

# Spinal Cord Stimulation: an introduction

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# Spinal Cord Stimulation: an introduction

- CONSULTANT: SORRENTO THERAPEUTICS – RESINIFERATOXIN
- GRANT/RESEARCH SUPPORT: WEX PHARMACEUTICALS – HALNEURON (TETRODOTOXIN)
- SPEAKER’S BUREAU: NONE
- SHAREHOLDER: NONE
- OTHERS:
  - Co-director of Advocacy and Legislative Fellowship, North American Neuromodulation Society
  - Board of Directors (Secretary), Pacific Spine and Pain Society
  - Board of Directors, American Society of Pain and Neuroscience

**This presentation contains no off-label and/or investigational uses of drugs or products.**

# Spinal Cord Stimulation

- Learning Objectives

- What is Neuromodulation?
- What are some selection criteria for patients considering SCS?
- What are the common complications of Spinal Cord Stimulation?

- Literature References


- Deer TR, Krames E, Mekhail N, et al. The appropriate use of Neurostimulation: New and evolving Neurostimulation therapies and applicable treatment for chronic pain and selected disease states. *Neuromodulation* 2013; 17: 599-615 DOI:10.1111/ner.12204.
- Kapural L, Yu C, Doust M, et al. 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. *Anesthesiology* 2015; 123:851-60.



# What is Neuromodulation?

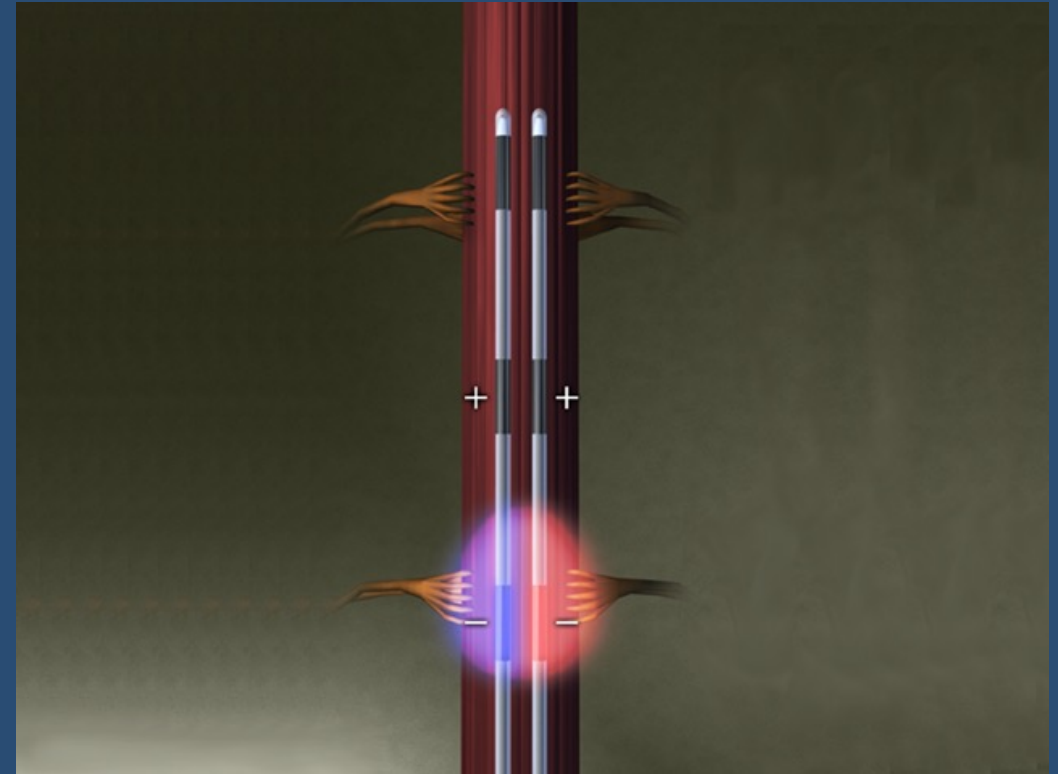
- Definition: “the alteration of nerve activity through targeted delivery of a stimulus, such as electrical stimulation or chemical agents, to specific neurological sites in the body”
- One of the fastest growth areas for technology to address acute and chronic pain
- Some common examples include:
  - Transcutaneous Electrical Nerve Stimulation
  - Intrathecal Drug Delivery Systems
  - Spinal Cord Stimulation
  - Peripheral Nerve Stimulation

Which device  
do I choose?  
Depends on  
the body  
area!

