Advances in Spinal Cord Stimulation

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No Disclosures

Objectives

- Identify suitable patients for spinal cord stimulation based on chronic pain conditions and clinical criteria
- Explain how traditional and newer spinal cord stimulation systems, including high-frequency and closed-loop technologies, relieve chronic pain
- Review how AI enhances spinal cord stimulation therapy, including real-time adjustments to improve clinical outcomes for complex pain management


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Outline

- History of Traditional SCS
- Indications for SCS
- Patient Selection
- High-frequency SCS
- Burst SCS
- Closed-loop SCS
- Aritificial Intelligence in SCS

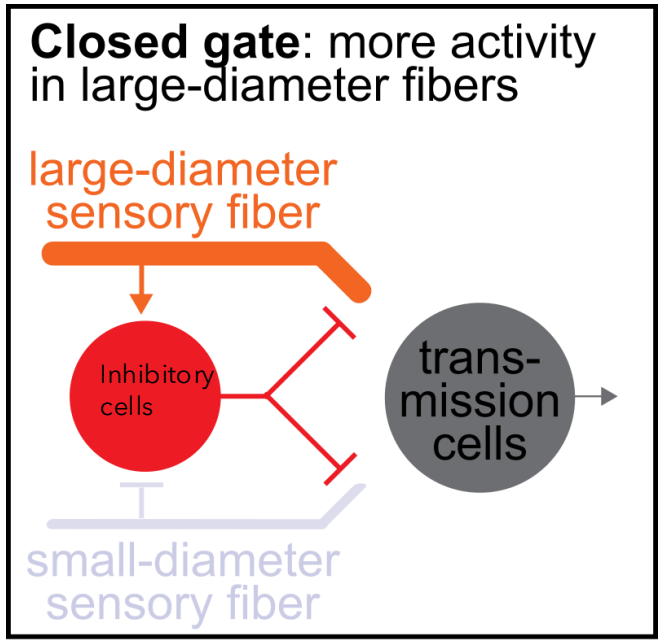
History of SCS

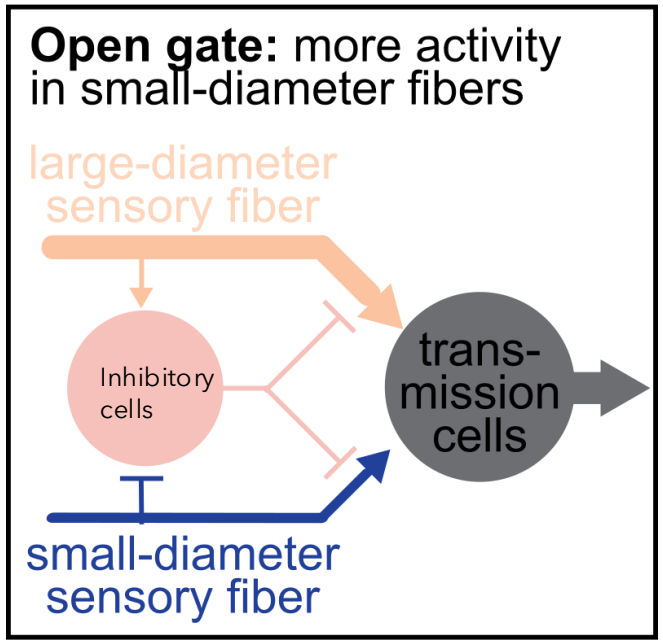
Pain Mechanisms: A New Theory

A gate control system modulates sensory input from the skin before it evokes pain perception and response.

Ronald Melzack and Patrick D. Wall

19 November 1965, Volume 150, Number 3699 SCIENCE





History of SCS

Anesthesia and Analgesia

46(4):489-491, 1967.

Norman Shealy

Assistant Professor of Neurosurgery

U. Wisconsin

Dr. Shealy

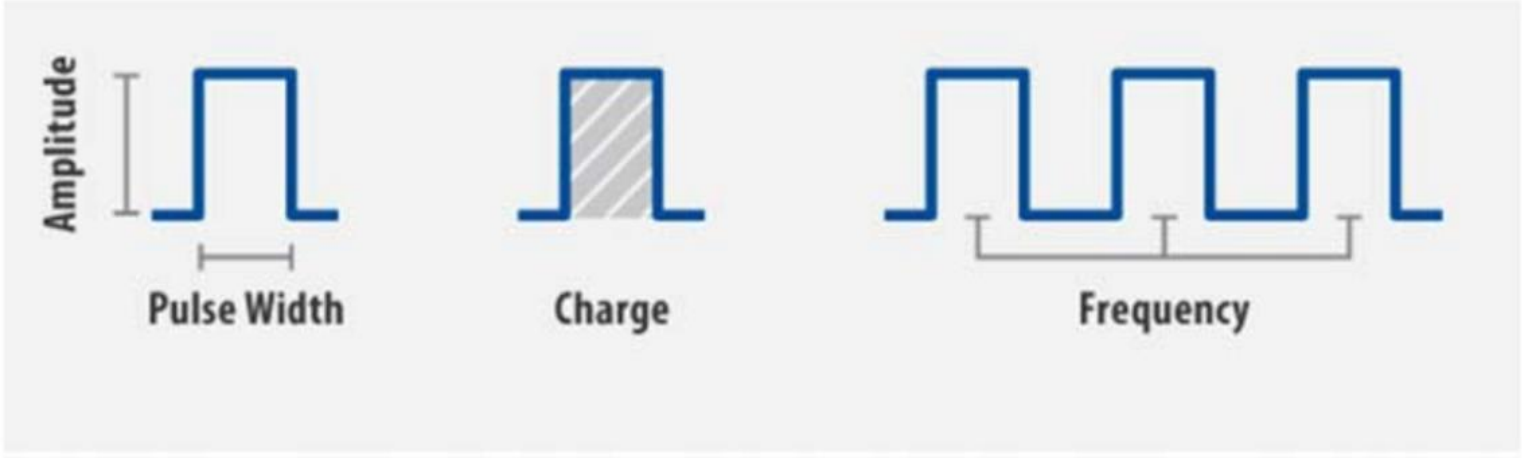
Electrical Inhibition of Pain by Stimulation of the Dorsal Columns:

Preliminary Clinical Report

- 70-year-old make with severe, diffuse chest and abdominal pain from bronchiogenic carcinoma
- Surgically implanted intrathecal electrode at T2-3
- Connected to external cardiac electrical generator
- Stimulation offered complete resolution of pain

