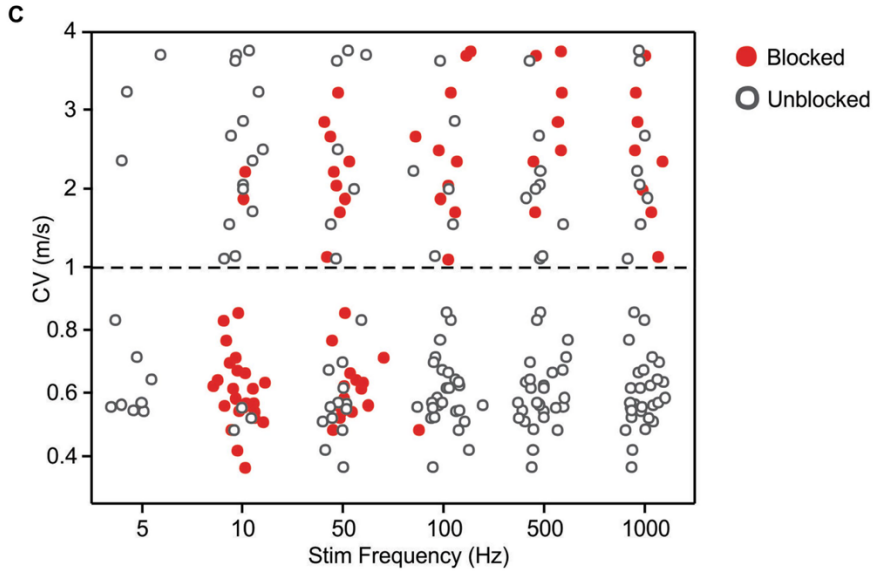
Blocking Aδ- and C-fiber neural transmission by sub-kilohertz peripheral nerve stimulation

Shaopeng Zhang†, Longtu Chen†, Sajjad Rigi Ladez, Ahmet Seferge, Jia Liu and Bin Feng*

Department of Biomedical Engineering, University of Connecticut, Storrs, CT, United States







Zhang S, et al. *Front Neurosci*. 2024:18:1404903.

Innovations for Active Healing

Peripheral Nerve Stimulation

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Appropriateness for PNS

Diagnostic Blocks: Are They Necessary?

Specificity of diagnostic nerve blocks: a prospective, randomized study of sciatica due to lumbosacral spine disease

Richard B. North [a,*], David H. Kidd [a], Marianna Zahurak [b] and Steven Piantadosi [b]

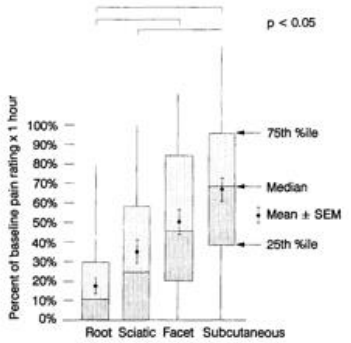


Fig. 3. Sustained relief of pain for at least 1 h was reported by a majority of patients following each of the active nerve blocks, including distal or collateral blocks, but not the control subcutaneous injection.

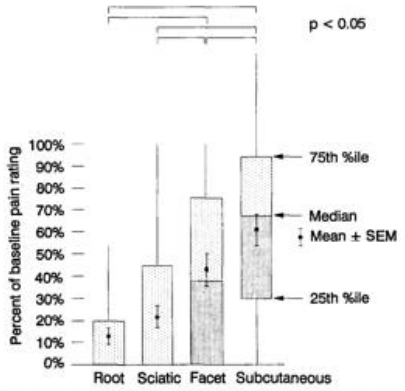
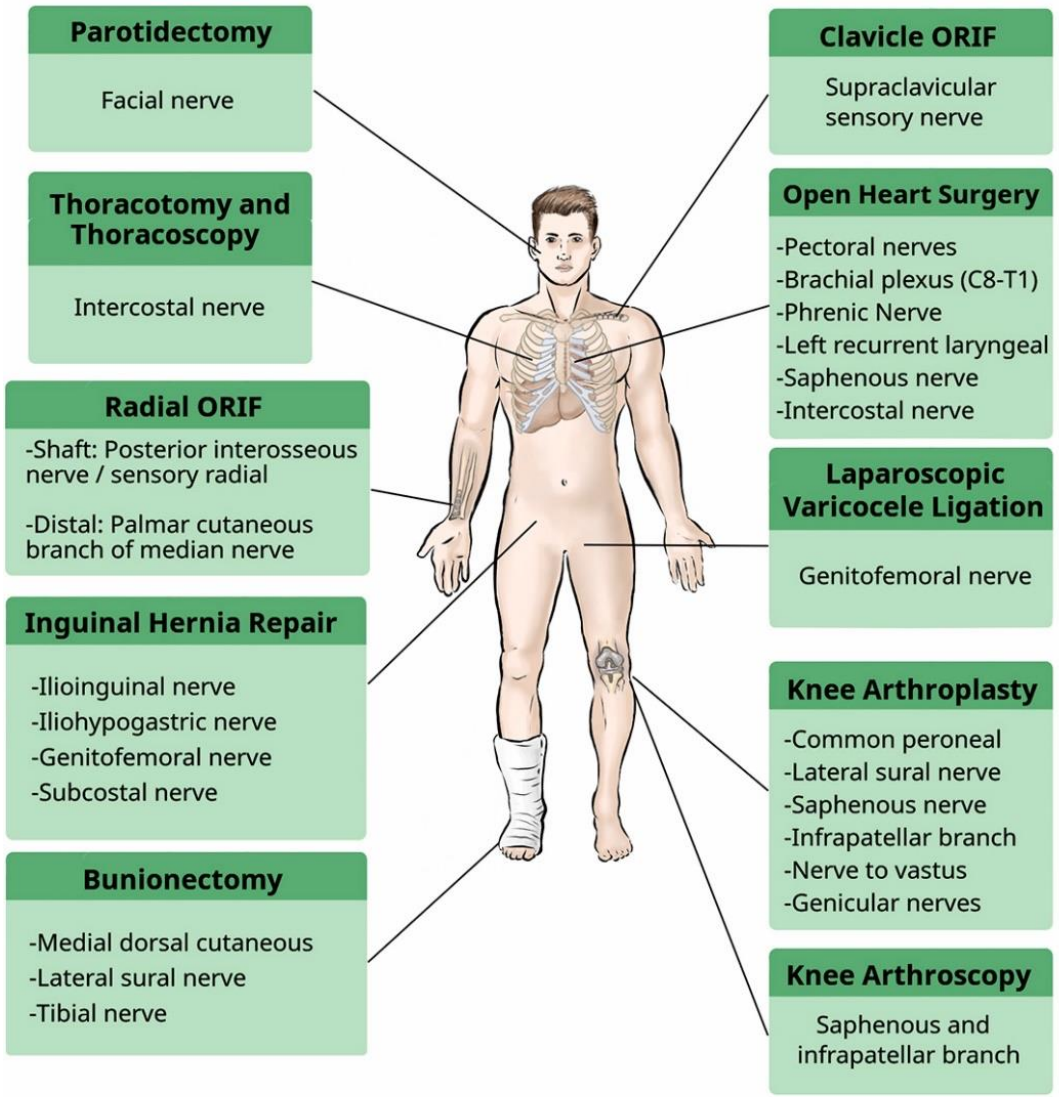


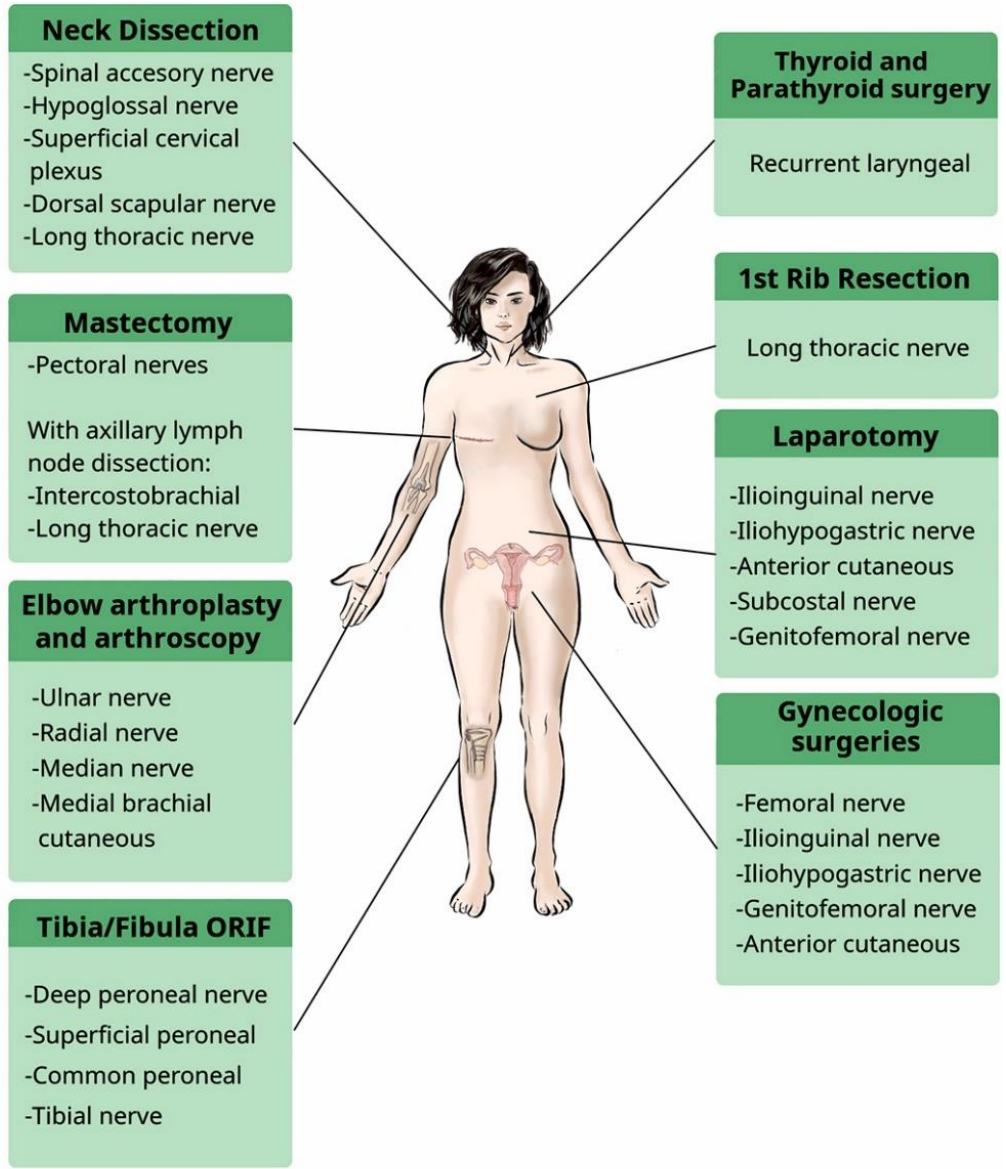
Fig. 2. The fraction of patients reporting at least 50% relief of pain was significantly greater for all 3 'active' nerve blocks than for the control subcutaneous injection (chi square, $P < 0.05$). The results for each of the 4 blocks are displayed here as quartile plots (showing median results and frequency distributions) with superimposed means + SEM of sustained 1-h ratings, as fractions of the baseline pain rating. Most patients reported sustained relief by at least 90% after the root blocks, and by at least 75% after the sciatic nerve blocks – distal or collateral to their known spinal pathology.

- Block response to identify target, not predict efficacy
  - Short-term analgesia with flare
    - Surgery/ablate
  - Long-term analgesia
    - Stimulate
- If we can block it, then we can stimulate it
  - Negative block does not equal no stimulus

MRI = magnetic resonance imaging; EMG = electromyography; NCV = nerve conduction velocity.

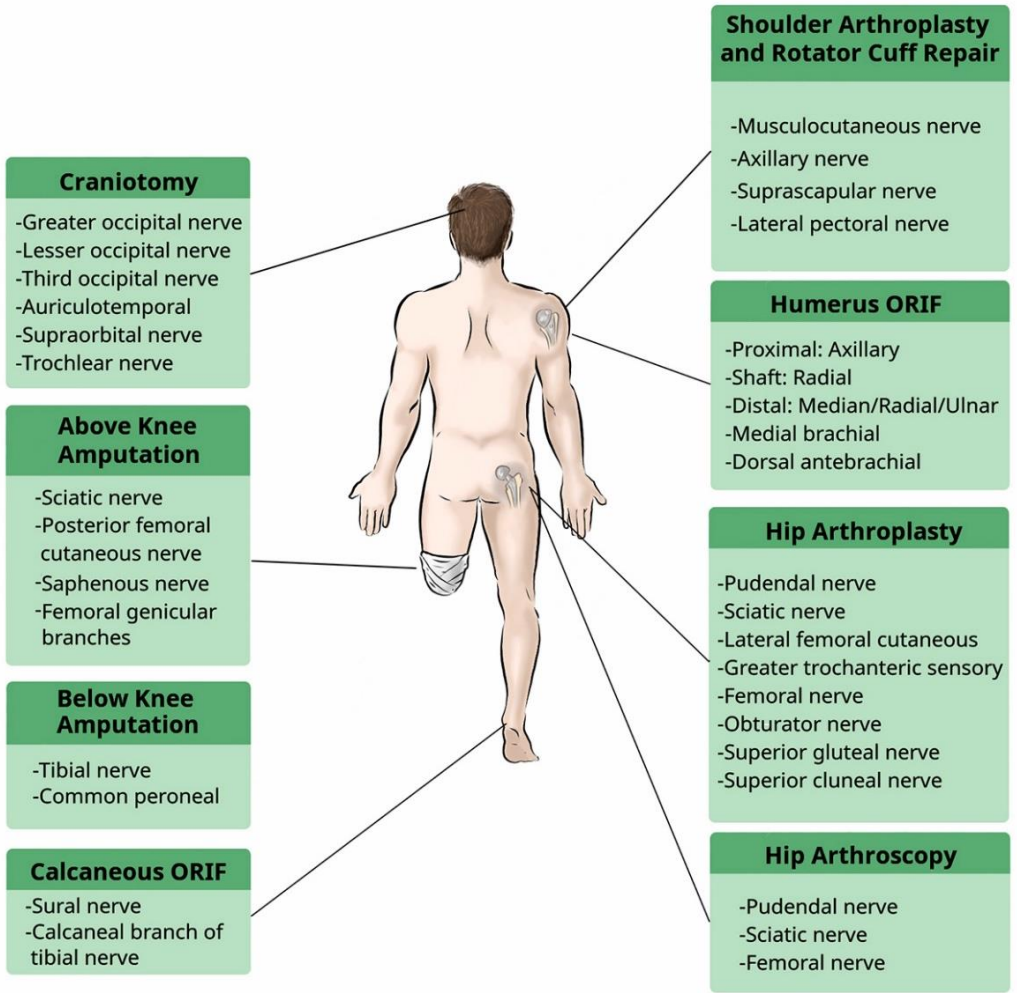
North RB, et al. *Pain*. 1996;65(1):77-85.





ORIF = open reduction and internal fixation.

Terkawi AS, et al. *Anesthesiol Clin*. 2023;41(2):489-502.



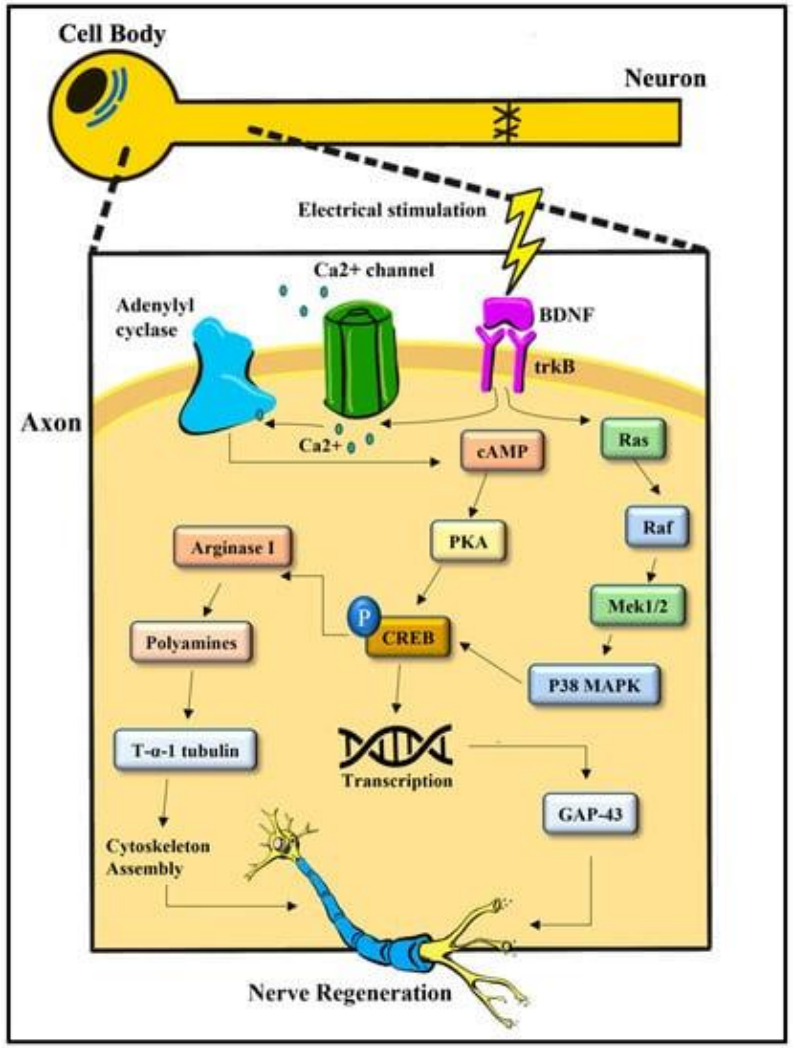
Terkawi AS, et al. *Anesthesiol Clin*. 2023;41(2):489-502.

Peripheral Nerve Stimulators

- Potential advantages of PNS
  - It mostly does not induce sensory, motor, or proprioception deficits
  - It can produce more sustainable benefits than other conventional methods like pulsed radiofrequency neuromodulation and cryotherapy
  - It is less invasive than spinal cord stimulators and easier to remove
  - The patient can control the amount of stimulation (ie, personalized treatment)
  - It may help regenerate injured nerves (ie, therapeutic treatment)
- Different mechanisms of action have been postulated for the effect of PNS
  - Modulation of pain gate control pathway (ie, distract the pain pathway)
  - Intrinsic capacity to regenerate axons into target tissues after nerve injury

Juckett L, et al. *Biomolecules*. 2022;12(12):1856.

Peripheral Nerve Stimulators



- Electrical stimulation (ES) proximal to injury site stimulates ***upregulation of regeneration-associated genes (RAG)*** through a calcium-dependent mechanism
- Increased expression of BDNF and trkB drives increased expression of cAMP, which activates CREB to ***maximize the pro-regenerative axon phenotype***, stimulating axonal sprouting and neuron survival
- ES causes ***calcium*** and sodium to ***flood the neuron***, creating an action potential that propagates retrograde to the cell body, like that which occurs naturally following an injury
- *In vitro* experiments demonstrated that following ES delivery (***20 Hz, 3-5 V, 100 µsec for 1hr***), and subsequent calcium influx, there is an increase in mRNA expression of BDNF and its high-affinity receptor, tyrosine receptor kinase B (trkB)

BDNF = brain-derived neurotrophic factor; cAMP = cyclic adenosine monophosphate; CREB = cAMP response element binding protein; mRNA = messenger ribonucleic acid.

Juckett L, et al. *Biomolecules*. 2022;12(12):1856.

Postsurgical Electrical Stimulation Enhances Recovery following Surgery for Severe Cubital Tunnel Syndrome: A Double-Blind RCT

- 31 patients, 11 surgery, and 20 surgery and PES
- 1hr of 20 Hz following surgery
- Followed for 3yrs
- Motor unit number estimation significantly improved, and grip strength and key pinch strength (3x greater)

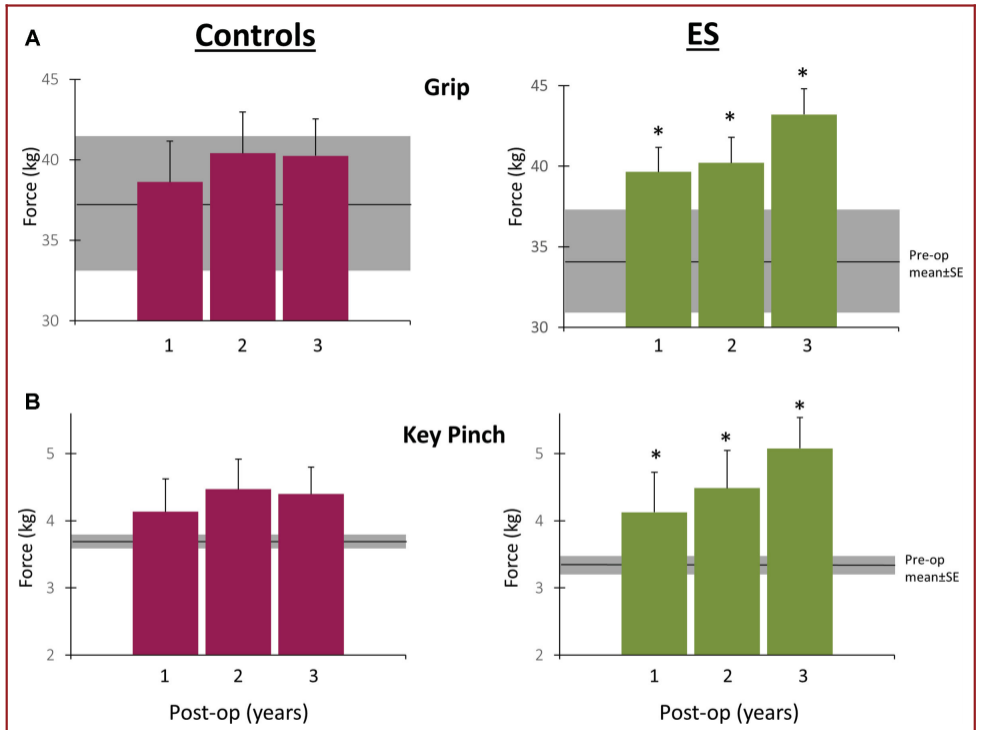


FIGURE 4. *Strength improvements in the hand.* **A**, *Postoperative changes in grip strength in the control group (left panel) compared to that in the electrical stimulation (ES) group (right panel).* **B**, *Postoperative changes in key pinch strength between the 2 groups. Layout is the same as in A. The black lines and grey bars represent mean ± SE at baseline. Asterisks (*) represent statistically significant (P < .05) postoperative improvement.*

PES = postoperative electrical stimulation; SE = standard error.

Power HA, et al. *Neurosurgery*. 2020;86(6):769-777.

PNS for Peripheral Neuropathic Pain

Table 4. Primary Efficacy Outcome; Responders by Randomization Group.

Total number of patients	Treatment ($N = 45$)	Control ($N = 49$)	Difference
94	17/45 (38%)	5/49 (10%)	28%

Table 5. Comparison of Randomization Groups on Number (Percent) of Responders by Anatomic Location.

Anatomic location of the implanted lead	# of patients	Treatment ($N = 45$)
UE	26	4/12 (33%)
LE	27	5/13 (38%)
Trunk	41	8/20 (40%)
Total	94	17/45 (38%)

Table 6. Comparison of Randomization Groups on Average Pain Reduction by Anatomic Location.

Anatomic location of the implanted lead	Treatment			Control	
	N	Mean	SD	*N*	Mean
UE	12	29.2	33.3	14	6.5
LE	13	21.0	30.8	14	1.2
Trunk	20	30.1	30.6	21	0.2
Total	45	27.2	30.9	49	2.3

LE = lower extremity; UE = upper extremity; SD = standard deviation.

Deer T, et al. *Neuromodulation.* 2016;9(1):91-100.

