# Neuromodulation

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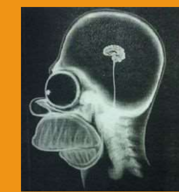
# History



1955: Gates theory - Melzak and Wall
1967: Spinal cord Stim

1967: Neurosurgeon C. Norman Shealy (Duke/Case western) has been credited with the first implantable neuromodulator device for the relief of intractable pain. His spinal cord stimulators, which he called "dorsal column stimulators," were intended exclusively for pain relief.

1974: , a group of physicians developed a less-invasive stimulating electrode. Implanting electrodes outside the subarachnoid space enabled stimulation to occur without side effects like spinal cord compression and leakage of cerebro-spinal fluid.

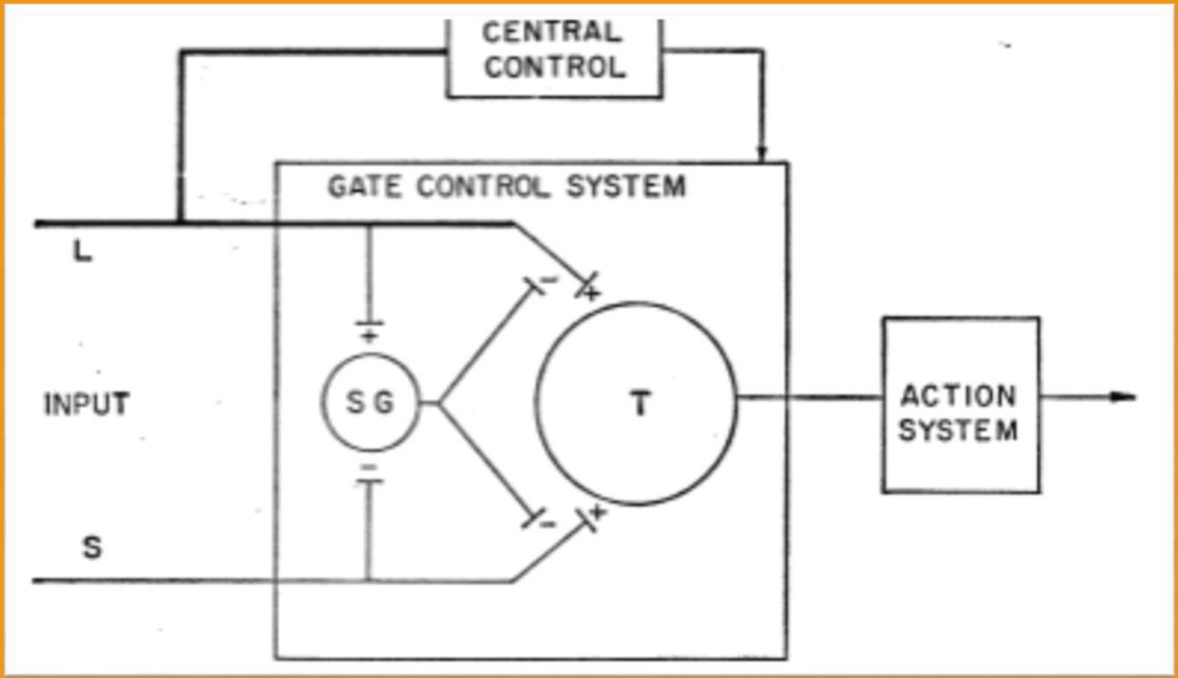
1981: Jan Holsheimer, PhD (University of Twente, The Netherlands), optimized computer modeling research and developed multiple electrode contacts which improved the placement and design of electrical field stimulation onto spinal and brain targets. This has informed clinicians and manufacturers about how to better position the electrodes in the epidural space to enhance therapeutic benefits.

# Science: Gate Theory

Both small (pain) and large diameter (touch, pressure, vibration) nerve fibers carry information from the site of injury to two destinations in the dorsal horn of the spinal cord: transmission cells that carry the pain signal up to the brain, and inhibitory interneurons that impede transmission cell activity.

Activity in both small and large fibers *excites* transmission cells.

