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Spinal Cord Stimulator for Pain Management: Review

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Abstract:

Spinal Cord Stimulator (SCS) is used as the most effective solution for chronic pain due to the destruction of nerves, axonal networks, and glial membranes caused by spinal injuries. Because of today's technological advances and updated materials, state-of-the-art neurostimulators are presented, and the materials used in the explained device are applied. Firstly, the method of stimulation is updated after considering that low-frequency stimulation can cause discomfort and that high-frequency stimulation can replace low-frequency stimulation, so by combining these two options, it was concluded that using low frequency to stimulate muscle tissue and high frequency to stimulate the nerves would give better results; secondly, the selection of materials was then considered in terms of four aspects: substrate, encapsulation, electrical tracks, electrodes, and the electrodes were found in the form of Pt-Ir film is a material with good adaptability; finally, the two significant aspects of material attachment to the skin and transmission of electrical energy are studied in the wearability. In the material attachment program to the skin, electronic skin have stretchability, adhesion, and breathability. In the study of power transmission, there are two approaches, wired transmission and wireless transmission, and the wired transmission pointed out the friction nanogenerator, thermoelectric generator, and temperature difference generator. Wireless transmission mainly consists of ultrasonic vibration transmission and inductive electrical energy transmission.

Keywords: Bioelectronic; Spinal cord stimulator; Materials chemistry.

1. Introduction

Spinal cord injury (SCI) is mainly caused by traumatic fractures leading to bone fragments or dislodged vertebrae, resulting in torn ligaments and destruction of nerves, axonal networks, and glial membranes [1]. It is a severe complication of spinal cord injury, resulting in the temporary loss of physiological functions of the body and, in severe cases, the permanent loss of functions [2]. The majority of spinal cord injuries are traumatic in origin and will account for 90% of the cases, including human factors such as car accidents and sports injuries. At the same time, a small number of causes due to non-traumatic injuries due to vascularity, tumors, and infections in advanced age are on the rise. It can be seen that the age distribution of sci cases is a bimodal distribution, with the peak cause being primarily traumatic in young adults aged 15-29. In contrast, the opposite is true for adults over 64 [3]. The main thing is that sci carries many complications, the common ones being chronic pain, abnormal autonomic reflexes, and urinary tract infections [4].

Nowadays, the most practical treatment options for the spinal cord are surgery, drugs, and hyperbaric oxygen. Surgery can relieve the pain caused by spinal cord compression and remodel the stability of the spinal cord to reduce the damage of spinal cord nerve repair caused by the secondary injury. Drugs can inhibit the activation of macrophages to prevent the cells from obstructing the spinal cord repair or to improve the blood supply. Hyperbaric oxygen can provide oxygen to the spinal cord to promote nerve cell repair and neovascularization [2].

Moreover, for relieving chronic pain from spinal cord injuries, sc has been the most effective and experienced method and can successfully help sci with neurological rehabilitation. However, cs is now used for neurological pain management because the use of epidural electrodes will lose its therapeutic effect over time, and the built-in pulsed generator may run out of power, or the electrodes may migrate or become infected, resulting in the need for re-surgery thus posing a risk.

Therefore, new techniques and methods are needed to update this technology for patients. This paper reviews subsequent research on spinal cord neurostimulators through stimulation protocols, implantable materials, the latest technology to achieve wearability, and power-generating devices continuously providing electrical energy [5].

2. Stimulation protocol

Firstly, reviewing the spinal cord stimulators (SCS) that have been commercially available, respectively extra-membranous SCS and intramodal SCS to give the current spinal cord stimulators, extra-membranous SCS need to be surgically and permanently implanted in a specified location in the spinal cord. In contrast, although percutaneous spinal cord stimulation does not need to be implanted, many indeterminate situations still arise. This is from the device to explore the current mainstream design options; after giving the pain gate control theory to make the theoretical basis for spinal cord stimulation, to make a judgment for the subsequent high-frequency stimulation or low-frequency good, and through the latest research gives a high-frequency stimulation of the nerve coupled with low-frequency stimulation of the muscle program.

2.1 review commercial spinal core stimulator

In the current context, several devices have been applied to the spinal nervous system to treat or accelerate the recovery of patients after spinal cord injury (SCI), which produces deficits in autonomic and sensory function [6].

One option for spinal cord stimulation utilizes extra-membranous SCS, where an electrode array is placed in the epidural space of the spinal canal and connected to a powered implantable pulse generator; the implantable pulse generator of this approach can be programmed differently to produce different effects. Providing safe and effective non-pharmacological adjustable therapy has become the dominant program to stimulate the spinal cord [7].