PNS for Focal Mononeuropathy

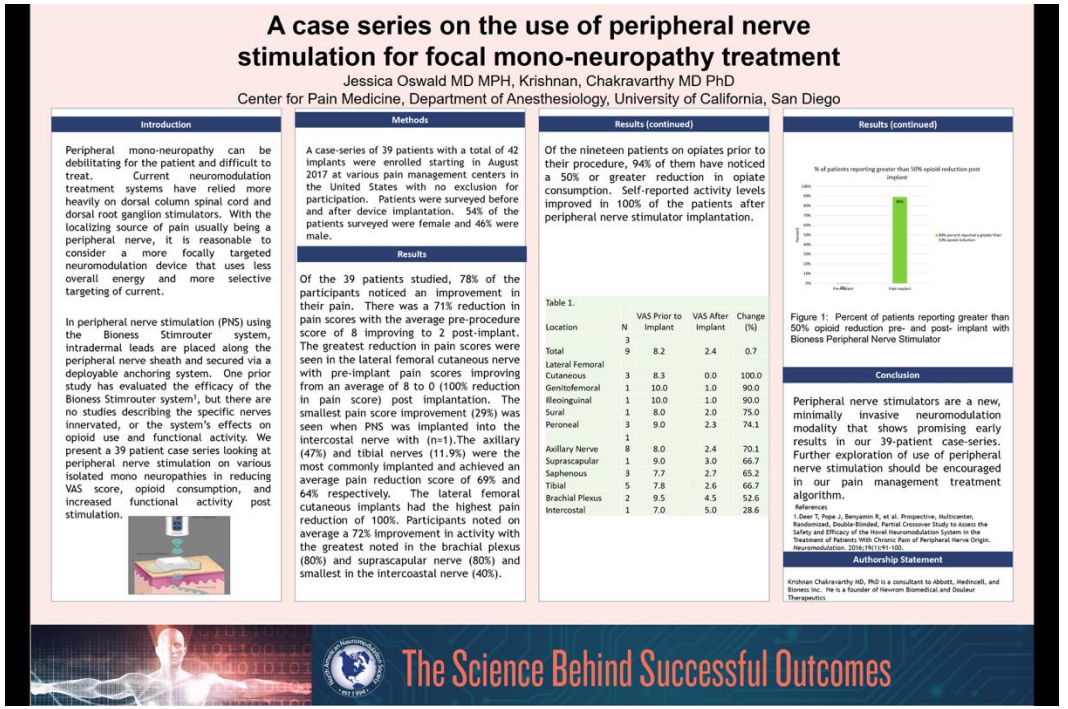
- 39 patients, 11 peripheral nerves, from 18 centers
- Average of 71% pain reduction and 72% increase in activity
- 89% of patients had at least a 50% reduction in opioid use

Table 3. Average change in visual analog scale score by peripheral nerve stimulated.

Location	N	Visual analog scale prior to implant	Visual analog scale after implant	Change (%)
Total	39	8.2	2.4	70.8
Lateral femoral cutaneous	3	8.3	0.0	100.0
Genitofemoral	1	10.0	1.0	90.0
Ilioinguinal	1	10.0	1.0	90.0
Sural	1	8.0	2.0	75.0
Peroneal	3	9.0	2.3	74.1
Axillary nerve	18	8.0	2.4	70.1
Suprascapular	1	9.0	3.0	66.7
Saphenous	3	7.7	2.7	65.2
Tibial	5	7.8	2.6	66.7
Brachial plexus	2	9.5	4.5	52.6
Intercostal	1	7.0	5.0	28.6

Table 4. Percent improvement in activity by peripheral nerve stimulated.

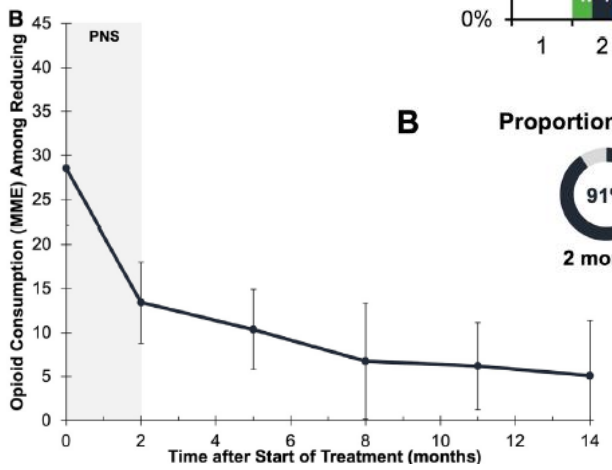
Nerve location	n	Improvement in activity (%)
Total	27	72.0
Axillary	14	73.5
Brachial plexus	1	80.0
Genitofemoral	1	75.0
Ilioinguinal	1	75.0
Intercostal	1	40.0
Lateral femoral cutaneous	2	70.0
Peroneal	2	75.0
Suprascapular	1	80.0
Sural	1	60.0
Tibial	3	73.3

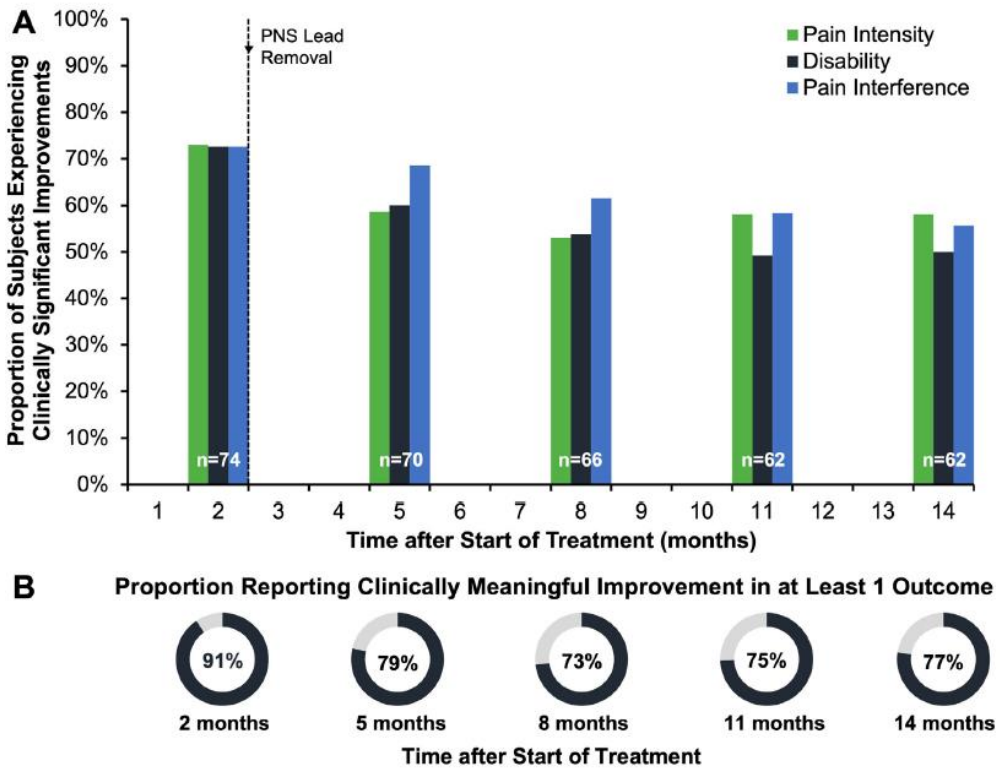


Oswald J, et al. *Pain Manag.* 2019;9(6):551-558. Oswald J, et al. Presented at: 26th NANS Annual Meeting; January 12-15, 2023; Las Vegas, Nevada.

Durable Patient-Reported Outcomes following 60-Day Percutaneous PNS of Medial Branch Nerves

- Multicenter prospective case series of 60-day PNS system for 14 months (74 patients)
- Clinically meaningful improvement in at least 1 outcome
  - Pain intensity, disability, and interference
  - No serious AE





AE = adverse event.

Gilmore GA, et al. *Interv Pain Med.* 2023;2(1):100243.

Four-Year Follow-Up from a Prospective, Multicenter Study of 60-day Medial Branch Nerve Stimulation for the Treatment of Chronic Axial Back Pain

Christopher A. Gilmore, MD,[1] Timothy R. Deer, MD,[2] Mehul J. Desai, MD, MPH,[3] Sean Li, MD,[4] Michael J. DePalma, MD,[5*]

[1]Center for Clinical Research, [2]The Spine and Nerve Center of The Virginias, [3]International Spine, Pain & Performance Center, [4]Premier Pain Centers, [5]Virginia iSpine Physicians

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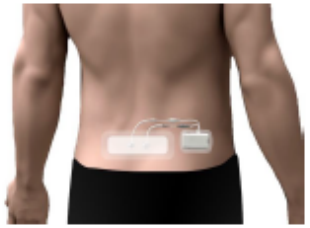
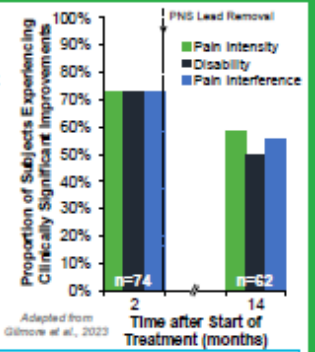
Introduction

Short-term, 60-Day percutaneous PNS treatment has demonstrated sustained reductions in pain and disability at least one year after treatment in patients with chronic low back pain (LBP) patients.[1,2]

- *Prior Prospective Multicenter Study Results*: 14 Months after starting treatment, 77% of subjects (n=48/62) experienced clinically significant improvements in pain, disability, and/or pain interference.





Adapted from Gilmore et al., 2023

Objective: Further explore the potential for long-term durability of relief following 60-day PNS for chronic axial LBP.

Methods

Long-term Follow-Up Survey Eligibility:
Subjects completing prior study were eligible to participate in the follow-up survey if they had clinically significant improvement(s) at final study visit 14 months after start of 60-day medial branch PNS with at least one of:

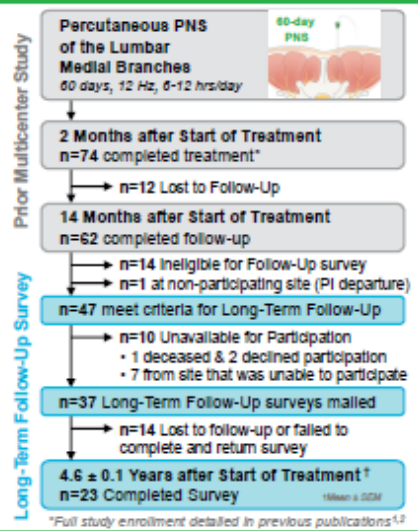
- ≥ 30% reduction in pain intensity (BPI5)
- ≥ 10-pt reduction in disability (ODI)
- ≥ 30% reduction pain interference (BPI9)

Participating Clinical Sites:
6 Sites from the prior study were invited to participate (sites with ≤ 1 subject meeting the survey eligibility criteria were not invited).

- 5 Sites participated (1 declined due to administrative bandwidth)

Survey Data Collection:
Subjects reported levels of pain relief, disability, pain interference, change in quality of life, LBP treatments used since last study visit, and satisfaction with PNS treatment.

- Safety outcomes were not assessed in survey.



*Full study enrollment detailed in previous publications[1,2]

Results

Survey Participant Demographics

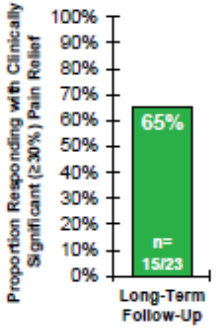
Participants Responding to Survey	23
Body Mass Index (BMI)	29.0 (4.9)
Age (years)	53.8 (13.4)
LBP Duration (years)	13.1 (13.9)
Sex (% Female)	65%
Average LBP Intensity at Baseline	6.6 (1.5)

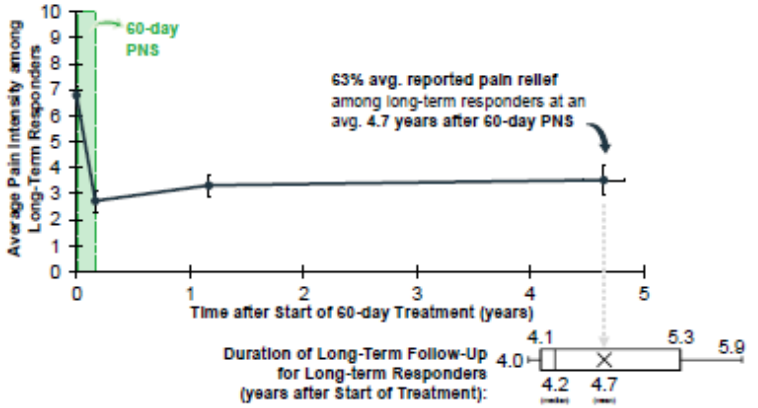
Results are Mean (SD) unless otherwise stated

Majority of Survey Respondents Reported Relief 4+ Years after PNS:

- **65% reported clinically significant (≥30%) relief of their LBP**
- 70% reported highly clinically significant (≥50%) pain relief and/or improvement in disability (≥10-pt ODI)

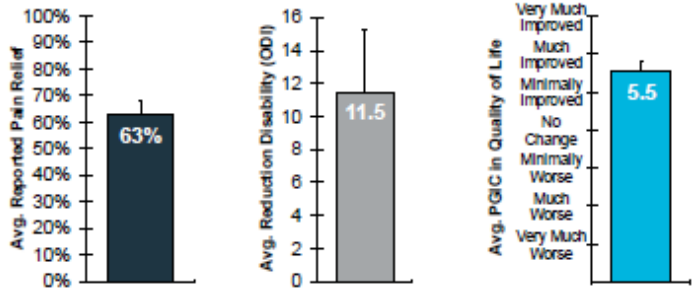
Clinically significant pain relief 4+ years after receiving temporary, 60-day PNS





Duration of Long-Term Follow-Up for Long-term Responders (years after Start of Treatment): 4.0 | 4.1 | 4.2 (median) | 4.7 (mean) | 5.3 | 5.9

Improvements in Pain, Disability, and PGIC Quality of Life



Data plotted as Mean (SEM)

Results Among Long-term Responders at 4+ Years after 60-day PNS

Long-term Healthcare Resource Utilization in Follow-Up

- 4.6+ years after 60-day PNS, a majority (70%, n=16/23) of survey respondents avoided progression to more costly, invasive, and/or destructive LBP pain interventions (*i.e.*, radiofrequency ablation, neurostimulation implant, and/or lumbar surgery) in long-term follow-up:
  - The rate of progression to interventions was 0.1 per subject per year of follow-up.

Use of Other Interventions (i.e., RFA, Neurostim., Surgery) in Long-Term Follow-Up	0.1 procedures per subject · year

- Medication usage by survey respondents at long-term follow-up was most commonly mild analgesics (e.g., NSAIDs). 6 subjects reported weak opioid use.

Conclusions

- Percutaneous PNS treatment provided clinically significant pain relief and/or improvements in disability among a majority of surveyed respondents an average of more than four years after the treatment.
- These results demonstrate that percutaneous PNS can provide remarkably durable outcomes that are often sustained for multiple (4+) years after the 60-day treatment for LBP, which may mitigate the need for more invasive treatment interventions.

References:

[1]Gilmore, C.A., et al. "Durable patient-reported outcomes following 60-day percutaneous peripheral nerve stimulation (PNS) of the medial branch nerves." *IPM* 2.1 (2023): 100243.

[2]Gilmore, CA., et al. "Treatment of chronic axial back pain with 60-day percutaneous medial branch PNS: Primary end point results from a prospective, multicenter study." *Pain Pract* 21.8 (2021): 877-889.

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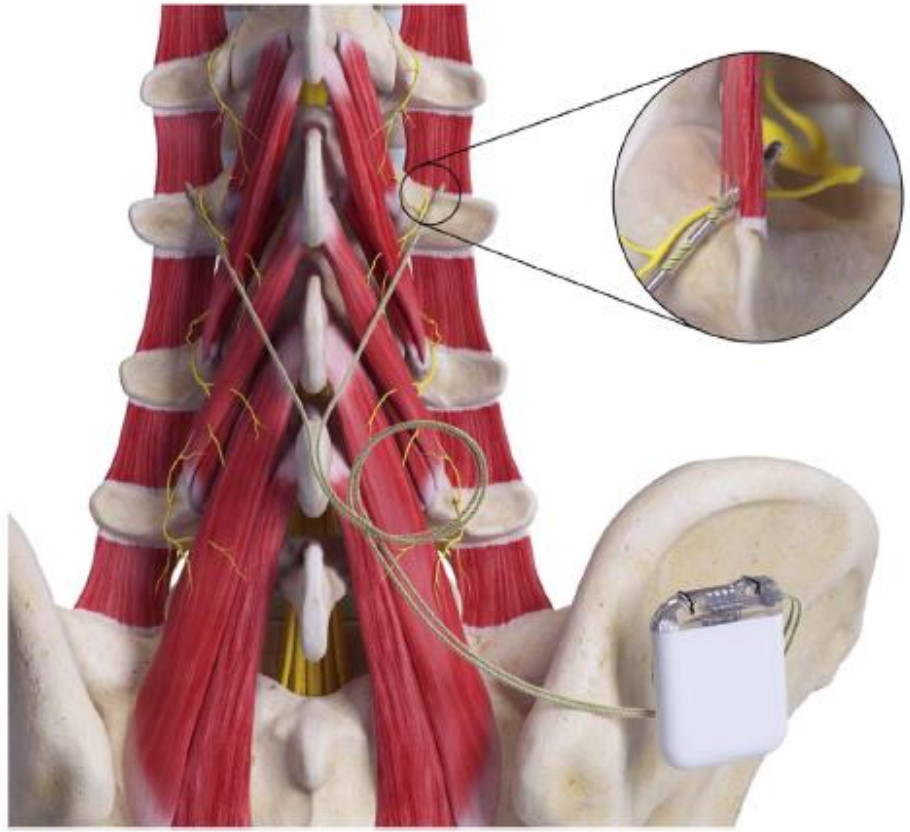
- Gilmore, Deer, Desai, Li, and DePalma have research sponsored by SPR Therapeutics. Gilmore, Deer, Desai and Li are consultants for SPR. Swan, McGee, and Boggs are employees of SPR. Deer, Desai, McGee, and Boggs have stock options in SPR.
- Thank you to site research staff and the Clinical Affairs team at SPR, including Lauren Easley, Sara Anderson, and Rosemary Zang.

BPI = Brief Pain Inventory; ODI = Oswestry Disability Index; PI = principal investigator; PGIC = Patient Global Impression of Change; RFA = radiofrequency ablation; NSAIDs = non-steroid anti-inflammatory drugs.

Gilmore GA, et al. Presented at: 23rd Annual Pain Medicine Meeting (ASRA); November 21-23, 2024; Las Vegas, Nevada.

Five-Year Longitudinal Follow-Up of Restorative Neurostimulation Shows Durability of Effectiveness in Patients with Refractory Chronic LBP Associated with Multifidus Muscle Dysfunction

- Prospective 5yr follow-up of Reactiv8-B pivotal trial
- Permanent multifidus stimulator implant
- 30 min BID
- N=204
- VAS, Oswestry disability, QoL
- VAS 7.3→2.4
- 71.8% had ≥50% reduction
- 46% discontinued opioids, 23% decreased intake
- No migration or IPG replacements



LBP = low back pain; BID = twice daily; VAS = visual analogue scale; QoL = quality of life; IPG = implantable pulse generator.

Gilligan C, et al. *Neuromodulation*. 2024;27(5):930-943.

Case Analysis Comparison

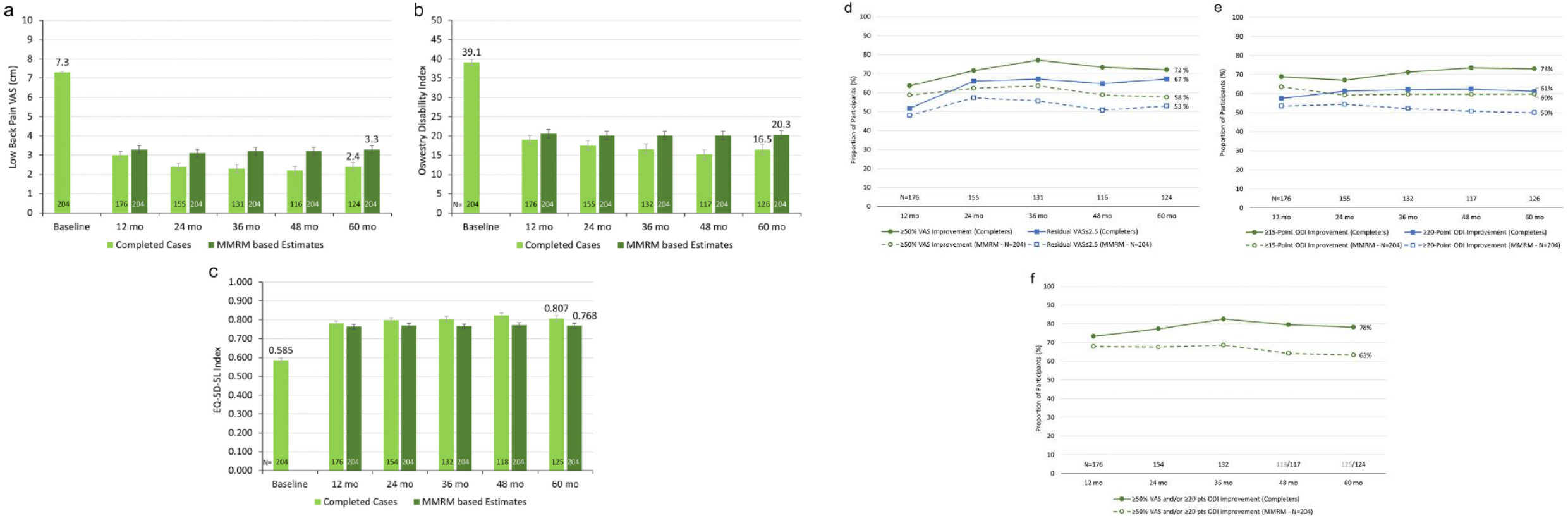


Figure 4. A comparison of the completed-cases analysis for VAS, ODI, and EQ-5D-5L index and the analysis with stratified imputation for missing data following the intention-to-treat principle (N = 204). a–c. The top panels show continuous outcome variables. d–f. The bottom panels show proportion of responders relative to various thresholds. MMRM, mixed model for repeated measures.

MMRM = mixed model for repeated measures.

Gilligan C, et al. *Neuromodulation*. 2024;27(5):930-943.

Head and Neck Pain

- Due to mechanism and efficacy, occipital stimulation has been studied more than other types of neuromodulation
  - Central and peripheral mechanisms
  - Promising for other types of head pain/headache
- ONS currently has most clinical evidence
  - Migraine, chronic headache, and occipital neuralgia
- Prior to newer technologies
  - Using leads made for SCS and internal pulse generator
  - 50-85% improvement
  - High complication rates—migration, erosion—up to 71%
    - IPG difficult

ONS = occipital nerve stimulation.

Salmasi V, et al. *Pain Med.* 2020;21(Suppl 1):S13-S17. Anthony AB, et al. *Pain Physician*. 2019;22(5):447-477. Slide used with permission from Matt Pingree, MD.

PNS of Occipital Nerves for Chronic Migraine

Safety and Efficacy of PNS of Occipital Nerves for Management of Chronic Migraine: Long-Term Results from a Randomized, Multicenter, Double-Blinded, Controlled Study

- 157 patients randomized to active or control for 12 weeks, then open label for 40 weeks
- HA days reduced by 6.7
- Excellent relief reported by 65.4%
- 183 adverse events, with 40.7% requiring surgery and 8.6% requiring hospitalization

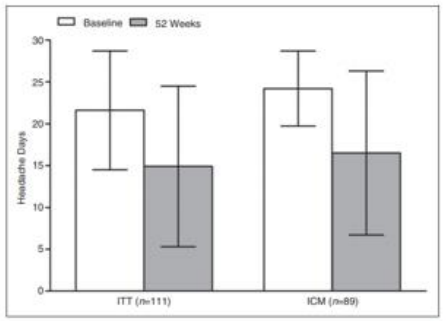


Figure 2. Headache days were significantly reduced by 6.7 (±8.4) days ($p < 0.001$) in the ITT population and by 7.7 (±8.7) days ($p < 0.001$) in the ICM population. After week 12, all patients (active and control) were collapsed into one group. Error bars represent standard deviations.