Small fiber activity *impedes* the inhibitory cells ( allows the transmission cell to fire) and large diameter fiber activity *excites* the inhibitory cells ( inhibits transmission cell activity )

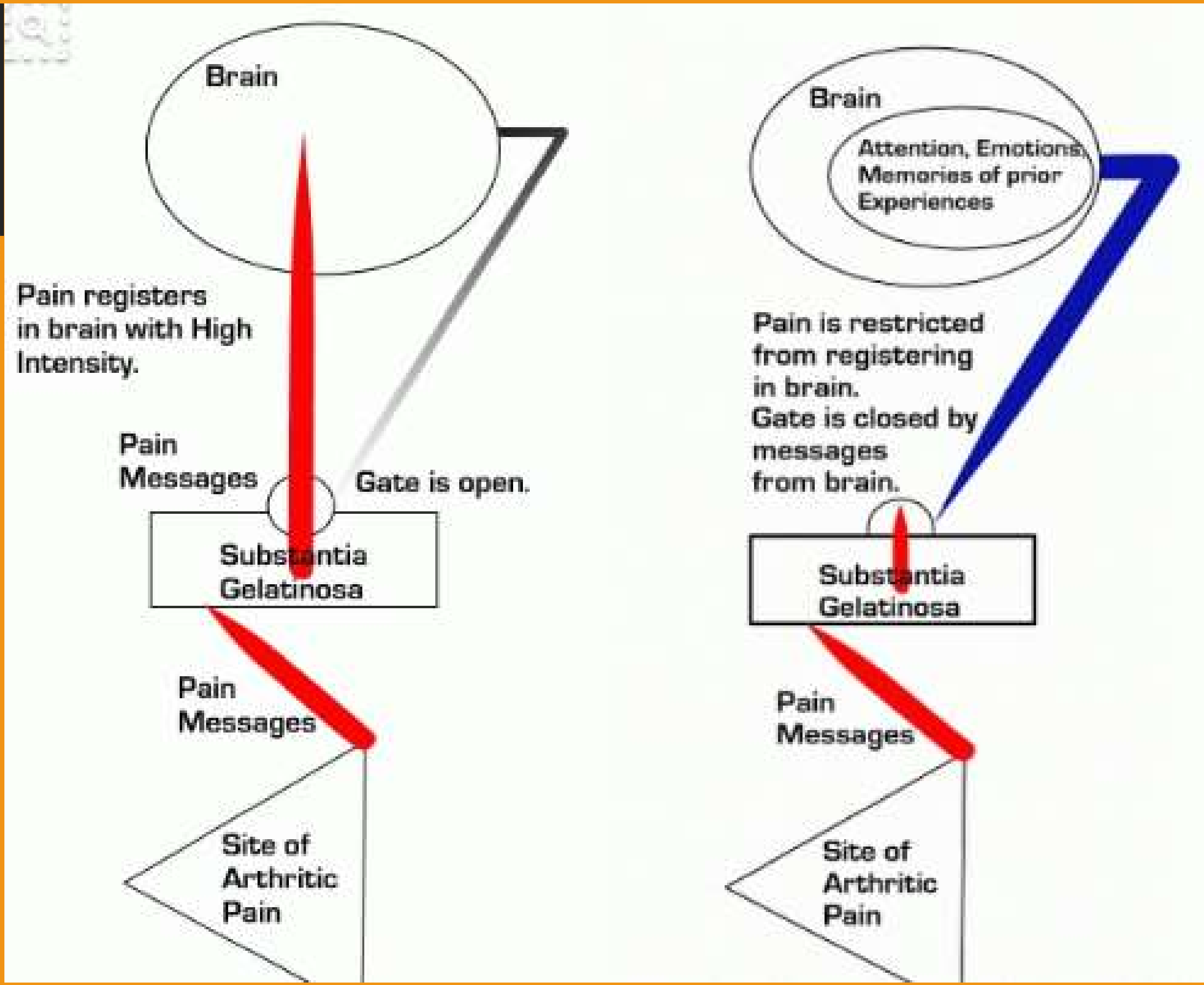



**The more large fiber (touch, pressure, vibration) activity relative to thin fiber activity at the inhibitory cell, the less pain is felt**

# Science: Gate Theory

Brain can modulate the degree to which pain is perceived

Brain is able to influence the spinal cord to intensify or inhibit pain transmission



# Science: Other mechanisms

The neurophysiologic mechanisms of SCS are not completely understood

some research suggests that SCS effects occur at local and supraspinal levels and also through dorsal horn interneuron and neurochemical mechanisms

Evidence exists for increased levels of GABA and serotonin, and perhaps, for reduced levels of excitatory amino acids, glutamate and aspartame

Fukshansky M, Burton AW. *Spinal cords stimulation.*
Oakley J, Prager J. Spinal cord stimulation. *Spine*. 2002. 22:2574- 83.
Linderoth B, Foreman R. Physiology of spinal cord stimulation: Review and update. *Neuromodulation*. 1999. 3:137-44.