Traditional SCS Programming

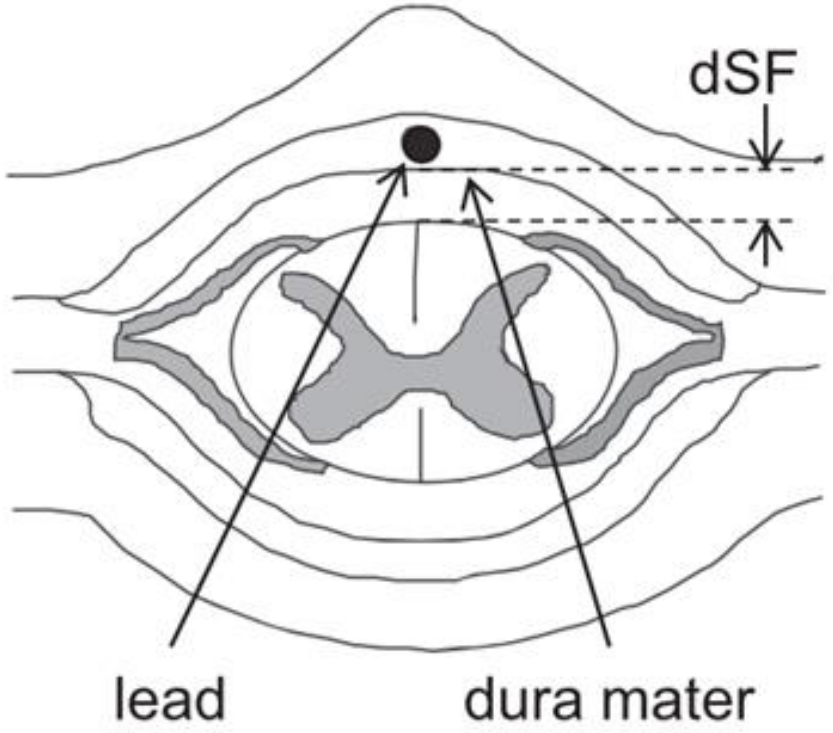
- **Amplitude**
  - 0-10 V or 3.5-8.5 mA
- **Pulse Width**
  - 100 – 400 microseconds (0.1-0.4 msec)
- **Frequency**
  - **20 - 200 Hz**



Miller JP, Eldabe S, Buchser E, Johanek LM, Guan Y, Linderoth B. Parameters of Spinal Cord Stimulation and Their Role in Electrical Charge Delivery: A Review. Neuromodulation. 2016 Jun;19(4):373-84.

Mechanism of Action

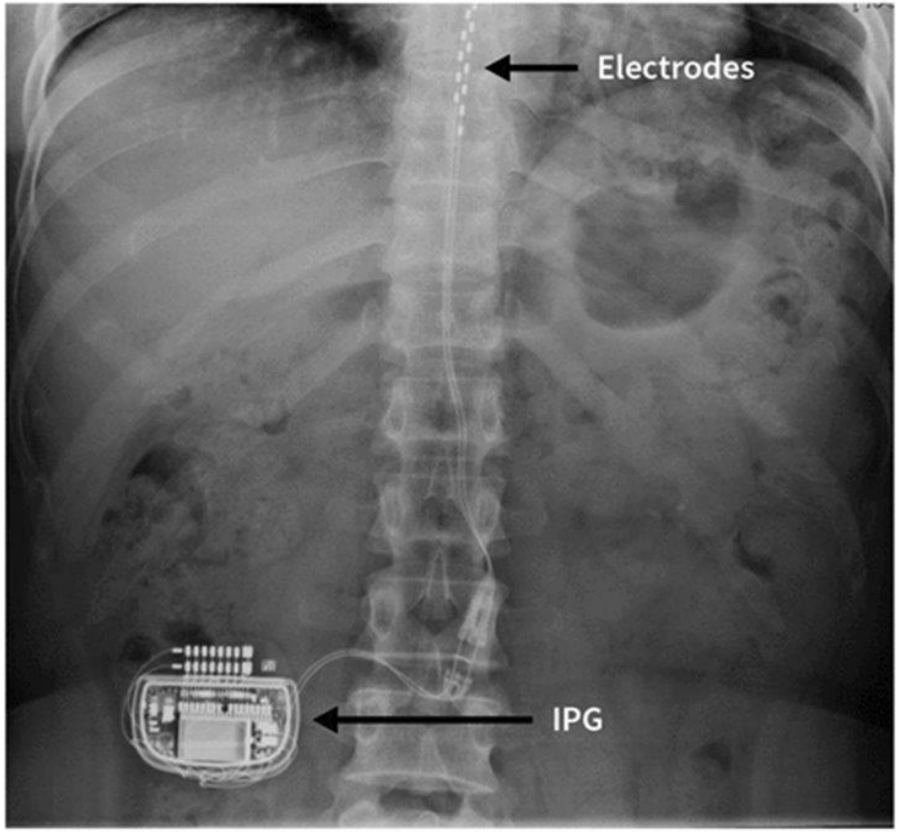
- Gate Control Theory
- Reduced Wide Dynamic Range (WDR) neuron activity
- Supraspinal neurochemistry changes
- Inhibition of sympathetic activity



Kunnumpurath, S., Srinivasagopalan, R. & Vadivelu, N. Spinal cord stimulation: principles of past, present and future practice: a review. *J Clin Monit Comput* **23**, 333–339 (2009).

SCS System

- **Modern SCS systems are made up of three components:**
  - Epidural array of contacts “leads”
  - Power source “implanted pulse generator (IPG)”
  - External programmer and controller
- **Lead Types:**
  - Percutaneous or “wire”
  - Paddle or “laminectomy”



Indications for SCS

- Intractable back and/or leg pain including:
  - Failed Back Surgery Syndrome (Persistent Spinal Pain Syndrome)
  - Complex Regional Pain Syndrome (CRPS)
  - Painful diabetic peripheral neuropathy / Refractory neuropathic pain

- Other:
  - Angina pectoris, ischemic leg pain

Persistent Spinal Pain Syndrome

- FBSS / Post-laminectoy syndrome / PSPS
  - Chronic radicular pain that has recurred or persists in the same distribution despite anatomically satisfactory previous spinal surgery
  - Incidence estimated at 20-40%, greater likelihood with repeated surgery
  - Mechanism: Scar/fibrous tissue formation, lack of full neurologic recovery, centralization of pain…

Spinal Cord Stimulation versus Repeated Lumbosacral Spine Surgery for Chronic Pain: A Randomized, Controlled Trial

- **North RB, et al. 2005**
- **50 patients, all with previous lumbar or sacral surgery. Randomized to reoperation vs SCS.**
  - Crossover allowed after 6 months
    - 67% of reoperation patients crossed over to SCS
    - 17% of SCS patients crossed over to reoperation
- **3 Year follow-up analysis:**
  - **47% of SCS vs 12% of reoperation** group reported >50% pain relief (P<0.01)
    - Reoperation group used significantly more opioids at 3 years
    - No changes in work or functional status

Spinal cord stimulation versus conventional medical management for neuropathic pain: A multicentre randomised controlled trial in patients with failed back surgery syndrome

- **Kumar K, et al. 2007 PROCESS Trial**
- **100 patients with FBSS. Conventional medical management (CMM) vs SCS + CMM.**
- **6 Month intention to treat analysis:**
  - **48% of SCS vs 9% of CMM** groups achieved primary endpoint (50% or greater relief of leg pain)
  - Improved functional capacity and QoL measures ($p<0.02$)
- **24 Month analysis:**
  - **47% of SCS vs 7% of CMM** groups achieved primary endpoint
  - Continued statistically significant improvements in QoL measures

