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Spinal Cord Stimulation – The “Pain Pacemaker”

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Introduction

Chronic pain may be the most costly health problem in America, with annual cost estimates exceeding \$100 Billion for the estimated 75 million people who suffer from it.¹ In fact, the NIH estimates that back pain expenditures alone cost \$50 – \$100 Billion.² While several etiologies of chronic pain exist, those with a neuropathic component may present as the most difficult to treat.

History

For centuries, cultures including the Egyptians, Romans and South American Indians employed some form of electrical treatment to treat pain.



In 1965, Melzack and Wall’s gate control theory proposed that the dorsal horn of the spinal cord acts like a “gate” that differentiates between the information carried by different nerve fibers.⁴ It states that pain is perceived through the balance of signal received by the small nerve fibers carrying nociceptive (pain) signals and large nerve fibers carrying non-nociceptive (touch) signals. When more signals are received from the small fibers, the “gate” is opened and results in a feeling of pain. Consequently, when signals are primarily received from the large fibers, the gate is “closed” and there is little to no pain.

Shealy et al. provided the first practical application of the gate control theory when he implanted the first spinal cord stimulator electrode directly on the dorsal column for the treatment of chronic pain.⁵ Shortly thereafter, in 1971, Shimoji and colleagues placed an SCS lead in the epidural space and reported the analgesic properties of epidural spinal cord stimulation.

Description

Spinal Cord Stimulation works by sending electrical impulses that trigger selective nerve fibers along the spinal cord. The result is that the patient feels paresthesia in areas where they typically feel pain and their overall pain levels are reduced. The representation of the dermatome level of pain distribution is typically much higher than the corresponding vertebral level. (i.e. low back pain may be covered around T-8) Despite Melzack and Wall’s theory, the true mechanism of action is still not completely understood.

The stimulation is provided by leads that are inserted into the dorsal epidural space. The leads are connected to a generator, which serves as the power source.



Products

Spinal Cord Stimulators are manufactured by Boston Scientific, Medtronic and St. Jude. Over the past few decades, technological developments have increased the effectiveness and utilization of these implantable devices. For example, Boston Scientific’s patented unit has 16 power sources which allow for greater adjustments in the stimulation fields (some compare it to a dimmer switch vs. turning something on or off.) The single most important feature of any SCS product is the ability to achieve the most effective stimulation.

The essential components of an SCS system differ depending upon whether the procedure is a trial or permanent placement. Percutaneous leads generally come

with either 4 or 8 electrodes, with 8 electrode leads more commonly used. Surgical paddles vary in size and the number of electrodes per lead.

SCS implantable generators are available as either a non-rechargeable or rechargeable system. Rechargeable systems provide long-lasting energy and allow patients to charge their units at varying intervals. Non-rechargeable systems offer the convenience of not having to charge; however, they must be replaced every few years.



Indications/Patient Selection

SCS is indicated for the treatment of chronic neuropathic pain of the back, trunk and/or limbs. With neuropathic pain, nerve fibers may be damaged, dysfunctional, or injured. The impact of a nerve fiber injury can include a change in nerve function both at the site of injury and areas around the injury.

Examples of Neuropathic Pain Successfully Treated with SCS

- Complex Regional Pain Syndrome (CRPS 1 and 2), formerly known as RSD
- FBSS (Failed Back Surgery Syndrome), frequently with radicular components
- Arachnoiditis
- PHN (post Herpetic Neuralgia)
- Phantom Limb Pain
- Neuropathic pain from Peripheral Diabetic Neuropathy
- Components of cancer pain

Candidates for this procedure usually have pain that has been unresponsive to other forms of treatment, which is why proper patient selection for SCS procedures is so critical. The levels of treatment for chronic pain patients can more understood through the following diagram:

Level 1 – Basic Pain Therapies

- Rest and Nutrition
- Exercise and PT
- NSAIDS

Level 2 – Mid-Level Pain Therapies

- TENS
- Opioids
- Nerve Blocks
- Thermal Procedures

Level 3 – Advanced Pain Therapies

- Surgery
- Spinal Cord Stimulation
- Implantable Drug Pumps
- Neuroablation

For those patients who have failed basic and mid-level treatment therapies, SCS may be indicated. The procedure has gained wide acceptance in coverage from insurance companies and several worker’s compensation plans. SCS is also covered under Medicare. Prior to scheduling the procedure, a full evaluation must be completed.

