Spinal Cord Stimulation

Overview

Spinal cord stimulation therapy masks pain signals before they reach the brain. A small device, similar to a pacemaker, delivers electrical pulses to the spinal cord. It helps people better manage their chronic pain and reduce their use of opioid medications. It may be an option if you suffer chronic back, leg or arm pain and have not found relief with other therapies.

What is a spinal cord stimulator?

A spinal cord stimulator (SCS) device is surgically placed under your skin and sends a mild electric current to your spinal cord (Fig. 1). Thin wires carry current from a pulse generator to nerve fibers of the spinal cord. When turned on, the SCS stimulates the nerves in the area where your pain is felt. Pain is reduced because the electrical pulses modify and mask the pain signal from reaching your brain.

Some SCS devices use a low-frequency current to replace the pain sensation with a mild tingling feeling called paresthesia. Other SCS devices use high-frequency or burst pulses to mask the pain with no tingling feeling. A paresthesia-free setting is an option on most devices.

Stimulation does not eliminate the source of pain. It simply changes the way the brain perceives it. As a result, the amount of pain relief varies for each person. The goal for SCS is a 50 to 70% reduction in pain. However, even a small amount of pain reduction can be significant if it helps you perform daily activities and reduces the amount of pain medication you take. SCS does not improve muscle strength.

Stimulation does not work for everyone. Some people may find the sensation unpleasant. Other people may not get relief over the entire pain area. For these reasons a trial stimulation allows you to try it for a week. If it doesn't work for you, the trial wires are easily removed in the office leaving no damage to the spinal cord or nerves.

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

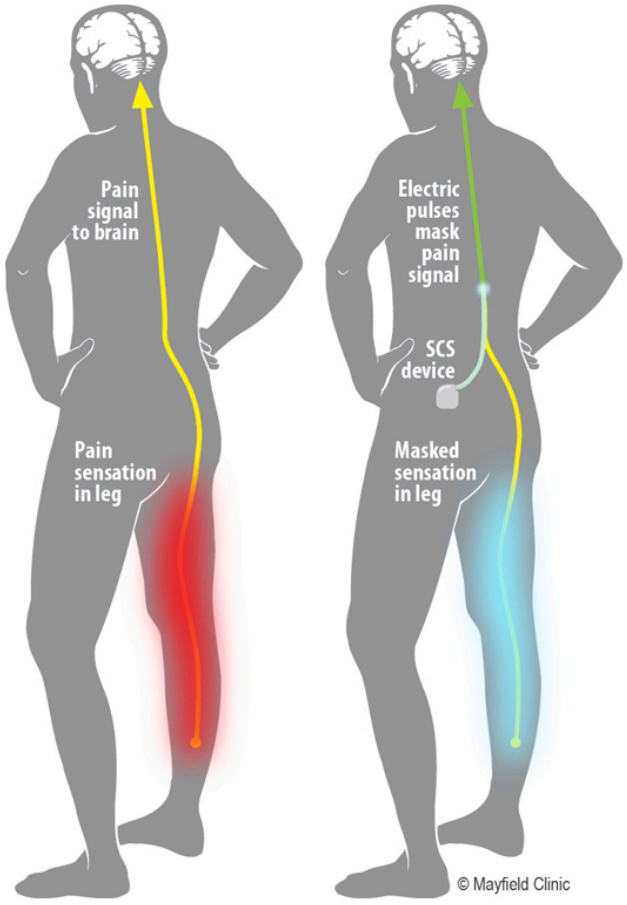

Figure 1. A spinal cord stimulator works by masking pain signals before they reach the brain. A stimulator device delivers electric pulses to electrodes placed over the spinal cord. Modified by the pulses, the pain signals are either not perceived or are replaced by a tingling feeling.

- A pulse generator with a battery that creates the electrical pulses.
- A lead wire with a number of electrodes (8-32) that delivers electrical pulses to the spinal cord.
- A hand-held remote control that turns the device on and off and adjusts the settings.

Systems with a non-rechargeable battery need to be surgically replaced every 2 to 5 years, depending on the frequency of use. Rechargeable battery systems may last 8 to 10 years or longer, but you must remember to charge the system daily.