Occipital Nerve Stimulation for the Treatment of Intractable Chronic Migraine Headache: ONSTIM Feasibility Study

- 75 patients to multisite RCT
- Adjustable or Preset stimulation vs medical management
- Field stimulation using epidural-style leads
- RR (>50% reduction in HA days or VAS decrease >3)
- Con: industry funding and underpowered for efficacy, adverse events (24% migration)

Table 4. Percentage change in number of headache days

		Mean ± SD		
Treatment group	*N*	Baseline	3 months	Percentage change from baseline
Adjustable stimulation	28	22.4 ± 6.3	15.7 ± 10.0	27.0 ± 44.8
Preset stimulation	16	23.4 ± 5.1	21.9 ± 7.8	8.8 ± 28.6
Medically managed	17	23.7 ± 4.3	22.8 ± 6.3	4.4 ± 19.1
Ancillary	5	25.3 ± 5.0	16.3 ± 14.3	39.9 ± 51.0

RCT = randomized controlled trial; RR = relative risk; HA = headache.

Dodick DW, et al. *Cephalalgia*. 2015; 35(4):344-358. Saper JR, et al. *Cephalalgia*. 2011;31(3):271-285.

PNS of Occipital Nerves for Chronic Migraine

Safety and Efficacy of ONS for the Treatment of Chronic Migraines: Randomized, Double-Blind, Controlled, Single-Center Experience

- 20 patients active or control for 12 weeks, then open label for 40 weeks
- HA days reduced by 8.51
- 35% had 50% reduction in HA days (0% in control group)
- 15/20 (75%) patients had adverse event; 45% hardware-related

Table 2. Patients with 30% and 50% Average Daily Visual Analog Scale (VAS) Reduction and No Increase in Headache Duration or Frequency

	Control (n = 6)	Active (n = 14)	All (N = 20)	P value
30% Reduction in VAS (n [%])				
12 weeks	4 (20%)	12 (60%)	16 (80%)	0.373*
52 weeks			12 (60%)	
50% Reduction in VAS (n [%])				
12 weeks	0 (0%)	4 (29%)	4 (20%)	0.018*
52 weeks			7 (35%)	

ONS Stimulation for Chronic Migraine: A Randomized Trial

- 30 patients for migraine and medication overuse
- Crossover at 4 weeks
- Significant difference P<.05 in HA intensity and frequency
- Con: Single center, unblinded, small, lack of control beyond 8 weeks

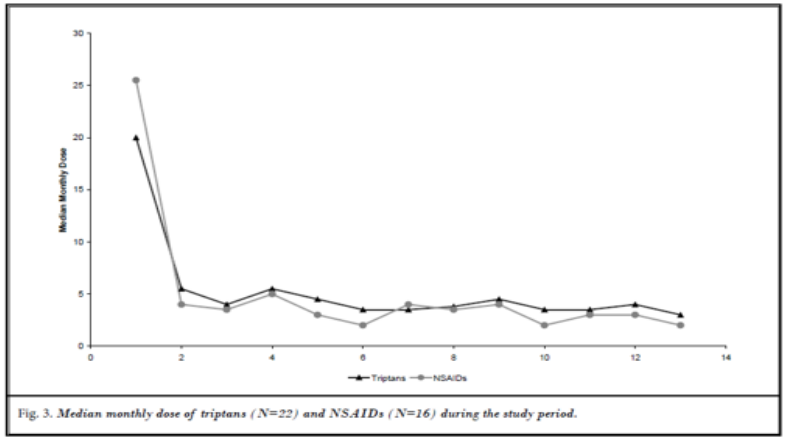


Fig. 3. *Median monthly dose of triptans (N=22) and NSAIDs (N=16) during the study period.*

Mekhail NA, et al. *Pain Pract*. 2017;17(5):669-677. Serra G, et al. *Pain Physician*. 2012;15(3):245-253.

Safety and Efficacy of ONS for Attack Prevention in Medically Intractable Chronic Cluster Headache (ICON)

Summary

- Background occipital nerve stimulation (ONS) has shown promising results in small, uncontrolled trials in patients with medically intractable chronic cluster headache (MICCH)
- We aimed to establish whether ONS could serve as an effective treatment for patients with MICCH

Methods and Results

- Randomized, double-blind, multi-center, Phase 3, electrical dose-controlled trial
- 24 weeks of occipital nerve stimulation at either 100% or 30% of the individually determined range between paraesthesia threshold and near-discomfort (double-blind study phase)
- 131 patients; 65 (50%) patients to 100% ONS and 66 (50%) to 30% ONS
- 100% ONS reduced weekly HA frequency from 17-58 to 9.50, at 21-24 weeks; the 30% ONS group from 15.00 to 6.75
- 17 with 100% ONS and 8 with 30% ONS were labelled as serious, given they required brief hospital admission for minor hardware-related issues
- The most common adverse events were local pain, impaired wound healing, neck stiffness, and hardware damage
- This study was interpreted as positive, although there was no sham control

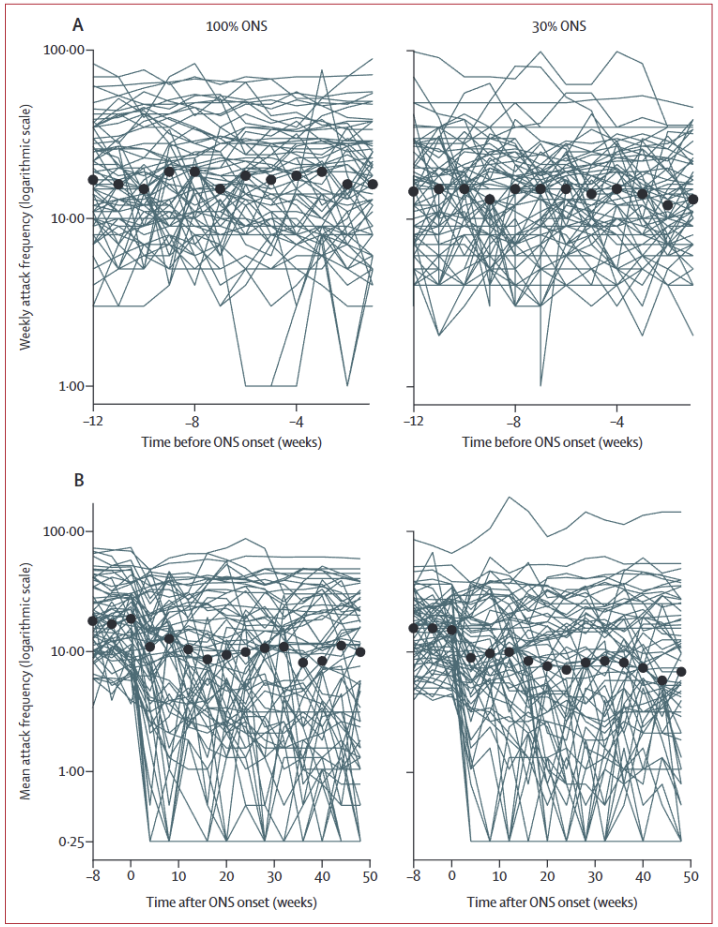


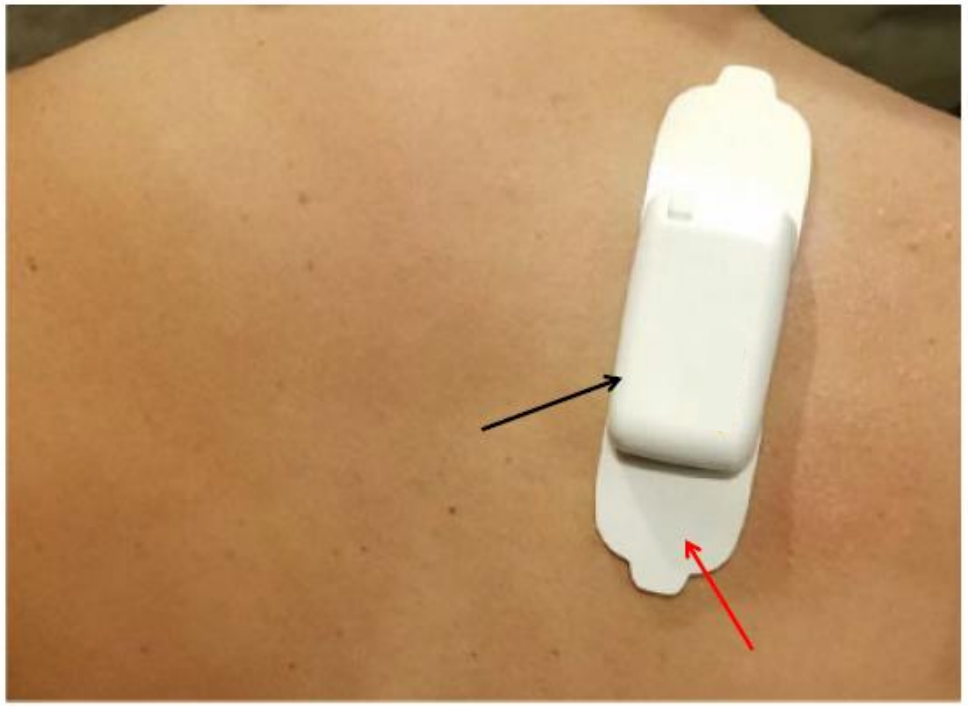
Figure 3: Attack frequency at baseline (A) and throughout the study period (B)

Wilbrink LA, et al. *Lancet Neurol*. 2021;20(7):515-525.

PNS for Occipital Neuralgia

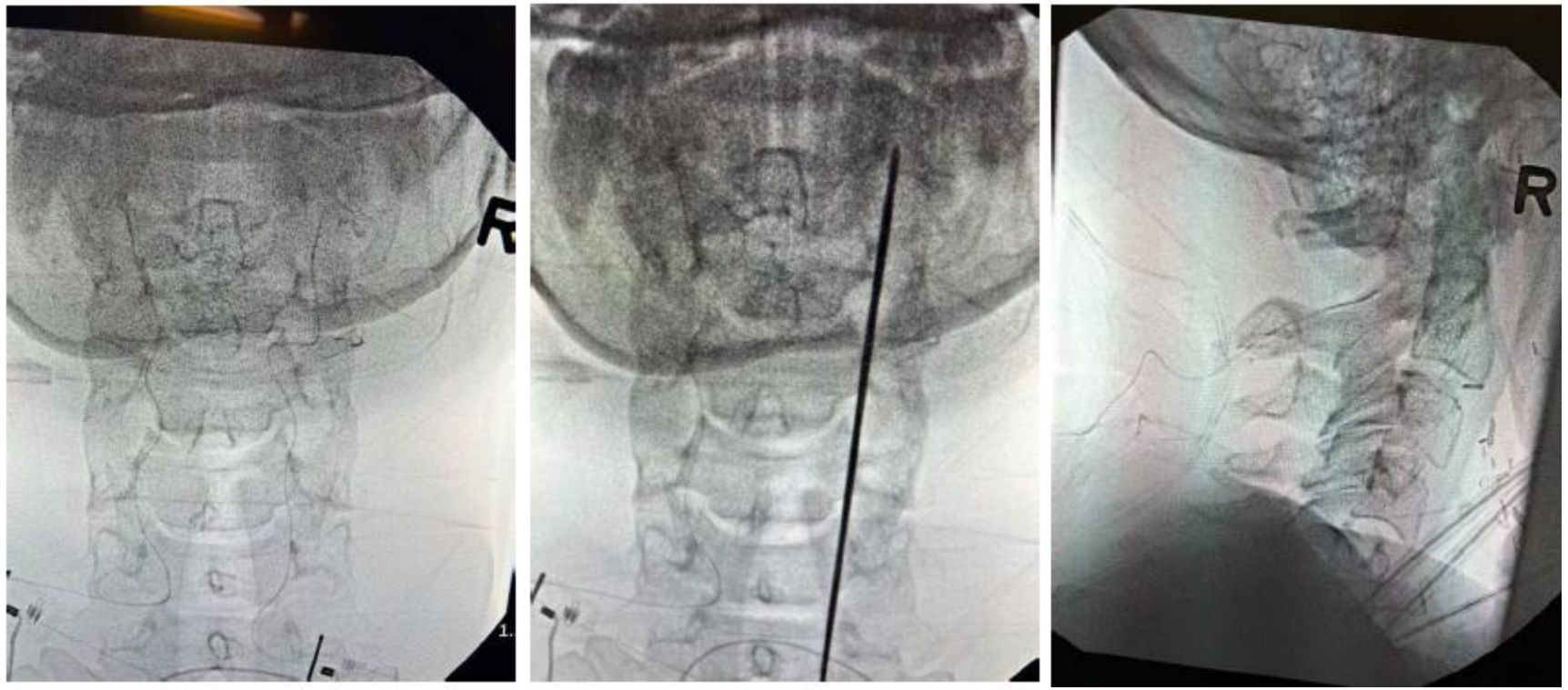
- US-guided lead placement
- After successful block
- 5 leads implanted in 3 patients
  - 2 bilateral

	Age, y, and Sex	Laterality	Secondary Diagnosis*	Other Comorbidities	Time to Last Follow-up, mo	Percent Pain Relief	Stimulation Use, h/d
1	62 male	Right	Migraine headache	History of sinus surgery, hypertension, obstructive sleep apnea, coronary artery disease	16	25	8
2	63 male†	Left	Migraine headache	History of sinus surgery, hypertension, obstructive sleep apnea, coronary artery disease	8	25	8
3	29 female	Right	Cervicogenic headache	None	6	100	7
4	70 female	Bilateral	Migraine headache	History of lung cancer, chronic obstructive pulmonary disease, bilateral hip and right knee arthroplasty	6	70	24



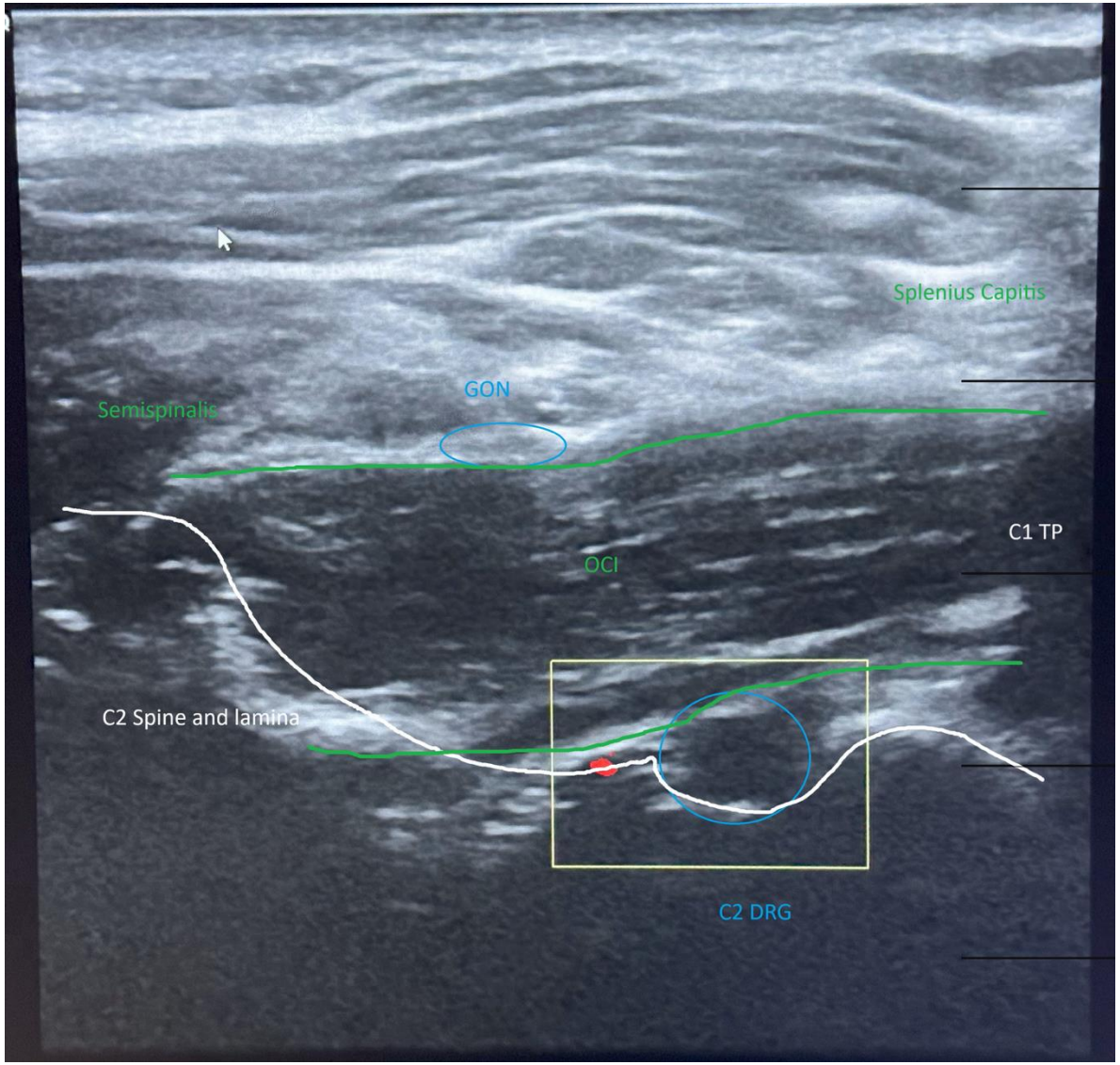
***Primary diagnosis for all these patients is "occipital neuralgia"; †Same patient as number 1.**
US = ultrasound.
Salmasi V, et al. *Pain Med*. 2020;21(Suppl 1):S13-S17.

Proximal Occipital Nerve Stimulation



Doppler Ultrasound

- Doppler confirms no vertebral artery near target, and black circle is nerve, not vessel

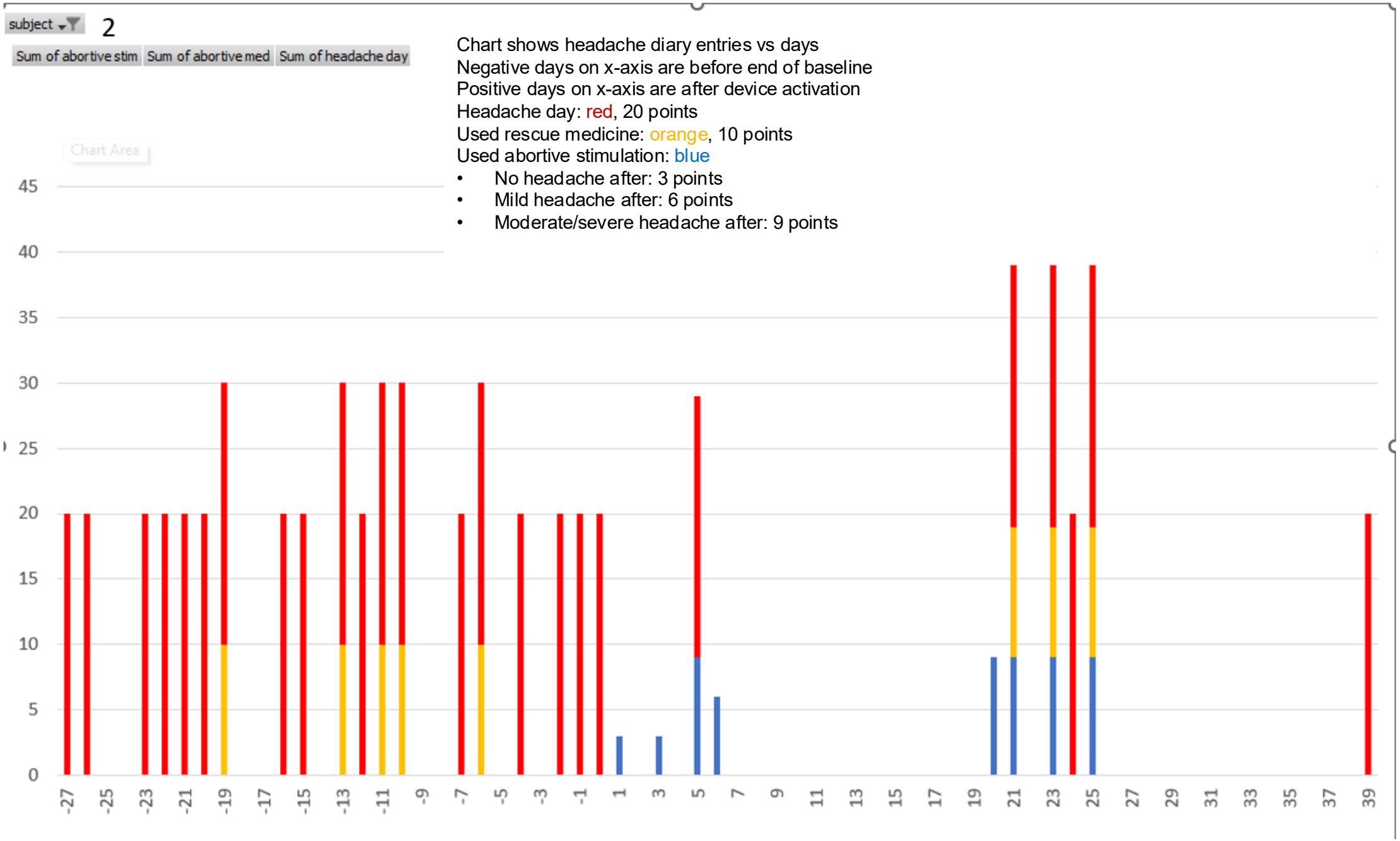


GON = greater occipital nerve; OCI = osteitis condensans ilii; TP = transverse process; DRG = dorsal root ganglion.

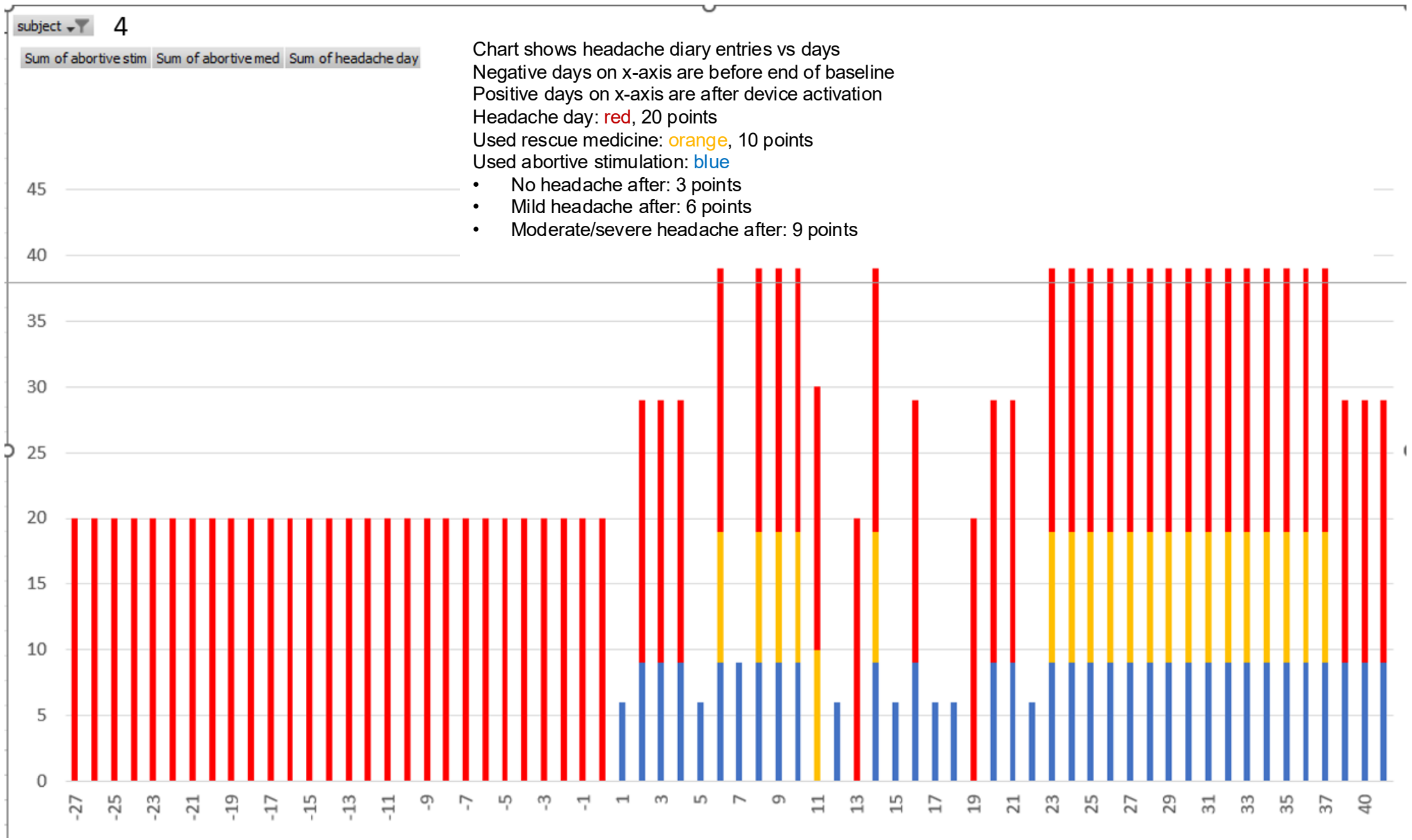
PNS of the Greater Occipital Nerve Feasibility and Efficacy As Both Prophylactic and Abortive Therapy for Migraine

- Xiang Qian, PhD, MD, is PI—no funding
- Meredith Barad and Einar Ottestad are co-investigators
- GON blocks can treat migraine HAs in the short term
- Will PNS provide extended relief?
- Primary endpoint abortive: Percentage of abortive stimulations that result in minimal HA after 2 hrs at 1, 2, and 3 months
- Primary endpoint prophylactic: Percentage of days with mod/sev HA
- Secondary: Percent of days with abortive medication usage; PROMIS Profile CAT v1.0 and Migraine-Specific QOL (MSQOL); responder rates

PROMIS = patient-reported outcomes measurement information system; CAT = computer adaptive test.