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Pre-procedure (Trial) Work-Up:

- Detailed history and physical examination, including a review of past treatments
- Spine x-ray of the lumbar, thoracic and/or cervical spine
- MRI of the lumbar, thoracic and/or cervical spine
- Psychological examination

Procedure

The SCS procedure is performed by trained pain physicians, as well as orthopedic and neurosurgeons. SCS is typically performed in two stages; the trial or “Test Drive” and the permanent implantation.

Trial

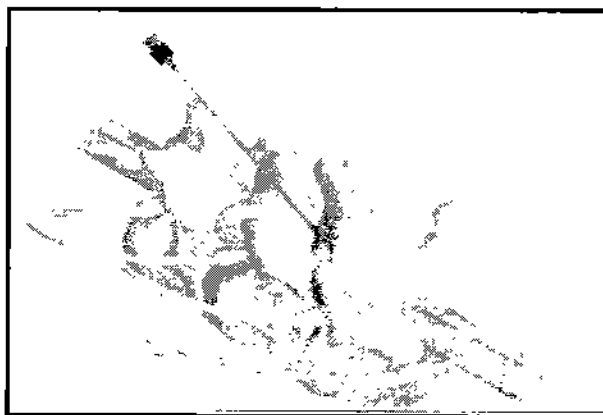
Under local anesthesia and very mild sedation, one or two leads are percutaneously placed into the epidural space. The final lead position is determined by testing the stimulation while the patient provides feedback. The lead(s) is then connected, via a small cable, to an external trial stimulator that is worn on a belt throughout the trial. A remote control is provided to the patient so they may control the intensity of the stimulation and adjust programs that may provide stimulation in different areas. The patient then uses the device for several days to determine how much pain relief can be achieved.

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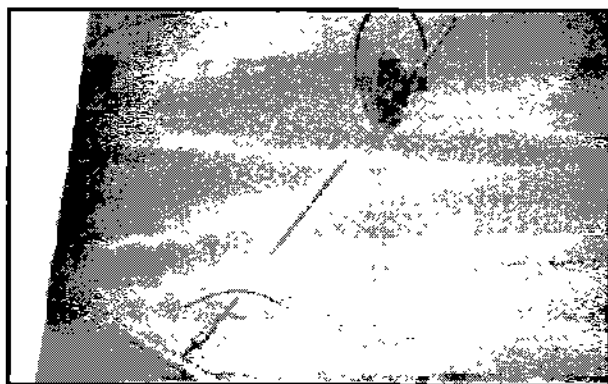
Meta**Trial Information**

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- Procedure time is typically 30-60 minutes
 - The trial lasts between three and seven days
 - Patients typically feel procedural pain for 24 hrs (an ice pack can be used for treatment)
 - Lead access site must remain dry and intact, no showering during the trial
 - Patients are not allowed to drive with stimulation “on”
 - No “BLT”s” – bending, lifting or twisting – to avoid causing lead migration

Despite the restrictions, patients are encouraged to be active during their trial and replicate activities which typically cause pain. Frequently, improvements in the distance or duration of walking or reduced pain in activities such as washing dishes are good signs of significant pain reduction.

Permanent

This stage follows a successful trial and involves placing the lead(s) and the implantable pulse generator (IPG). Permanent implants are accomplished with leads placed either percutaneously or surgically. Percutaneous lead placements are generally less invasive; however, they tend to have a higher migration rate than those placed surgically. Surgical implants utilize paddle-type leads which are placed through a laminectomy. Both procedures require tunneling the leads from the epidural entry site to the “pocket” where the IPG is implanted. The sites most often used for the IPG implant are posterior, above or below the belt line.



Risks/Warnings/Considerations

Procedure risks are relatively minimal, with lead migration being the most common.⁷ Infection, CSF leakage, epidural bleeds and hemorrhages are all potential risks that are mitigated by proper technique. Lead fractures, while not prevalent, may occur.

SCS is contraindicated for those who are poor surgical candidates, pregnant, unable to operate the remote control and/or have failed an SCS trial. SCS has not been established for use in children.

Many warnings that come with SCS systems are managed on a patient to patient basis.