The pulse generator has programmable settings. Some SCS devices are able to sense a change in body position (sitting vs. lying down) and adapt the stimulation level to your activity. Other systems have leads that can be independently programmed to cover multiple pain areas. Some send a sub-perception pulse with no tingling. Your doctor will select the best type of system for you.

Who is a candidate?

An evaluation of your physical condition, medication regime, and pain history will determine whether your goals of pain management are appropriate for SCS. A neurosurgeon, physiatrist, or pain specialist will review all previous treatments and surgeries. Because chronic pain also has emotional effects, a psychologist will assess your condition to maximize the probability of a successful outcome.

Patients selected for SCS usually have had chronic debilitating pain for more than 3 months in the lower back, leg (sciatica), or arm. They also typically have had one or more spinal surgeries.

You may be a candidate for SCS if:

- Conservative therapies have failed.
- You would not benefit from additional surgery.
- The pain is caused by a correctable problem and should be fixed.
- You do not want further surgery because of the risks or long recovery. Sometimes SCS may be chosen over a large, complex spine surgery.
- You do not have untreated depression or drug addiction; these should be treated prior to having a SCS.
- You have no medical conditions that would keep you from undergoing implantation.
- You have had a successful SCS trial.

SCS works better in the earlier stages of a chronic condition, before a cycle of pain-suffering-disability-pain is established.

An SCS can help lessen chronic pain caused by:

- **Chronic leg (sciatica) or arm pain**: ongoing, persistent pain caused by arthritis, spinal stenosis, or by nerve damage.
- **Failed back surgery syndrome:** failure of one or more surgeries to relieve persistent leg or arm pain, but not a technical failure of the original procedure.
- **Complex regional pain syndrome**: a progressive disease in which patients feel constant, chronic burning pain, typically in the foot or hand.
- **Arachnoiditis:** painful inflammation and scarring of the protective lining of the spinal nerves.
- **Other**: stump pain, angina, peripheral vascular disease, multiple sclerosis, or spinal cord injury.

Who performs the procedure?

Neurosurgeons and doctors who specialize in pain management (an anesthesiologist or physiatrist) implant spinal cord stimulators.

The surgical decision

Determining whether a spinal cord stimulator will be a good option for you is a two-step process. First, you must undergo a temporary trial to see if the device decreases your level of pain.

Stage 1. Trial "test drive"

Trial stimulation is a "test drive" to determine if an SCS will work for the type, location, and severity of your pain. It is performed at an outpatient center.

If you take blood-thinners, you are required to stop the medication 3 to 7 days prior to the trial.

A local anesthetic is given to numb the area in the lower back. Using X-ray fluoroscopy, a hollow needle is inserted through the skin into the epidural space between the bone and spinal cord. The trial lead is inserted and positioned over specific nerves. The wires are attached to an external generator worn on a belt (Fig. 2).

You will be sent home with instructions on how to use the trial stimulator and care for your incision site. Keep a written log of the stimulation settings during different activities and the level of pain relief. After 4 to 7 days, you will return to the doctor's office to discuss permanently implanting the stimulator or removing the trial leads.

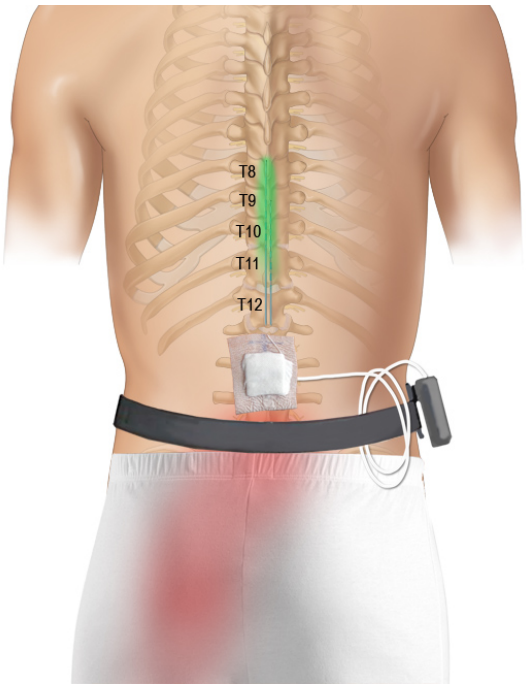

Figure 2. During a Trial SCS, temporary leads are placed in the spinal canal and a stimulator is worn on a belt. For several days you will test the device to see if it relieves your pain during various activities.

