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Development of flexible multi-channel muscle interfaces with advanced sensing function

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ABSTRACT

Functional Electrical Stimulation (FES) helps individuals with paralysis recover their muscle function. As opposed to voluntary muscle movement, which involves probabilistic recruitment of different muscle fibers at the neuromuscular junction, FES is usually performed using electrodes with just one channel, and as a result, tends to stimulate the same muscle fibers repeatedly. This induces excess muscle fatigue, which manifests itself as a loss of generated force after extended stimulation. Since the force generated is not typically measured in a FES system, electrical stimulation parameters need to be adjusted manually when muscle fatigue occurs. To address the problems of current FES, we propose a flexible muscle interface device with multiple stimulation electrodes and an integrated pH sensor. By using different subsets of electrodes for stimulation, alternating excitation of muscle fibers can be achieved to reduce fatigue in the muscles. At the same time, the pH sensor helps to provide quantified information about the state of the muscles, potentially allowing the stimulation parameters to be altered in a closed-loop fashion. Different interfacing materials were compared in terms of impedance and charge delivery ability. IrOx exhibited lower impedance of 0.7 kΩ at 1 kHz, and higher charge storage capacity (CSC) of 23.77 mC/cm^2. In *in vivo* muscle stimulation experiments, the use of alternating electrodes during stimulation induced less muscle fatigue, as well as less pH change, compared to using fixed electrode pairs. This flexible multi-channel stimulation device can potentially be used to reduce and monitor muscle fatigue during functional electrical stimulation.

1. Introduction

Paralysis is the loss of ability for a muscle or a group of muscles to move voluntarily. It is often caused by stroke and spinal cord injury, after which the voluntary movement of muscles is lost due to the inability of the brain to communicate with the corresponding muscles. Functional Electrical Stimulation (FES) is often used for individuals with paralysis to recover voluntary movement of muscle, by applying electrical stimulation to excitable muscles [1–5].

Currently, three kinds of muscle stimulation interfaces are commonly used: transcutaneous [6–8], percutaneous [9–11], and implanted interface [12–14]. The main advantage of transcutaneous stimulation is that it is non-invasive and easy to apply, but it has difficulty reaching deep muscles and selectively activating specific muscles. This is because when the electrical field is generated by the transcutaneous interface device, it spreads in the cutaneous layer, and will often activate other muscles along with the targeted muscle. It may also activate cutaneous pain receptors and cause pain in the subject. Percutaneous stimulation involves inserting needle electrodes through the skin to stimulate the underlying muscles. It has the ability to target deeper muscles, as well as isolating muscles for stimulation, but some subjects may be uncomfortable with the use of these needles, and improper sterilization of the needles or skin may result in infections that are hard to manage. Stimulation through wireless implanted devices requires surgery, and is thus the most invasive. However, once implanted, the devices can be powered and controlled transcutaneously through the skin,

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providing a safe interface that can be used repeatedly to stimulate deep muscles, as well as isolated muscles.

Implantable interfaces for FES have been developed for decades, but significant drawbacks still remain. The critical problem is that FES induces excessive fatigue. FES tends to activate muscle fibers simultaneously [15], and the activated muscles fibers are random [16,17]. In this way, FES induces muscle fatigue easily, and is different from normal voluntary muscle contraction, which has two mechanisms to lower fatigue [18]: one is to activate smaller and fatigue-resistant fibers first to delay the onset of fatigue [19,20]; another is to recruit fibers in an unsynchronized pattern to replace the fatigued fibers with others. Currently, most FES devices are unable to quantify the force generated through the muscle stimulation, so when fatigue sets in, the adjustment of the stimulation parameters needs to be made manually by experienced clinicians.

Till now, researchers have not reached a consensus on the chemical releasing mechanism that leads to muscle fatigue, and fascial muscle pH value may be an indicator of muscle fatigue. Some researchers agree that accumulated lactate leads to muscle fatigue [21]. While others agree that muscle fatigue is related to energy supply, under which circumstances faster expenditure of ATP than generation of ATP releases NH3 and monophosphate into blood [22].

In recent years, implantable devices based on flexible polymer substrates have started to emerge. These devices have been applied in other fields, including a 3D membrane for cardiac monitoring and stimulation [23], foldable electrode array for brain activity mapping [24], adaptive neural ribbon electrode for small nerve recording [25], instrumented surgical sutures for wound monitoring and therapy [26], and absorbable silk device for infection abatement [27].