There will be two phases of implantation. First, the patient undergoes a short-cycle test period where the electrode array is temporarily in the epidural space on the dorsal side of the spinal cord, during which multiple parameters will be tested (e.g., amplitude, pulses, stimulus configurations, etc.) [8]. The second phase is a permanently implanted pulse generator in a designated spinal cord location.

Another is that since extra-membranous SCS requires invasive surgical implantation of a pulse generator, non-invasive transcutaneous spinal cord stimulation (TSCS) has been generated to promote neuroplasticity and, thus, restoration of locomotion by stimulating intraspinal circuits to generate neural and motor responses [9]. TSCS, which modulates the excitability of spinal neurons and stimulates the spinal nerves differently than direct stimulation, is generally accepted that this protocol is more effective and less damaging in the presence of more severe or chronic injuries. The current situation still needs to be confirmed due to the parameters and experimental protocols for optimal stimulation.

2.2 Gate control theory

In 1965, Canadian psychologist Ronald Melzack and British physician Patrick Wall proposed the gate control theory to support the idea that spinal cord stimulation could relieve pain. A-fibers, C-fibers, and "gated" interneurons produce pain in humans, and these neurons vary in size; the larger the diameter, the faster the pulse and the stronger the pain. The larger the diameter, the faster the pulse is and the greater the pain.

Three primary neurons are A-beta fibers, A-delta fibers,

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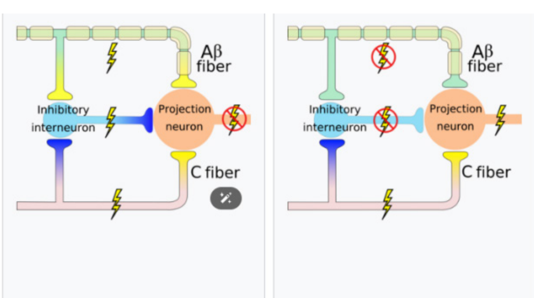
and c-fibers. The A-beta fibers have a fast pulse transmission; the A-delta fibers are smaller in diameter, but the pain sensation transmits rapidly. It will be stimulated by pain or heat, and the c-fibers are very slow to communicate and will only activate pain if it is produced over a long time.

Initially, large-diameter A-beta fibers will burst. Then, they are picked up by interneurons in the colloid stroma of the spinal cord. In that case, they are inhibitory but increase the duration of activity of the small diameter A-delta and C-fibers in the spinal cord, which increases pain sensitivity. If interneurons pick up the tiny diameter fibers, they open the valves, which cause pain sensations. Figure 1 shows the gate open, and the gate closed. In the spinal cord, three neurotransmitters are released if primary nerve afferent neurons; the first is glutamate, which produces excitation to activate the dorsal horn neurons; the second is glycine and gamma-aminobutyric acid (GABA), which has inhibitory effects; and the third is substance P which counteracts tissue damage through vasodilation and pain.

Although these reasons cause pain, there is also a theory that it is controlled through the brain. The opening or closing of valves is affected by impulses in the brain, and some negative emotions affect the central control triggers to increase pain. On the contrary, some positive emotions lead to doors closing, affecting the pain sensation [10].



Gate closed Gate open

Fig.1 The opening and closing of the interneuron gate [10]

2.3 Low-frequency SCS and high-frequency SCS

Low-frequency stimulation works by counter-stimulating axons in the dorsal columns of the spinal cord and suppressing pain signals to relieve neuropathic pain. Still, patients who receive low-frequency stimulation may react abnormally to this stimulation because it also stimulates anteriorly oriented axons. In contrast, a new type of stimulation, high-frequency stimulation, does not irritate the patient. The underlying mechanism of the approach results from an experiment by Dr. Jeffrey E. Arle, MD, PhD. By confirming field potentials on axons in superficial DC white matter and analyzing fiber activation and obstruction, the group concluded that the underlying cause of high-frequency stimulation (HFS) was the blockage of both larger fibers and dorsal root fibers and the inhibition of pain signals by stimulation of the smaller dorsal column [11].