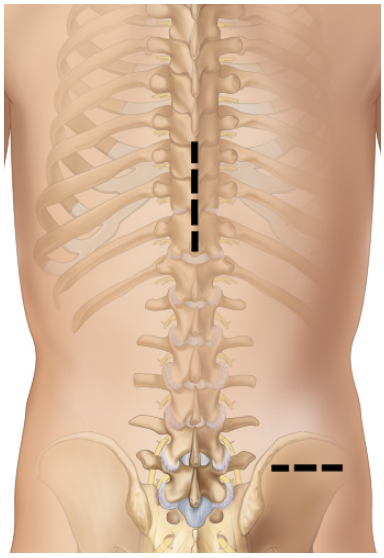

Figure 3. A skin incision is made in the middle of your back for the leads and another is made in your buttock for the generator.

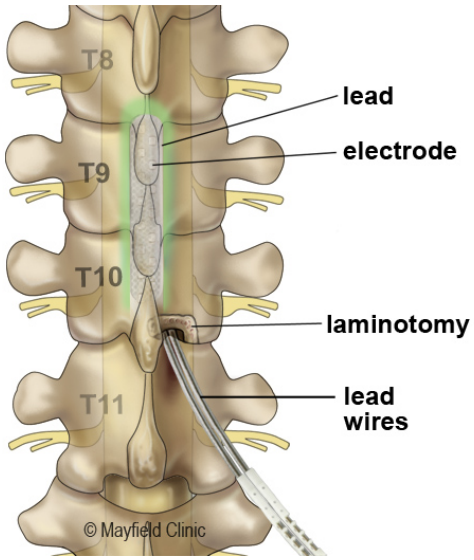

Figure 4A. A laminotomy is cut in the bone to make room to insert the leads into the spinal canal.

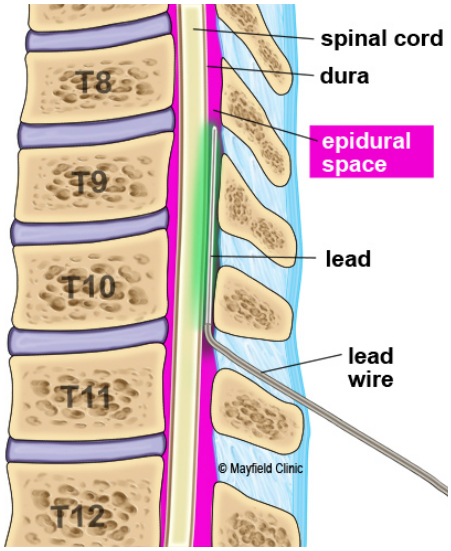

Figure 4B. The leads are positioned in the epidural space above the spinal cord to deliver electrical current to the nerves.

Stage 2. Surgical implant
If the trial is successful and you felt greater than 50% improvement in pain, surgery can be scheduled to implant the SCS device in your body.

What happens before surgery?

In the doctor's office, you will sign consent and other forms so that the surgeon knows your medical history (allergies, medicines/vitamins, bleeding history, anesthesia reactions, previous surgeries). Inform your healthcare provider about all the medications (over-the-counter, prescription, herbal supplements) that you are taking. Presurgical tests (e.g., blood test, electrocardiogram, chest X-ray) may need to be done several days before surgery. Consult your primary care physician about stopping certain medications and ensure you are cleared for surgery.

Continue taking the medications your surgeon recommends. Stop taking all non-steroidal anti-inflammatory medicines (ibuprofen, naproxen, etc.) and blood thinners (Coumadin, aspirin, Plavix, etc.) 7 days before surgery. Stop using nicotine and drinking alcohol 1 week before and 2 weeks after surgery to avoid bleeding and healing problems.

You may be asked to wash your skin with Hibiclens (CHG) or Dial soap before surgery. It kills bacteria and reduces surgical site infections. (Avoid getting CHG in eyes, ears, nose or genital areas.)