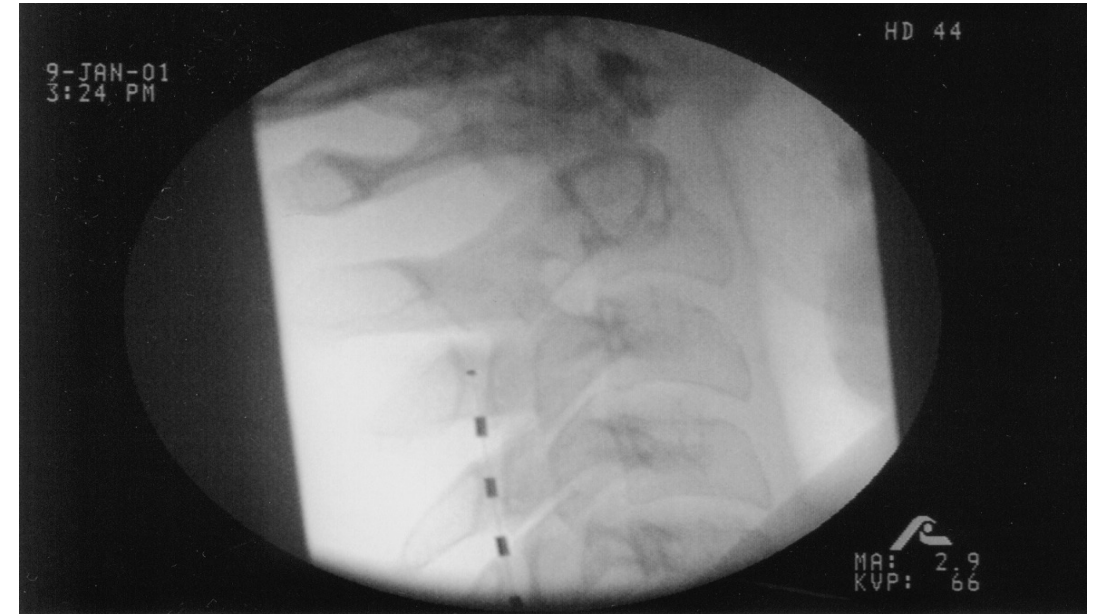
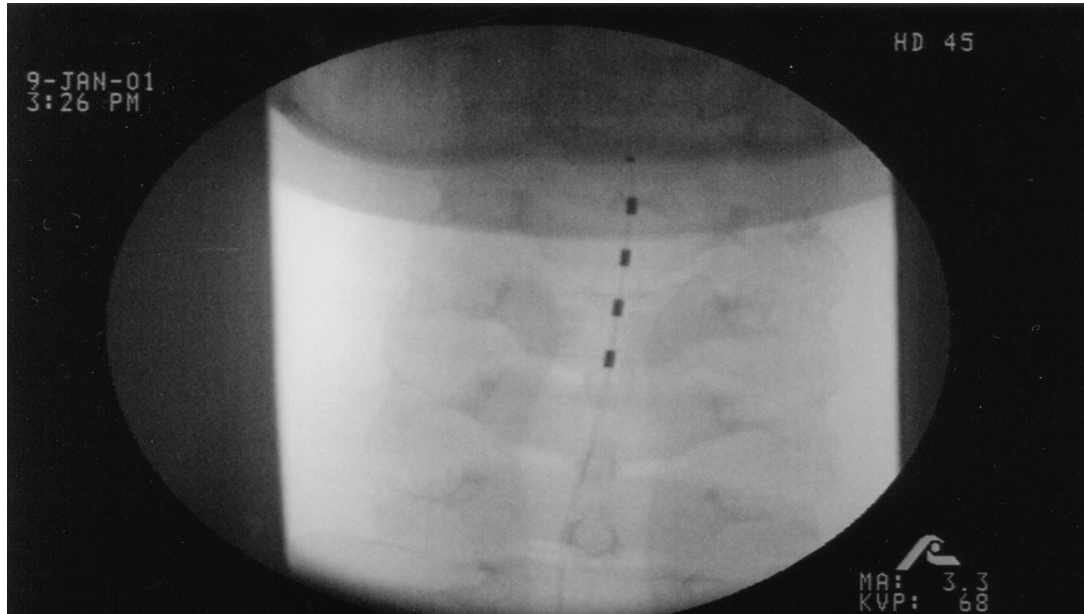
- Head:
    - Transcranial Magnetic Stimulation
    - Deep Brain Stimulation
  - Neck: Vagal Nerve Stimulation
  - Shoulders: TENS, H-wave, Interferential units
  - Back: Spinal Cord Stimulation, Dorsal Root Ganglion Stimulation
  - Arms and Legs: Peripheral Nerve Stimulation
  - All over: Intrathecal Drug Delivery Systems
- 

# Medicine by Edison

- **Electrical fields at axial spine and periphery**
- **Failed back surgery syndrome**
- **Complex regional pain syndrome**
- **Other areas: face, trunk, abdomen, pelvis, arms and legs**



