

Applications and Future Trends of Spinal Cord Stimulation

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Abstract. There are various causes of chronic pain, such as almost any nerve damage has the potential to develop into a chronic pain. This pain can be felt depending on where the nerve damage is. Nerve damage may result from physical trauma, other medical disorders, or drugs. Spinal Cord Stimulation (SCS) is a rising technology to cure different types of chronic pain. Though the mechanism of SCS is still unclear, it has been proved effective as a useful method and shows several superiorities against the traditional one. This article reviews the mechanism of SCS, then mainly focus on the application of SCS in the applications of failed back surgery symptom (FBSS), complex regional pain syndrome (CRPS), peripheral neuropathy, and critical limb ischemia (CLI), respectively. Each application would also be discussed based on their advantages and disadvantages. Finally, we introduce our perspectives of future trends of SCS.

Keywords: Spinal cord stimulation; Failed back surgery symptom; Complex regional pain syndrome.

1. Introduction

Implantable medical devices, such as pacemakers, blood pressure sensors and cochlear implants, are gradually being developed and are in the trial stage. However, these simple implants are not enough to solve the patient's symptoms from the source, only to alleviate the effects of various diseases on the body. With the development of science and technology, people began to study the control of the central nervous system to treat diseases or reduce pain. Among them, the implantation of therapeutic equipment and treatment on the central nervous system has become a novel treatment method, such as electrocorticogram implanted in the brain's cortex and SCS implanted in the spine.

However, the use of any device implanted in the center of the body (brain and spine) is very risky, and no matter how small the implanted chip is, it will very easily cause the body to cause rejection. If an accident occurs, it will cause great harm or even death to the human body, so this treatment method that requires implanting medical devices in the central nervous system cannot be accepted by everyone. In contrast, the SCS treatment method is more acceptable than the electrocorticogram, requires craniotomy and has played a significant role in medical treatment [1].

SCS works by interrupting the transmission of pain signals before they reach the brain, so the body will not receive pain feedback from the brain. When the brain does not receive pain signals, people experience pain relief. A brief overview of the principle of SCS is the implantation of a stimulator (a small implantable pulse generator) and leads into the body. The stimulator produces some electrical current pulses, which are tiny and warm and will go through wires and be sent to patients' spinal cord-specific nerves. The pulses the SCS produces will cover pain signals sent to the brain. The device will also provide a remote control that allows patients to voluntarily reduce or increase the level of pain stimulation. Patients can use the remote control to adjust and minimize pain for different pain areas in other areas of the body. While this approach does not treat and resolve the condition at the source of the pain, it reduces how the brain perceives pain (the patient's perceived pain becomes a mild tingling). The ability of Spinal Cord Stimulation treatment to minimize pain varies from person to person, and even a small number of people will not feel any pain because of SCS. Still, in any case, the pain reduction of this treatment must be more than 50% of the overall pain. Otherwise, the SCS treatment will be considered to fail.

Today's Spinal Cord Stimulation devices are often small and portable. Only the external battery and some very small parts will be placed outside the body, and the battery that powers it is stored in a relatively hidden place. When the device is low, charging or replacing the battery does not require completely undressing or reaching into awkward places. Usually, the battery is placed with a zipper, such as the rear zipper. For women, when wearing a skirt, the battery can be hidden under the skirt to achieve a concealed effect [2]. And the SCS has been widely used in many neural disorders. In this review, we will introduce the mechanism of action for SCS and its use in treating FBSS, CRPS, peripheral neuropathy, and CLI.

2. Mechanism of Action

Served as the direct inspiration, the gate control theory prompted the development of SCS technology. Melzack and Wall proposed that cutaneous touch signals, which are sent by bigger myelinated fibers, counteract afferent pain signals, which are transmitted by small fibers to the spinal cord. This low threshold epidermal activity might reduce central pain perception by "gating" the dorsal horn output... This hypothesis served as the foundation for SCS: Continual stimulation of the A fibers' axonal branches in the dorsal columns was supposed to release transmitters through the fibers' spinal collaterals, preventing C fiber responses in dorsal horn neurons, as shown in Figure 1. The gate would be closed, and the central transmission of pain signals would be reduced [3]. Shealy and colleagues first introduced SCS in 1967, and it has developed into a therapy option for persistent neuropathic pain. Stimulation electrodes must be implanted in the epidural space.