## Spinal Cord stim

- Refractory chronic pain
  - Failed back
  - CRPS
- Chronic peripheral neuropathy or plexopathy
- Painful limb in Multiple sclerosis
- Post-Thorocotomy
- Post-herpetic neuralgia
- Phantom limb pain
- Intercostal neuralgia
- **Refractory angina**
- Ischemic-Critical limb
- Chronic visceral pain

## Deep Brain stim

- Movement disorders (Parkinson's )
- Severe intractable depression
- obsessive compulsive disorder
- Dystonia
- Refractory chronic pain (initial indication)

## Peirophearal stim

- Periphral nerve injury (CRPS)
- Peripheral vascular
- occipital nerve stimulation for chronic migraine/headache
- Vagal nerve stimulation
  - Depression
  - OCD


Simpson A, Meyerson BA, Linderoth B. Spinal cord and brain stimulation. McMahon SB, Koltzenbburg M, eds. *Wall and Melzack's textbook of pain*. 5th ed. Elsevier Churchill Livingstone: Philadelphia; 2006. 569.
Kreis PG, Fischman SA. *Spinal cord stimulation: percutaneous implantation techniques*. New York: Oxford University Press; 2009
Fogel GR, Esses SI, Calvillo O. Management of chronic limb pain with spinal cord stimulation. *Pain Pract*. 2003 Jun. 3(2):144-51.
Kumar K, Hunter G, Demeria D. Spinal cord stimulation in treatment of chronic benign pain: challenges in treatment planning and present status, a 22-year experience. *Neurosurgery*. 2006 Mar. 58(3):481-96; discussion 481-96. [
Weiner RL, Alo' KM. Occipital neurostimulation for treatment of intractable headache syndromes. Krames ES, Peckham PH, Rezai, AR, eds. *Neuromodulation*. London: Elsevier Ltd; 2009. 409.

# Work Injury population



- Failed back surgery syndrome

- Complex regional pain syndrome
  - Hand Injuries
  - Cruch injuries with neuropathic pain
  - Foot and ankle injuries
  - Postoperative CRPS   (orthopedic)
  - Stump pain in Traumatic  ampuitee

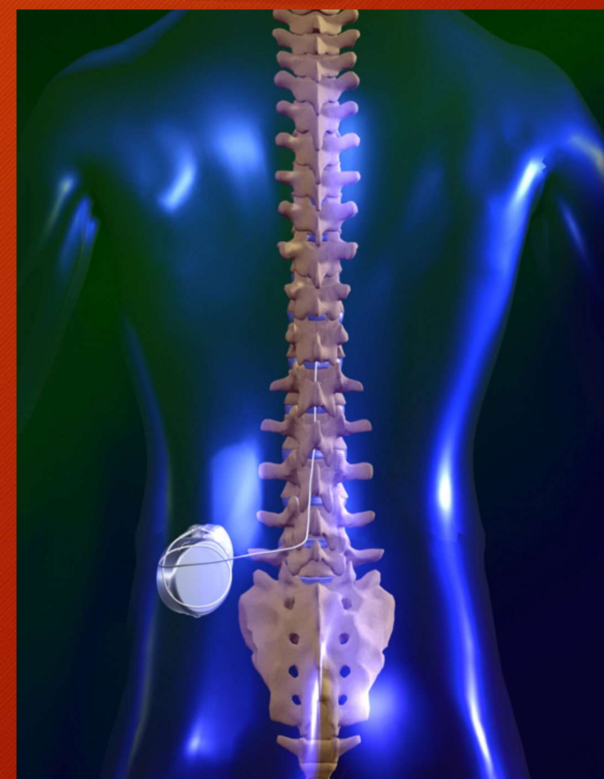
- Chronic leg (sciatica) or arm pain
  - Chemical exposure
  - Radiation exposure
  - Acquired neuropathy

# Technology

There are several types of SCS device systems. However, all have three main parts:

1. Pulse generator / battery
2. Lead wire with 8-32 contacts
3. A hand-held remote control .

# Technology – IPG and Leads


# Technology : Pulse generator


## Conventional Low Frequency SCS with Paresthesia (60 Htz)

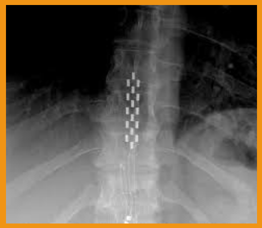
- Conventional stimulation (60 Hz/350 µsec)
- Replacing painful sensation with amore
- pleasant Paresthesia (tingling or vibration) in the same areas that the patient has pain
- Effective with limb pain in failed back or CRPS but will not help axial back or neck pain

## Paresthesia-Free High-Density Spinal Cord Stimulation (1200 Htz)

- May involve different peripheral and spinal segmental mechanisms.
- Paresthesia is not necessary for pain relief
- Pain suppression seems as good as or potentially better than that achieved by conventional low frequency stim
- Can help with back pain in failed back syndrome

Neuromodulation. 2016 Apr;19(3):260-7. doi: 10.1111/ner.12357. Epub 2015 Oct 20.

# SCS



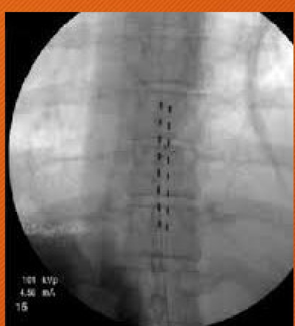
- Who is a candidate ?

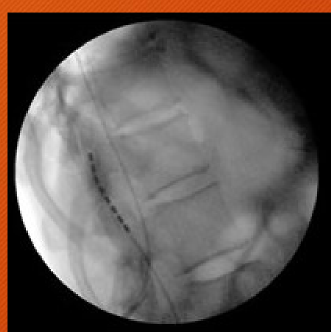
- Applicable diagnosis
- No contraindications
- Passed Psych Test
- Successful trial with >50% reduced pain
- Successful trial with improved function
- Medically stable for implantation surgery

Who is not a candidate ?

- Serious neurological deficit with surgically correctable pathology
- Severe spondylolisthesis with stenosis
- Pregnant patients
- Active systemic infection
- Patient with a demand-type cardiac pacemaker
- Patient with untreated bleeding disorders
- Patient with untreated drug addiction issues or substance abuse
- Coagulopathy, immunosuppression, or any medical condition that compromises surgical benefit over risk
- Ongoing requirement for therapeutic diathermy
- Severe cognitive impairment that interferes with evaluation or operation
- Previous spinal surgery with extensive epidural scarring
- Scoliosis that creates difficulty with lead steering
- Operant factors (secondary gain)
- Psychogenic factors that suggests a somatoform pain disorder
- Unstable axis I or II co-morbidities