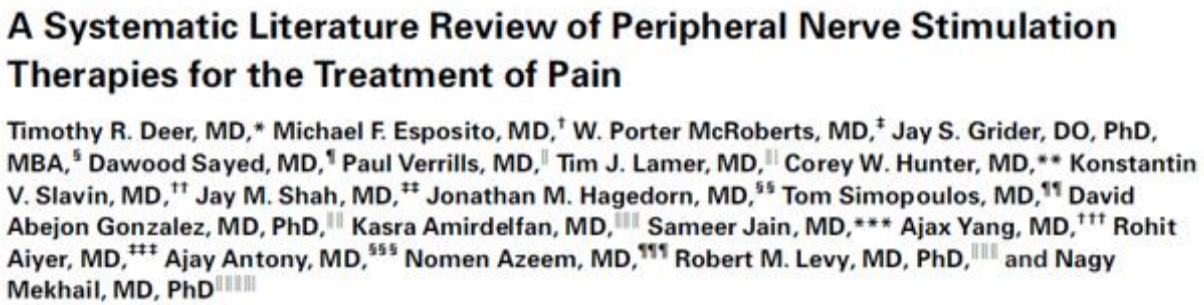


Ottestad E. Unpublished.



Ottestad E. Unpublished.

Systematic Reviews



A Systematic Literature Review of Peripheral Nerve Stimulation Therapies for the Treatment of Pain

Timothy R. Deer, MD,* Michael F. Esposito, MD,† W. Porter McRoberts, MD,‡ Jay S. Grider, DO, PhD, MBA,§ Dawood Sayed, MD,¶ Paul Verrills, MD,‖ Tim J. Lamer, MD,‖ Corey W. Hunter, MD,** Konstantin V. Slavin, MD,†† Jay M. Shah, MD,‡‡ Jonathan M. Hagedorn, MD,§§ Tom Simopoulos, MD,¶¶ David Abejon Gonzalez, MD, PhD,‖‖ Kasra Amirdelfan, MD,‖‖ Sameer Jain, MD,*** Ajax Yang, MD,††† Rohit Aiyer, MD,‡‡‡ Ajay Antony, MD,§§§ Nomen Azeem, MD,¶¶¶ Robert M. Levy, MD, PhD,‖‖‖ and Nagy Mekhail, MD, PhD‖‖‖‖

REVIEW

Peripheral Nerve Stimulation for Chronic Pain: A Systematic Review of Effectiveness and Safety

Standiford Helm · Nikita Shirsat · Aaron Calodney · Alaa Abd-Elsayed · David Kloth · Amol Soin · Shalini Shah · Andrea Trescot

Systematic Review

Peripheral Nerve Stimulation in Pain Management: A Systematic Review

Jijun Xu, MD, PhD[1-3], Zhuo Sun, MD[4], Jiang Wu, MD[5], Maunak Rana, MD[6], Joshua Garza, MD[6], Alyssa C. Zhu, MD[7], Krishnan V. Chakravarthy, MD, PhD[7], Alaa Abd-Elsayed, MD[8], Ellen Rosenquist, MD[9], Hersimren Basi, MD[1], Paul Christo, MD[10], and Jianguo Cheng, MD, PhD[1,11]

REVIEW

Evidence-Based Clinical Guidelines from the American Society of Pain and Neuroscience for the Use of Implantable Peripheral Nerve Stimulation in the Treatment of Chronic Pain

Natalie Strand[1], Ryan S D'Souza[2], Jonathan M Hagedorn[3], Scott Pritzlaff[4], Dawood Sayed[5], Nomen Azeem[6], Alaa Abd-Elsayed[7], Alexander Escobar[8], Mark A Huntoon[9], Christopher M Lam[5], Timothy R Deer[10]

Deer TR, et al. *Pain Med*. 2020;21(8):1590-1603. Helm S, et al. *Pain Ther*. 2021;10(2):985-1002. Xu J, et al. *Pain Physician*. 2021;24(2):E131-E152. Strand N, et al. *J Pain Res*. 2022;15:2483-2504.

Appropriateness for PNS

Pain Medicine, 21(8), 2020, 1590–1603
doi: 10.1093/pm/pnaa030
Review Article

OXFORD

A Systematic Literature Review of Peripheral Nerve Stimulation Therapies for the Treatment of Pain

Timothy R. Deer, MD,* Michael F. Esposito, MD,† W. Porter McRoberts, MD,‡ Jay S. Grider, DO, PhD, MBA,§ Dawood Sayed, MD,¶ Paul Verrills, MD,‖ Tim J. Lan
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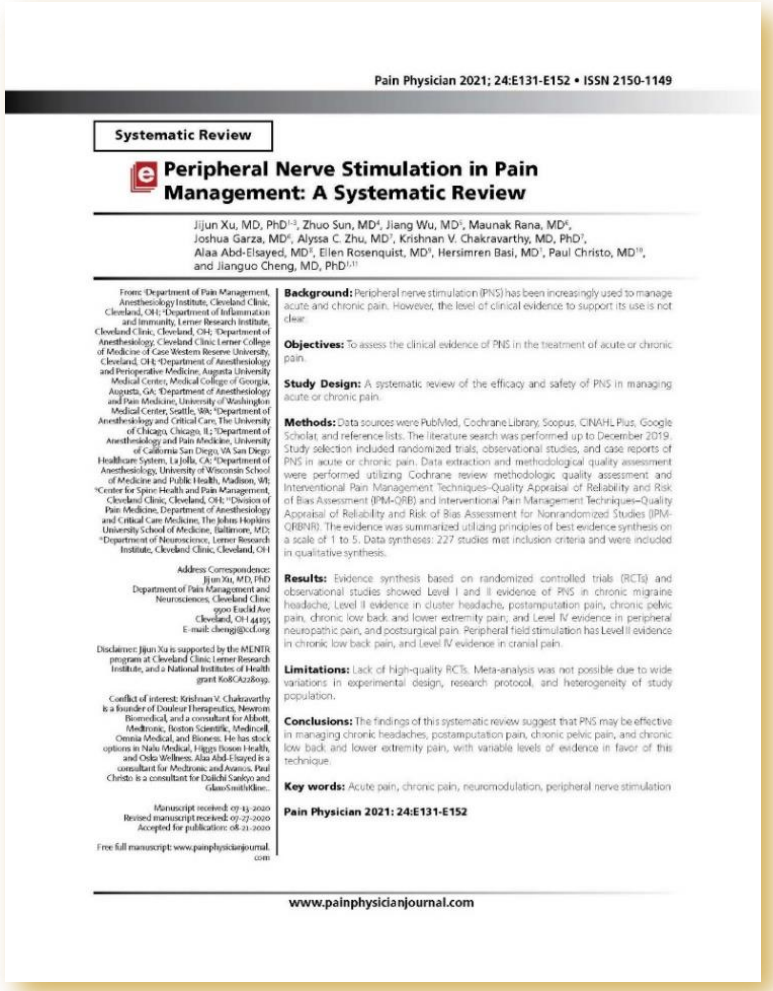
Aiyer, MD,‡‡‡ Ajay Antony, MD,§§§ Nomen Azeem, MD,¶¶¶
Mekhail, MD, PhD‖‖‖‖

Level I	Strong	Evidence obtained from multiple relevant high-quality randomized controlled trials for effectiveness or Evidence obtained from multiple relevant high-quality observational studies or large case series for assessment of preventive measures, adverse consequences, and effectiveness of other measures
Level II	Moderate	Evidence obtained from at least one relevant high-quality randomized controlled trial or multiple relevant moderate- or low-quality randomized controlled trials or Evidence obtained from at least two high-quality relevant observational studies or large case series for assessment of preventive measures, adverse consequences, and effectiveness of other measures
Level III	Fair	Evidence obtained from at least one relevant high-quality nonrandomized trial or observational study with multiple moderate- or low-quality observational studies or At least one high-quality relevant observational study or large case series for assessment of preventive measures, adverse consequences, and effectiveness of other measures
Level IV	Limited	Evidence obtained from multiple moderate- or low-quality relevant observational studies or Evidence obtained from moderate-quality observational studies or large case series for assessment of preventive measures, adverse consequences, and effectiveness of other measures
Level V	Consensus based	Opinion or consensus of a large group of clinicians and/or scientists for effectiveness, as well as to assess preventive measures, adverse consequences, and effectiveness of other measures

- Level I for occipital nerve stimulation
  - 5 RCTs
- Level I for LBP
  - 3 RCTs
- Level II for sphenopalatine ganglion
  - 1 RCT
- Level II for post-stroke shoulder pain
  - 1 RCT
- Level II for mononeuropathy of trunk or extremities
  - 1 RCT
- Level III for posterior tibial nerve stimulation
  - 3 RCTs

Deer TR, et al. *Pain Med*. 2020;21(8):1590-1603.

PNS in Pain Management



Pain Physician 2021; 24:E131-E152 • ISSN 2150-1149

Systematic Review

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Conflict of interest: Krishnan V. Chakravarthy is a founder of Doulour Therapeutics, Newron Biomedical, and a consultant for Abbott, Medtronic, Boston Scientific, Medincell, Omnia Medical, and Bioness. He has stock options in Nalu Medical, Higgs Boson Health, and Ocka Wellness. Alaa Abd-Elsayed is a consultant for Medtronic and Avanos. Paul Christo is a consultant for Daiichi Sankyo and GlaxoSmithKline.

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Free full manuscript: www.painphysicianjournal.com

Background: Peripheral nerve stimulation (PNS) has been increasingly used to manage acute and chronic pain. However, the level of clinical evidence to support its use is not clear.

Objectives: To assess the clinical evidence of PNS in the treatment of acute or chronic pain.

Study Design: A systematic review of the efficacy and safety of PNS in managing acute or chronic pain.

Methods: Data sources were PubMed, Cochrane Library, Scopus, CINAHL Plus, Google Scholar, and reference lists. The literature search was performed up to December 2019. Study selection included randomized trials, observational studies, and case reports of PNS in acute or chronic pain. Data extraction and methodological quality assessment were performed utilizing Cochrane review methodologic quality assessment and Interventional Pain Management Techniques-Quality Appraisal of Reliability and Risk of Bias Assessment (IPM-QRB) and Interventional Pain Management Techniques–Quality Appraisal of Reliability and Risk of Bias Assessment for Nonrandomized Studies (IPM-QRBNR). The evidence was summarized utilizing principles of best evidence synthesis on a scale of 1 to 5. Data syntheses: 227 studies met inclusion criteria and were included in qualitative synthesis.

Results: Evidence synthesis based on randomized controlled trials (RCTs) and observational studies showed Level I and II evidence of PNS in chronic migraine headache; Level II evidence in cluster headache, postamputation pain, chronic pelvic pain, chronic low back and lower extremity pain; and Level IV evidence in peripheral neuropathic pain, and postsurgical pain. Peripheral field stimulation has Level II evidence in chronic low back pain, and Level IV evidence in cranial pain.

Limitations: Lack of high-quality RCTs. Meta-analysis was not possible due to wide variations in experimental design, research protocol, and heterogeneity of study population.

Conclusions: The findings of this systematic review suggest that PNS may be effective in managing chronic headaches, postamputation pain, chronic pelvic pain, and chronic low back and lower extremity pain, with variable levels of evidence in favor of this technique.

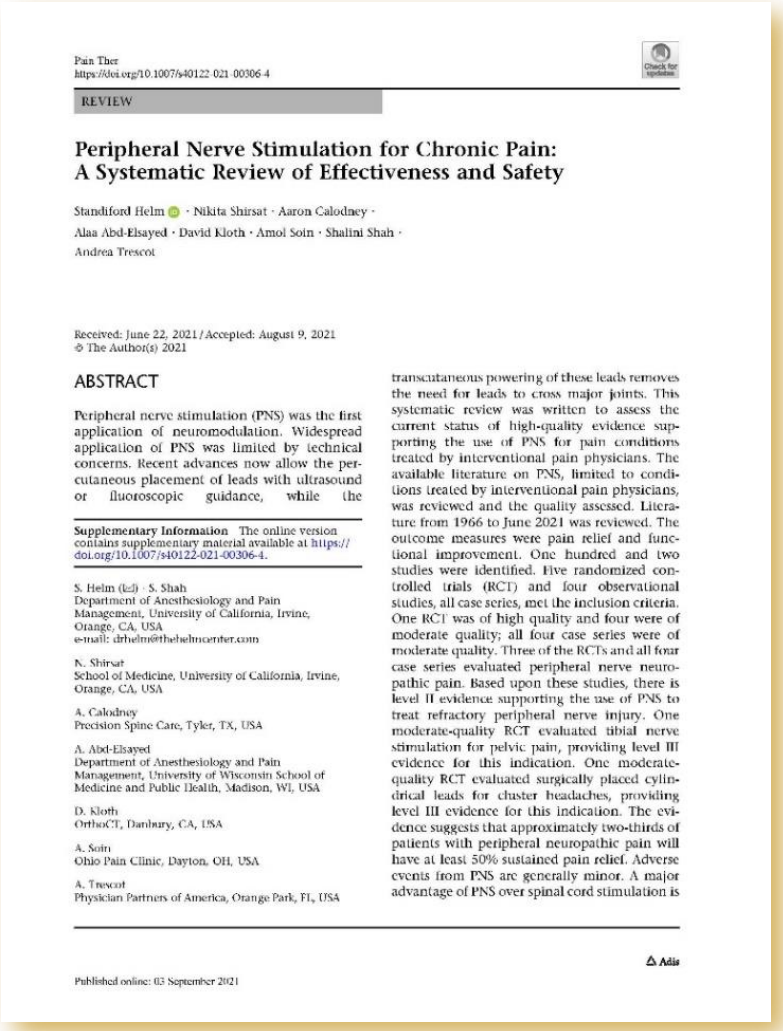
Key words: Acute pain, chronic pain, neuromodulation, peripheral nerve stimulation

Pain Physician 2021: 24:E131-E152

- Level I evidence in chronic migraine
- Level II evidence in cluster HA, PAP, CPP, CLBP, lower extremity pain
- Level IV in peripheral neuropathic pain and post-surgical pain

PAP = post-amputation pain; CPP = chronic pelvic pain; CLBP = chronic LBP.
Xu J, et al. *Pain Physician*. 2021;24(2):E131-E152.

PNS for Chronic Pain



Pain Ther
https://doi.org/10.1007/s40122-021-00306-4

REVIEW

Peripheral Nerve Stimulation for Chronic Pain: A Systematic Review of Effectiveness and Safety

Standiford Helm · Nikita Shirsat · Aaron Calodney · Alaa Abd-Elsayed · David Kloth · Amol Soin · Shalini Shah · Andrea Trescot

Received: June 22, 2021 / Accepted: August 9, 2021

ABSTRACT

Peripheral nerve stimulation (PNS) was the first application of neuromodulation. Widespread application of PNS was limited by technical concerns. Recent advances now allow the percutaneous placement of leads with ultrasound or fluoroscopic guidance, while (the transcutaneous powering of these leads removes the need for leads to cross major joints. This systematic review was written to assess the current status of high-quality evidence supporting the use of PNS for pain conditions treated by interventional pain physicians. The available literature on PNS, limited to conditions treated by interventional pain physicians, was reviewed and the quality assessed. Literature from 1966 to June 2021 was reviewed. The outcome measures were pain relief and functional improvement. One hundred and two studies were identified. Five randomized controlled trials (RCT) and four observational studies, all case series, met the inclusion criteria. One RCT was of high quality and four were of moderate quality; all four case series were of moderate quality. Three of the RCTs and all four case series evaluated peripheral nerve neuropathic pain. Based upon these studies, there is level II evidence supporting the use of PNS to treat refractory peripheral nerve injury. One moderate-quality RCT evaluated tibial nerve stimulation for pelvic pain, providing level III evidence for this indication. One moderate-quality RCT evaluated surgically placed cylindrical leads for cluster headaches, providing level III evidence for this indication. The evidence suggests that approximately two-thirds of patients with peripheral neuropathic pain will have at least 50% sustained pain relief. Adverse events from PNS are generally minor. A major advantage of PNS over spinal cord stimulation is

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s40122-021-00306-4.

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Published online: 03 September 2021

- 102 studies identified 1966-2021
- 5 RCTs, 4 observational
- Level II evidence to use PNS to treat peripheral nerve pain
- 2/3 of patients have at least 50% improvement
- “Therefore, there is level II evidence supporting PNS in the treatment of refractory peripheral nerve neuropathic pain.”

Helm S, et al. *Pain Ther*. 2021;10(2):985-1002.

ASPN Guideline

Open Access Full Text Article REVIEW

Evidence-Based Clinical Guidelines from the American Society of Pain and Neuroscience for the Use of Implantable Peripheral Nerve Stimulation in the Treatment of Chronic Pain

Natalie Strand[1], Ryan S D'Souza[2], Jonathan M Hagedorn[3], Scott Pritzlaff[4], Dawood Sayed[5], Nomen Azeem[6], Alaa Abd-Elsayed[7], Alexander Escobar[8], Mark A Huntoon[9], Christopher M Lam[5], Timothy R Deer[10]

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Abstract: The objective of this peripheral nerve stimulation consensus guideline is to add to the current family of consensus practice guidelines and incorporate a systematic review process. The published literature was searched from relevant electronic databases, including PubMed, Scopus, Cochrane Central Register of Controlled Trials, and Web of Science from database inception to March 29, 2021. Inclusion criteria encompassed studies that described peripheral nerve stimulation in patients in terms of clinical outcomes for various pain conditions, physiological mechanism of action, surgical technique, technique of placement, and adverse events. Twenty randomized controlled trials and 33 prospective observational studies were included in the systematic review process. There is Level I evidence supporting the efficacy of PNS for treatment of chronic migraine headaches via occipital nerve stimulation; chronic hemiplegic shoulder pain via stimulation of nerves innervating the trapezius, supraspinatus, and deltoid muscles; failed back surgery syndrome via subcutaneous peripheral field stimulation; and lower extremity neuropathic and lower extremity post-amputation pain. Evidence from current Level I studies combined with newer technologies facilitating less invasive and easier electrode placement make peripheral nerve stimulation an attractive alternative for managing patients with complex pain disorders. Peripheral nerve stimulation should be used judiciously as an adjunct for chronic and acute postoperative pain following adequate patient screening and positive diagnostic nerve block or stimulation trial.

Keywords: post-amputation pain, low back pain, peripheral neuropathy, chronic postoperative pain

Summary of Evidence Level

- Stimulation of occipital nerves may be offered to patients with chronic migraine headache when conservative treatments have failed. The average effect size for relief of migraine symptoms is modest to moderate (Level I, Grade B).
- There is presently insufficient evidence to recommend stimulation of supraorbital and infraorbital nerves for neuropathic craniofacial pain (Level II-3, Grade C).

Summary of Evidence Level

- PNS may offer modest and short-term pain relief, improved physical function, and better quality of life for chronic hemiplegic shoulder pain. (Level I, Grade B)
- PNS for mononeuropathies of the upper extremity may be offered following a positive diagnostic ultrasound-guided nerve block of the targeted nerve and is associated with modest to moderate pain relief. (Level II-2, Grade B)

Summary of Evidence Level

- Subcutaneous peripheral field stimulation combined with optimal medication management may offer moderate improvement in pain intensity for failed back surgery syndrome compared to optimal medication management alone (Level I, Grade B).
- There is evidence that PNS of medial branch nerves may improve pain intensity, physical function, and pain interference in patients with axial, mechanical low back pain (Level II-2, Grade B).
- There is limited evidence that PNS alleviates pain in neuropathic pain syndrome involving the trunk and back, including radiculopathy and post-herpetic neuralgia (Level III, Grade C).

Summary of Evidence Level

- PNS may be considered for lower extremity neuropathic pain following failure of conservative treatment options and is associated with modest pain relief (Level I, Grade B).
- PNS may be considered for lower extremity post-amputation pain following failure of conservative treatment options and is associated with modest to moderate pain relief (Level I, Grade B).

Summary of Evidence Level

- As a less-invasive modality compared to SCS therapy, PNS may be offered to patients with CRPS Type I/II or peripheral causalgia, and may be associated with modest improvement in pain intensity and functional outcomes. However, high-quality evidence is limited and other neuromodulation interventions such as dorsal root ganglion SCS are recommended. (Level III, Grade C).

ASPN = American Society of Pain and Neuroscience.

Strand N, et al. *J Pain Res*. 2022;15:2483-2504.

PNS by Nerve

Review

Peripheral Nerve Stimulation for Lower Extremity Pain

Clayton Busch [1], Olivia Smith [2], Tristan Weaver [1], Jayesh Vallabh [1] and Alaa Abd-Elsayed [3,*]

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[2] Wright State University Boonshoft School of Medicine, Dayton, OH 45324, USA; smith.2651@wright.edu
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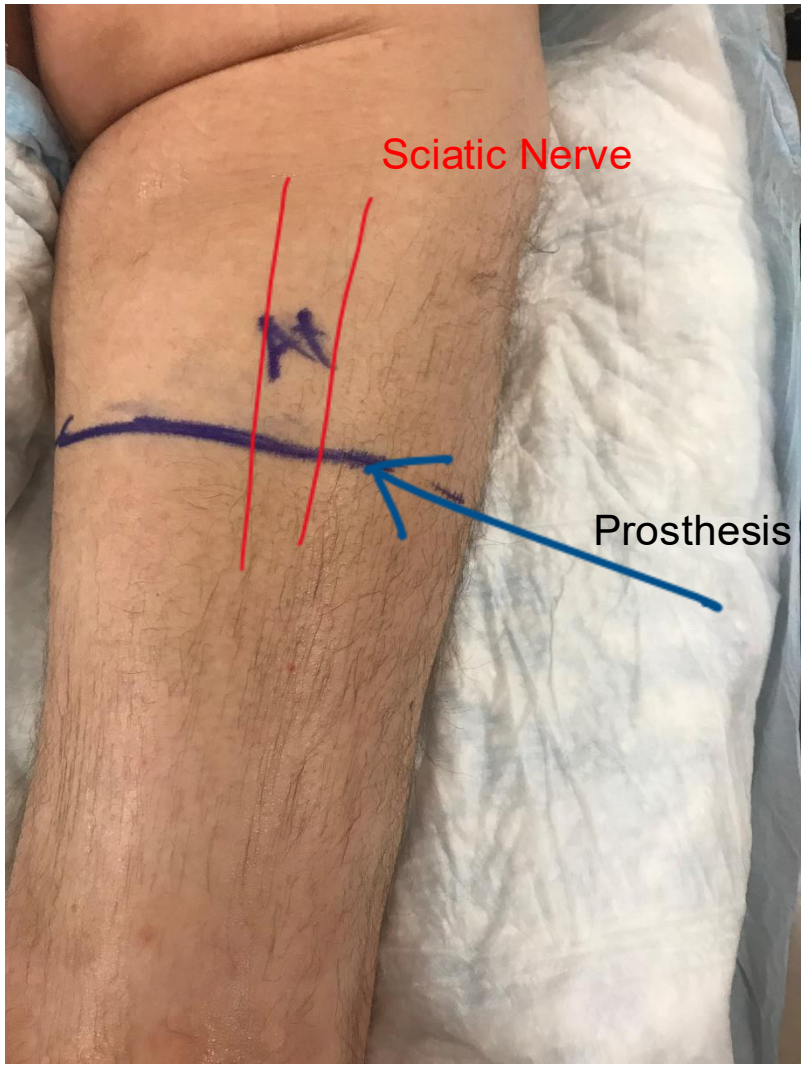
Table 2. Individual nerves of the lower extremity described by level of evidence as well as a summary of findings.