# Spinal Cord Stimulation



# First uses of electrical stimulation

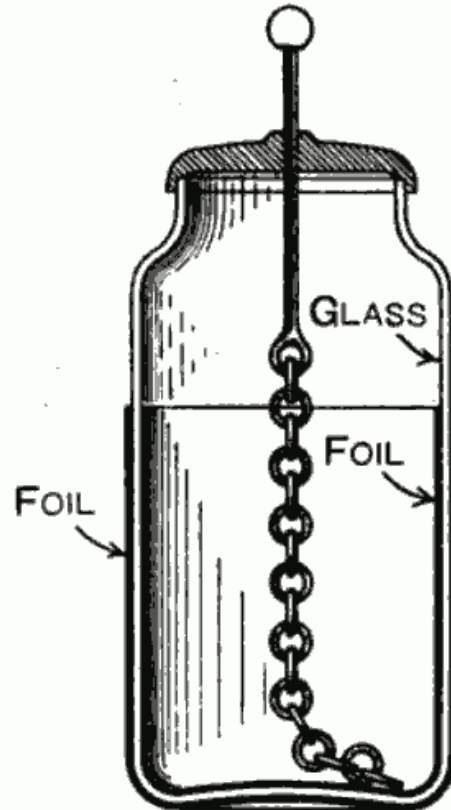


Torpedo Fish “electric ray” up to 220V: stand on them to relieve gout

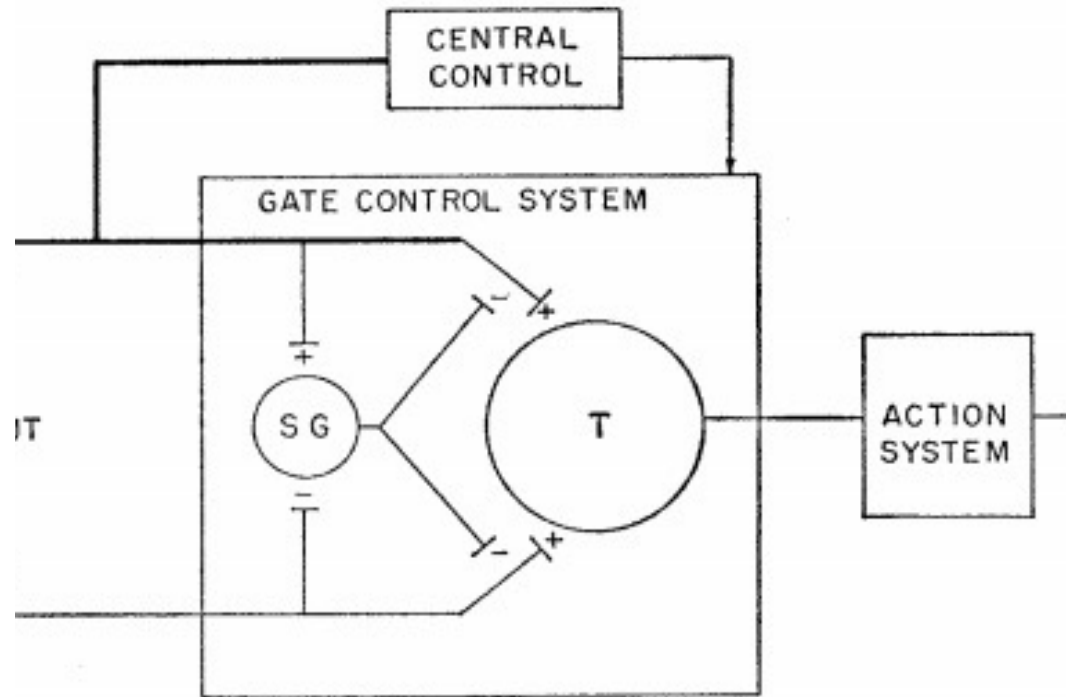


# Creating, storing and controlling electricity

- 1745 Leyden jar was developed. Now, humans are able to generate, store and discharge electricity at any time - Capacitor



# Gate Control Theory by Wall and Melzack 1965



Schematic diagram of the gate control theory of pain mechanisms:  $L$ , large-diameter fibers;  $S$ , the small-diameter fibers. The fibers project to the subsidiary ( $SG$ ) and first central transmission ( $T$ ) cells. The inhibitory effect exerted by the afferent fiber terminals is increased by activity in  $L$  fibers and decreased by activity in  $S$  fibers. The central control trigger is represented by a line running through the gate-fiber system to the central control mechanisms; these mechanisms, in turn, project back to the gate control system. The  $T$  cells project to the entry cells of the action system. +, Excitation; -, inhibition (see text).



TENS device



## Spinal Cord Stimulation

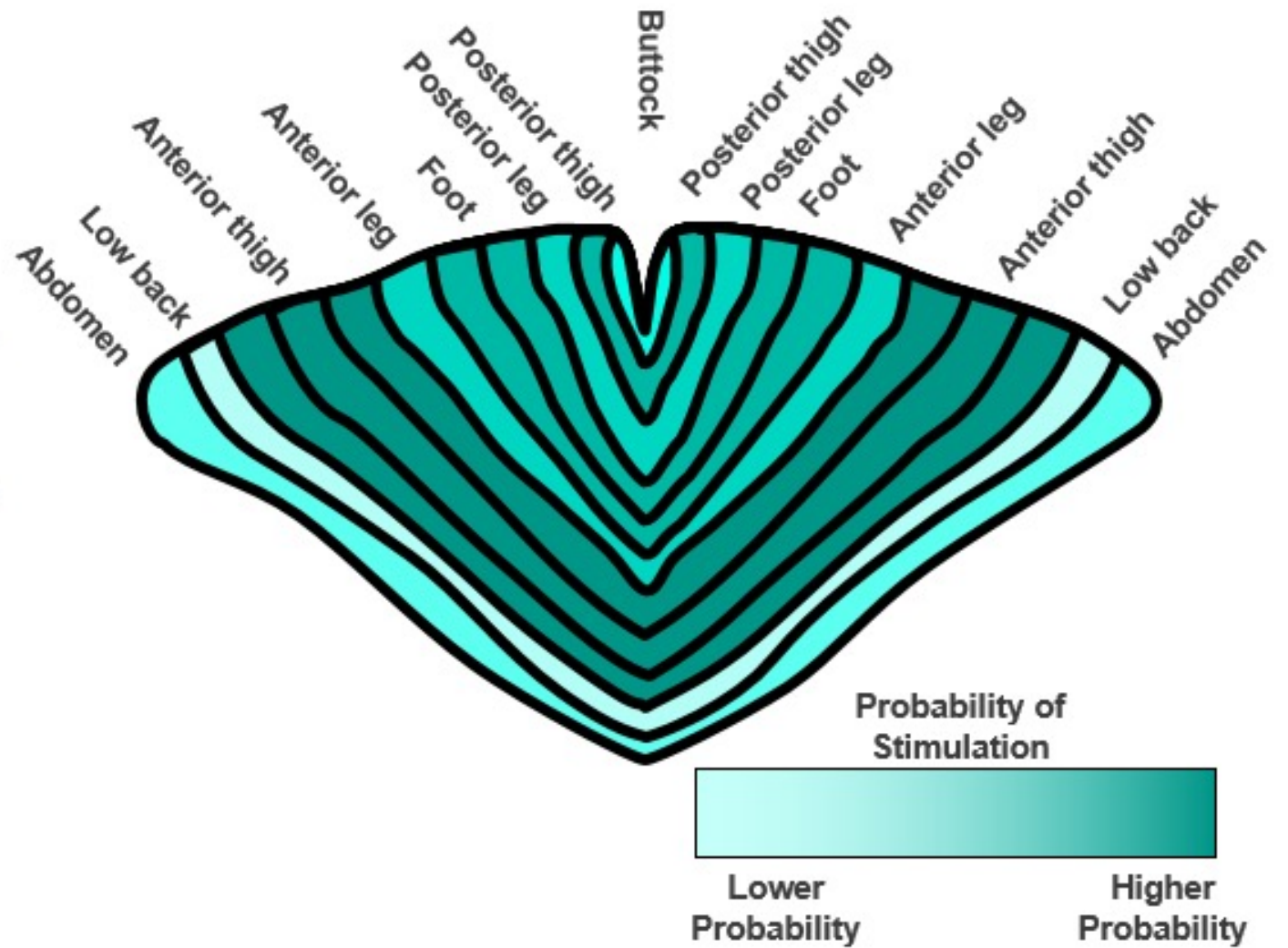
**Also in 1967, neurosurgeon C. Norman Shealy, using the mechanisms from Gate Control Theory, applied electrodes to the the dorsal columns**