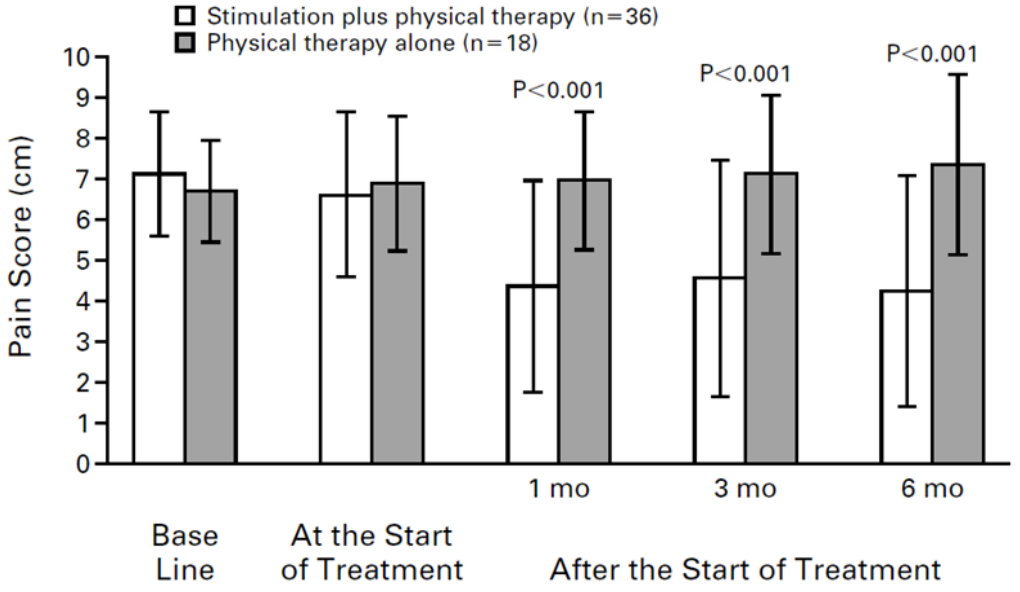
Complex Regional Pain Syndrome (CRPS)

- Chronic pain condition characterized by regional pain with allodynia, often accompanied by autonomic, inflammatory, sensory and vasomotor symptoms
- Incidence rate of 6-26 per 100,000 person-years
- Pathogenesis: likely multifactorial with increased sympathetic activity, inflammation and autoimmunity playing roles

The New England Journal of Medicine

SPINAL CORD STIMULATION IN PATIENTS WITH CHRONIC REFLEX SYMPATHETIC DYSTROPHY

- **Kemler MA, et al. 2000**
- **54 patients with 6-month history of CRPS. Randomized to physiotherapy (PT) vs SCS + PT.**
- **6 Month intention-to-treat analysis:**
  - **56% of SCS vs 6% of PT** group achieved primary endpoint (P=0.008).
  - **VAS reduction:** 2.4 in SCS vs increase of 0.2 in PT group (P=0.01).
  - SCS group had a significant improvement in health-related QoL (P=0.02).
  - No change in functional improvement.

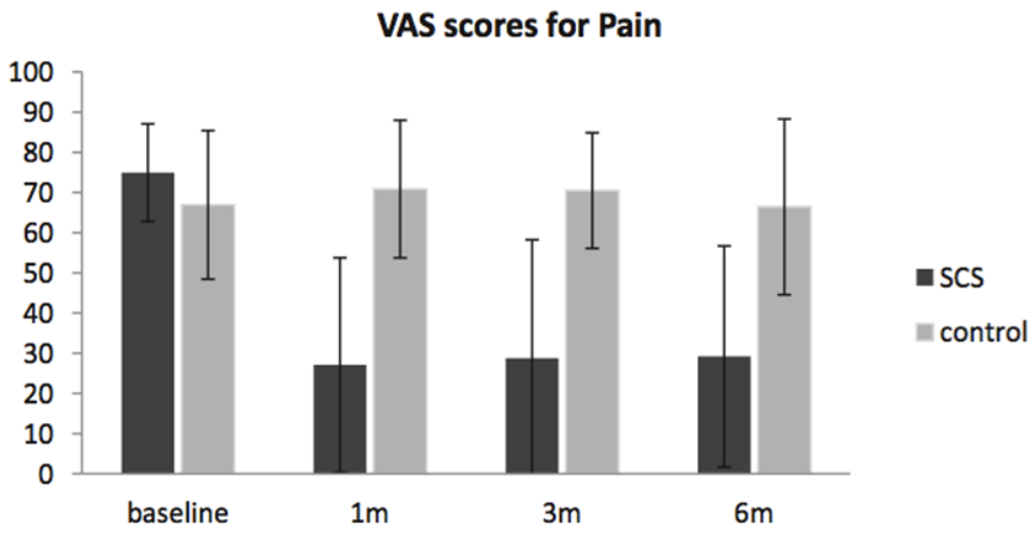


Painful Diabetic Peripheral Neuropathy

- Complication of diabetes resulting in damage to peripheral nervous system, commonly manifesting as pain and impaired sensation in the extremities
- Reported in about 50% of patients with diabetes, with painful neuropathy reported in 10-20% of diabetic patients
- Pathogenesis: associated with microvascular and metabolic impairments leading to damage and death of nerve fibers
  - Hyperglycemia, impaired insulin signaling

Spinal cord stimulation in patients with painful diabetic neuropathy: A multicentre randomized clinical trial

- **De Vos CC, et al. 2014**
- **60 patients with 1 year history of refractory diabetic neuropathic pain. Randomized to CMM vs SCS + CMM.**
- **6 Month intention-to-treat analysis:**
  - **63% of SCS vs 5% of CMM** group achieved > 50% reduction in pain (P<0.001).
  - **VAS reduction:** 4.2 in SCS vs 0 in CMM group (P<0.001).
  - SCS group had a significant improvement in health-related QoL & reduction in opioid use (P<0.05).



Patient Selection

- Failed acceptable conservative therapy
- Patient considerations
  - No bleeding disorders/uniterritable anticoagulation
  - No active systemic infection / infection at implant site
  - Spinal condition that may limit epidural access (spinal stenosis, significant spondylolisthesis)
  - No untreated substance use disorders
  - Psychologically stable
- Disease characteristics
  - Primarily neuropathic in nature
  - Duration of at least 3 months
  - Moderate to severe pain
  - Stable location and nature of pain

High probability of successful pain reduction
Chronic radicular pain (cervical and lumbar)
Complex regional pain syndrome, Types I and II
Painful peripheral mononeuropathies
Angina pectoris refractory to conventional drug therapy and not amenable to surgical bypass
Painful ischemic peripheral vascular disease not amenable to conventional drug therapy or surgical bypass
Low probability of successful pain reduction
Neuropathic pain following spinal cord injury
Central pain (eg, post-stroke pain)
Nerve root avulsion (eg, brachial plexus avulsion)
Unknown probability of pain reduction (case reports of successful treatment)
Postherpetic neuralgia
Axial low back pain
Phantom limb pain