Nerve	Evidence Level	Summary of Evidence
Ilioinguinal nerve	Level V	- Four patients decreased pain scores by 5–9 points, decreased pain medicine use, and improved functional ability [8,37].
Genitofemoral nerve	Level V	- Four patients reported 70–90% pain improvement, decreased opioid use, and improved functional ability [8,9,38].
Lateral femoral cutaneous nerve	Level V	- Total of 80–100% improvement in symptoms [8,39].
Femoral and sciatic nerves	Level II	- In an RCT PNS in PLP provided significantly improved benefit over placebo and reduced opioid use by 71% [40]. - Sciatic and femoral nerve PNS may provide relief for acute post-operative pain [12,13,41,42].
Obturator nerve	Level V	- One case report with robust response. Prior to PNS the patient consumed 255mg of morphine daily but was able to discontinue analgesics after PNS [43].
Saphenous, infrapatellar saphenous, and genicular nerves	Level V	- Total of 90–100% improvement in knee pain in 2 case reports [8,44,45]. - Decrease in VAS from 7.7 to 2.7 in another case report [8].
Peroneal nerve	Level V	- Total of 60–80% pain relief or more with PNS [8,46,47]. - 75% improvement in activity [8].
Posterior Tibial nerve	Level V	- Most patients report at least 50% improvement in pain after 6 sessions of PNS [48].
Sural nerve	Level V	- Total of 50–75% improvement in pain at 6 months [8,49]. - 60% improvement in activity [8].

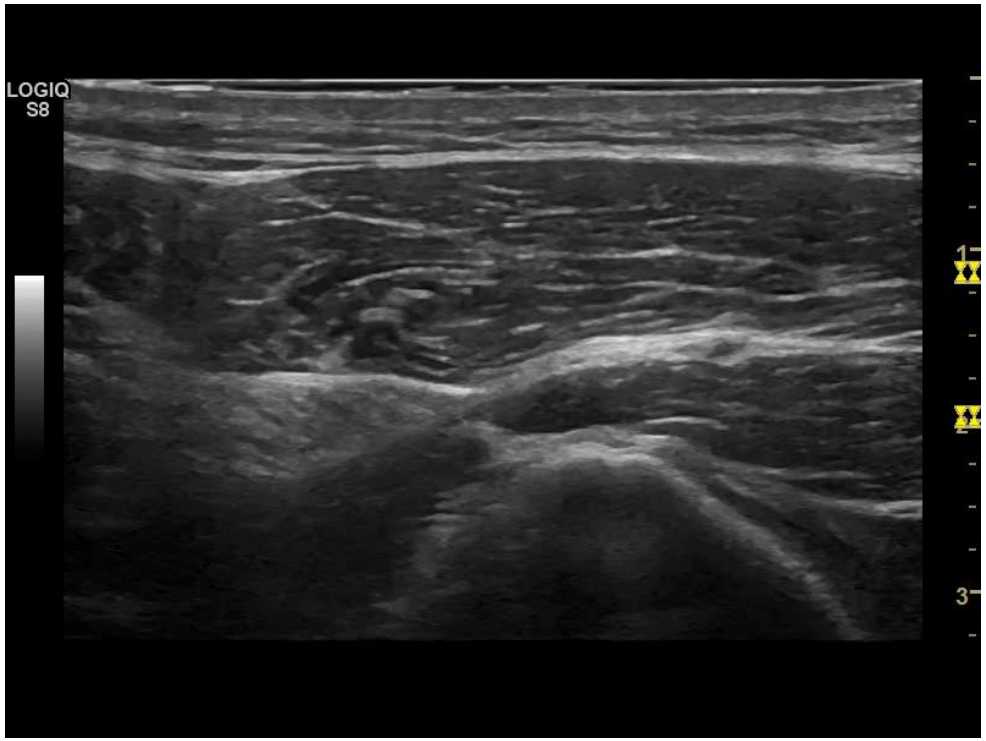
PLP = phantom limb pain.

Busch C, et al. *Biomedicines*. 2022;10(7):1666.

Sciatic PNS Implant Preoperative Scan

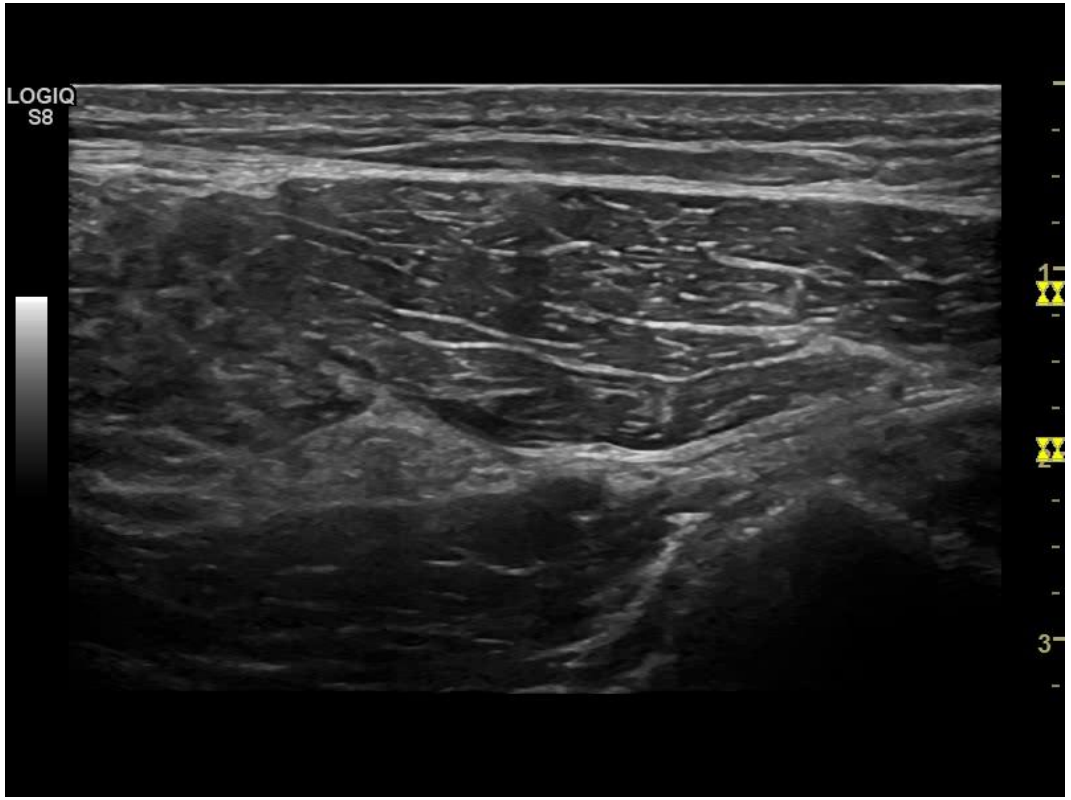


- 48yo Male s/p traumatic BLE amputation with R residual limb pain greater than phantom pain
- Common peroneal neuroma at fibular head and at tibial insertion from previous nerve decompression surgery



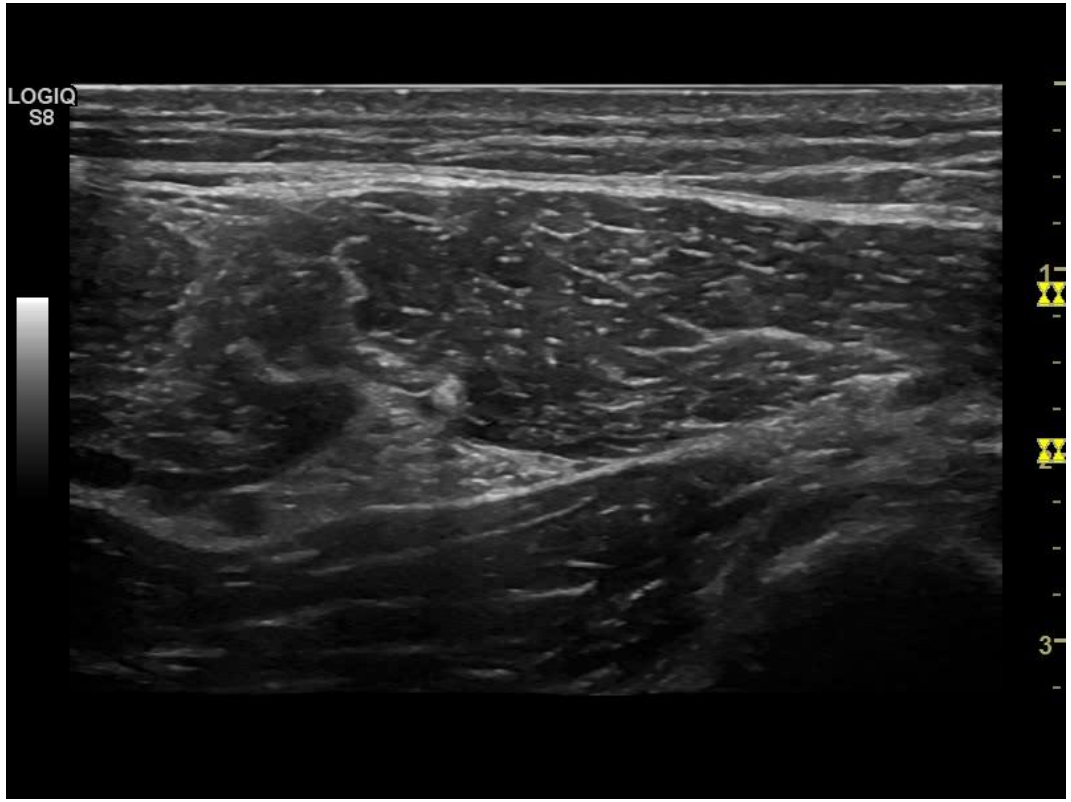
s/p = **status** post.

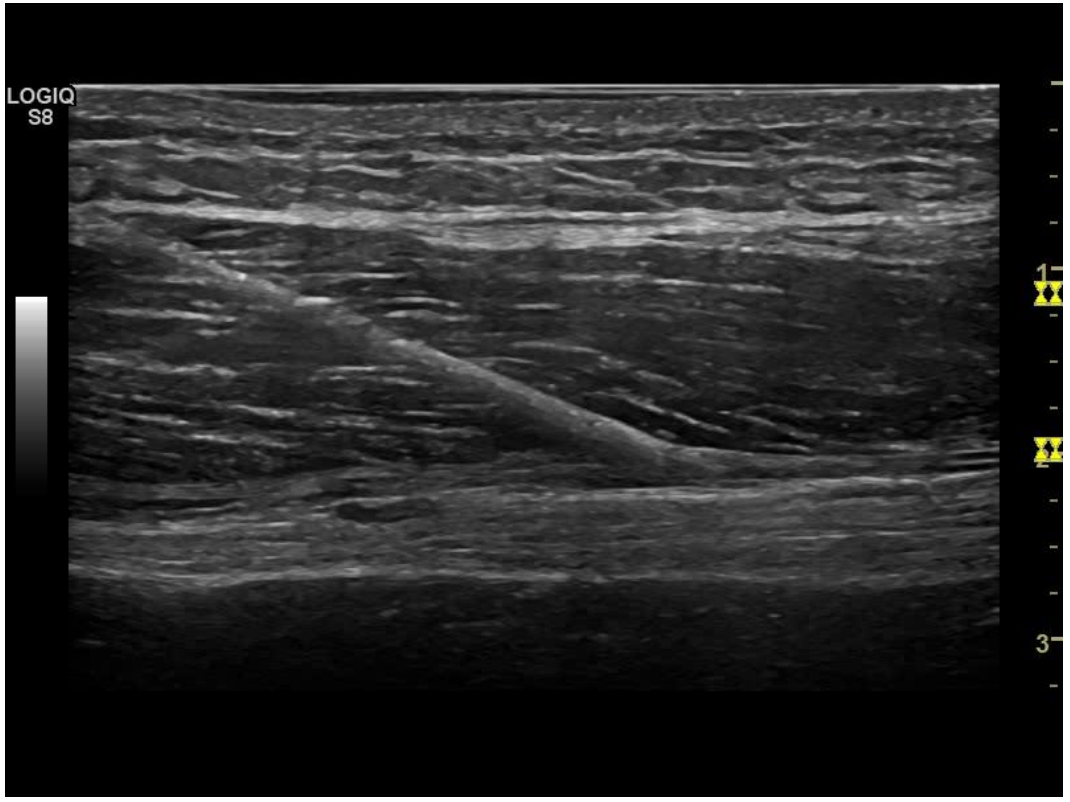
Sciatic Nerve OOP View of Needle



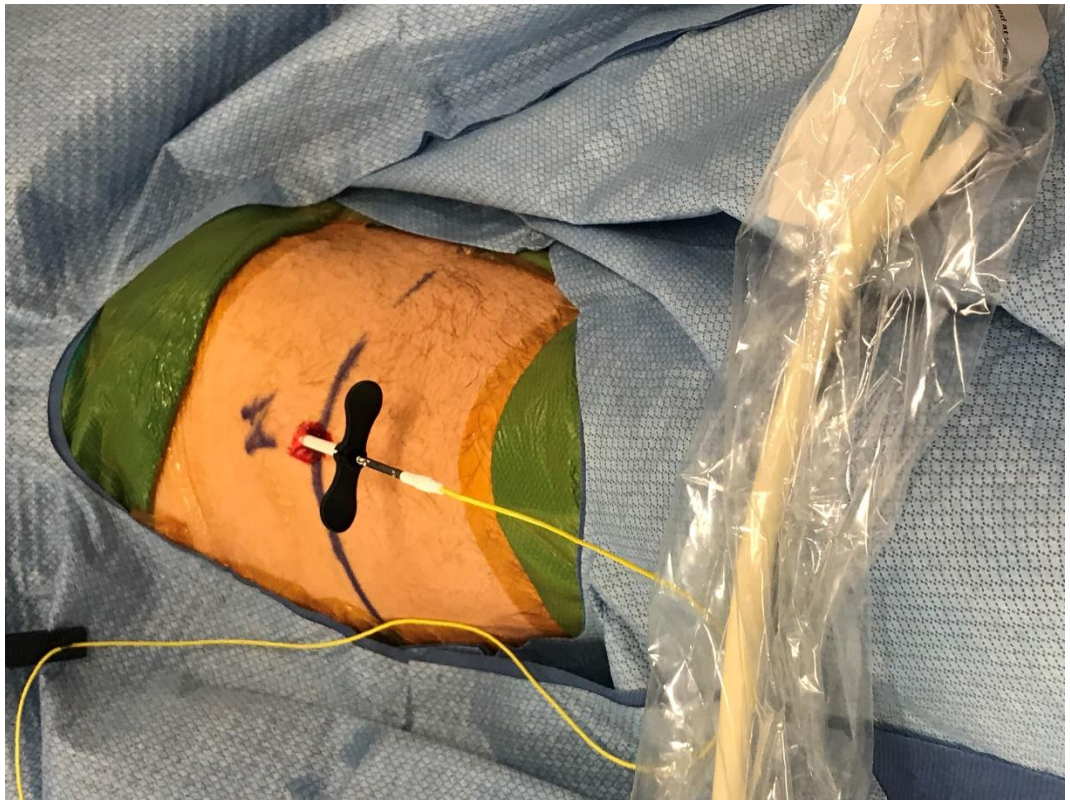
OOP = out of phase.

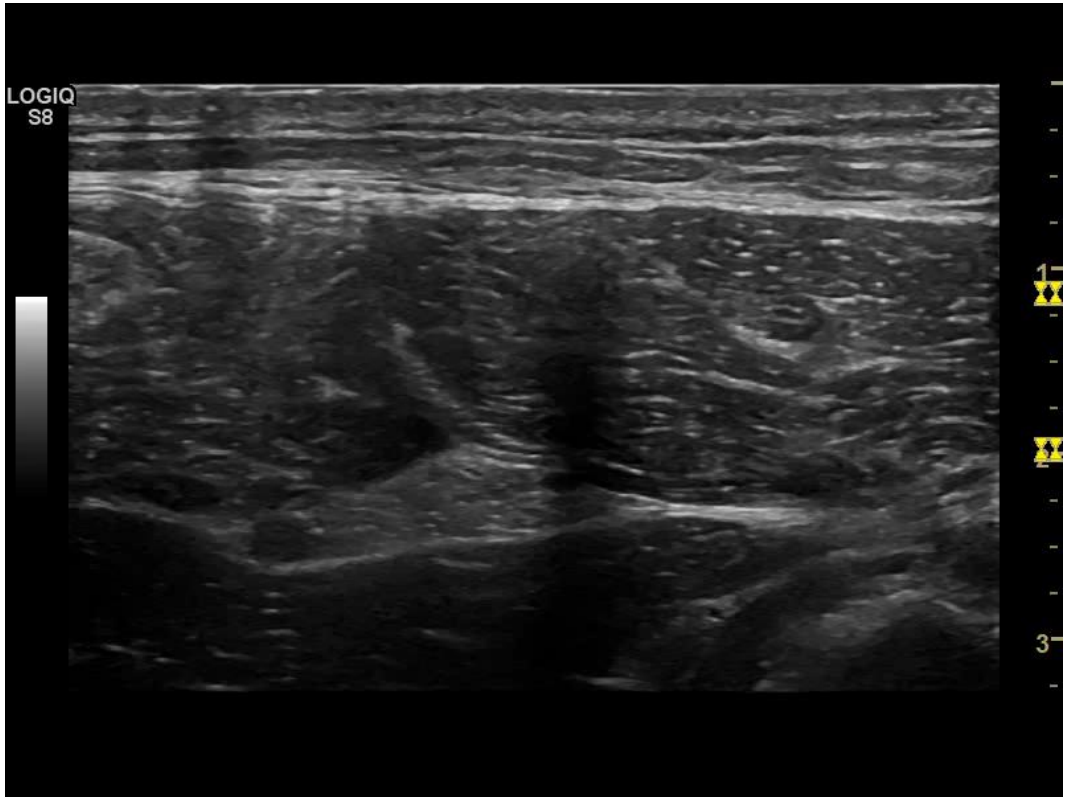
Sciatic Nerve Stimulation Probe in Plane View