In recent studies, low-frequency (2-8 Hz) SCS electrodes produced muscle stimulation. Patients found this method to be very comfortable in relieving pain, so the treatment of muscle stimulation can also be used as a direction for neuromodulation because back pain activates the muscles of the back, causing the muscles to stabilize the spine to relieve the pain., however, when a muscle is atrophied, other muscles are contracted at the same time, and this time to However when muscles are atrophied, other muscles are also contracted, and stimulation of the spinal cord can lead to muscle tension, which can increase the damage to the muscles and cause more pain. Combined with the fact that massage promotes recovery, reduces the release of pro-inflammatory cytokines from M1 macrophages, and reduces neuro sensitivity, Matthias Hubert Morgalla‘s group made the treatment comfortable and effective for the patient by combining muscle stimulation with SCS stimulation. It was concluded that muscle stimulation would cause rhythmic contractions of the muscles that protect the dorsal column, thus supporting the idea that SCS stimulation would not cause the patient pain and that this technique could be programmed to be more personalized [12]. It can be concluded that muscle stimulation causes rhythmic muscle contractions to exercise the muscles to protect the dorsal column, thus supporting the idea that SCS stimulation does not cause pain to the patient and that the technique can be programmed to be more personalized [12].

3. Materials

Selecting substrates, encapsulation, electrical tracks, and electrodes is very important in terms of materials for implanted devices.The substrate needs to be judged based on the mechanical properties of elastic modulus and viscoelasticity; the encapsulation needs to be selected in terms of material and technology since it is the part that directly touches the target tissue. The electrical track uses conductive materials to transmit electrical signals, proposing a relatively new way of arc interconnections; the most crucial choice of material is the electrode when there. A better choice is the Pt-Ir film, which has many advantages.

3.1 Substrate

The substrate is furthest from the target tissue to handle the implanted device. The material composition and mechanical properties result in the thickness of the substrate as well as the application of surface arrays, which depend on the modulus of elasticity and viscoelasticity of the material; for spinal cord stimulation, the elastic properties need to be chosen between 10^3 pa and 10^6 pa, and for viscoelasticity the spinal cord stimulation device needs 0.4 to 0.5 G''/G' (loss modulus/storage modulus), for which the Hydrogels are a good match [13].

Hydrogels are suitable substrate materials because they contain more than 90% water, are biocompatible, and have a three-dimensional porous structure that allows them to adhere to nerve cells, exchange metabolic substances, and are electrically conductive [14]; however, the current problem is that hydrophilic gels do not adhere well to the usually hydrophobic insulating layer, and hydrogels can lose water in a vacuum or at high temperatures, which can be a processing challenge This is also a challenge at the processing level [13].

3.2 Encapsulation

The encapsulation layer is the part that has direct access to the target tissue. Therefore, consideration should be given to whether the encapsulation material will cause neuroinflammation, which is caused by triggering the immune system; immediately after probe implantation, active microglia will wrap around the probe, which will cause additional impedance and thus will reduce the performance of the electrical stimulation, therefore addressing this issue will require the determination of the material‘s stiffness and rigidity [15]. However, the material of the encapsulation layer is essentially the same as the substrate, so this aspect must be considered when selecting the substrate.

At the level of encapsulation technology, Christina M. Tringides suggests that laser etching is very promising because the intensity, power, and focus of the light can be adjusted to create patterned substrate materials and that between plastic and viscoelastic films, viscoelastic films are preferred to recover the initial state and to support prolonged flow [13].

3.3 Electrical track

The method of communication requires conductive materials to transmit electrical signals, which are used to record the stimulus situation or stimulation; at first, people chose to come to the snake pattern of the metal mold because it can be stretched and cut accurately [13].While the design of curved interconnections can be used because it has the following advantages:

(1) Curved interconnections can effectively deform the plane to accommodate applied strains

(2) It can provide effective mechanical isolation

(3) its maximum strain of 0.08% is much less than the practical strain of 2% Si

(4) With pre-strain greater than 50%, tensile and compressive properties increase due to the increased interconnect length.

(5) There can be complex deformation-specific device properties. Depending on the surface, three deformation modes can be used on biological soft tissue surfaces: overall flexure, local flexure, and non-flexure. This permits better adhesion to the surface, thus providing portable medical functionality [16].

3.4 Electrodes

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4. Wearable

In wearable devices, the initial idea was to set the device on the clothes after the discovery that the clothes can only be accurate in special tests because the daily activities of people can not ensure that the device is close to the skin, so the development of the use of tattoos HWD, but there is also the problem that can not be used for a long time, and ultimately in the choice of wearable devices are realized through the e-skin; In choosing how to transmit electricity, there are two general directions one is the traditional power generation device, using friction vibration power generation, using the heartbeat power generation, using temperature difference power generation; the other is the wireless power generation device, in the field of spinal cord stimulation, the more common is the induction power transmission and ultrasonic vibration transmission.