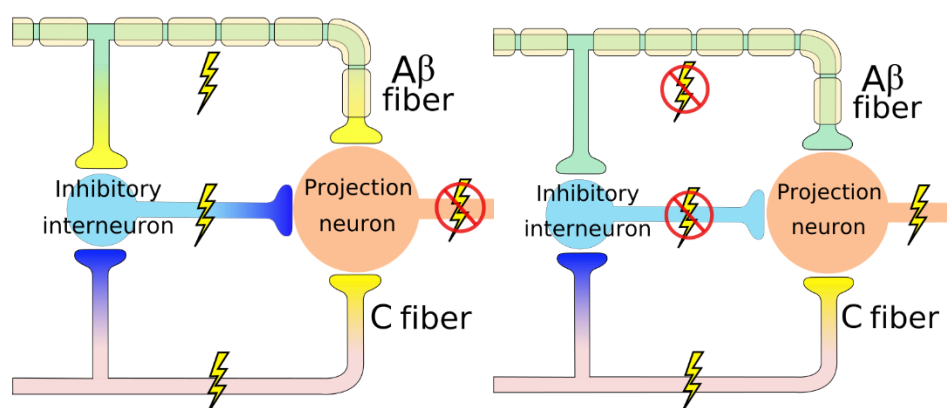


Fig 1. (Left) The gate will be shut, preventing pain impulses from ascending to the brain and avoiding the perception of pain. (Right) The gate will be opened, allowing pain signals to enter and be transmitted to the brain for the perception of the pain.

3. Clinical Applications of SCS

3.1. FBSS

The condition known as the failed back surgery symptom (FBSS) is when you anticipate that your back or neck issue will be addressed following spine surgery, whereas it doesn't always happen. Pain and other problems may reappear immediately or months after your procedure FBSS. This can occur anywhere along the spine and is stressful for patients and doctors.

In the typical scenario, spinal surgery can only release a pinched nerve root or fix an uncomfortable joint. Unfortunately, back or spinal surgery cannot eliminate patients' discomfort. It can only alter anatomy. Hence it is important to identify any injuries that are likely to be the source of back pain before having the surgery. The most common reason back operations are unsuccessful and some patients continue to have pain following surgery is that the surgically removed damage was not the actual source of the patient's problem.

Conventional medical management (CMM), which mostly comprises analgesic and depression medications, physiotherapy, and psychosocial counseling, is the usual course of treatment for people with FBSS. Since the inception of SCS in the 1960s, numerous advancements—including more precise electrodes, smaller electrodes, and improved surgical methods—have made SCS a more appealing choice for treating persistent back pain and also, therefore, FBSS [4]. There is mounting proof that SCS successfully treats FBSS, with most research proving its effectiveness, particularly for those whose primary symptom was leg pain. Numerous randomized controlled trials have demonstrated that SCS provides better pain relief than CMM.

SCS was investigated in FBSS cases. In the investigation, SCS or reoperation was randomly assigned to 50 patients, who were then supervised for an evenly 3 years after surgery by independent third-party interviewers. If the outcomes of the randomized therapy were unacceptable, patients had the option of switching to the alternative. Success was evaluated using patient satisfaction and self-reported pain relief. The resulting metric was converted to the alternative method. Self-reports were used for daily activities, painkiller use, and employment status. In the 45 patients(90%), SCS was more successful than revision surgery, who were available for follow-up. Patients initially assigned to SCS had a considerably lower crossover rate than those assigned to revision surgery, and this difference was statistically significant. Compared to patients randomized to SCS, patients randomized to revision surgery required higher opiate analgesics more frequently. Other variables of daily life activities and employment status did not vary significantly [5].

3.2. CRPS

CRPS is a kind of pain with chronic condition with the feature which is autonomic and inflammatory. It affects the arms and legs mostly and usually occurs after an injury. For the minor or moderate tissue injury CRPS patients, the part injuries will render red and warm. The patients will also feel extremely painful, which may change over time and depend on personal fitness[6]. CRPS can be divided into two categories based on experiments: CRPS I and CRPS II. Common causes of neuropathic pain in CRPS I arise from injuries affecting the peripheral or central nervous system, but this group of patients does not have overt neuropathy. CRPS II is a neuropathic pain syndrome. CRPS is a central nervous system disease known as central sensitization; it results from increased excitability of nociceptive neurons caused by tissue damage or nerve damage [7].