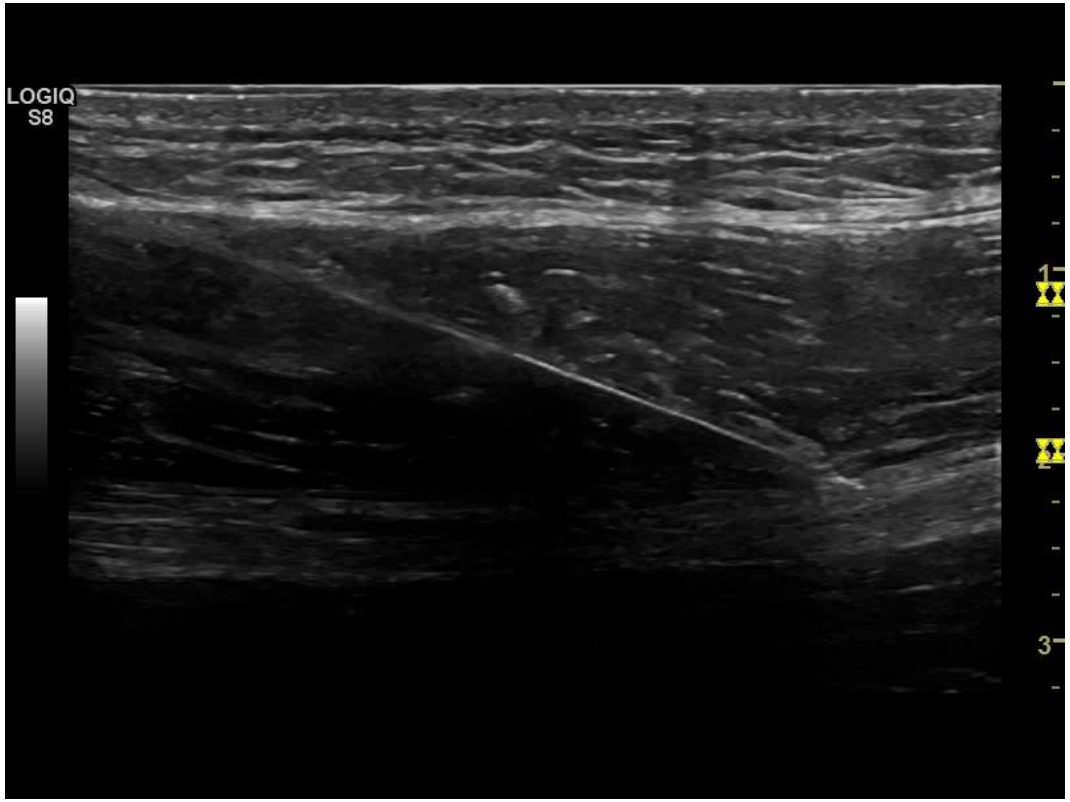


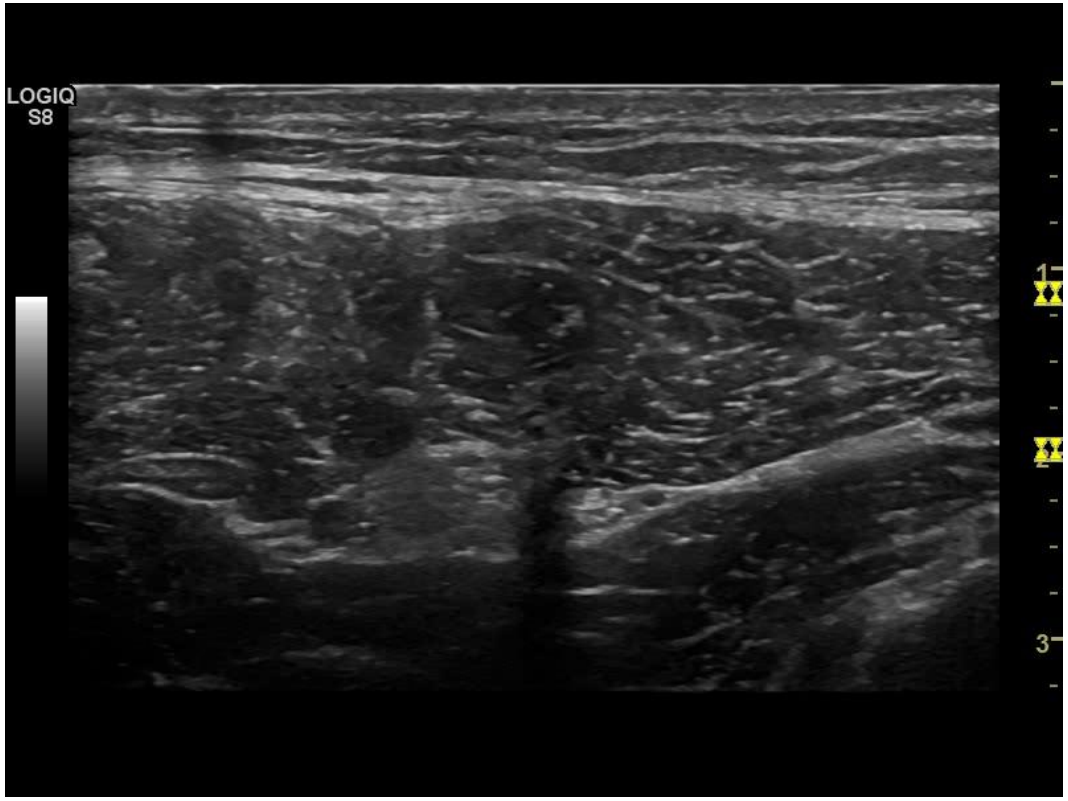
Sciatic Nerve with Introducer



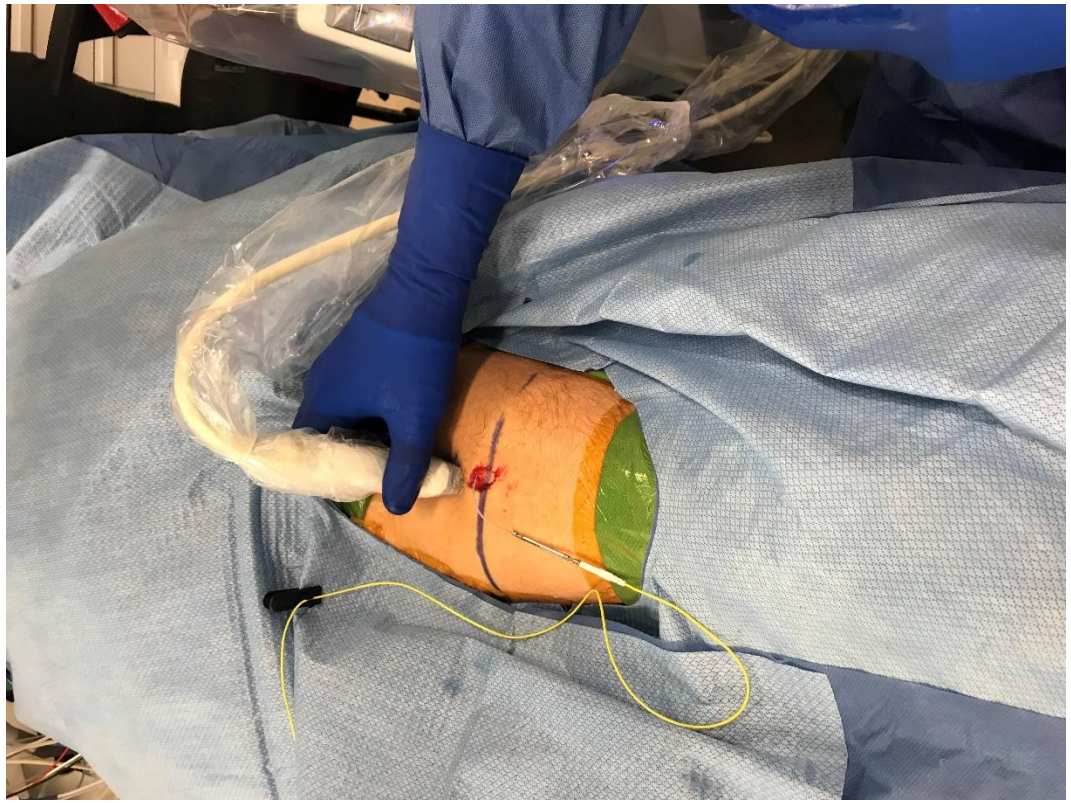


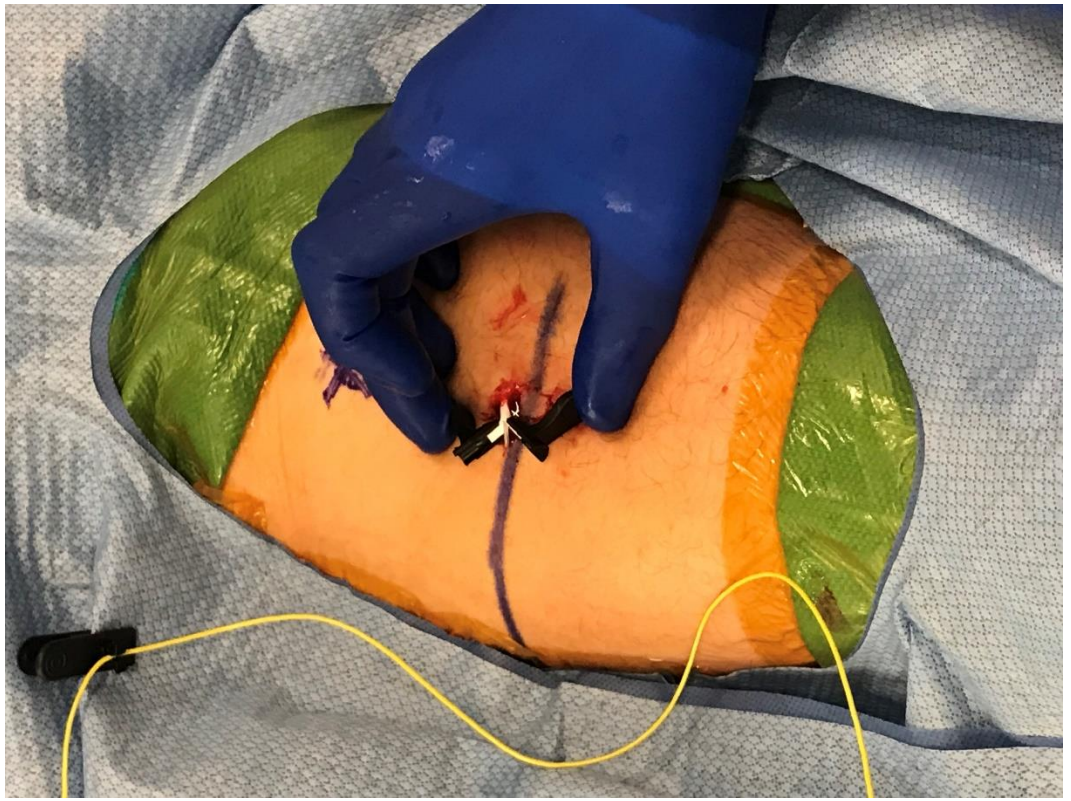
Sciatic Nerve Lead in Distal Introducer



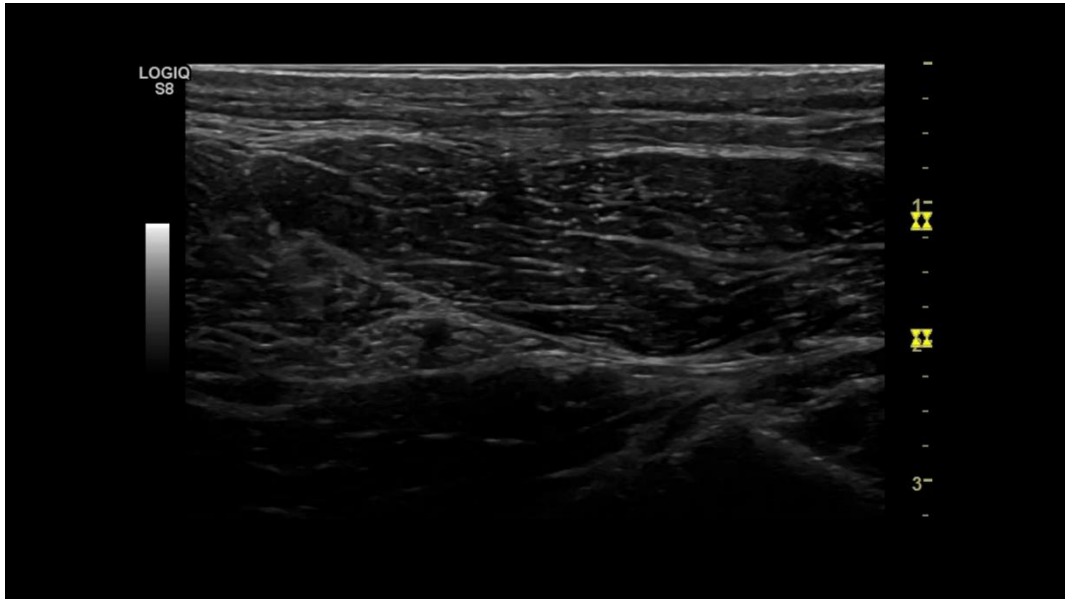


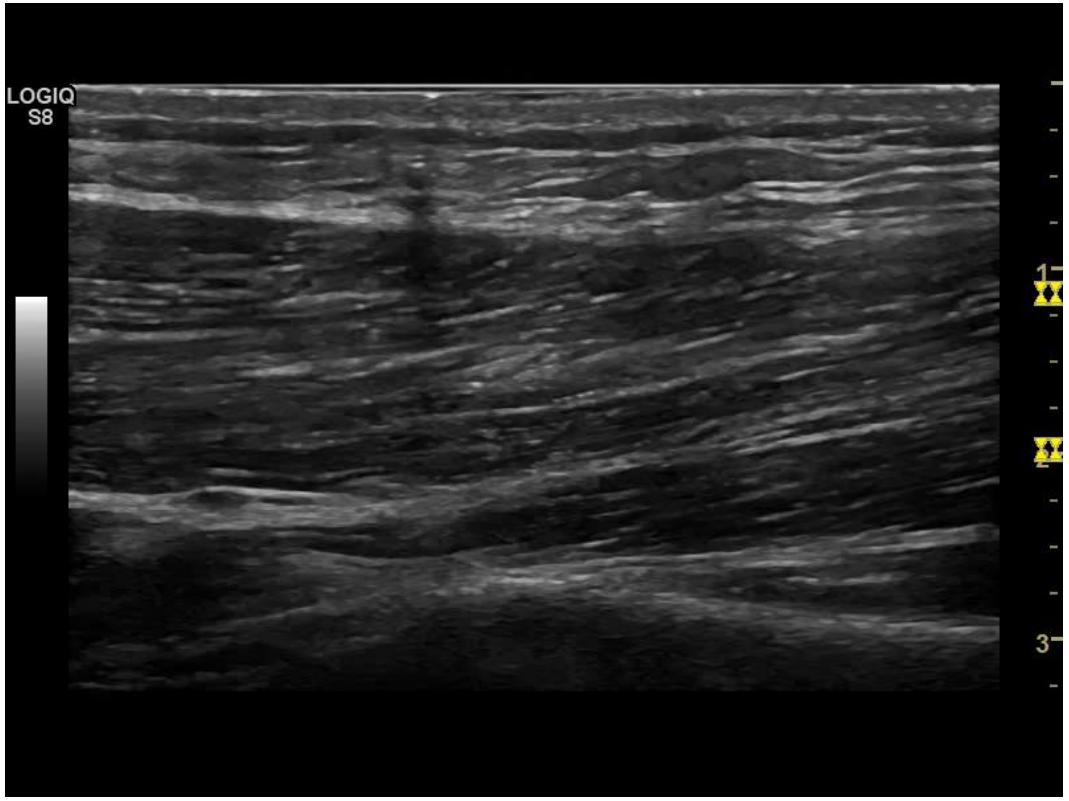
Sciatic PNS Burying Lead



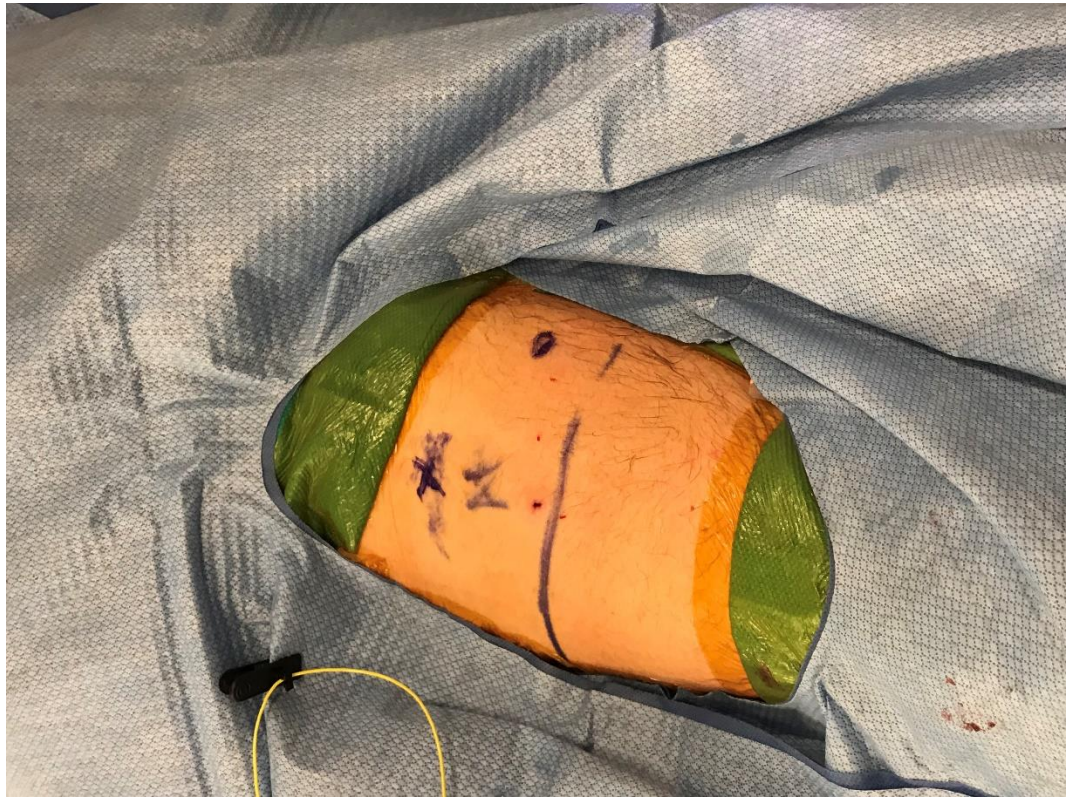


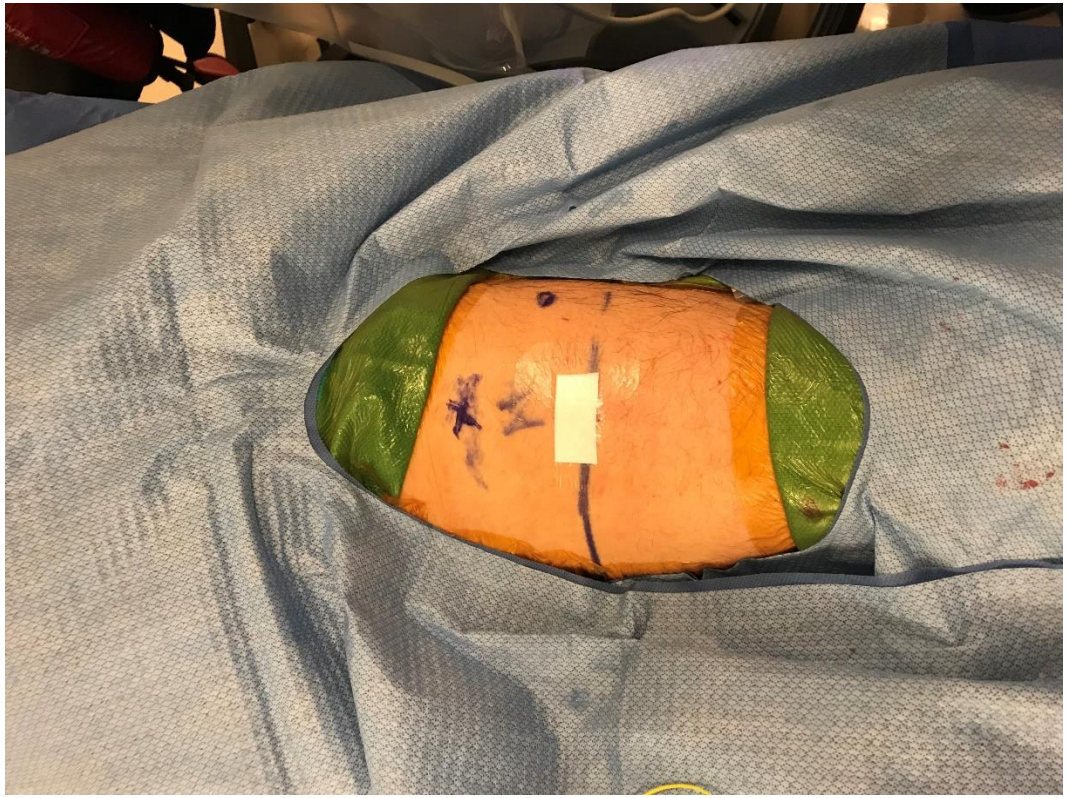
Marking Lead and Antenna Location





Sciatic PNS Implant

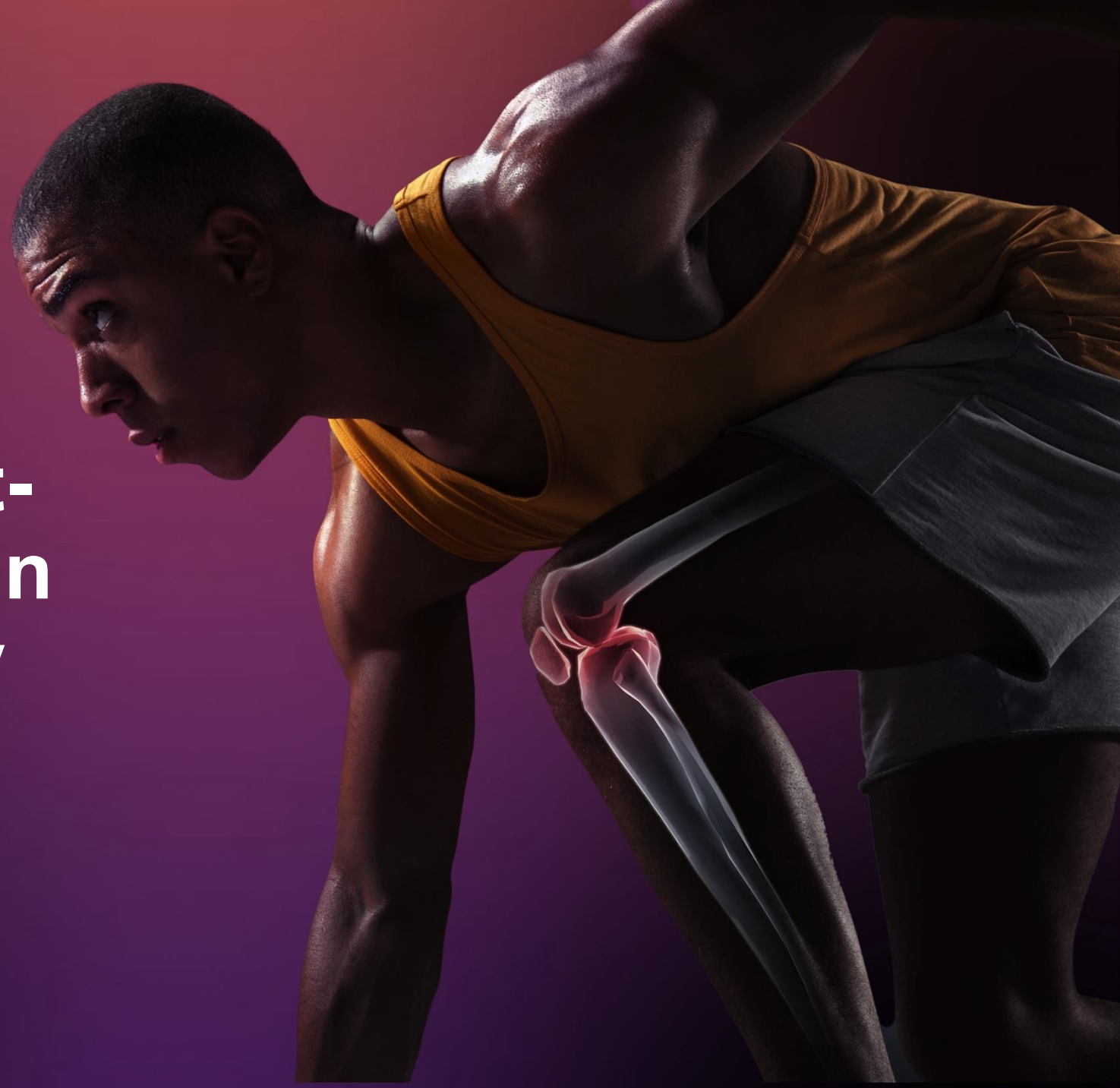




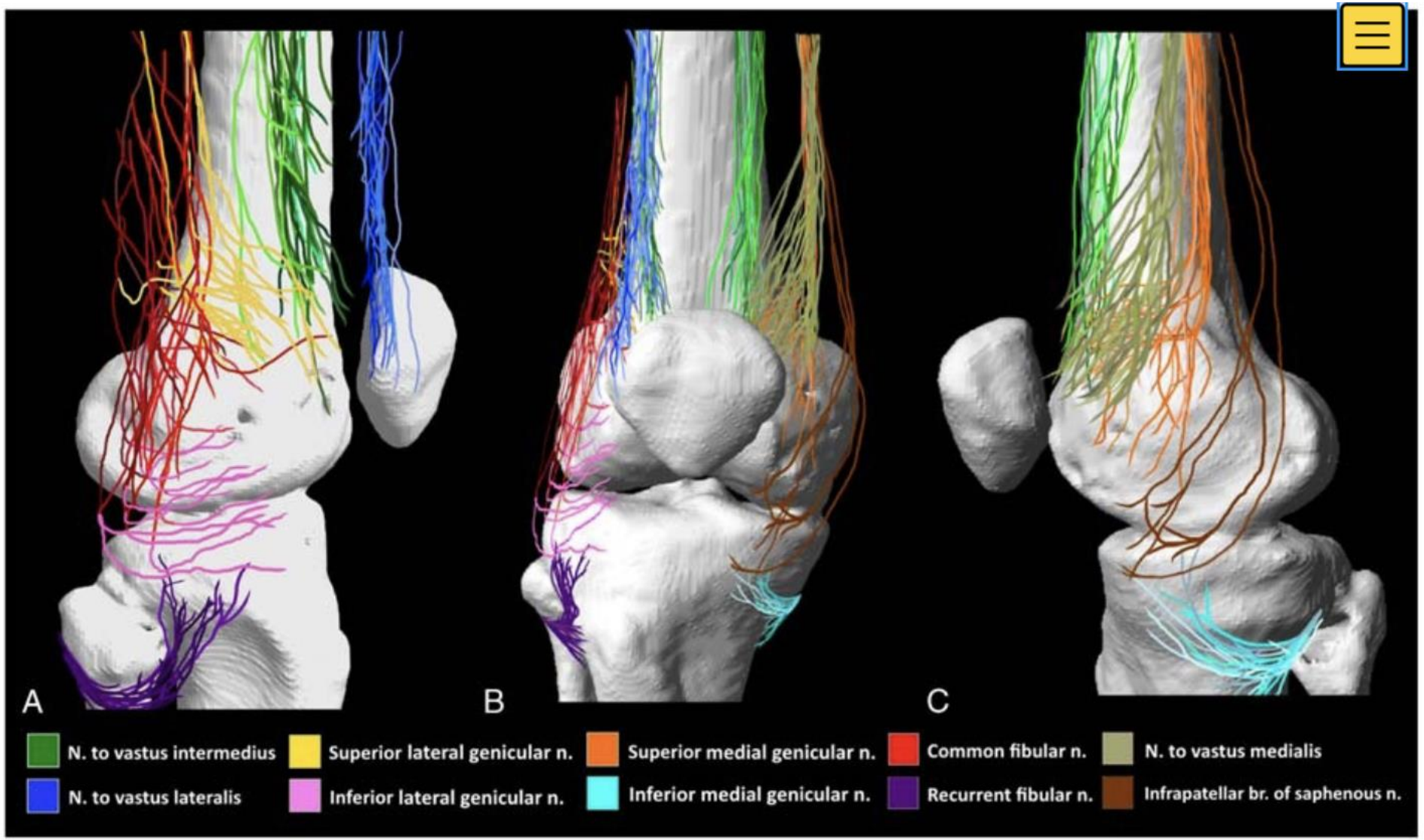
Innovations for Active Healing

Treatment of Post-Surgical Knee Pain in the Ambulatory Pain Clinic

Vinod Dasa, MD
Vice Chair, Orthopedic Surgery
Irvin Cahen Endowed Professor
LSU Health Sciences Center
New Orleans, Louisiana

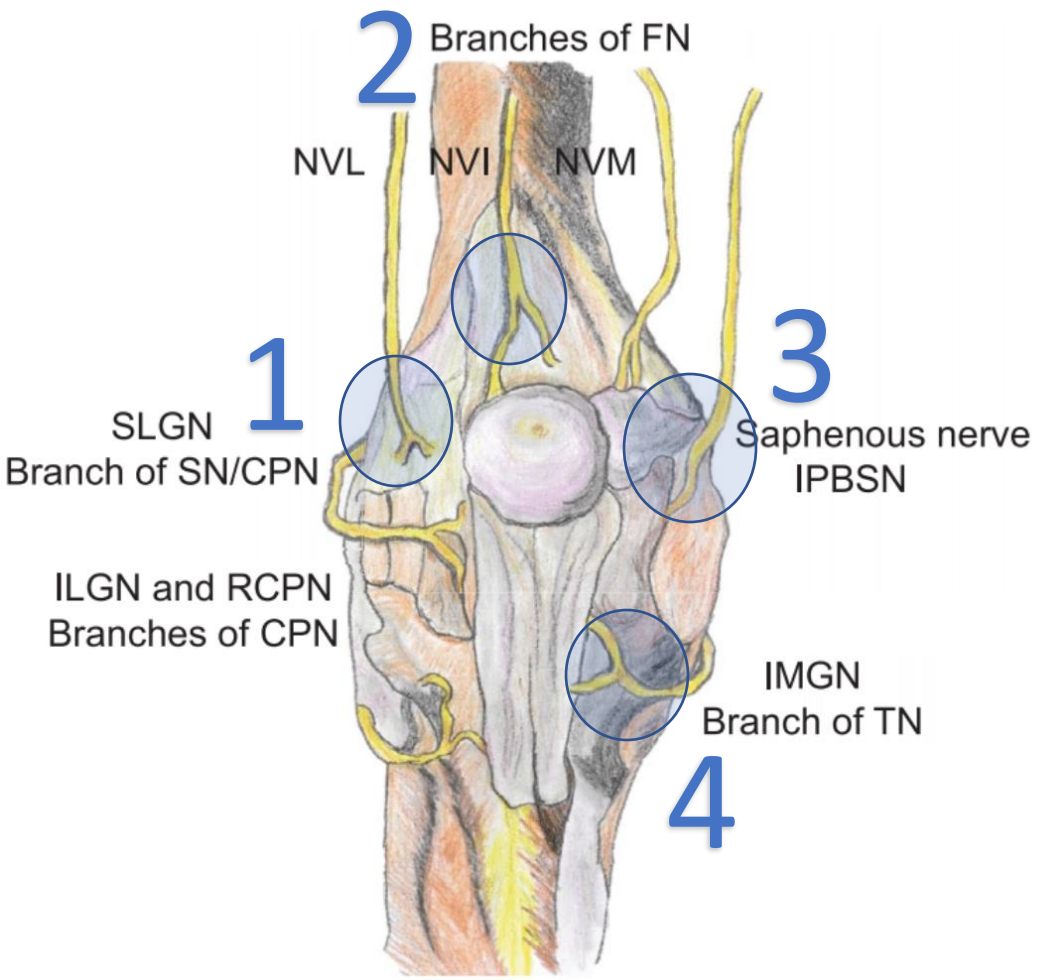


Nerves of the Knee



Tran J, et al. *Reg Anesth Pain Med*. 2018;48(4):407-414.

