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Wireless Spinal Cord Stimulator with Bipolar Multi-Channel Electrode Array

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Abstract. Spinal cord stimulators (SCS) are a method used to treat chronic pain and are widely used in the field of modern neuroregulation. Based on the existing literature, this paper compares and discusses the principle and structure of a new wireless spinal cord stimulator with a small range of precise stimulation and the choice of working plan. In this spinal cord stimulator, a bipolar structure combined with multi-channel electrodes is considered, and a passive resonator is used to improve the efficiency of wireless energy transmission. The literature search and research show that the combination of bipolar structure and multi-channel electrode array can produce more concentrated stimulation areas, reduce the stimulation of non-target areas, and thus reduce side effects. In the selection of electrode materials and external equipment, this paper mainly considers the biocompatibility, considering the use of carbon nanotube (CNT) composite materials for the internal electrode materials, at the same time, this paper also considers the impact of voltage overshoot on the electronic equipment, and considers the work plan and material selection to reduce the impact.

Keywords: Bipolar; Multi-channel; Wireless; Spinal cord stimulator.

1. Introduction

Spinal cord stimulation (SCS) represents a critical advancement in the management of chronic pain, offering a non-pharmacological alternative for patients whose conditions are refractory to conventional treatments. Rooted in the gate-control theory proposed by Melzack and Wall in 1965, SCS employs electrical impulses to modulate pain signals at the spinal level, positing that the activation of non-nociceptive fibers can inhibit the transmission of nociceptive signals to the brain. This mechanistic approach underscores the complex interplay between the nervous system's structural components and its perceptual outcomes, particularly in the context of chronic pain—a condition that afflicts a significant portion of the global population, impacting quality of life and imposing substantial healthcare costs.

Despite its widespread application and the evolution of SCS technologies, the exact mechanisms by which SCS exerts its analgesic effects remain an area of active investigation. Early implementations of SCS targeted the dorsal columns, aiming to elicit paresthesia in the affected areas, thereby masking pain perception. However, advancements in our understanding of neurophysiology and pain mechanisms have led to the exploration of novel SCS paradigms, including high-frequency SCS and paresthesia-free modalities, which challenge the traditional reliance on paresthesia as a marker of therapeutic efficacy [1].

Emerging evidence suggests that SCS may modulate pain through a variety of mechanisms, including direct inhibition of nociceptive signal transmission, alteration of spinal cord neurochemistry, and modulation of supraspinal centers involved in pain perception and processing. The basic principle of SCS in the treatment of pain is the gating principle. In addition, SCS is also believed to increase blood flow and reduce local inflammatory response by promoting vascular dilation. Therefore, SCS is also considered for ischemic pain. In addition, SCS can also promote the release of pain-suppressing substances in the brain and spinal cord, providing analgesic effects, so SCS are also widely used in neuropathic pain. The diverse therapeutic potential of SCS for different pain substrates offers hope for patients with complex, multifactorial pain manifestations.

Moreover, the integration of SCS with comprehensive pain management strategies emphasizes the shift towards personalized medicine, where treatment modalities are tailored to the individual's specific pathophysiological and psychological profiles. As research continues to unravel the intricacies of SCS mechanisms and optimize its clinical application, this approach stands as a testament to the interdisciplinary nature of pain management, bridging the gap between technological innovation and therapeutic intervention.

In conclusion, spinal cord stimulation embodies a dynamic and evolving treatment paradigm in the landscape of chronic pain management. Its foundation in the gate-control theory, coupled with ongoing advancements in technology and a deepening understanding of pain physiology, underscores its significance as a modality that not only alleviates suffering but also enriches our comprehension of the human pain experience.

2. Implant part

2.1. Basic Principles

In 1967, Shealy et al. introduced spinal cord stimulation (SCS) [2], and since then SCS has been widely used in the treatment of chronic pain disorders. Examples include failed back surgery syndrome, complex regional pain syndrome, and ischemic pain.

The mechanism of spinal cord stimulation (SCS) in managing chronic pain is elucidated through its impact on spinal neuron activity and responses to noxious stimuli, leveraging the "gating theory." This theory posits that non-painful sensations can inhibit the transmission of pain signals [3]. By delivering mild electrical pulses to targeted areas of the spinal cord, SCS devices aim to disrupt and block these pain signal pathways to the brain, thus potentially diminishing or eliminating chronic pain. This intervention highlights the strategic use of electrical stimulation to modulate sensory processing within the spinal cord for pain relief.