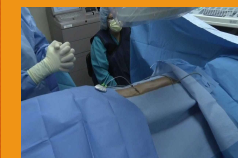
# SCS : Trial Period

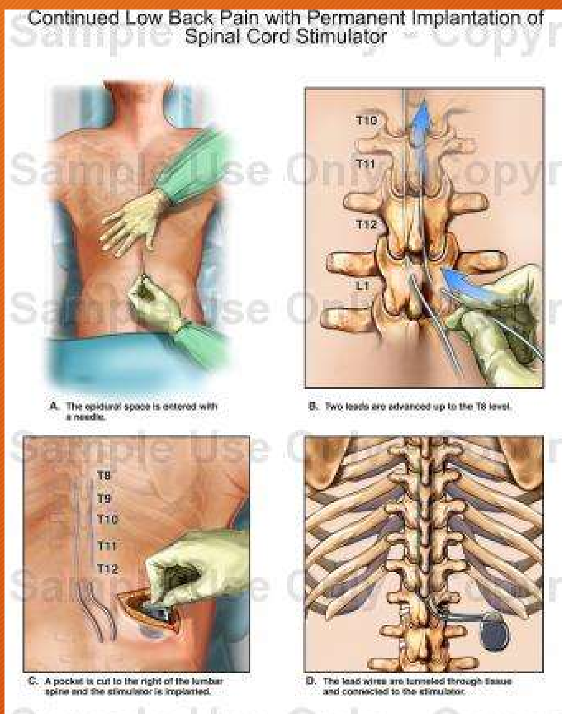




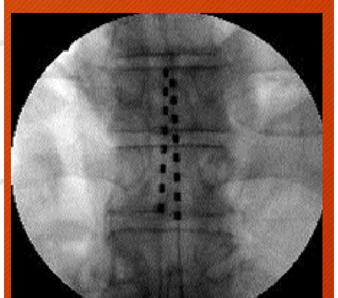
- After psychological evaluation
- Takes 30-60 minutes to complete in ASC
- On-table testing for partesthesia in conventional stim
- No on-table tasting for high frequency stim
- Typically between 3-7 day trial
- Pain relief >70-80% + improved quality of life + improved function

# SCS :  Implantation










# SCS success

| | | | level of evidence |
|---|---|---|---|
| FBS<br>Conventional stim | Taylor et al.<br>CT<br>N: 60 | showed that SCS not only reduces pain, but it also improves the quality of life, reduces analgesic consumption with minimal significant adverse effects, and may also result in significant cost savings over time. | moderate |
| FBSS<br>Conventional stim | North et al. 2005<br>RCT<br>N 50 | SCS is superior to re-operation for the treatment of failed back surgery syndrome ijn pts with FBSS that mainly possessed radicular neuropathic pain | |
| CRPS | Kemler et al. 2008<br>RTC | SCS resulted in significant improvements in the pain-rating index McGill Pain Questionnaire<br>patient satisfaction at the 5-year follow-up remains high and 95% | |
| FBS<br>Back + Leg<br>High frequency | Russo et al 2015<br>RTC<br>N 186<br>30% had failed conventional stim | FBSS | |
| FBS<br>High frequency<br>vs conventional | Kapural et al 2016<br>2<br>RCT<br>n=198 | Mean back pain: HF SCS: 68.5% versus conventional SCS 36.3%. Mean leg pain: HF SCS 67.4% versus conventional SCS 42.5% | |

# SCS success

| | | | |
|---|---|---|---|
| Refractory angina pectoris | Mannheimer et al. | reduce hospital admissions, and improve the quality of life.<br><br>Significant decrease in the frequency of anginal attacks and the consumption of short-acting nitrates, | |
| Peripheral ischemic limb pain | Jivegard et al<br><br>Petrakis IE | SCS provides long-term pain relief, but limb salvage at 18 months was not significantly improved by SCS >75% and limb salvage were achieved in 85 patients.<br><br>In 28 patients, partial success was obtained with pain relief >50% and limb salvage for at least 6 months | |

# COST EFFECTIVENESS OF SCS

- 2015 study investigating the cost-effectiveness of conventional medical management with or without SCS in patients with FBSS compared a summary of the total direct and indirect costs incurred in the 12 months prior and 24 months following SCS

CRPS: SCS was shown to be cost-effective in select CRPS patients, with a probability exceeding 80% that SCS is cost-effective

FBS: SCS is cost-effective both as an adjunct to conventional medical management and as an alternative to reoperation; likelihood SCS would be cost-effective versus conventional medical management and versus reoperation exceeds 80%

SCS vs medical management: Mean cost of SCS was offset within 6 months by a reduced use of drug and nondrug therapies. Studies also demonstrated improved quality of life over the same period which was significantly greater for the SCS group

Zucco F, Ciampichini R, Lavano A, et al. Cost-effectiveness and cost-utility analysis of spinal cord stimulation in patients with failed back surgery syndrome: results from the PRECISE study. Neuromodulation. 2015;18(4):266-276.

43. Bala MM, Riemsma RP, Nixon J, Kleijnen J. Systematic review of the (cost-)effectiveness of spinal cord stimulation for people with failed back surgery syndrome. Clin J Pain. 2008;24(9):741-756.

# Summery

- Old technology with new enhancement including high frequency stim and rechargable unit
- Works based on Gait theory of pain modulation
- Large fibers stimulation would inhibit and modulate transmision of pain signals traveling through small fibers.
- Best candidates are FBS /CRPS/neuropathy which is not responding to less invasive care
- Good candidate for SCS = Successful pain relief with SCS trial + stable psychiatric state

- High frequency stim may be suypperior to conventionaal based on more recent evidence.
- High frequency stim helps back pain which (not with conventional stim)
- Cost effectiveness over 24 moths care as compare to medical management
- Improved quality of life