**Dr. Shealy**

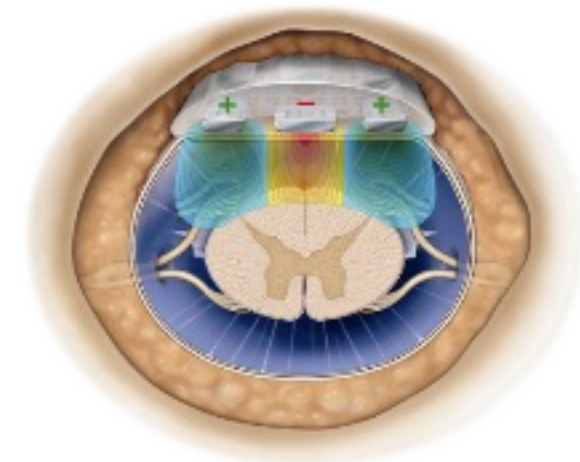
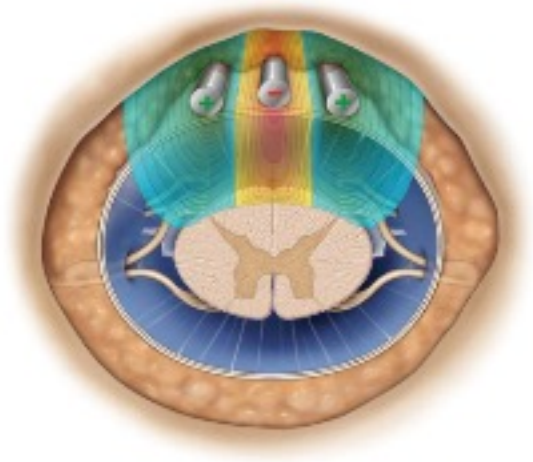
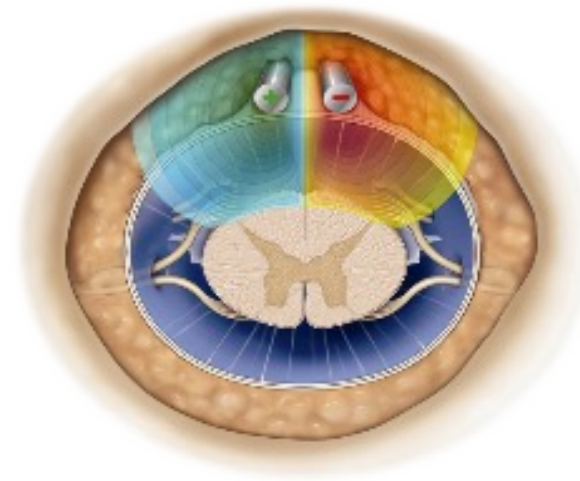
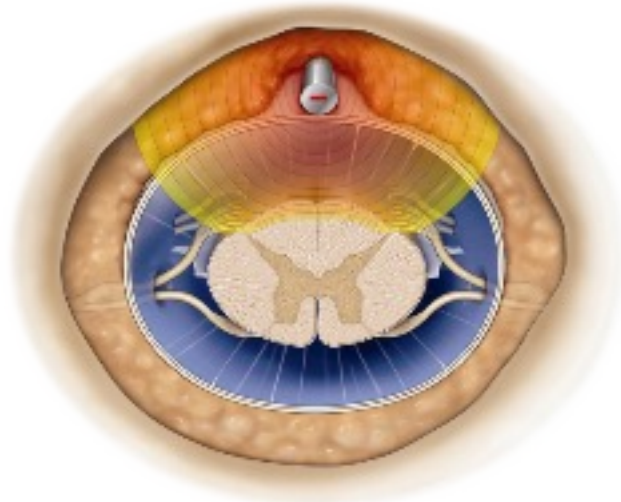
# Spinal Cord Stimulation – Dorsal Column Organization