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4.1 Wearable technology

Traditionally, people wanted to achieve wearability by attaching devices to textiles because clothes are something that people put on their bodies every day, embodying ease of use and comfort, and technology has been able to measure important biosignals such as electrocardiograms, even though this is a bit uncomfortable [17]. For spinal cord stimulation programs, the equipment needs to be tested all the time to ensure that the electrical stimulation is error-free, and traditional textiles are not able to follow people's regular schedules and follow the test. Therefore, to solve this problem, the latest technology has been developed for tattoo-based HWD, through which compliance and flexibility, and most importantly, the ability to adhere to the skin to realize the spinal cord stimulation non-stop detection or input of electrical signals. This technology needs to be upgraded in terms of durability and can only be used for a maximum of 96 hours, after which it will crack and, therefore, is not compatible with prolonged use for spinal cord stimulation [18].

Another new wearable technology that is more appropriate for spinal cord stimulation programs is stretchable, breathable, self-adhesive e-skin, which is able to pick up signals, has multi-signal sensing capabilities to increase the multi-data nature of the device, and can be made more user-friendly by sending electrical signals to regulate the frequency of the electrical stimulation to match the current response to the patient's pain symptoms. And figure 2 show that through the electrostatic spinning method to build thermoplastic TPU manufactured into a fiber mold, and then the mixed solution MXene-CNTs coated on the TPU and then further electrospun TPU on both sides and finally sprayed with MXene-WPU so that the e-skin has a stretchable, adhesive, breathable [19].

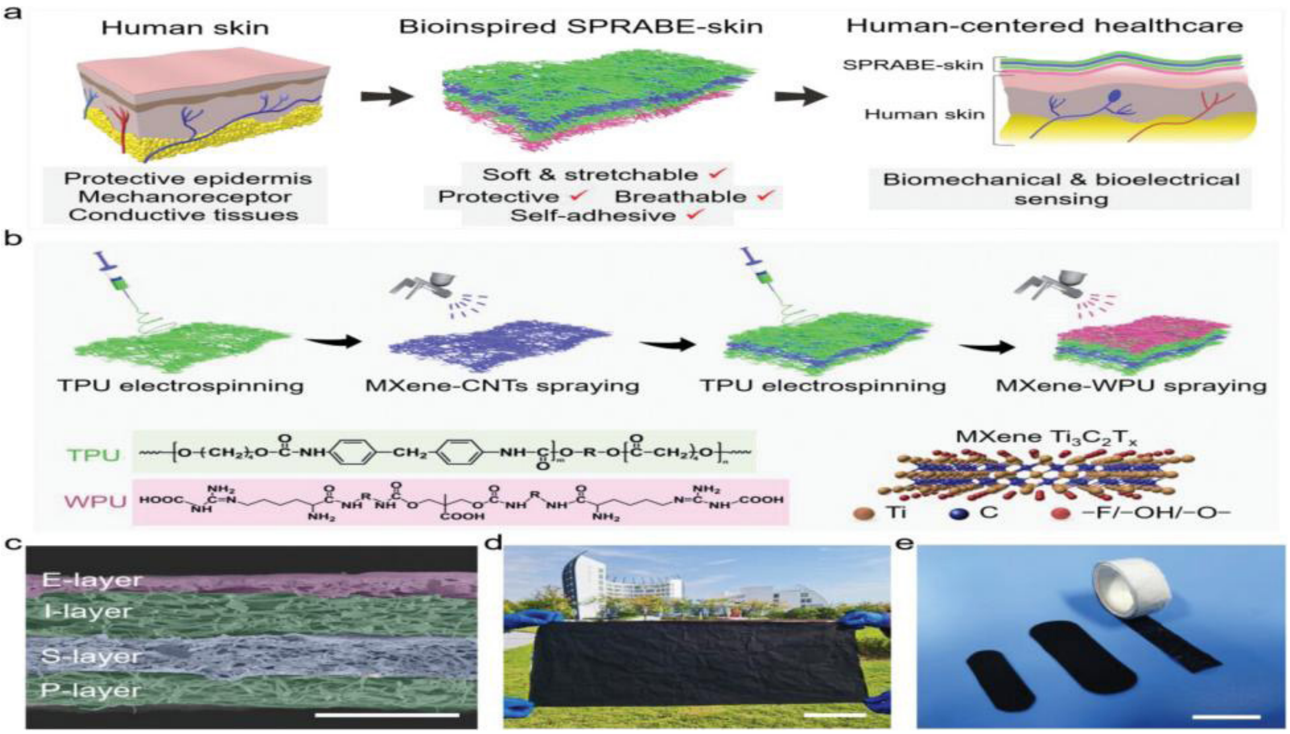

Fig2. Related processes make electronic skin stretchy, adhesive and breathable [19]