Barriers to SCS

- Failed psychological screening (untreated depression, psychosis)
- Failed SCS trial (<50% pain relief or functional improvement)
- Anatomical considerations: central canal spinal stenosis at level of epidural access or lead placement target, or other significant central canal stenosis – especially cervical spine, severe scoliosis, prior extensive spine fusion and inability to access epidural space, scarring
- Other contraindications: anesthesia associated risk, bleeding abnormalities, current infection or immunosuppression, poorly controlled diabetes, pregnancy

Complication Rates

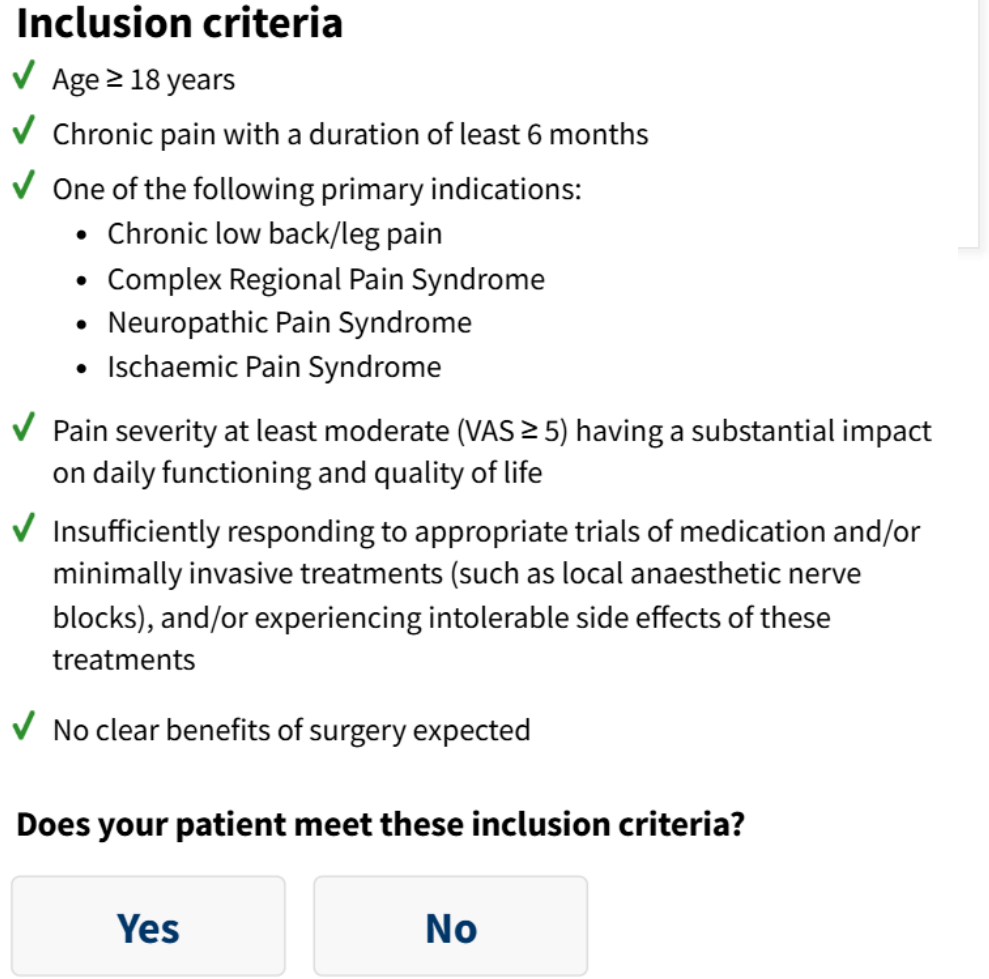
- Stimulator Revision
  - Electrode migration ~10%
  - Equipment failure ~5-10%
  - Pain at Generator Site ~2-5%
- Infection of Implanted Hardware
  - Superficial infection ~3-5%
  - Edpiral abcess < 0.1%
- CSF Leak

Sears NC, et al. Neuromodulation. 2011; 14: 312–318

Incidence of Lead Migration With Loss of Efficacy or Paresthesia Coverage After Spinal Cord Stimulator Implantation: Systematic Review and Proportional Meta-Analysis of Prospective Studies and Randomized Clinical Trials. West, Tyler et al. Neuromodulation, Volume 26, Issue 5, 917 - 92

SCS e-Health Tool

- European panel created tool to assist referring providers detemine patient appropriateness for SCS
- Scstool.org



Thomson S, Huygen F, Prangnell S, De Andrés J, Baranidharan G, Belaïd H, Berry N, Billet B, Cooil J, De Carolis G, Demartini L, Eldabe S, Gatzinsky K, Kallewaard JW, Meier K, Paroli M, Stark A, Winkelmüller M, Stoevelaar H. Appropriate referral and selection of patients with chronic pain for spinal cord stimulation: European consensus recommendations and e-health tool. Eur J Pain. 2020 Jul;24(6):1169-1181.

Exclusion criteria

- ✕ Unwilling to have an implant
- ✕ Unable to manage the device
- ✕ Absolute contra-indications for active treatment (e.g. unfit for undergoing SCS, pregnancy, spine infection, coagulation disorder)
- ✕ Uncontrolled disruptive psychological or psychiatric disorder
- ✕ Ongoing alcohol and drug misuse
- ✕ Widespread pain

Are any of these conditions present?

No | **Yes**

Chronic low back/leg pain

Complex Regional Pain Syndrome

Neuropathic Pain Syndromes

Ischaemic Pain Syndromes

Patient profile

Previous spine surgery: **No** | **Yes**

Main location of pain: **Leg** | **Back** | **Mixed**

Dominant type of pain: **Neuropathic** | **Mixed** | **Neuropathic-like** | Nociceptive

Anatomic abnormality: **None or not concordant with symptoms**

Response to root block, TENS, epiduroscopy, RF and/or NP medication: **No clinically relevant response** | **At least partial/temporary effect**

Appropriateness of SCS (clinical aspects)

May be appropriate

1 2 3 4 5 6 7 8 9

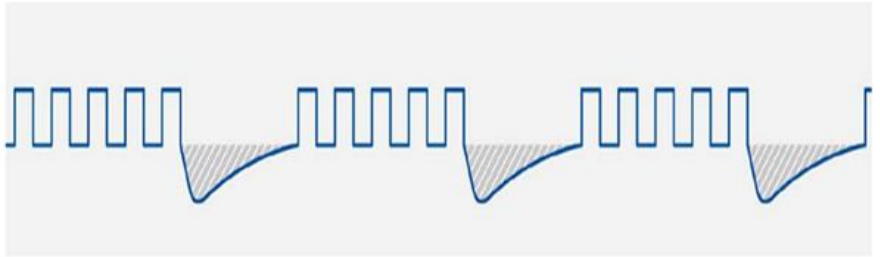
SCS may be an option in this patient, but the probability of success is uncertain. A trial may be considered.

Panel considerations

SCS may be indicated in patients without a clear anatomic abnormality explaining the symptoms after previous spinal surgery, and for whom no clear benefits from surgery are expected.
The probability of success is higher if the neuropathic component of pain is larger, and/or if there has been at least a partial or temporary effect of a root block, TENS, epiduroscopy and/or neuropathic pain medication.