It has been shown that SCS is effective in reducing pain and dysfunction of the muscle. In addition, the blood flow ability can also be improved when treating CRPS type. It involves two mechanisms: the release of a vasoactive substance after the inverse curve of sensory fibers have been activated and, under certain conditions, inhibition of sympathetic efferent activity, which reduces vasoconstriction [8].

From the early evidence, more than 73 percent of the patients had reduced pain with SCS; it can also reduce edema. In 2000, Kemler et al. conducted a series of studies on chronic CRPS type I among patients. In the experiment, 42 chronic complex regional pain syndrome type I patients joined it(n=42), and controlled experiments with PT alone (n=18) and SCS+PT (n=24) were performed. The Visual Analog Scale (VAS) is a measurement tool that visually represents pain levels between 0 to 100 mm, from no pain to painful. Finally, it has been shown that these patients who received both treatments had a 3.6 cm reduction in pain intensity on the VAS, but there was a 0.2 cm-inclination of pain in patients who received only PT. Not only that, but the HRQL scores improved for patients using SCS. Eighty percent of the patients who had applied SCS experienced pain relief of up to 50 percent on the QoL assessment. And SCS has great cost-effectiveness for CRPS. According to statistics, the treatment cost of patients receiving SCS treatment is reduced by \$48,464 per patient compared with patients not receiving SCS treatment. An expensive SCS+PT treatment can save 58,471 euros per patient [9].

3.3. Peripheral neuropathy

Peripheral neuropathy is caused and can cause both debilitating pains in the hands and feet and impact the operation of other portions of the patient's body, for example, the gastrointestinal tract, urinary system, and body circulation. Peripheral nerve information transmission is the process through which information is conveyed from the central nervous system, specifically the brain and spinal cord, to other regions of the body(peripheral nerves), and the sensory feedback information will be transferred to the central nervous system by peripheral nerves. Peripheral neuropathy can be caused by serious causes, like trauma, genetics, and viral infections. The most common example is diabetes, which has caused a huge economic burden to many countries. Diabetes affects approximately 472 million people worldwide, and the risk of peripheral neuropathy is between 5.8% and 34%. It greatly affects people's quality of life (QoL) [10]. Peripheral neuropathy often causes pain in patients, and SCS can be used as a pain relief method.

In the experiment, a 79-year-old man developed peripheral neuropathy due to diabetes with complications of the lumbar spine and lower extremity pain. The man also had a history of vascular disease and failed back surgery. At the initial visit, without the help of SCS, his Pain Visual Analog Scale (VAS) reported a value of 90 (with a maximum of 100), and after treatment with SCS, his Pain Visual Analog Scale (VAS) dropped to 30. SCS implantation covers the painful area with a wire passed through the T4 cone. One month after the SCS was implanted and treated, the patient's VAS value dropped to 20, an overall decrease of 70. Before his SCS treatment, he required daily oral painkillers of various types to maintain his daily activities, but he has been successfully weaning off oral painkillers since then. In addition, experts studied the proportion of pain relief by SCS at different times and compared it with BMT. Experimental data showed that SCS reduced pain by more than 50% regardless of day or night, but the BMT group was far less effective in reducing pain than SCS.

However, SCS implantation also has certain risks. Individual patients will experience symptoms such as retroviral puncture headaches and even lead symptoms such as subdural hematoma, threatening people's lives.

3.4. CLI

Critical limb pain is pain that occurs at rest or impending limb loss caused by significant blood flow compromise to the injured extremity. Inadequate blood flow to supply vital oxygen to the limbs is frequently the cause of peripheral arterial occlusive disease. CLI develops after a protracted period of inadequate blood supply, prompting a sequence of pathophysiological processes that finally result in resting circumstances. Legs with pain or nutritional lesions, or both [11]. CLI is typically treated with a revascularization surgical procedure to improve peripheral circulation, alleviate ischemic pain, and salvage the limb [12]. However, due to disease progression or the inability to revascularize: this traditional treatment method does not work. In these inoperable cases, until amputation is unavoidable, Conservative treatment with analgesics, vasodilators, and topical wound care are the only remaining options. SCS can be used as an alternative treatment, Which relieves pain by improving local skin microcirculation [13]. SCS therapy has the potential to save a limb while also greatly enhancing pain alleviation and ulcer progression.