Nerve Targets in the Knee



Spence E, et al. WFSA. Published May 25, 2021. Accessed August 21, 2025. https://resources.wfsahq.org/atotw/motor-sparing-blocks-for-the-knee.

PNS Candidates

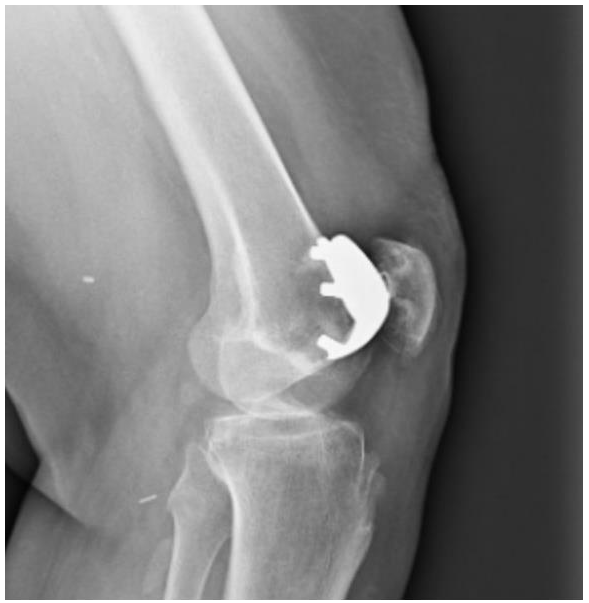
- Non-surgical knee OA candidates
  - Age
  - Non-modifiable comorbidities (eg, CHF, PVD, CAD/stent…)
  - “Modifiable” comorbidities (eg, BMI, smoking)
- Painful arthroplasty (? Loosening, ? Failure)
  - Painful UKA
  - Painful TKA
  - Painful revision

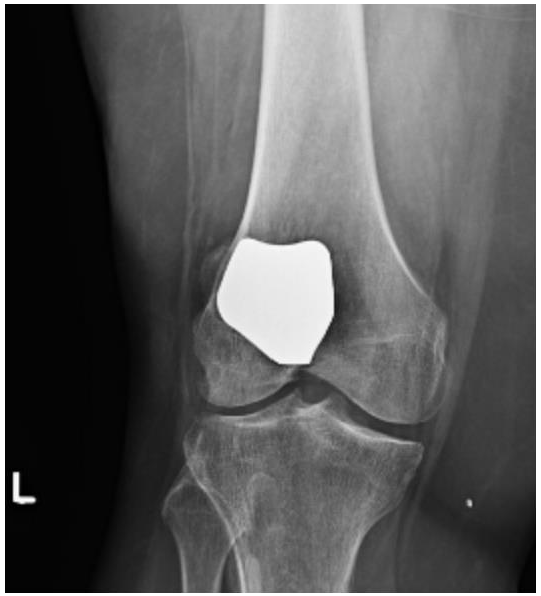
OA = osteoarthritis; CHF = congestive heart failure; PVD = peripheral vascular disease; CAD = coronary artery disease; BMI = body mass index; UKA = unicompartmental knee arthroplasty; TKA = total knee arthroplasty.

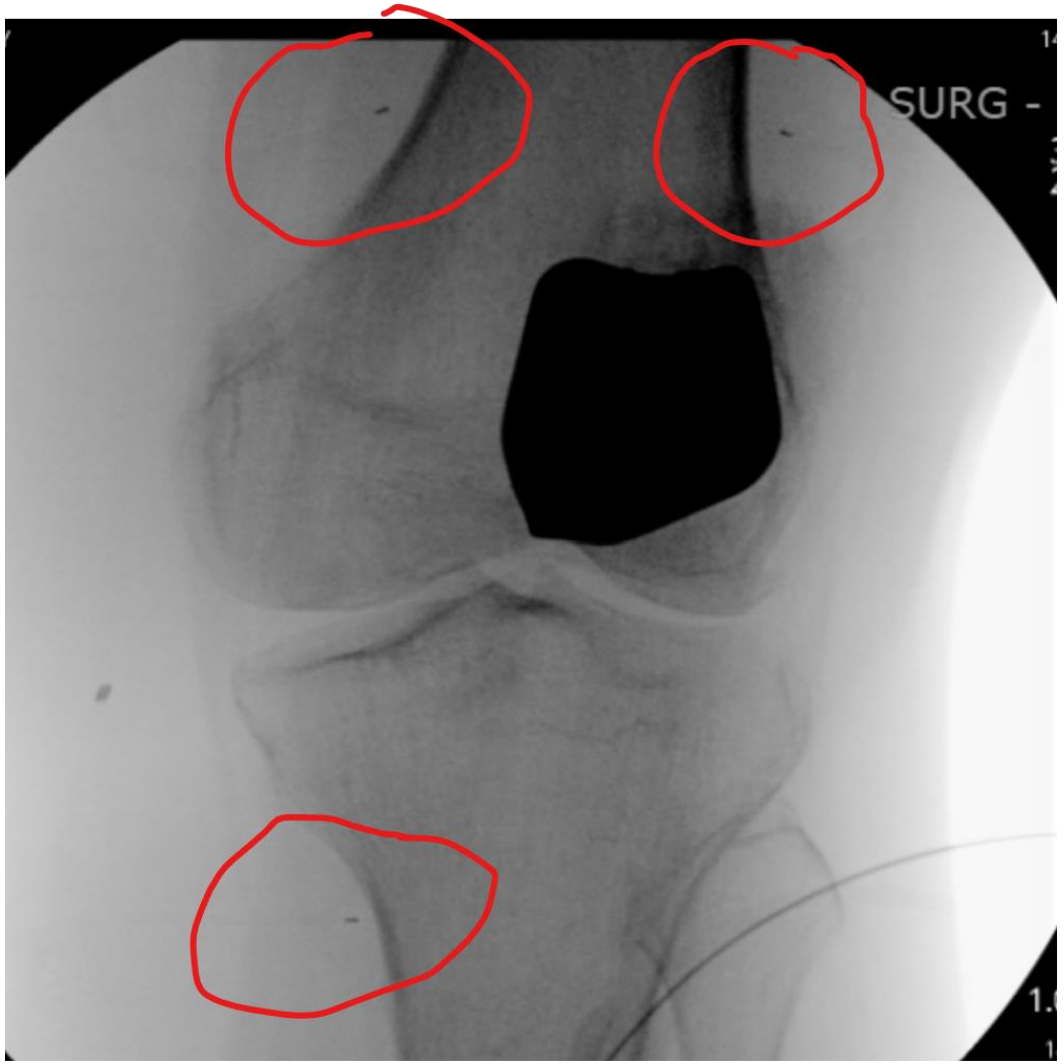
PNS Candidates

- Trial (try it before you buy it)
  - Test treatment with temporary removable leads
  - Sedation
  - Trial leads placed percutaneously
  - Patient ambulates to assess effectiveness
  - ? >50% pain reduction

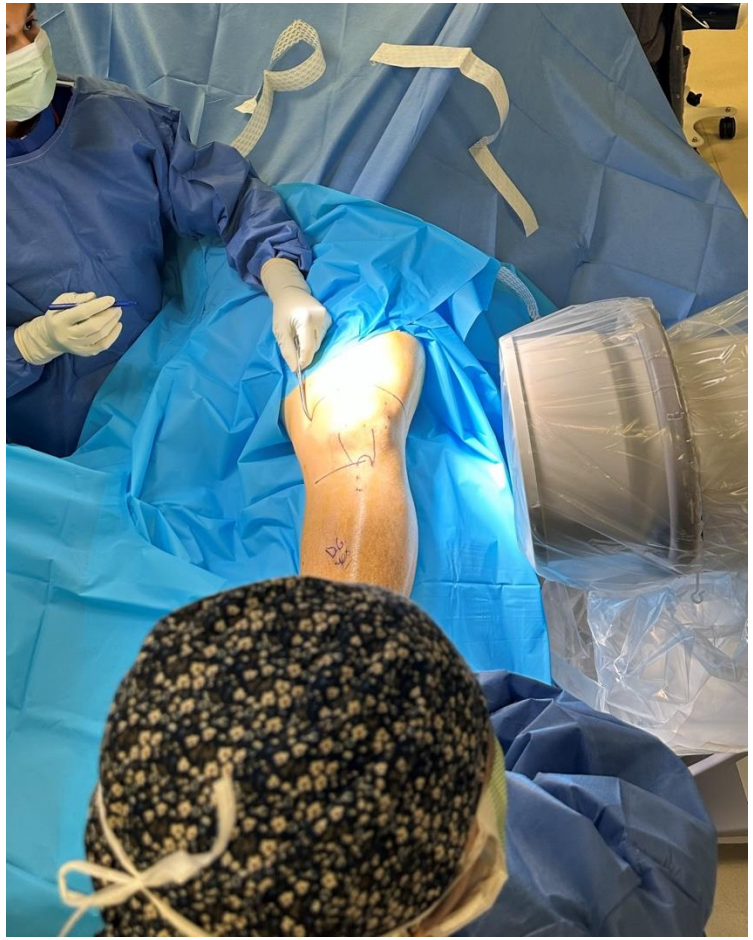
Painful PFJ

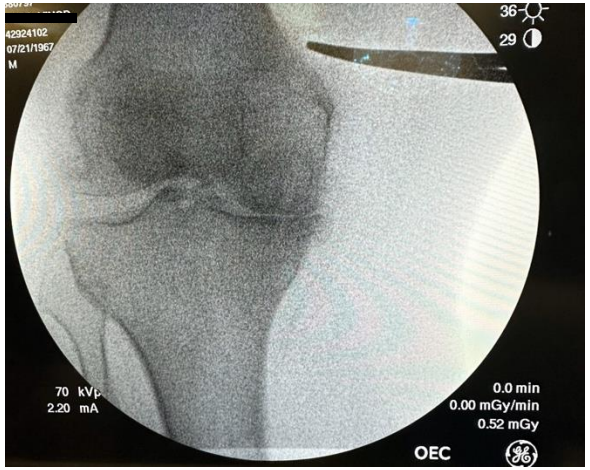






PFJ = patellofemoral joint.

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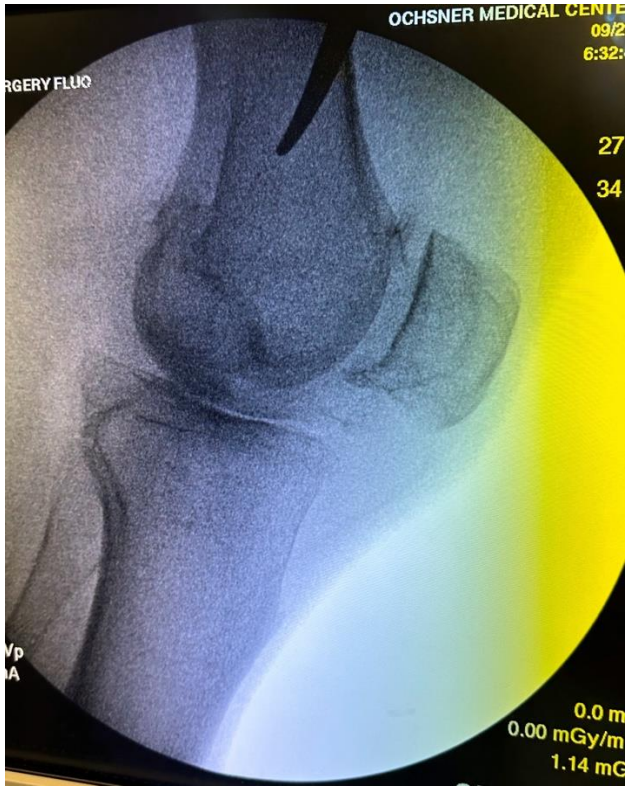
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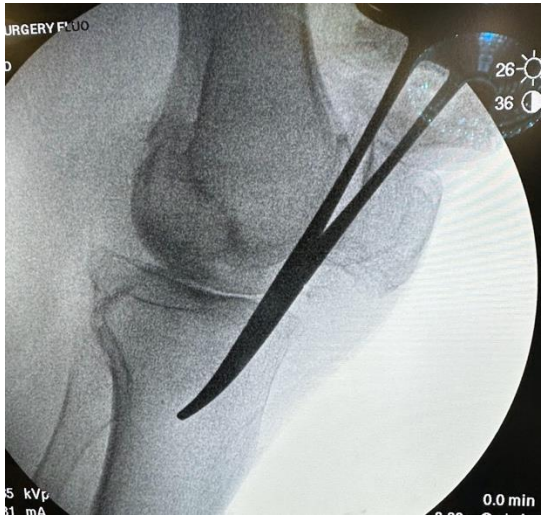
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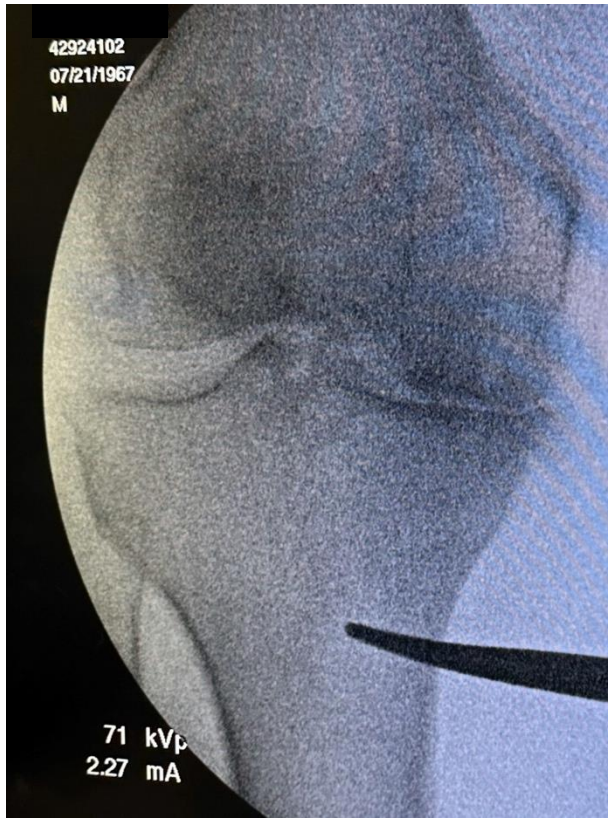
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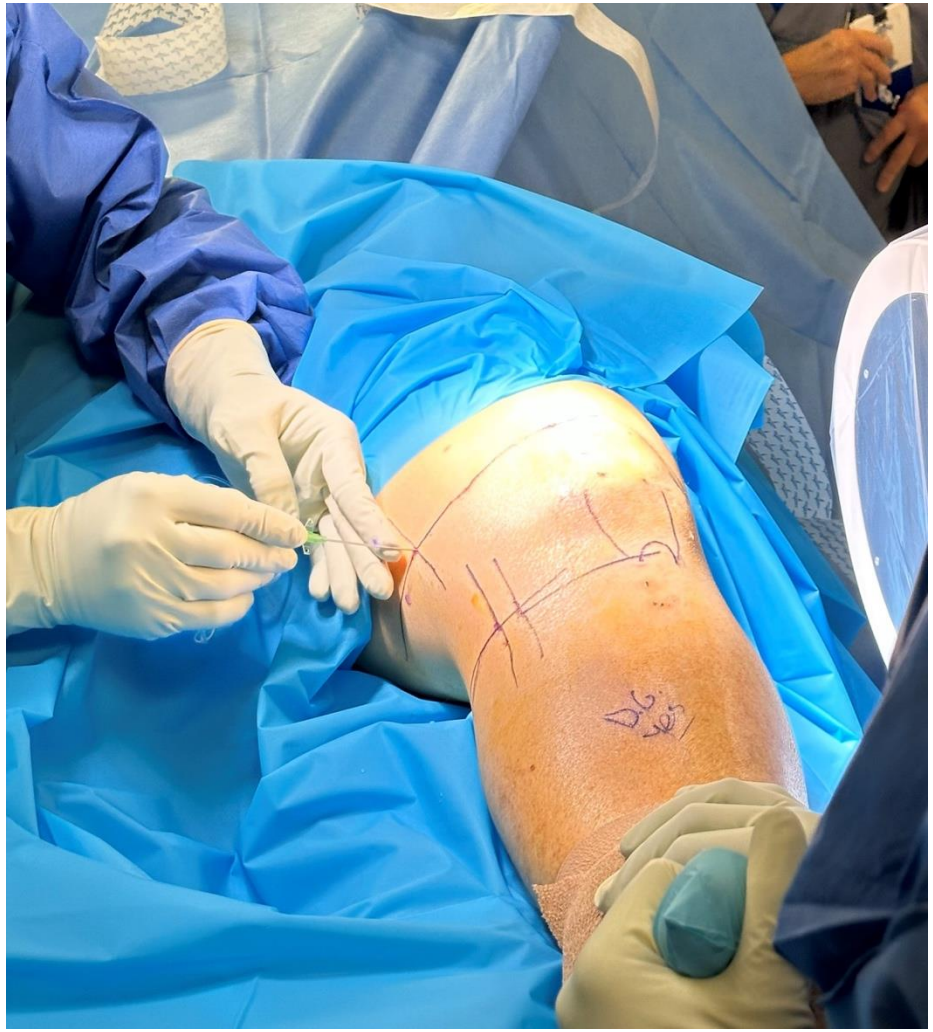
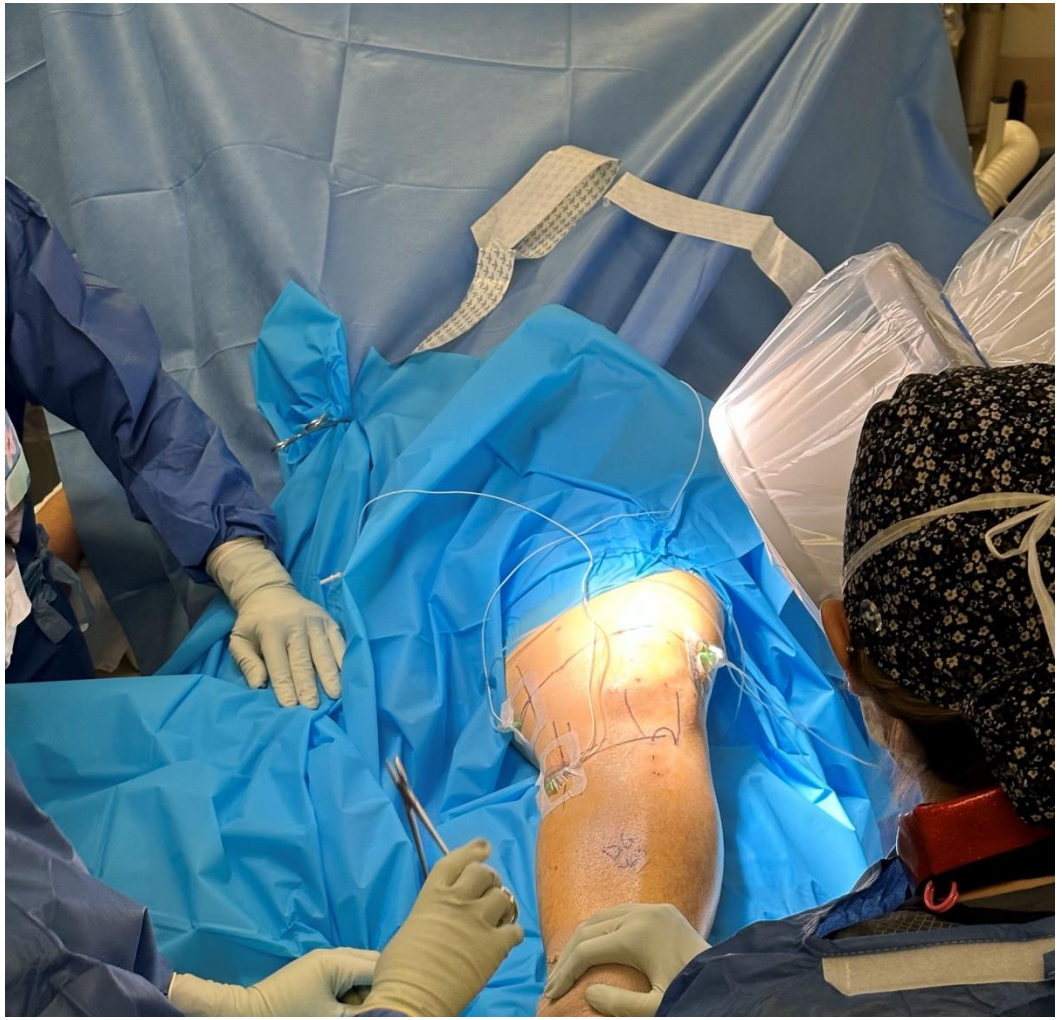
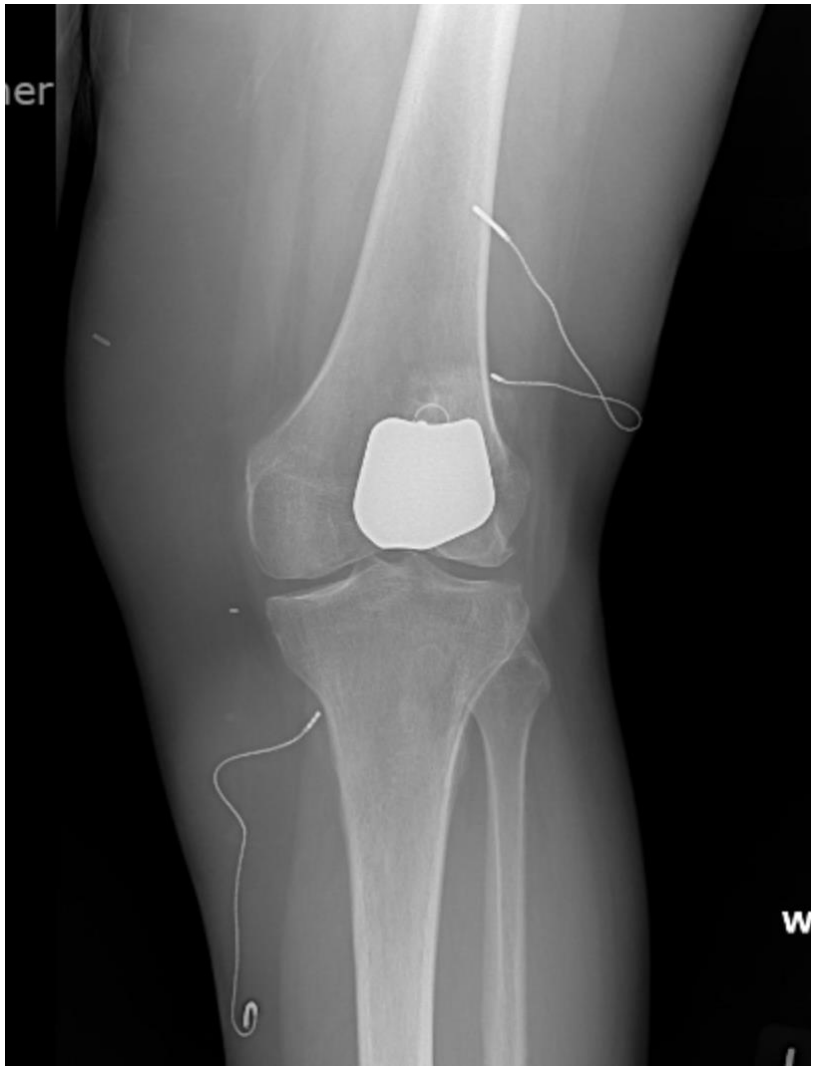