Morning of surgery

- Don't eat or drink after midnight before surgery (unless the hospital tells you otherwise). You may take permitted medicines with a small sip of water.
- Shower using antibacterial soap. Dress in freshly washed, loose-fitting clothing.
- Wear flat-heeled shoes with closed backs.
- Remove make-up, hairpins, contacts, body piercings, nail polish, etc.
- Leave all valuables and jewelry at home.
- Bring a list of medications with dosages and the times of day usually taken.
- Bring a list of allergies to medication or foods.

Arrive at the hospital 2 hours before your scheduled surgery time (1 hour before at the outpatient surgery center) to complete the necessary paperwork and pre-procedure work-ups. An anesthesiologist will talk with you and explain the effects of anesthesia and its risks.

What happens during surgery?

The surgery generally takes 1 to 2 hours.

Step 1: prepare the patient
You will lie on your stomach on the table and be given light anesthesia. Next, the areas of your back and buttock are prepped where the leads and generator are to be placed.

Step 2: place the leads
The electrode leads are inserted with the aid of fluoroscopy (a type of X-ray). A small skin incision is made in the middle of your back (Fig. 3), and the bony vertebra is exposed. A portion of the bony arch is removed (laminotomy) to allow room to place the leads. The leads are positioned in the epidural space above the spinal cord and secured with sutures (Fig. 4). The leads do not directly touch your spinal cord.

Step 3: test stimulation (optional)
Depending on the SCS device being implanted, you may be awakened to help the doctor test how well the stimulation covers your pain areas. However, modern SCS device leads can be positioned based on anatomy or electric monitoring of the nerves. Settings from the trial will be used to program the pulse generator at the end of surgery, so your feedback is important to ensure the best pain relief.

In some cases, if the leads implanted during the trial are positioned perfectly, there is no need to reposition or insert new leads.

Step 4: tunnel the wire
Once the lead electrodes are in place, the wire is passed under the skin from the spine to the buttock, where the generator will be implanted.

Step 5: place the pulse generator
A small skin incision is made below the waistline. The surgeon creates a pocket for the generator beneath the skin (Fig. 5). The lead wire is attached to the pulse generator. The generator is then correctly positioned within the skin pocket.

Step 6: close the incisions
The incisions are closed with sutures and skin glue. A dressing is applied.

What happens after surgery?

You will wake up in the recovery area. Your blood pressure, heart rate, and respiration will be monitored, and your pain will be addressed. Most patients are discharged home the same day or the following morning. The pulse generator will be programmed before you leave. You will be given written instructions to follow when you go home.

Follow the surgeon's home care instructions for 2 weeks after surgery or until your follow-up appointment. In general, you can expect:

Restrictions
- Don't bend, lift, twist your back or reach overhead for the next 6 weeks. This is to prevent the leads from moving out of place until it heals.
- Don't lift anything heavier than 5 pounds.
- No strenuous activity including yard work, housework, and sex.
- Don't drive until after your follow-up appointment.
- Don't drink alcohol. It thins the blood and increases the risk of bleeding. Also, don't mix alcohol with pain medicines.

Incision Care
- Wash your hands before and after cleaning your incision to prevent infection.
- You may shower the day after surgery.
- Gently wash the incision covered in Dermabond skin glue with soap and water every day. Don't rub or pick at the glue. Pat dry.
- If there is drainage, cover the incision with a dry gauze dressing. If drainage soaks through two or more dressings in a day, call the office.
- Don't soak the incision in a bath or pool.
- Don't apply lotion/ointment on the incision.
- Dress in clean clothes after each shower. Sleep with clean bed linens. No pets in the bed until your incision heals.
- Some clear, pinkish drainage from the incision is normal. Watch for spreading redness, colored drainage, and separation.