Show recommendations | **Save profile** | **Clear profile** | **Continue**

Traditional vs High-frequency vs Burst SCS



Traditional SCS

- Amplitude
  - 0-10 V or 3.5-8.5 mA
- Pulse Width
  - 100 – 400 µs
- Frequency
  - 20 - 200 Hz

HF-SCS

- Amplitude
  - Sub-paresthesia 0.5-6 mA
- Pulse Width
  - 30 µs
- Frequency
  - 10,000 Hz

Burst SCS

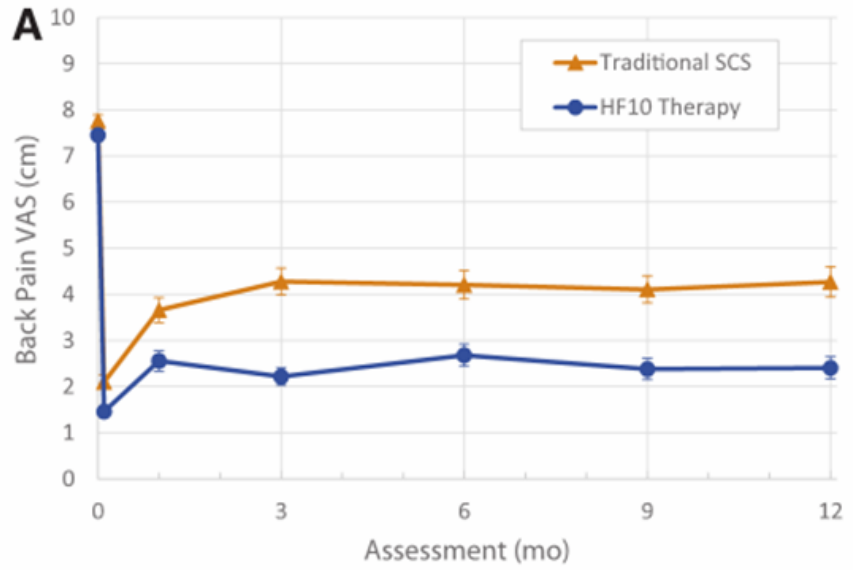
- Amplitude
  - Sub-paresthesia 0.5-6 mA
- Pulse Width
  - 1000 µs
- Frequency
  - 500 Hz

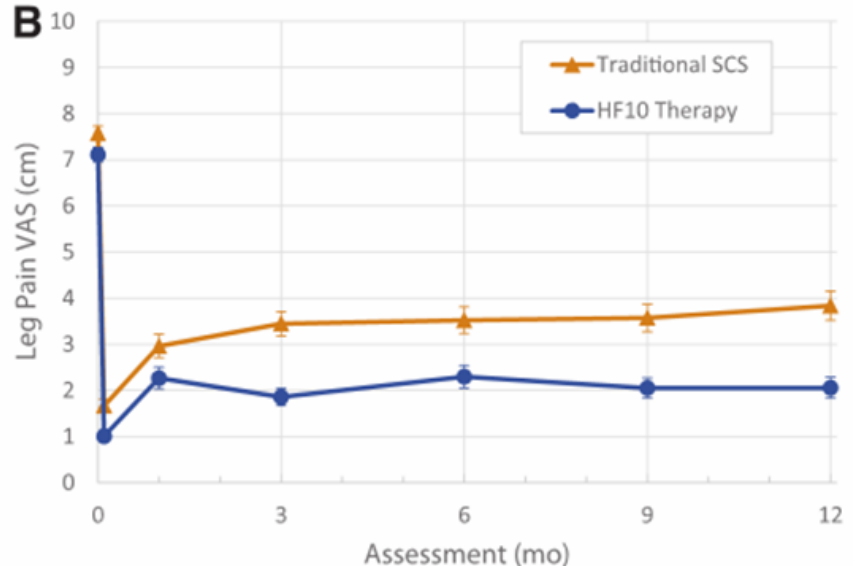
Miller JP, Eldabe S, Buchser E, Johanek LM, Guan Y, Linderoth B. Parameters of Spinal Cord Stimulation and Their Role in Electrical Charge Delivery: A Review. Neuromodulation. 2016 Jun;19(4):373-84.

Novel 10-kHz High-frequency Therapy (HF10 Therapy) Is Superior to Traditional Low-frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain

The SENZA-RCT Randomized Controlled Trial

- Kapural et al. Anesthesiology 2015
- 189 patients underwent trial, 171 (90.5% implanted)
- 77.1% with FBSS, mean duration of pain 13 years
- Primary Endpoint of 50% VAS Pain Reduction
  - 78.7% of 10 kHz vs 51.3% of CS at 12 months
- Back Pain VAS Decrease
  - 10 kHz: 7.4 ± 1.2 to 2.5 (-67%)
  - CS: 7.8 ± 1.2 to 4.3 (-44% $p < 0.001$)
- Leg Pain VAS Decrease
  - 10kHz: 7.1 ± 1.5 to 2.1 (-70%)
  - CS: 7.6 ± 1.4 to 3.8 (-49% $p < 0.001$)
- Opioid Usage (in morphine mEq/day)
  - 10 kHz: 112.7 mg to 87.9 mg ($p = 0.014$)



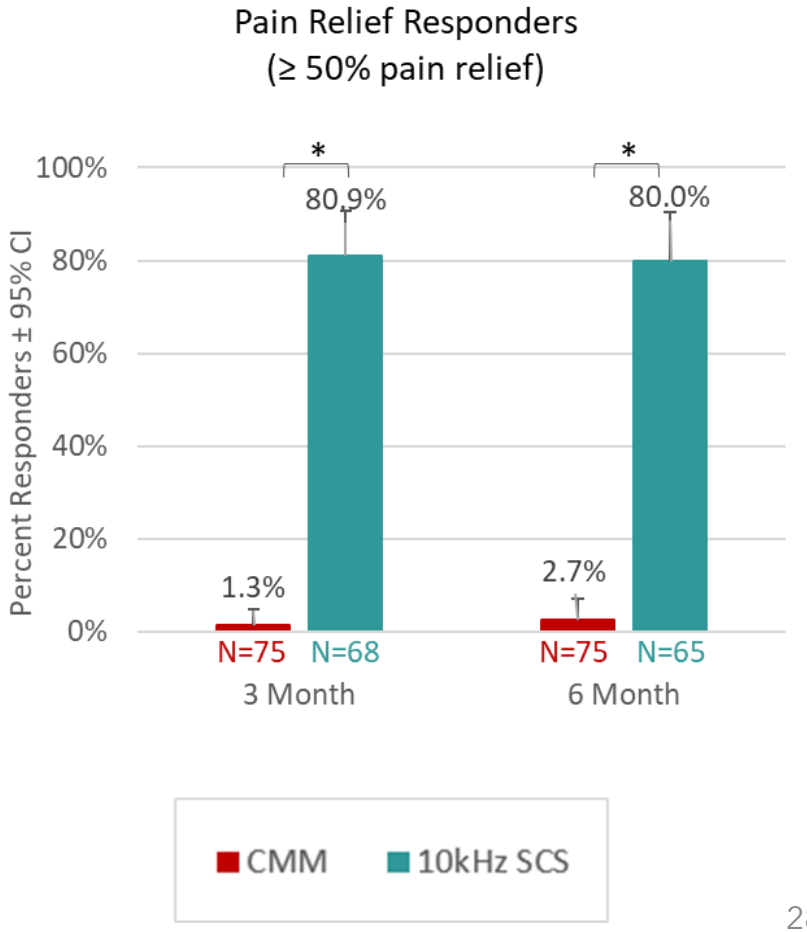


Durable responses at 24 months with high-frequency spinal cord stimulation for nonsurgical refractory back pain