4.2 Wearables that transfer power to implants

4.2.1 traditional energy transmission technology

2.1.1 Sub heading

The traditional ways of transmitting electricity are :

The first, rubbing nanogenerators, use kapton and polyester fibers to act as a friction electric layer, generating electricity through friction extrusion and electrostatic reaction; in 2012, Teng was studied, capable of generating more voltage and power so it can support powering a capacitor, and therefore can be used as a self-powered spinal cord neurostimulation device to adapt to the electrical conductivity of more than 10 -1cm-1, and the inner layer of the Kapton and polyester fibers are risky to implant in the human body, so natural biodegradable chitosan (CS) electrospun into the inner layer is needed [20].

The second type of thermoelectric generator, the human body's heat, is also a kind of energy because the human body temperature and the outside temperature difference is the same, so it can be concluded that people can generate electricity through their heat, thus generating self-sufficient energy supply, so that there is no need to carry out a secondary operation to replace. The movement of the Seebeck effect is the principle of thermoelectric generators, which are generally flexible thermoelectric generators using inorganic and organic thermoelectric generators. One challenge, however, is that the nature of the device is temperature differential, and the internal temperature of the human body does not change very significantly, so it may not be able to generate enough electrical energy for direct spinal cord stimulation [20]. The third is electromagnetic generators for spinal cord stimulation, which can be realized by converting the movement of the heartbeat into electrical energy. The underlying principle is Faraday's Law of Electromagnetic Induction, and generating electricity from the heartbeat is a clockwork mechanism created by automatic watches developed by Zurbuchen and others [20]. This generator is also a self-sufficient solution for powering spinal cord stimulation but still needs a long time.

4.2.2 Wireless energy transmission technology

These devices can be cumbersome when compared to those used to obtain mechanical and thermal energy from the human body, and the mechanical energy obtained from daily human activities tends to be low in frequency and amplitude, resulting in limited energy output from electromagnetic and thermoelectric generators. While friction generators do have sufficient voltage and power, there is no way to ensure that the wiring associated with energy harvesters and the like will result in other infections that cause the immune system to produce a greater impedance. Therefore, if wireless energy is used, it can be connected to the transmission device by direct energy input from the outside, which ensures that there is an adequate supply of electrical energy as well as the implantation device becomes more simplified, thus reducing the risk Wireless power transmission technology can be categorized into induced power transmission and ultrasonically induced transmission [20]. Induced power transmission is the most widespread wireless method of transmitting electrical energy over short distances and is achieved through two induction coils [20]; outside the body, the coil wiring can be designed through the e-skin, while inside the body, a receiving coil is placed, which generates a voltage through electromagnetic induction to transmit the electrical energy. Sivaji designed an implantable neurostimulation system as a result of the use of implanted pulse generators as well as the placement of a relay outside of the body coupled with Near Field Communication (NFC). NFC allows for wireless communication and energy harvesting, which can be implemented to spinal cord stimulation through NFC, from 3V outside the body to input inside the body rises to 12V for feeding [20].

Ultrasonic-induced transmission of energy is safer and more capable of transmitting sufficiently large and deep amounts of energy than induced power transmission because the attenuation of ultrasonic transmissions is lower than that of other wireless energy transmission technologies. By using piezoelectric material as a transceiver to receive ultrasonic waves and convert them into electrical energy [20].In Chen Chen and others' team research, through the understanding of teng new power conversion technology, designed to miuTUD, in fact, is a micro capacitor, figure 3 show that the bottom of the highly doped silicon layer is the bottom electrode, while the top is for the silicon film and the top of the gold layer of the combination as the electrode. In the ultrasonic transmission to the device, it will stimulate the vibration to cause the formation of friction between the silicon and the silicon oxide to create a redistribution of charge to generate electrical energy. The spinal cord stimulator provides electrical energy. Still, as an implantable device, more requirements for encapsulation are needed because silicon is harmful to the human body [21].