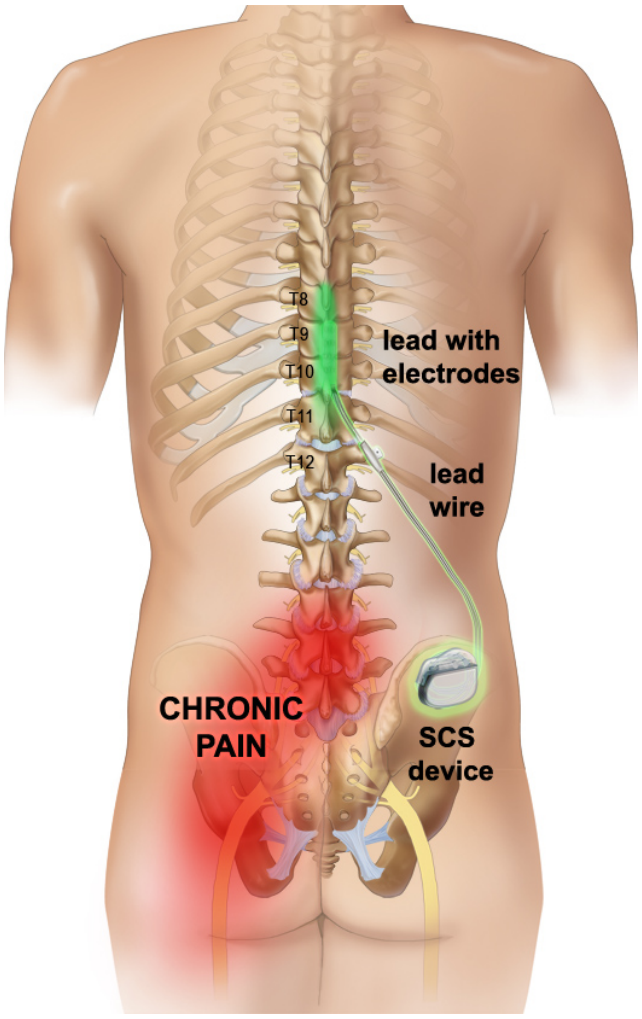

Figure 5. The SCS generator pocket is created below the waist, under the skin of the buttock.

Medications
- Take pain medication as directed by your surgeon. Reduce the amount and frequency as your pain subsides. If you don't need the pain medicine, don't take it.
- Narcotics can cause constipation. Drink lots of water and eat high-fiber foods. Stool softeners and laxatives can help move the bowels. Colace, Senokot, Dulcolax, and Miralax are over-the-counter options.

Activity

- Ice your incision 3-4 times per day for 15-20 minutes to reduce pain and swelling.
- Don't sit or lie in one position longer than an hour unless you are sleeping. Stiffness leads to more pain.
- Get up and walk 5-10 minutes every 3-4 hours. Gradually increase your walking time, as you are able.

When to Call Your Doctor

- Fever over 101.5° F (unrelieved by Tylenol)
- Unrelieved nausea or vomiting.
- Severe unrelieved pain.
- Signs of incision infection.
- Rash or itching at the incision (allergy to Dermabond skin glue).
- Swelling and tenderness in the calf of one leg (sign of a blood clot).
- New onset of tingling, numbness, or weakness in the arms or legs.
- Dizziness, confusion, nausea or excessive sleepiness.
- Fluid may accumulate under the skin around the leads or the device, creating a visible swelling (seroma). Call the doctor if this occurs.
- Sudden severe back pain, sudden onset of leg weakness and spasm, loss of bladder and/or bowel function - **this is an emergency -** go to a hospital and call your surgeon.

Recovery

Approximately 10 days after surgery you will come to the office to have the incision checked. Bring your device remote and product box to your follow-up appointment with the surgeon. Programming of the pulse generator can be adjusted at this time if needed. It is important to work with your doctor to adjust your medications and refine the programming of the stimulator.

Your pain specialist and device representative will work with you to fine-tune adjustments to the SCS.

What are the results?

The results of SCS depend on careful patient selection, successful trial stimulation, proper surgical technique, and patient education. Stimulation does not cure the condition that is causing pain. Rather, it helps patients manage the pain. SCS is considered successful if pain is reduced by at least half.

Published studies of spinal cord stimulation show good to excellent long-term relief in 50 to 80% of patients suffering from chronic pain [1-6]. One study reports that 24% of patients improved sufficiently to return to gainful employment or housework with stimulation alone or with the addition of occasional oral pain medication [7].

SCS therapy is reversible. If a patient decides at any time to discontinue, the electrode wires and generator can all be removed.