- Dorsal Column
- Organization of body area
- at lower thoracic spinal cord

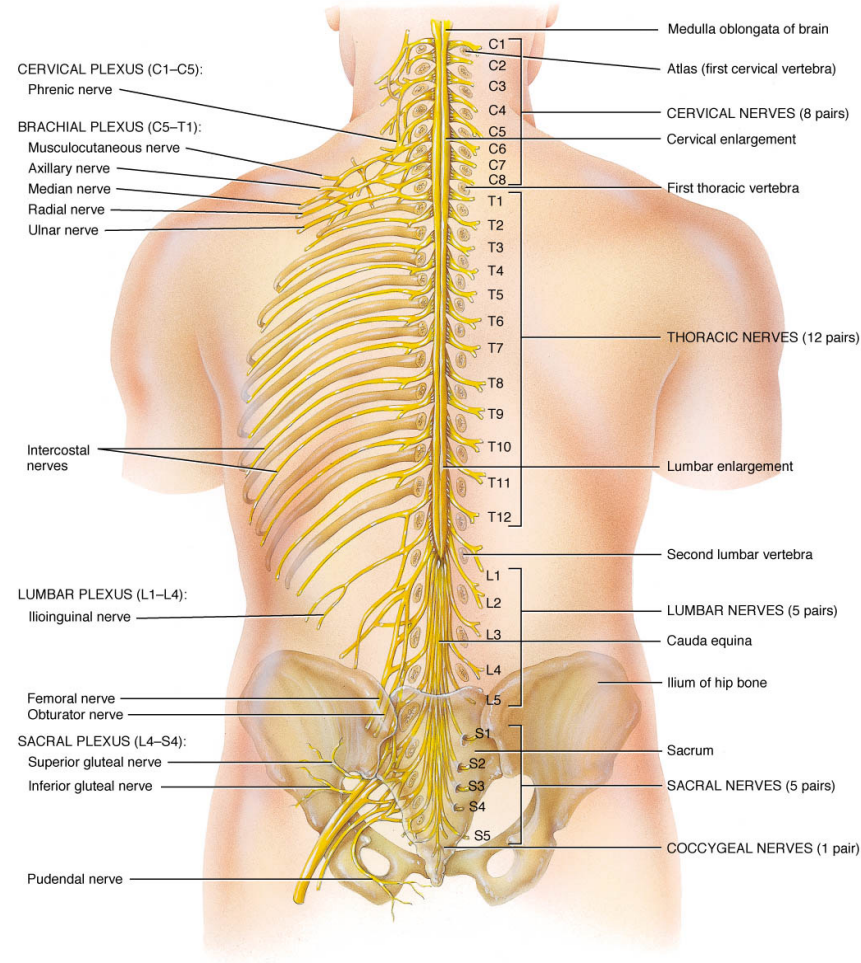


# Spinal Cord Stimulation

With single lead, as power increases, the depth and lateral area of the negative potential lines increases, possibly stimulating lateral nerves.



# Spinal Nerves Exit Higher Than The Level of the Low Back



Posterior view of entire spinal cord and portions of spinal nerves and their branches

# Spinal Cord Stimulation Patient Selection

## Physician Screening

- Is SCS effective for your type of pain?
  - Especially good for back and radiating pain to legs
  - Can help for other pain conditions as well but not as effective
- Typical interdisciplinary therapies have not provided sufficient relief
  - Medications, Interventions, Physical Rehabilitation, Mind / Body (Pain Psychology)
- Social habits: alcohol, opioids, tobacco
  - Tobacco can prevent wound healing and can promote infection
- No medical or structural problems with the procedure
  - Lab studies
  - MRI or CT myelogram prior to SCS trial



# Spinal Cord Stimulation Patient Selection

## Pain Psychological Evaluation

- To predict and improve the effectiveness of SCS for your therapy
- To assess and treat any factors that could interfere with the SCS trial: severe anxiety and depression, active thought disorders (psychoses)
- Everyone has similar expectations: > 50% pain control, increased function, lower medications; everyone understands the risks and potential problems
- Required by insurance companies
- Outcomes:
  - Timing is good
  - May require a few (1 to 4 sessions) for preparation
  - Other factors need to be addressed first

# SCS and Complications

	Event	General Frequency	
Technical Problems	Lead migration	Frequent	
	Hardware malfunction		
	Lead fracture		
Complications	Seroma/cerebrospinal fluid leakage	Infrequent	
	Pain (at pulse generator)		
	Infection		
	Hematoma (subcutaneous)		
	Injury (nerve/spinal cord)		Very rare
	Hematoma (epidural)		
	Allergic reaction		
	Skin erosion		
	Other		

# Neuromodulation

Identification of SCS candidate by treating pain physician

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graph TD; A[Identification of SCS candidate by treating pain physician] --> B[Evaluation by pain psychologist]; B --> C[Discussion at multidisciplinary team conference]; C --> D[Randomization];
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Evaluation by pain psychologist

Discussion at multidisciplinary team conference

Randomization

# Neuromodulation Team Conference

Comparison of Trial Outcomes		
	With Conference	Without Conference
# of trials	87	70
# of implants	73 (84%)	32 (46%)
# of revisions	9 (12%)	6 (19%)
# of explants	5 (7%)	7 (22%)

# Spinal Cord Stimulation and Failed Back Surgery Syndrome (FBSS)

- **FBSS is a group of disorders in which pain continues or recurs after spinal surgery**
- **Etiologies are complex**
  - Inside the spinal column: degenerative disc disease, canal stenosis, fibrosis
  - Outside the spinal column: radiculopathy, facet disease
- **Back pain with radiation to the legs in Failed Back Surgery Syndrome (FBSS) is the most common indication for SCS**