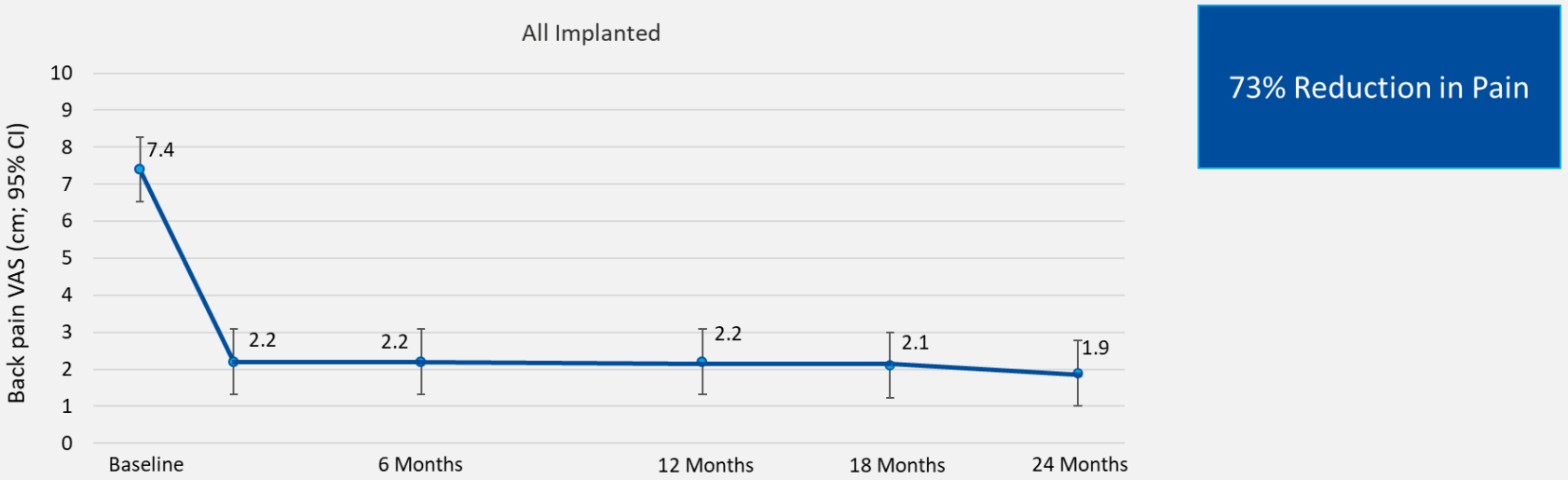
- Patel et al. Journal of Neurosurgery 2023

- 144 participants with back pain VAS ≥ 5 cm
- Refractory to conservative treatments
- No previous spine surgery and not a candidate for spine surgery
- CMM vs 10 kHz + CMM
  - Optional crossover at 6mo

Primary Endpoint:



Response at 24 months



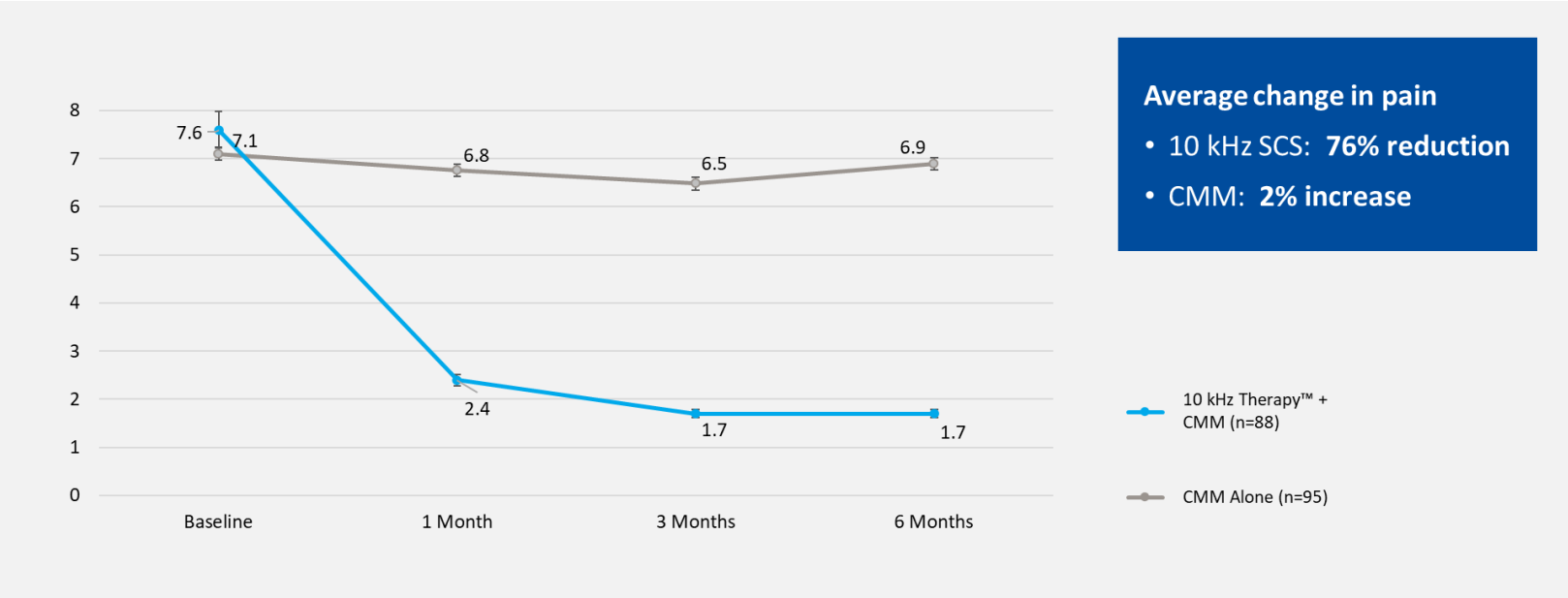
- 82% responders
- 58% profound responders
- 47% reduction in severely disabled patients, as measure by ODI
- 67% reduction in sleep disturbances
- 62% stopped or decreased opioid use
- Improved 50 ft walk test on average by 2 seconds

JAMA Neurology | Original Investigation

Effect of High-frequency (10-kHz) Spinal Cord Stimulation in Patients With Painful Diabetic Neuropathy
A Randomized Clinical Trial

- Petersen, et al. JAMA Neurology 2021 – 12mo data published 1/2022, 24mo data published 8/2023