2.2. Selection of electrode array

In the field of modern neuroregulation, the selection of electrode arrays is critical to the success of treatment. Some companies commonly use single-channel electrode arrays or plate electrode arrays, each has advantages and disadvantages. Single-channel electrode arrays are favored because of their simple structure, low cost, and relatively simple implantation procedures. This type of electrode is particularly suitable for basic applications that are not demanding, but because of its limited stimulation range and accuracy, it may not be flexible and precise enough when fine-tuning the stimulation range is required.

Plate electrode arrays have wide coverage and good stability, making them ideal for applications that require stimulation in complex or specific areas. This type of electrode array is widely used in various spinal cord stimulators because it provides stable and long-lasting stimulation. The plate electrode can provide a more uniform electric field distribution, suitable for long-term implantation in the body, and can reduce the stimulation instability caused by electrode displacement during stimulation.

However, the focus of this article is to introduce a spinal cord stimulator suitable for the treatment of local chronic pain. For this specific need, multi-channel electrode arrays show their unique advantages. Multi-channel electrode arrays provide precise stimulation control, are highly adaptable and adjustable, and are suitable for complex and personalized treatment programs. This electrode array is designed with multiple independently controlled channels to target the area precisely and administer treatment, which is particularly critical for managing chronic pain.

Multi-channel electrode arrays allow physicians and researchers to independently adjust each electrode's signal strength, frequency, or duration to achieve optimal therapeutic results. This design allows the electrode array to be precisely tailored to the patient's pain site, resulting in more precise control of the pain area, reducing unnecessary stimulation of peripheral nerves and side effects.

Figures 1A and 1B show the design of a multi-channel electrode [4]. The electrode array is designed to be placed between the dural material and the upper vertebrae in the epidural space. The electrode can be closer to the nerve fiber, improving the stimulation efficiency. This design considers the human anatomy's complexity and ensures the electrodes' effectiveness and safety. This electrode array layout helps reduce the discomfort caused by the stimulation while maintaining the stimulation effect.

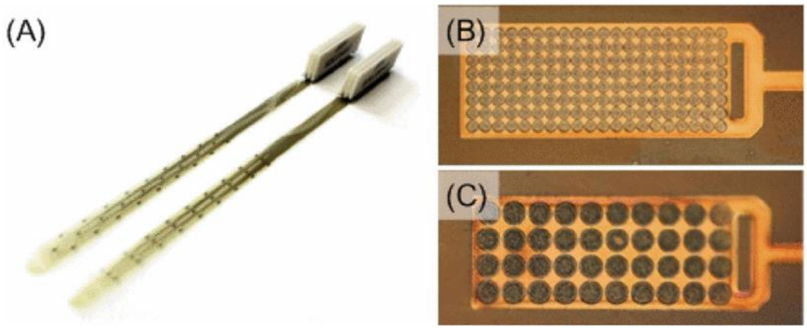

Fig. 1 Multi-channel Spinal Cord Stimulator Electrodes. (A) Dual-lead spinal cord stimulator electrodes. (B) Close-up of the high-density electrode array for targeted spinal stimulation. (C) Enlarged view showing the individual electrode contacts [4].

Future directions may include further optimization of electrode materials to improve their biocompatibility and conductivity and develop novel electrode designs, such as fabricating electrodes using micro-etching technology or nanotechnology to achieve finer stimulus control. In addition, the introduction of intelligent control systems, such as real-time adjustment of stimulus parameters using machine learning algorithms, will also greatly improve treatment efficiency.

2.3. Working principle of multi-channel electrode array

Place the stimulator in the specific spinal cord region that produces pain, and connect the stimulator through a wire to an electrode that is placed in the epidural space. The stimulator can send a weak, regular pulse current to stimulate a specific section of the spinal cord nerves and transmit to the relevant nerves, which can prevent the pain signal from the corresponding area to the brain, thus relieving people's pain to varying degrees.