# Spinal Cord Stimulation and FBSS

Reference	Number of patients	Results
<a href="#">Tiede et al (2013)</a> <sup>1</sup>	24	Significant improvement in overall pain score ( $P < 0.001$ )
Moriyama et al (2012) <sup>2</sup>	17	Decrease in pain intensity (VAS) from 68.9 to 39.5
De Vos et al (2012) <sup>3</sup>	45	For lower limb and low back pain, significant decrease in pain intensity from 8.0 and 7.5 to 3.2 and 3.5, respectively ( $P < 0.001$ )
Sears et al (2011) <sup>4</sup>	17	29.4% had $\geq 50\%$ pain relief
<a href="#">Eldabe et al (2010)</a> <sup>5</sup>	100	69% had $\geq 30\%$ pain relief
Kumar et al (2008) <sup>6</sup>	100	Significant improvement in pain intensity ( $P < 0.001$ )
Kumar et al (2007) <sup>7</sup>	100	48% had $\geq 50\%$ pain relief
North et al (2005) <sup>8</sup>	50	SCS was successful in 47%
North et al (1994) <sup>9</sup>	27	Significant reduction in crossover to reoperation ( $P = 0.018$ )

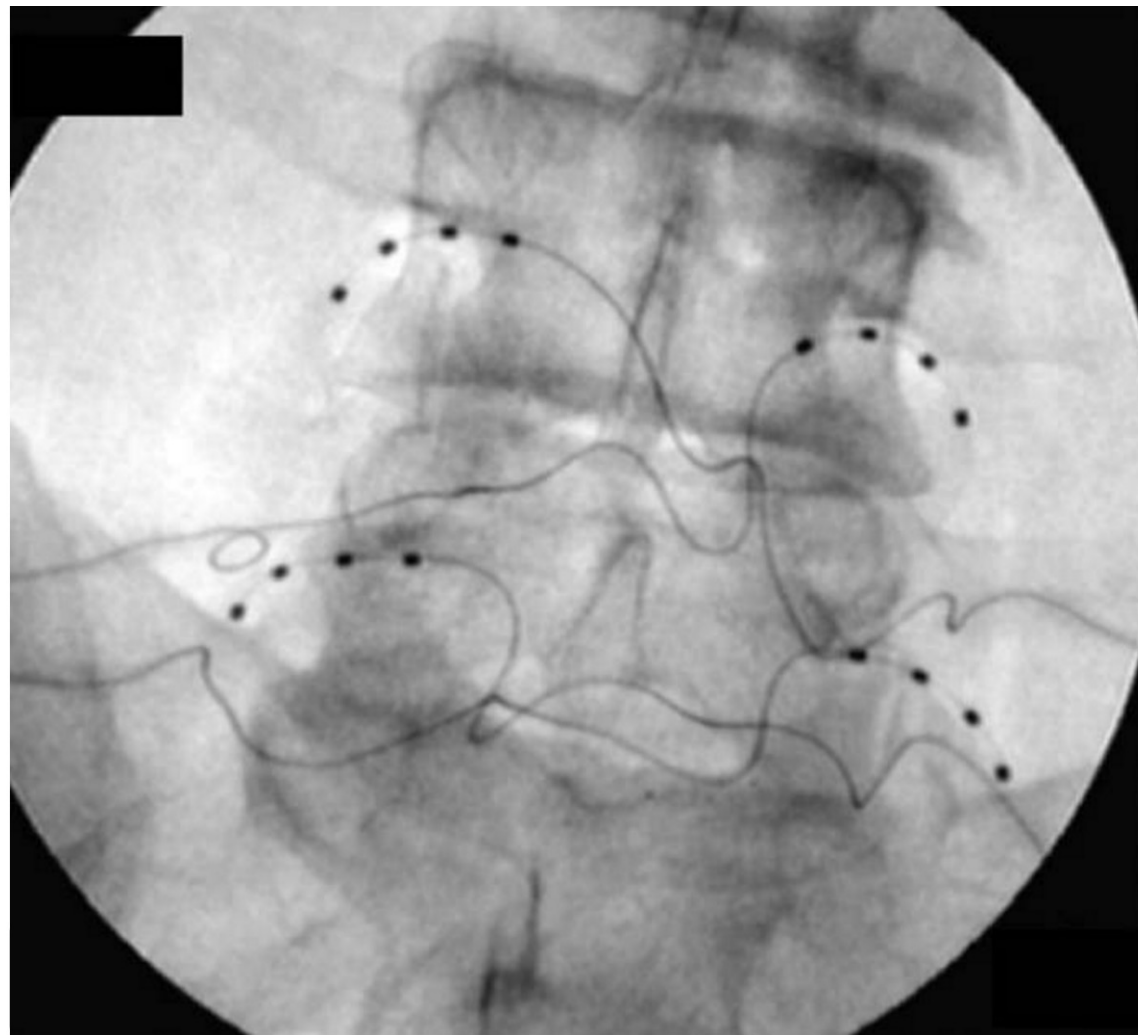
# SENZA Study – 2015

## **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*

Leonardo Kapural, M.D., Ph.D., Cong Yu, M.D., Matthew W. Doust, M.D., Bradford E. Gliner, M.S., Ricardo Vallejo, M.D., Ph.D., B. Todd Sitzman, M.D., M.P.H., Kasra Amirdelfan, M.D., Donna M. Morgan, M.D., Lora L. Brown, M.D., Thomas L. Yearwood, M.D., Ph.D., Richard Bundschu, M.D., Allen W. Burton, M.D., Thomas Yang, M.D., Ramsin Benyamin, M.D., Abram H. Burgher, M.D.