These include:

- Potential interference with defibrillators and pacemakers
- Use of thermal devices such as radiation therapy, high-output ultrasound, lithotripsy and electrocautery
- Potential interference with electrical scanners that may briefly increase or decrease stimulation

Patients receiving an SCS system cannot receive an MRI of the body. Some manufacturers have labeling for head-only MRI in a 1.5T magnet. Should a patient require an MRI, the SCS system may be explanted.

Summary

Spinal cord stimulation is utilized as a treatment method for chronic, intractable pain when other therapeutic measures have been exhausted. As with many pain therapies, the goal of SCS is to reduce pain so that quality of life can be significantly improved. With proper patient selection, as well as correct device selection and positioning, SCS can be a highly successful and long-term solution for those with chronic neuropathic pain.

For any patient with chronic pain, a multidisciplinary approach that includes their primary-care physician along with physical therapists, psychologists, psychiatrists, and pain management specialists should be utilized.

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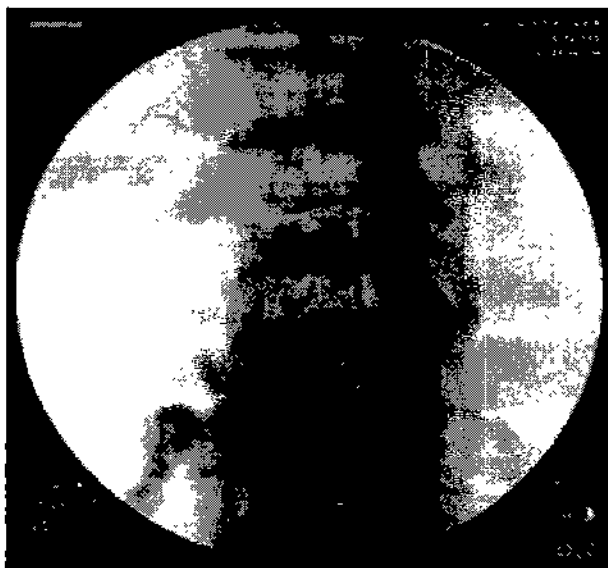
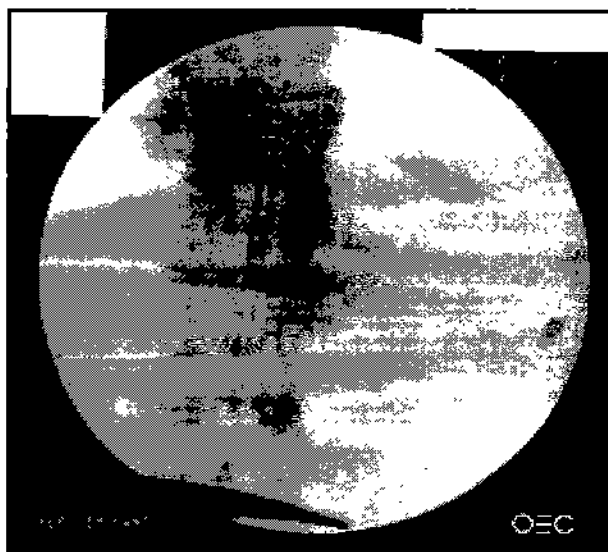
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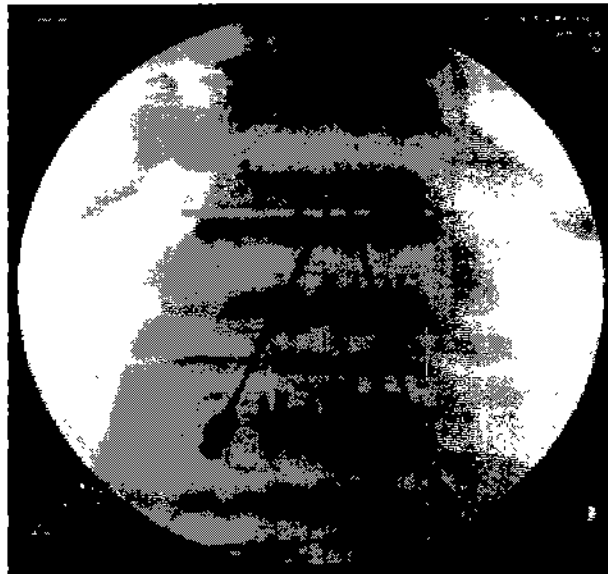
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