2.4. Electrode Configuration

Electrode configuration refers to where and how the electrodes are placed near the spinal cord.Currently, the electrode configuration methods on the market are generally divided into unipolar configuration and multi-level configuration [5]. A unipolar configuration generally means an anode in the principle treatment area and a cathode near the treatment area. This configuration can cover a large area of stimulation. Because of this feature, many companies choose this configuration method. However, after clinical trials, it can be known that although this configuration has a wide treatment area, it will produce a lot of stimulation in non-target areas, and cause insufficient precision, resulting in side effects. Both the anode and cathode in the bipolar configuration are placed near the treatment area, and such a layout can produce a more concentrated area of stimulation and reduce stimulation in non-targeted areas, thus reducing side effects. It can improve the comfort of the patient, so this placement method is used from the point of view of comfort and accuracy.

3. Voltage overshoot solution

When designing electronic systems, especially spinal cord stimulators, it is critical to address voltage overshoot to ensure system stability and performance. Voltage overshoot can damage components, reduce signal integrity, and affect system reliability. Strategies to mitigate voltage overshoot mainly involve careful electrode design, material selection and precise control of stimulus signals.

3.1. Electrode design and precise control of electrical stimulation

First, the precision of electrode design and electrical stimulation is key for spinal cord stimulators. In electrode selection and electrical stimulation, a combination of multi-channel electrode array and bipolar configuration is considered.Multi-channel band electrode arrays allow for more precise current distribution and control, thereby reducing unnecessary voltage fluctuations [6].The bipolar configuration in this way will generate an internal electric field and reduce the diffusion of current. Thanks to this method, which uses a combination of multi-channel electrodes and bipolar placement, more precise current distribution and control can be provided. Reduce the possibility of voltage overshoot.

3.2. Material selection

The selection of appropriate electrode materials is crucial to ensure the stability and performance of the system. Electrode materials need to have high conductivity not only to reduce the interface impedance between electrode and biological tissue but also to improve the stimulation efficiency. It also has good chemical stability to reduce voltage overshoot and ensure long-term reliability. Traditional electrode materials, such as metals (platinum, titanium), carbon and silicon, have a wide range of applications in electronic and medical devices, but there are many shortcomings. For example, these materials may have low biocompatibility and cause uncomfortable reactions in biological tissues, especially metal electrodes that may trigger inflammation. In addition, the mismatch between the mechanical properties of the carbon and silicon electrodes and the biological tissue may lead to post-implantation instability, affecting the therapeutic effectiveness and patient comfort.

To address these issues, researchers have begun to look for novel electrode materials, such as conductive polymers and carbon nanotube (CNT) composites, to make electrodes for spinal cord stimulators. Conductive polymers have attracted attention because of their good electrical conductivity, mechanical properties, and biocompatibility. Carbon nanotube (CNT) composites, because of their unique nanostructure, provide higher conductivity and mechanical properties, while being better matched to biological tissues, reducing discomfort and rejection after implantation in the body.

In addition, the application of conductive polymer and CNT composite materials can also adjust the reaction of the electrode and biological tissue interface through its unique electrochemical characteristics, which can not only further improve the accuracy of electrical stimulation, but also automatically adjust the stimulus intensity according to the response of biological tissue through intelligent regulation, so as to effectively avoid voltage overshooting. In addition to advances in hardware, the use of biomaterials in spinal cord injury treatment has been identified as a promising area for future research. Regenerative biomaterials, including tissue engineering and biological scaffolds, are considered very promising for transporting cells or drugs to injury sites to facilitate repair and regeneration. This approach highlights the growing promise of SCS device development, where the integration of cutting-edge materials and technologies aims to improve the quality of life for patients with spinal cord injury or chronic pain by providing more effective, comfortable and adaptable solutions [7].

Of course, the application of these new materials also needs to take into account the cost-benefit ratio and the feasibility of the manufacturing process. Materials with high electrical conductivity and good chemical stability tend to be more expensive and difficult to process.

4. Wearable part

4.1. Energy transmission

The use of wireless energy transmission was considered, which can avoid the risk of infection caused by skin piercing. However, this also requires a good energy coupling efficiency between the external device and the implanted part in vivo, and a passive resonator is considered to improve the energy coupling efficiency of wireless energy transmission [8].