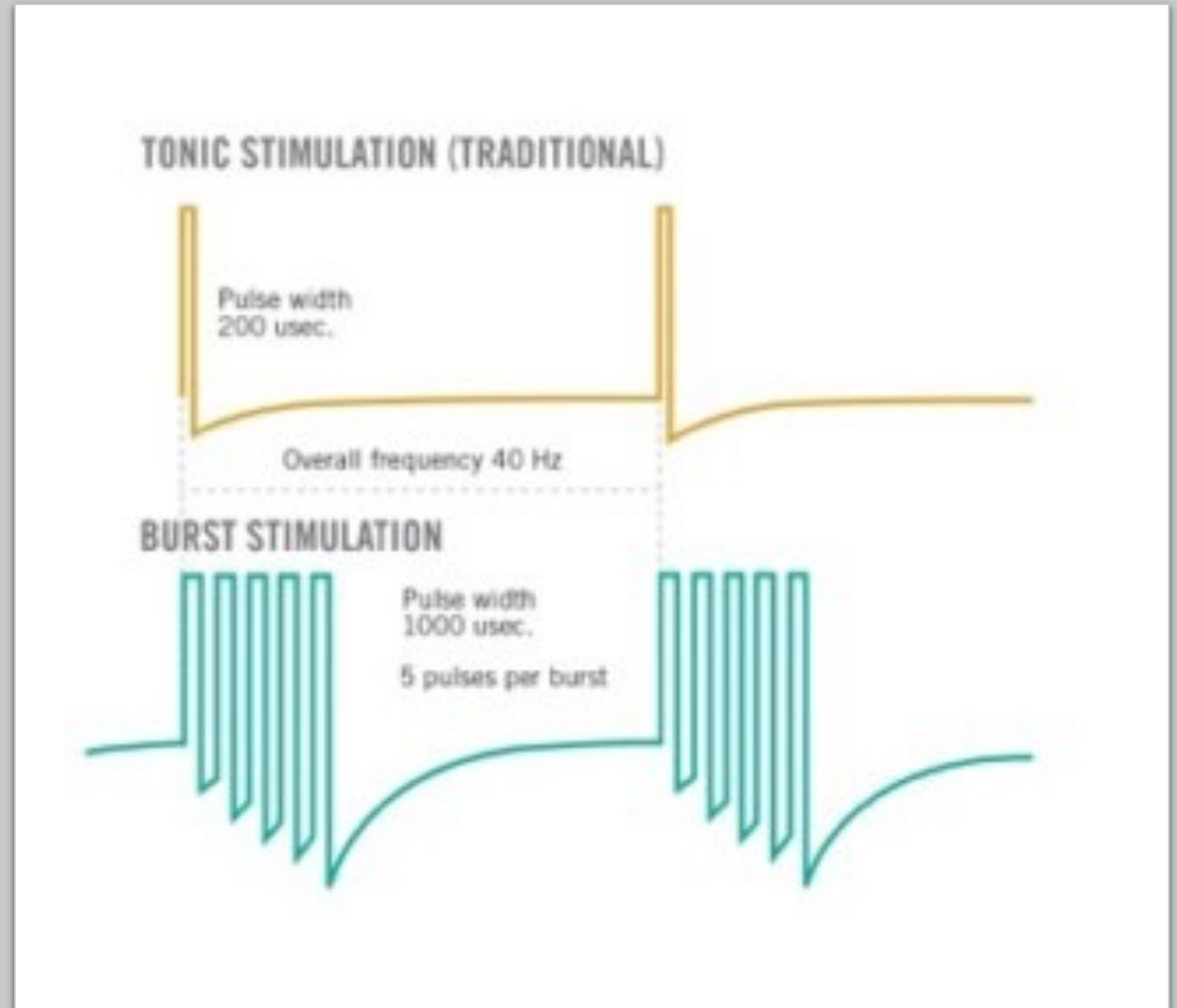
Dorsal Root  
Ganglion  
Stimulation





# Newest Spinal Cord Stimulation Patterns

- High frequency stimulation at 10kHz frequency
- Burst DR – bundles of stimulation mimicking nerve action potentials
- Closed-loop stimulation – feedback loop adjustments
- Combination of traditional and novel waveforms – “chaos stimulation”



Wave	Tonic	HF-10	Burst DR	DRG	eCaps	Freedom	Nalu	DTM
Ind	FBS, radic	FBS, radic	Back, leg	CRPS	Back, leg	Back, leg	Back, leg	FBS, radic
Ref	Process 2007	Senza 2015	Sunburst 2017	Accurate 2017	Evoke 2019	Freedom 2019	nPower 2021	DTM 2021
Out	> 50%	>50%	noninf	> 50%	> 50%	HF vs LF	> 50%	>50%
Effic	48% 6 mos	84% back 83% leg 3 mos	70% pref to tonic 12 mos	81% vs 56% SCS 3 mos	82% at 3 & 12 mos	77% HF 64% LF 7 mos	83% leg 78% back 3mos	80% at 3 & 83.7% at 12 months
Adv	MRI comp	Pares free	Emotion	target	Real time	wireless	micro	Pares free; glial cell
Disad		recharge		placing		knot	disc	recharge
Future		DPN, NSBP		Beyond CRPS	Closed loop	PNS	PNS	Pares free closed loop

Michael Leong, MD

Pragmatic  
Neuromodulation  
Clinical Trials at  
Stanford

- **Stanford Pragmatic Effectiveness Comparison (SPEC) trials**
  - Comparing long-term effectiveness of high-frequency and burst spinal cord stimulation (**SPEC-HB**)
    - **High frequency (HF-10)**
    - **Burst DR**
    - Real world application for back pain
    - Stanford CHOIR data
    - *No industry funding*

# S.A.F.E analysis for Pain Therapies – Krames 2009

- Safety, Appropriateness, Fiscal or cost neutrality, and Efficacy (S.A.F.E.) principles for any pain treatment to be given to a patient.
- **Safety**: Risk of complications – compared with Opioids
- **Appropriateness**: Pain diagnosis and assess any medical or psychosocial contraindications
- **Fiscal neutrality**: Cost of implementing a **new therapy does not** result in greater financial expenditure than a **current or comparator therapy over a given time period** – Insurance reviews
- **Efficacy**: Level of medical evidence comparing interventional therapies with non-interventional treatments