During follow-up, patients treated with SCS utilized significantly fewer non-opioid and opioid medications than those treated conservatively [14]. Traditional treatments tend to be extremely risky, with a 2009 study showing a 1-year amputation rate of 12% for CLI patients after lower extremity bypass, compared with 1% for limping patients [15]. Compared with the risk rate close to one-tenth, the treatment of SCS can greatly reduce the probability of amputation. The study found that the most suitable TcpO₂ parameters for predicting SCS to promote limb salvage in patients were the baseline TcpO₂ in the supine position (ideally should be between 10 - 30 mmHg) and the increase in TcpO₂ in the leg dependence (should be greater than 15 mmHg), the 1-year limb salvage rate was increased by 83% in patients selected using these two TcpO₂ criteria.

4. Discussion Board

FBSS problems would come from any possible spine surgery, which in the past needed to take long-term traditional therapies, including the possibility of failure, and even repeat the surgery. Both would result in increasing the risks of complications and curing expenses. The emergence of SCS technology has been proven that could significantly address this problem. Enough clinical evidence supports the efficacy and safety of SCS using the electrode implanted into a human body. However, the mechanisms of SCS are still not clear. With more research and new observations from the data, the future of SCS would be bright in the field of medical science.

SCS, as an alternative treatment for CLI, relieves pain by improving local skin microcirculation. It can greatly reduce the dependence of patients on opioids. In addition, for those CLI patients who cannot undergo traditional surgery, SCS has better limb salvage and pain relief efficacy than conservative treatment alone, especially when they are selected according to foot TcpO. According to the experiment results, a limb salvage rate of up to 83 percent is possible after one year. This collection of data indirectly demonstrates the efficacy of SCS therapy.

As a new pain relief method, SCS can greatly help patients reduce their dependence on traditional pain relief methods, such as taking opioids. However, because of its novel features, we can still not obtain sufficient experimental data to demonstrate the complications and subsequent effects of SCS. We still need to do more simulation experiments to obtain further data to more comprehensively evaluate the safety of SCS.

CRPS is very common in people's lives, and the pain it brings is very large. The use of SCS in CRPS can not only greatly reduce the suffering of patients with the disease but also reduce the economic burden on individuals and countries compared with other treatments, and increase people's quality of life index. In the future, SCS in CRPS will provide people with more pain relief and risk reduction.

The role of SCS in peripheral neuropathy cannot be underestimated. Compared with other treatments, the pain it can relieve is very large. However, as an implantable treatment method, what it implants may have a certain invasive behavior on the human body and cause a series of adverse reactions or even death in the human body, which needs attention and further research.

5. Conclusion

SCS works by implanting a stimulator in the body that delivers electrical pulses with wires. These current pulses can interrupt the transmission of pain signals before they reach the brain, allowing the body to reduce pain feedback when the brain does not receive pain signals. Compared to traditional implantation devices that require craniotomy, SCS can develop different implantation locations depending on the location of the pain source, which can significantly improve the surgical outcome and ensure the patient's safety after surgery. SCS has been successfully used to treat neurological diseases such as FBSS, CRPS, peripheral neuropathy, and CLI. In addition, surveys of patients have found that SCS reduces patient suffering more than traditional treatments. According to reported data, patients take significantly fewer opioids with SCS, so SCS can also reduce patients' dependence on opioids.

SCS has been successful in the experimental stage as a new treatment, but there are still many difficulties in turning it into a more mature industrialized medical device. One of the main limitations is the price of SCS, which is still very expensive, sometimes even more expensive than conventional treatments. Secondly, SCS is by nature an electronic device, which means it has many technological limitations, such as vulnerability and energy issues. In addition, a large amount of experimental data does not point out the problems it faces in medical treatment, complications and rejection of the body by the implanted device. Overall, SCS has great potential as a new medical device, but it still needs the efforts of all industries to make it popular.

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