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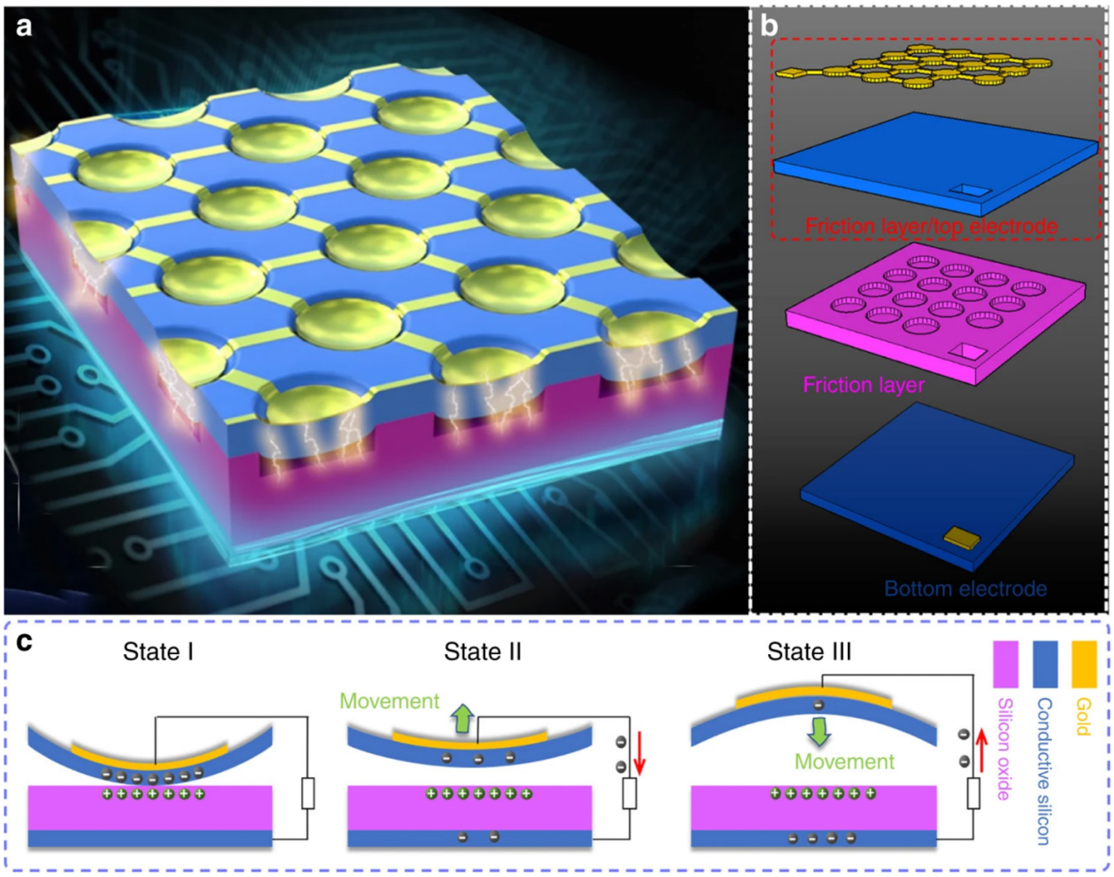

Fig 3.a Representative diagram of the μTUD. b Exploded view structure of the μTUD. c Schematic of the working mechanism of the μTUD during vibration [21].

5. Conclusion

This article describes a new approach to spinal cord stimulators in three main areas. For the stimulation protocol, the spinal cord stimulation is made more effective by combining the low-frequency stimulation of muscle stimulation and the high-frequency SCS stimulation, and the muscle stimulation will make the muscle contract rhythmically to exercise the muscle to protect the dorsal column, thus supporting the high-frequency SCS stimulation will not cause pain to the patient. In the choice of electrode material, Pt-Ir film is a good choice, with good durability, mechanical strength, low impedance and strong conductivity; in support of wearable devices, stretchable, breathable, self-adhesive e-skin, and able to collect signals with multi-signal sensing function, which is a new technology that can be worn in a very convenient and comfortable way;And finally there are various methods proposed for transmitting electrical energy, especially in the temperature difference generator and electromagnetic generator utilizing heart beat because it is not possible to get enough temperature difference from the body and there is no device yet that can make the heart beat into electrical energy, therefore it is still in the stage of exploring and developing, so the more suitable way for transmitting electrical energy nowadays is the wireless transmission, which utilizes the induced electric energy transmission or ultrasonic transmission, which can be good to make the implantation of the device more minimalist, thus reducing the risk. Therefore, it is hoped that the various aspects of new technologies and methods mentioned above will lead to further developing spinal cord stimulators.

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