- 216 participants with lower extremity PDN refractory to medications
- ≥5 of 10 cm on pain VAS, HbA1c ≤10%, BMI ≤45
- CMM vs. 10 kHz + CMM

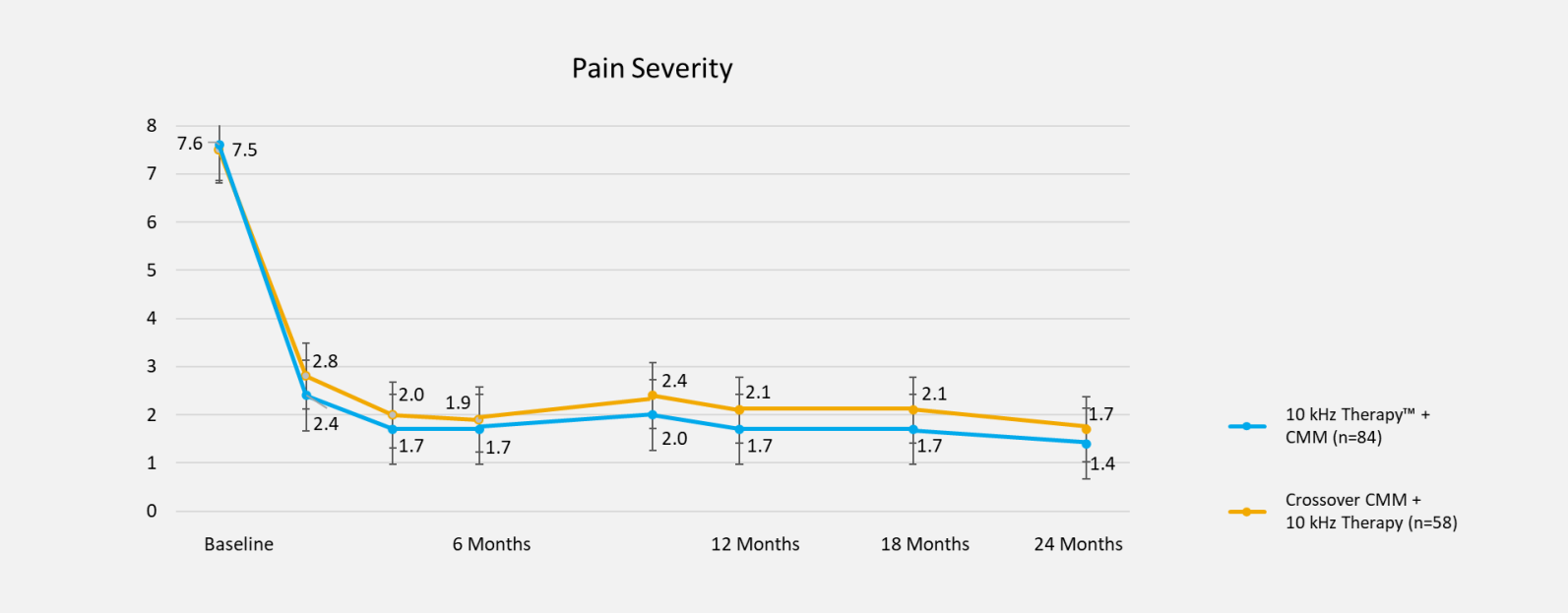


*p<0.001 vs. Baseline
#p<0.001 vs. CMM alone

Long-term efficacy of high-frequency (10 kHz) spinal cord stimulation for the treatment of painful diabetic neuropathy: 24-Month results of a randomized controlled trial

- Petersen et al. Diabetes Research and Clinic Practice 2023

- 90% responders (128/142)
  - 65% profound responders
- Average 80% pain relief
- Improvement in dysesthesias
- Reduction in sleep disturbance

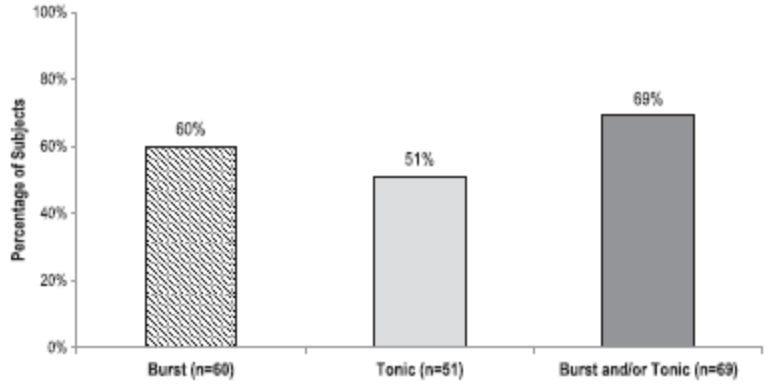


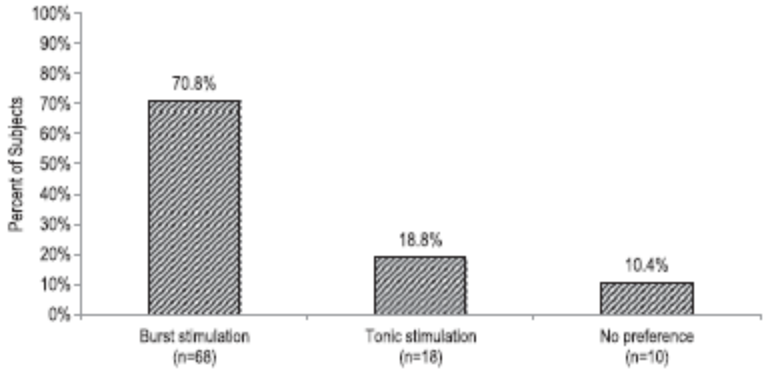
*Error Bars: 95% CI

Success Using Neuromodulation With BURST (SUNBURST) Study: Results From a Prospective, Randomized Controlled Trial Using a Novel Burst Waveform

- Deer et al. 2017 Neuromodulation

- 100 participants with chronic intractable pain of trunk and/or limbs with VAS ≥60
- Within-subject crossover design
- Two phases:
  - 12 weeks in traditional SCS and 12 weeks in burst SCS
  - Open-label phase in which patient can choose either waveform