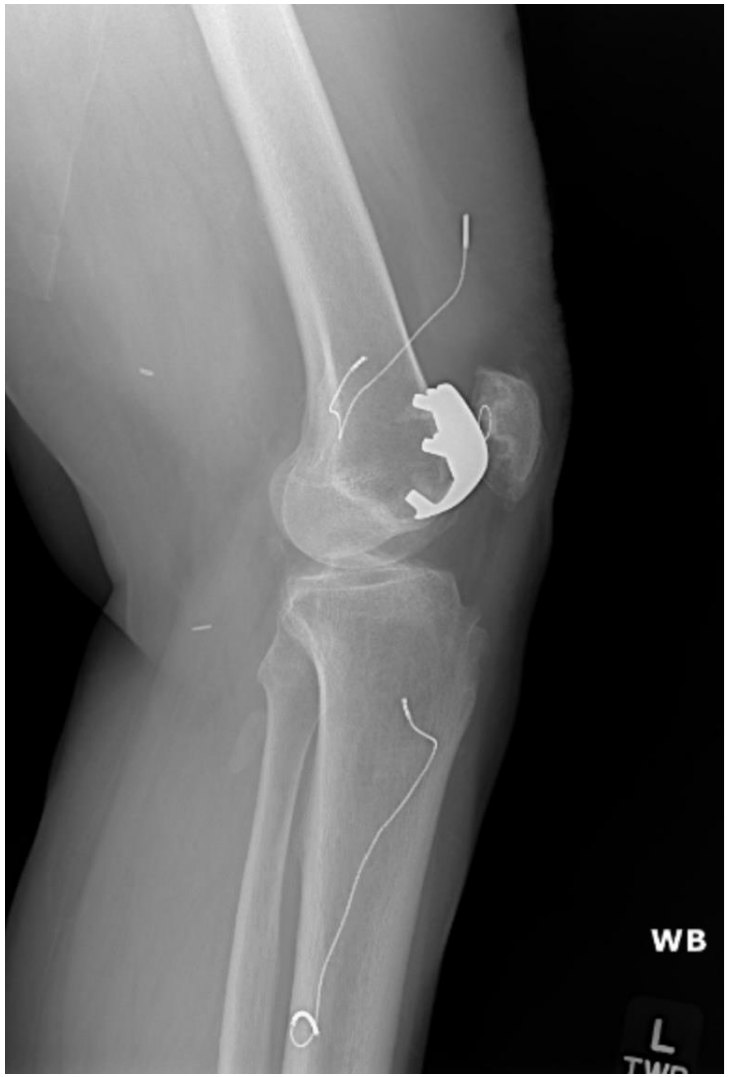


Did It Work?

PNS for Painful PFJ

- Permanent
  - If trial is successful (>50% pain relief)
  - General anesthesia
  - Percutaneous placement and tunneling of lead
  - Post-implantation managed by rep

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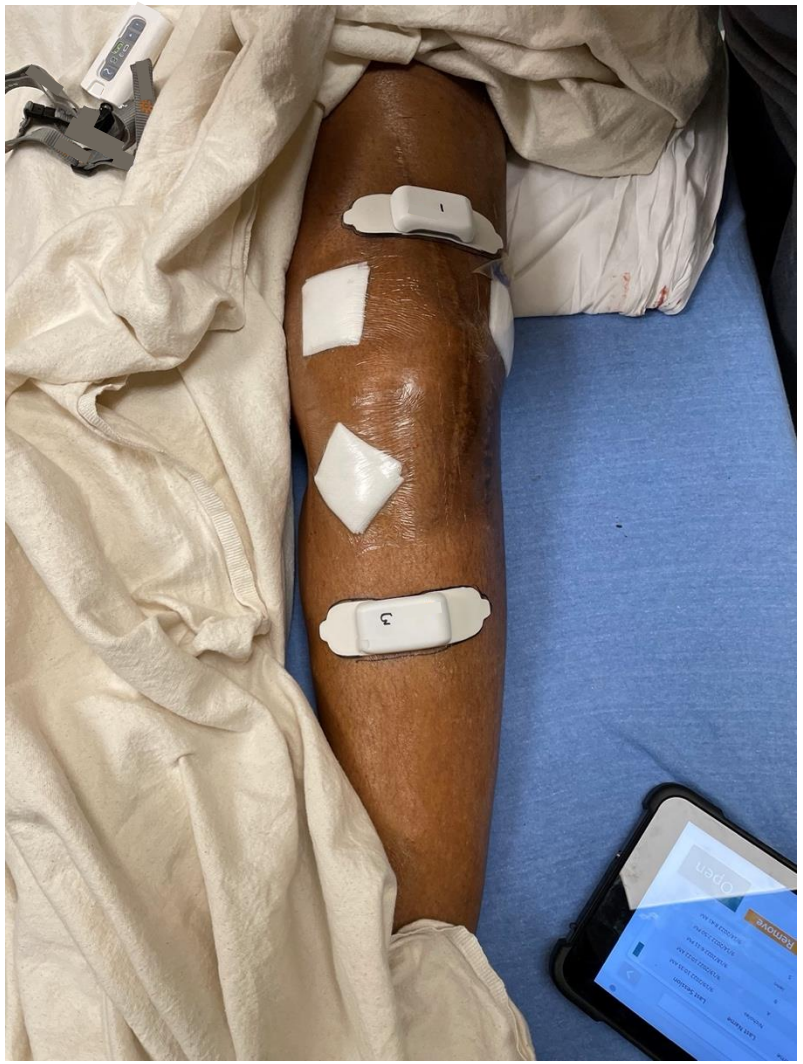

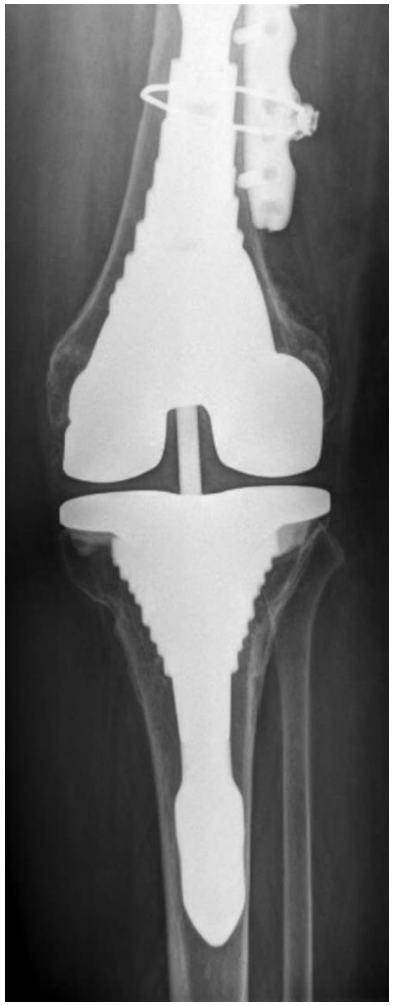

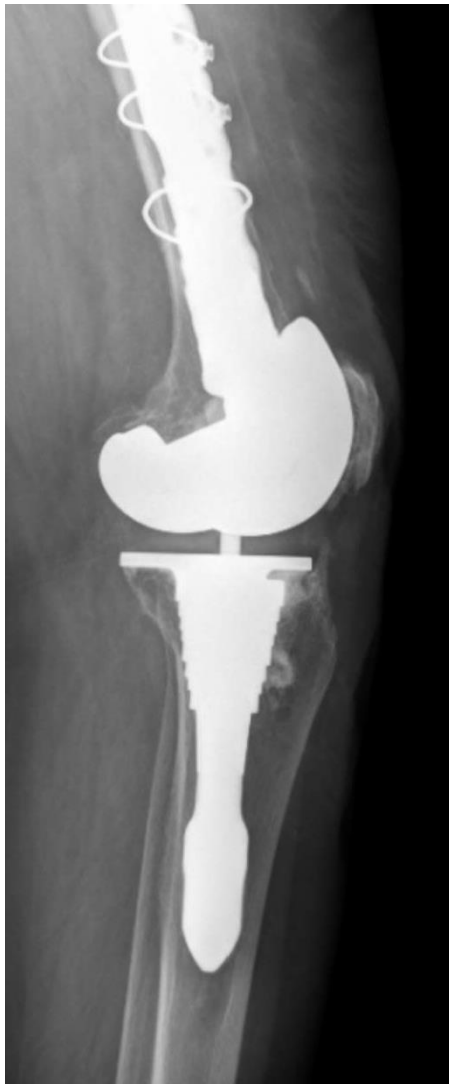

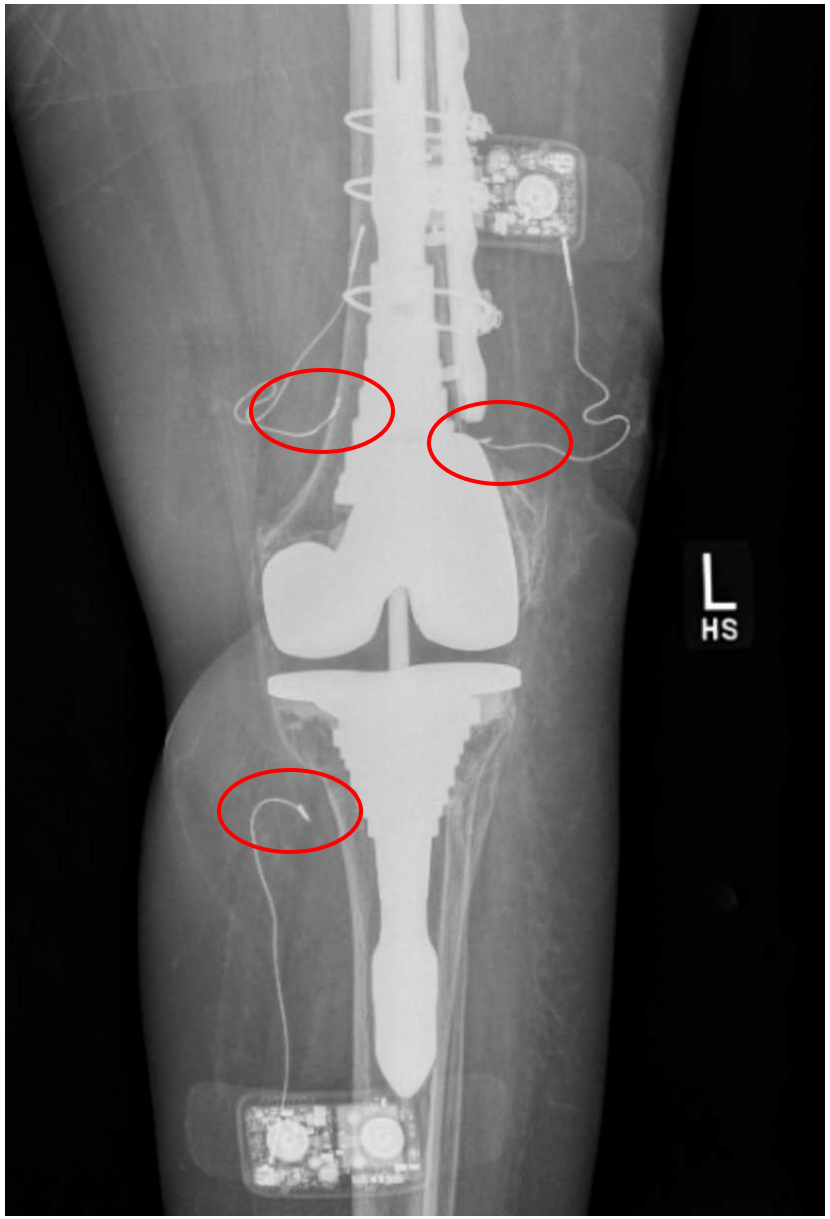
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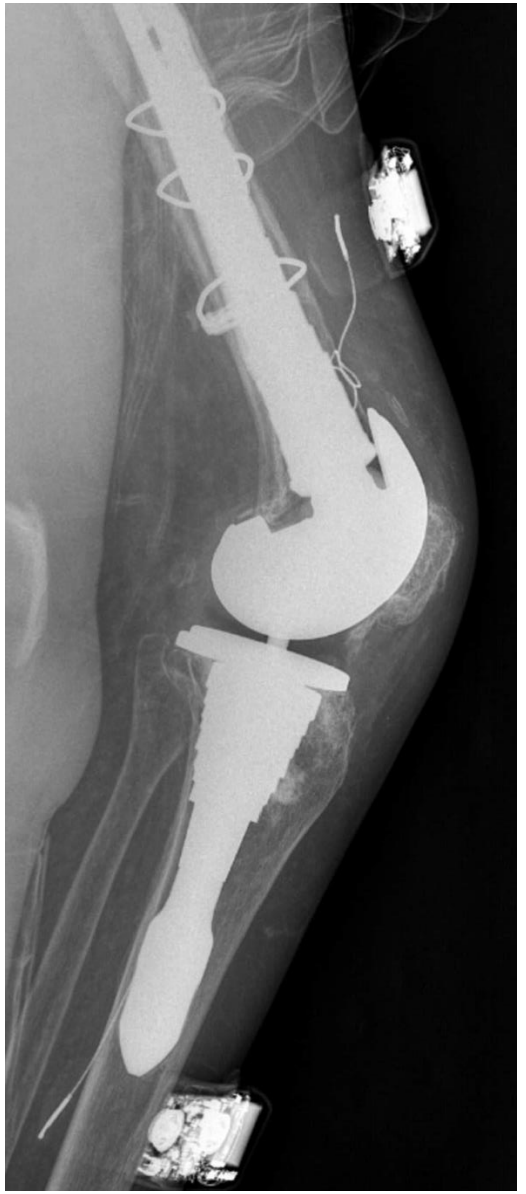
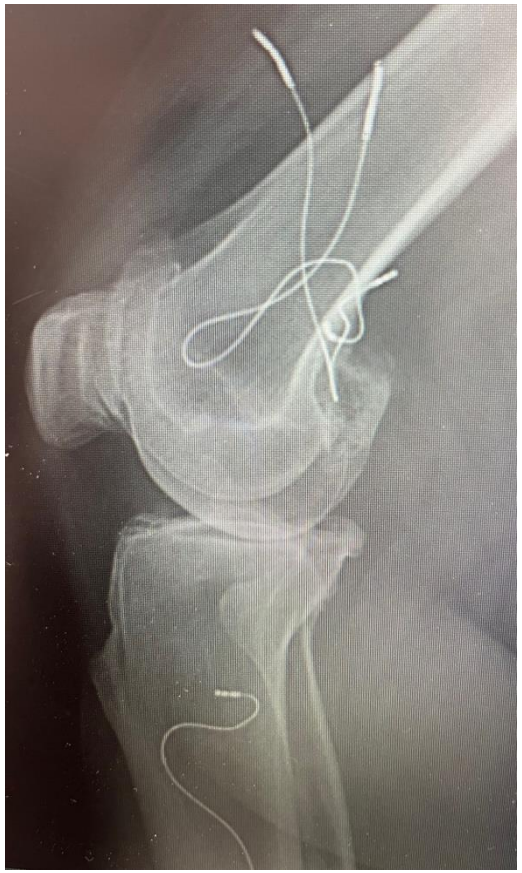
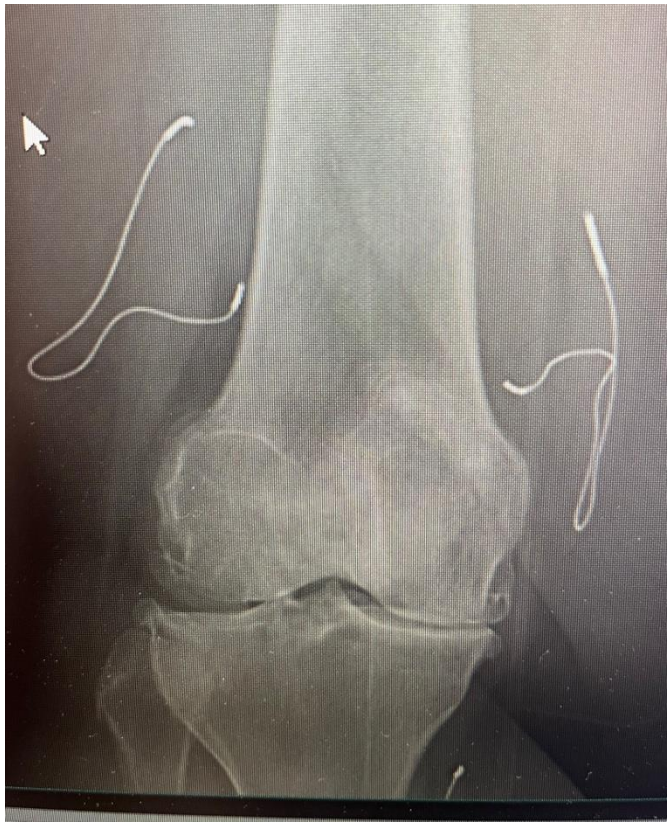


PNS for Ortho: Where to Start

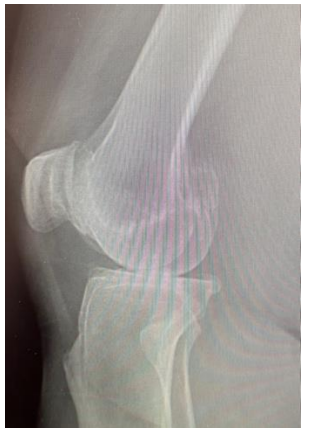
- Relationship with rep is different than traditional ortho
  - Rep is the patient's concierge post op, similar to pacemaker
- Meet with rep and learn their role
- Patient education
  - Anxiety about a "wire" in their leg – compare to pacemaker/defibrillator/SCS…
- Lab/site visit
  - Easier/safer than arthroscopy
- Patient selection
  - Pre-auth/insurance approval (start with Medicare)
- Psych evaluation?

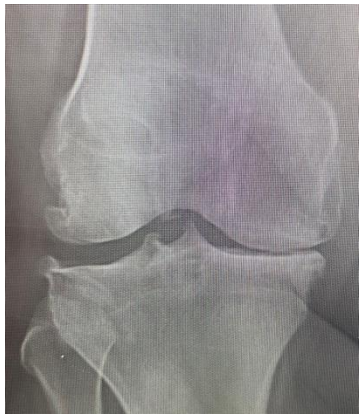
Nerve Targets in the Knee



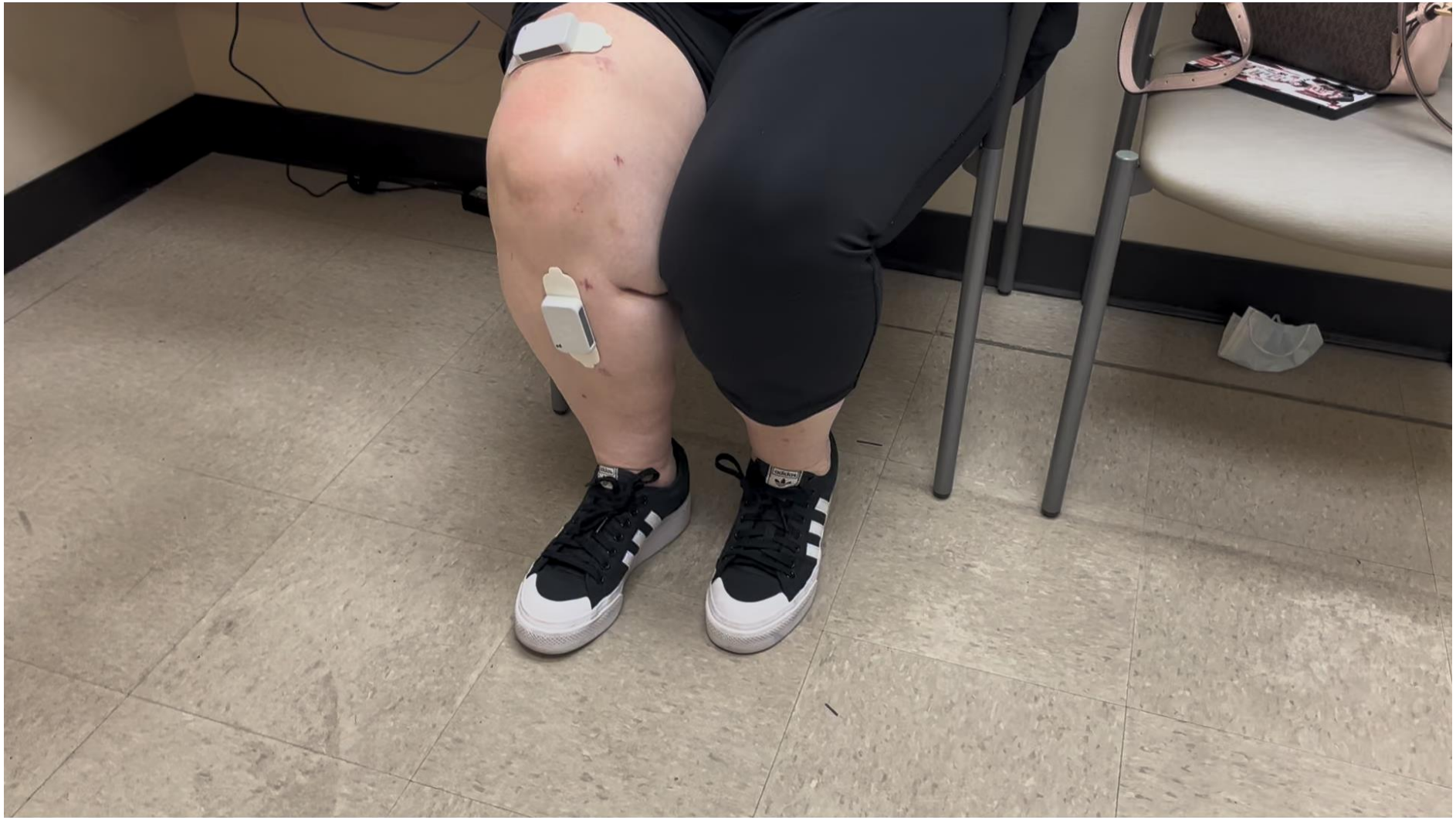


- 55yo Female
- Bone on bone knee OA (KL4)
- BMI 41
- Severe anterior and medial knee pain limiting function
- Does not want TKA





3 Months s/p PNS



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Conclusions

- PNS for chronic peripheral nerve pain is supported by moderate to high level evidence
  - Occipital Nerve Stimulation has level I for migraine, MOH
  - SPG has level II evidence
  - Lower back pain has level I evidence
  - PSSP has level I evidence
  - PTNS has level III evidence
- PNS for chronic neuropathic pain in the limbs or trunk
- Musculoskeletal pain
- Phantom limb pain
- Non-specific lower back pain
- Post-surgical – if we can block it we can stimulate it and this may aid regeneration

MOH = medication overuse headache; SPG = sphenopalatine ganglion; PSSP = post-stroke shoulder pain; PTNS = percutaneous tibial nerve stimulation.

Q&A