What are the risks?

No surgery is without risks. General complications of any surgery include bleeding, infection, blood clots, and reactions to anesthesia. Specific complications related to SCS may include:

- Undesirable changes in stimulation (can possibly be related to cellular changes in tissue around electrodes, changes in electrode position, loose electrical connections, and/or lead failure)
- Epidural hemorrhage, hematoma, infection, spinal cord compression, and/or paralysis (can be caused by placing a lead in the epidural space during a surgical procedure)
- Battery failure and/or battery leakage
- Cerebrospinal fluid leak
- Persistent pain at electrode or stimulator site
- A pocket of clear fluid (seroma) at the implant site. Seromas usually disappear by themselves but may require a drain.
- Lead migration, which can result in changes in stimulation and reduction in pain relief
- Allergic response to implant materials
- Generator migration and/or local skin erosion
- Paralysis, weakness, clumsiness, numbness, or pain below the level of implantation

Conditions for which you might need additional surgery include movement of the lead, breakage of the lead or extension wire, or (in rare cases) mechanical failure of the device. Reasons for removal of the device include infection and failure to relieve pain.

Sometimes scar tissue develops around the electrode and can make the stimulation less effective.

Living with a stimulator

Once the SCS has been programmed, you are sent home with instructions for regulating the stimulation by controlling the strength and the duration of each stimulation period. Your doctor may alter the pulse width, amplitude, and frequencies on follow-up visits if necessary.

The pulse generator has programmable settings:

1. Frequency (rate): number of times stimulation is delivered per second. Too few pulses results in no sensation. Too many results in a washboard or bumpy effect.
2. Pulse width: the area the stimulation will cover.
3. Pulse amplitude: determines threshold of perception to pain.

The handheld programmer lets you turn the stimulator on and off, select programs, and adjust the strength of the stimulation. Most people are given multiple programs to achieve the best possible pain relief at any point throughout the day or during specific activities. You can use your spinal cord stimulator around the clock if necessary.

Some people feel differences in stimulation intensity depending on their position (e.g., sitting versus standing). This is caused by variations in the spread of electricity as you change positions and is normal.

Just like a cardiac pacemaker, your stimulator cannot be damaged by devices such as cellular phones, pagers, microwaves, security doors, and anti-theft sensors. Be sure to carry your Implanted Device Identification card when flying, since the device is detected at airport security gates. Department store and airport security gates or theft detectors may cause an increase or decrease in stimulation when you pass through the gate. This sensation is temporary and should not harm your system. However, as a precaution, you should turn off your system before passing through security gates.

The various SCS systems have different restrictions to their use with MRI, ultrasound, defibrillator, electrocautery, diathermy, and cardiac pacemakers. Be sure to know the limitations of your specific SCS device. Also, chiropractic manipulation may cause the lead to move. Consult your surgeon first.

Sources & links

If you have more questions, please contact Mayfield Brain & Spine at 800-325-7787 or 513-221-1100.

Sources

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7. Sundaraj SR, et al: Spinal cord stimulation: A seven-year audit. J Clin Neurosci 12:264-270, 2005

Links

www.spine-health.com
www.nevro.com
www.controlyourpain.com
www.poweroveryourpain.com
www.tamethepain.com

Glossary

laminotomy: surgical cutting of the laminae or vertebral arch of the vertebra.
lead: a small medical wire that has electrodes at one end. Electrical current passes from a battery, along the wire, to the electrodes. Two types: percutaneous and surgical leads.
fluoroscopy: an imaging device that uses x-ray or other radiation to view structures in the body in real time, or "live". Also called a C-arm.
percutaneous: by way of the skin (e.g., injection).
peripheral nerve stimulation: a surgical treatment for pain in which specific nerves are stimulated rather than the general area of the spinal cord.
sciatica: pain that courses along the sciatic nerve in the buttocks and down the legs. Usually caused by compression of the 5th lumbar spinal nerve.
seroma: a mass formed by the collection of tissue fluids following a wound or surgery.
spinal hygroma: an accumulation of cerebrospinal fluid under the skin, which produces a visible swelling, caused by leakage around a catheter, drain, or shunt.

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