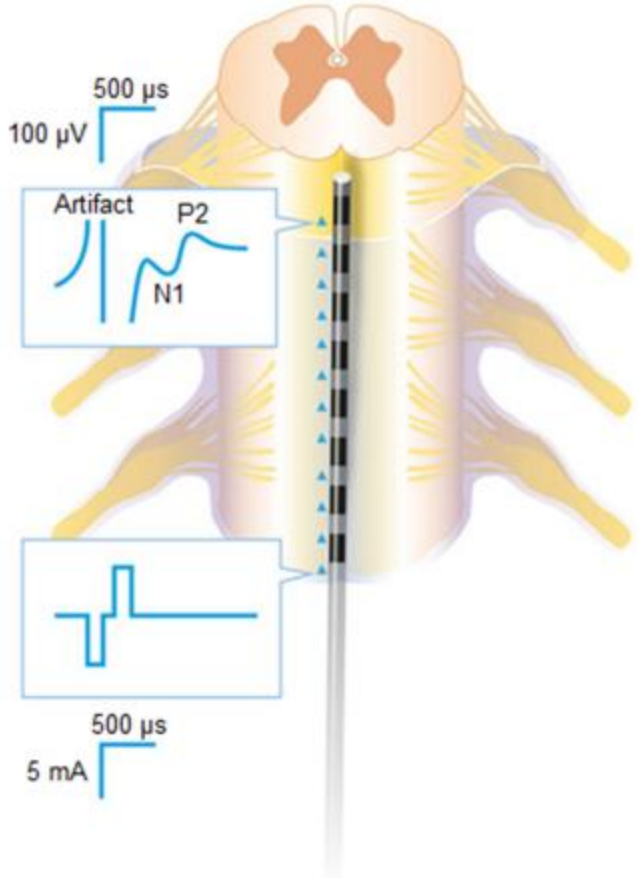
A New Direction for Closed-Loop Spinal Cord Stimulation: Combining Contemporary Therapy Paradigms with Evoked Compound Action Potential Sensing

- Historically stimulation has been delivered with fixed parameteres (open-loop)
  - Does not account for fluctuations in spacing between the electrodes and the spinal cord with postural changes and activity
  - Results in inconsistent therapeutic efficacy and durability
- Closed-loop stimulation was developed to compensate for this variability and automatically adjust stimulation parameters

Vallejo R, Chakravarthy K, Will A, Trutnau K, Dinsmoor D. A New Direction for Closed-Loop Spinal Cord Stimulation: Combining Contemporary Therapy Paradigms with Evoked Compound Action Potential Sensing. J Pain Res. 2021 Dec 29;14:3909-3918.

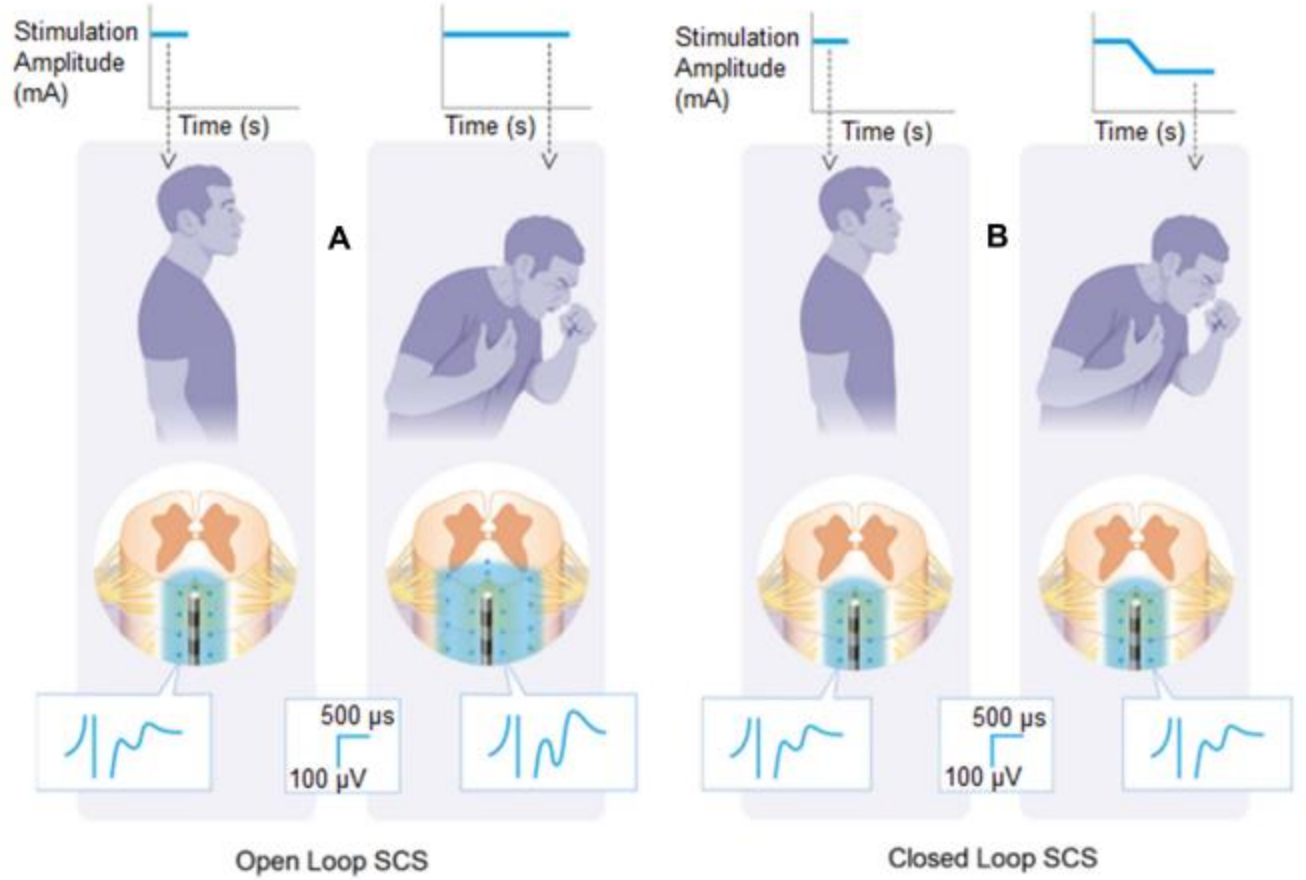
Evoked Compound Action Potentials (ECAPs)

- ECAPs – electrophysiological recording of axons' action potentials as a result of stimulation
- ECAPs work as a feedback control to adjust stimulation amplitude and consistently maintain the proper volume of tissue activation and optimal SCS dose



Closed-Loop SCS Systems

- Algorithm sense neural responses 50 times/second and adjust stimulation accordingly
- Patient only senses consistent stimulation



The Application of Artificial Intelligence to Enhance Spinal Cord Stimulation Efficacy for Chronic Pain Management: Current Evidence and Future Directions

- Goal is to improve patient outcomes through predictive modeling for real-time adaptive stimulation
- Algorithm trained on real-world patient data
- Designed to maintain pain relief without the challenges seen with in-person reprogramming
- Promotes more active patient participation

Prunskis, J.V., Masys, T., Pyles, S.T. *et al*. The Application of Artificial Intelligence to Enhance Spinal Cord Stimulation Efficacy for Chronic Pain Management: Current Evidence and Future Directions. *Curr Pain Headache Rep* **29**, 85 (2025).

Artificial Intelligence in SCS

- One system prompts daily app check-ins on:
  - Overall pain relief
  - Pain score
  - Activity level
  - Pain medication intake
  - Sleep quality
- Then it uses the AI algorithm to make therapy adjustments
- Can contact in-person care team for proactive intervention

Take-home Points

- SCS can be a successful way to treat chronic painful conditions in the right patient for the right indication
- Newer SCS waveforms have shown to be more effective than traditional SCS
- Closed-loop techonology aims to make SCS dosing more consistent
- Artificial Intelligence aims to increase patient engagement and therapy personalization

Questions?

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