# Neuromodulation

Identification of SCS candidate by treating pain physician

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Evaluation by pain psychologist

Discussion at multidisciplinary team conference

Randomization

# Neuromodulation Conference 2021 - 2022

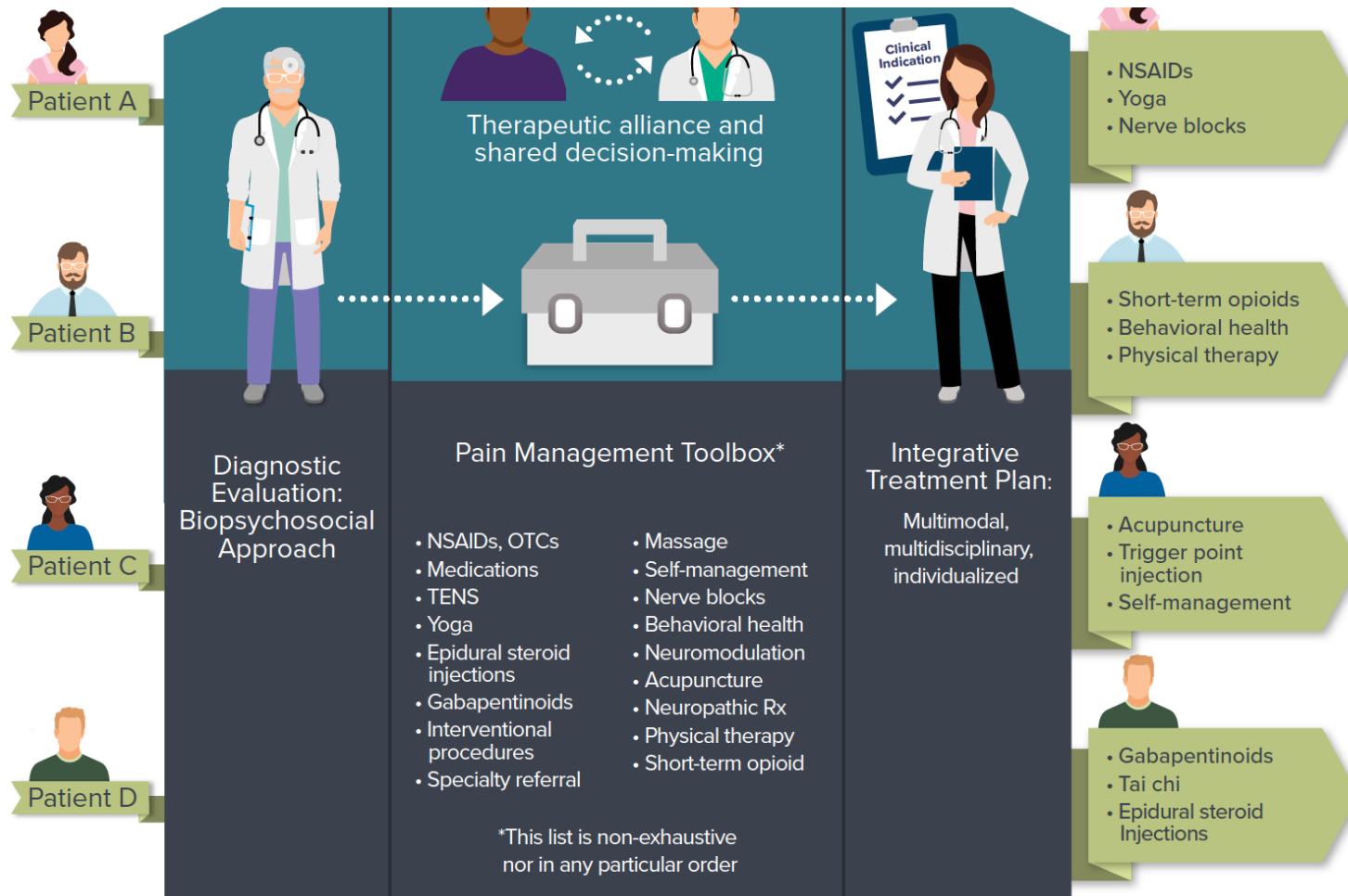
Identification of patient for Neuromodulation by pain physician or by referral

Evaluation by pain psychologist > Neuromodulation Conference: physicians (trainees to attendings), psychologists, nurses, anyone who wants to learn

Has the patient considered Minimally Invasive Spine procedures vs Peripheral Nerve Treatments – blocks / ablation to Peripheral Nerve Stimulation?

What is the optimal Neuraxial Neuromodulation for the patient and pain condition?





# Integrative Pain Management Treatment

# Multidisciplinary Care

Integrated, personalized plan with functional goals



- 1. Medication Optimization – Nonopioids and Opioids**
- 2. Interventional Techniques**
- 3. Physical Functioning**
- 4. Pain Psychology (Mind / Body Connection)**



# Stimulation Summary and Conclusions

- TENS for surface pain
- Spinal Cord Stimulation
  - High quality evidence for Back Pain with Radiation to Legs
  - Interdisciplinary care and patient selection optimizes outcomes
  - S.A.F.E analysis to practice the best medicine
- The Future of Neuromodulation for Pain Treatment
  - High Frequency and / or Burst: cannot feel tingling, may be effective longer
  - Dorsal Root Ganglion for specific back, trunk, and extremity regions
  - Smaller devices implanted in spine or peripheral nerves with **wireless** stimulation

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