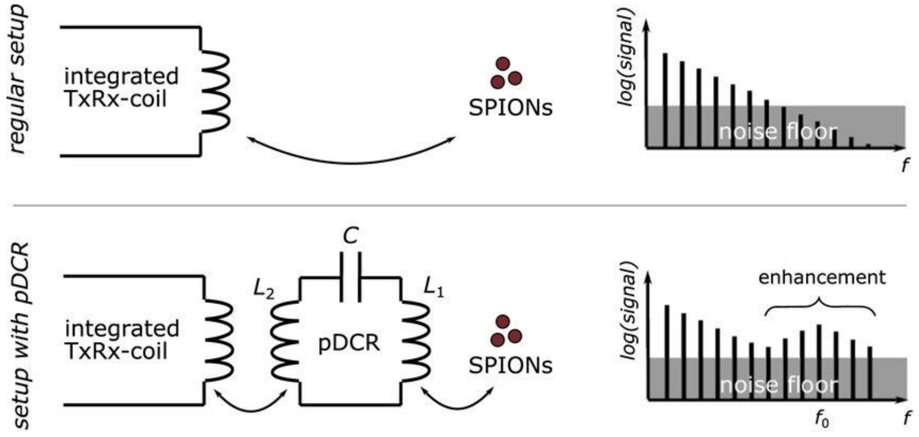

Fig. 2 Passive resonator[8].

The figure 2 shows the working principle of the passive resonator, the one on the left is the receiving coil, and the one on the right is the external energy signal [8]. Consider adding a resonator (pDCR) to the implant portion of the spinal cord stimulator. The working principle of the passive resonator involves the use of two coils (L1 and L2) and a capacitor (C) configuration. The center coil L1 captures the signal with high sensitivity, and then the signal is coupled to the integrated transmit/receive coil via the external coil L2. The two coils are connected by a capacitor, enabling frequency-selective signal enhancement near the resonant frequency f0, receiving energy through resonance and increasing energy collection efficiency.

4.2. External Devices

The spinal cord controller also contains part of the external device, which is important for the efficiency of the entire neuroregulatory system and for patient comfort. The in vitro device mainly consists of two parts: a signal transmitter and a control unit, which generate and transmit electrical stimulation signals to the implanted electrodes in the body. At the same time, due to the close-fitting wearability of this device, its design requirements not only ensure the effectiveness of signal transmission, but also reduce adverse reactions to the human body, that is, reduce biological incompatibility reactions.

In terms of material selection, external devices are often made with biocompatible materials, such as medical-grade silicone or polycarbonate, which are gentle on the skin and reduce the risk of allergic reactions. These materials should also have sufficient mechanical strength and flexibility to resist wear and tear in everyday use and be able to adapt to changes in body temperature. At the same time, long-term wear should also consider its comfort, the integration of flexible electronic devices and the use of monolithic device structure ensure the mechanical elasticity and thermal adaptability of the device, while not affecting the therapeutic effect [9]. In addition, the shape of the device should be ergonomic to adapt to different body types of patients and reduce local pressure when wearing.

5. Conclusion

In this paper, the selection and working principle of electrode array, the selection of electrode configuration, the selection of material, and the wireless energy transmission of spinal cord stimulator were studied. Studies show that multi-channel electrode arrays and bipolar configurations can generate more concentrated stimulation areas, reduce stimulation in non-target areas, and thus reduce side effects, and can more accurately control current distribution and reduce current diffusion. This configuration can not only improve the accuracy of the spinal cord stimulator, but also reduce the possibility of voltage overshoot, which is essential to improve the stimulation effect and patient comfort, and provides a valuable reference for the further development of current control technology.

Secondly, in terms of material selection, for the electrode material selection of the implanted part, this paper considers the use of carbon nanotube (CNT) composite material after comparison with several papers, which can automatically adjust the stimulus intensity according to the response of biological tissues, and can effectively avoid voltage overshoot. This material selection demonstrates not only a deep understanding of innovative materials, but also a strong focus on patient safety and comfort.

Finally, for the part of wireless energy transmission, this paper considers the use of passive resonators to improve the energy coupling efficiency of wireless energy transmission. This option can significantly improve the efficiency of wireless energy transmission, providing support for the long-term stable operation of the spinal cord stimulator. This not only reduces the need for frequent charging of patients, but also improves the overall reliability of the system.

Overall, this article provides a comprehensive overview of the technical aspects of spinal cord stimulators, focusing on electrode design, material selection, and system configuration for optimal pain management and patient comfort. These results not only have important guiding significance for the future development of spinal cord stimulator technology, but also provide a valuable reference for the field of electrical stimulation therapy, helping to promote the progress and innovation of related technologies.

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