The flexible polymer substrates, together with the usage of inert metal (gold) or absorbable metal (magnesium) as conductive layer, have been shown to be biocompatible as well [28–30]. The integration of different sensors and actuators, including electrical stimulation sites, electrical recording sites, temperature sensor, strain sensor, and micro-heater, makes these devices applicable for healthcare monitoring and functional stimulation. Unlike previous bulky implantable devices, these devices are flexible, so that they can conformably attach to target nerves, tissues, or organs for better recording and stimulation.

To address the problems of FES interfaces mentioned above, and take advantage of the development of multi-functional, implantable devices based on flexible substrates, we propose a flexible multi-channel muscle interface to reduce muscle fatigue and monitor pH to reflect muscle fatigue during FES. By alternating the stimulation electrode site pairs during FES, different muscle fibers located on the same muscle are excited alternatively, to mimic the voluntary muscle contraction pattern. Meanwhile, the IrOx pH sensor on the implanted interface monitors pH change to quantify the degree of muscle fatigue, so that corresponding adjustments on the stimulation parameters can potentially be made.

2. Design and fabrication

Fig. 1 shows the design of the muscle interface device. Six rectangular electrode pads were designed to fit a flexible printed circuit (FPC) connecter. Every electrode pad was connected to one electrode site with interconnects of 50 μm width. We designed the electrode site to be as large as possible to provide lower impedance (so as to consume less power during electrical stimulation) and to generate less heat during electrical stimulation. However, due to the limitation in device size, 600 μm was chosen as the electrode site diameter. Suture holes were designed to facilitate the fixation of the device on the target muscle with surgical suture.

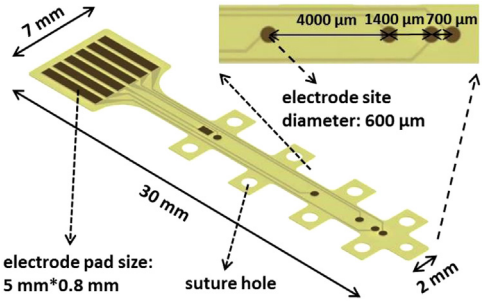

Fig. 1. Schematic illustration of device design. Six electrodes of same diameter are distributed with uneven distance between each other. Two arrays of suture holes facilitate the fixation of the device on the target muscle.

All chemicals were used directly after purchasing, without further purification. The chemicals were: Durimide 7500, Durimide developer HTRD-2, and RER 600, purchased from Fujifilm; AZ 9260, and AZ developer AZ 400 K, purchased from MicroChemicals; potassium carbonate, iridium chloride, and oxalic acid, purchased from Alfa Aesar.

As shown in Fig. 2, the fabrication of the sandwich-structure muscle interface started from a silicon wafer with a 200 nm aluminium layer. First, polyimide was spin coated, patterned with UV lithography, developed, and cured at 200 °C in N_2 to form the bottom layer (Fig. 2 (b)). The middle metal layer was realized by a liftoff process. The AZ layer was spin coated, UV pattered, and developed to generate the metal layer pattern. Two layers of 10 nm chromium and 200 nm gold were deposited by electron beam evaporator subsequently. Then, the liftoff process in acetone removed the extra Cr/Au by dissolving the AZ layer, and left the desired metal pattern on the device (Fig. 2 (c)). A top polyimide layer was fabricated using the same method as the bottom layer.

IrOx was coated on the electrode sites, to be used as electrical stimulation and pH monitoring material. The electroplating solution was prepared in the following way: 300 mg iridium chloride was dissolved in 200 ml DI water, and stirred for 15 min. Then, 1000 mg oxalic acid powder was added to the solution, and stirred for 10 min. To adjust the pH to 10.5, potassium carbonate was slowly added to the solution. The prepared solution sat at room temperature for 2 days before use, during which it turned into a violet color. It was stored in a dark bottle at 4 °C in the fridge until it was used.

To electroplate the electrode sites with IrOx, the electrode pads were connected to the negative terminal of an external voltage source, with only the electrode sites immersed in the prepared solution. The positive terminal of the external voltage source was connected to a platinum mesh electrode immersed in the solution. Pulsed voltage, with peak-to-peak magnitude of 3 V and bias voltage of 1.5 V, was applied for 3 min to plate IrOx.

The device was then released from the substrate, by dissolving the Al sacrificial layer, as described previously [31]. The silicon substrate and platinum mesh electrode were immersed in a conductive solution of 2 M NaCl. The wafer was connected to the positive terminal of the external voltage source, and the platinum mesh electrode was connected to the negative terminal. DC voltage of 1 V was applied for 15 min, and then raised to 15 V for another 3 h. The released device is shown in Fig. 2 (f).

Fig. 3 shows the connection between the muscle interface device and a FPC connector. Since the muscle interface was designed to fit the FPC connector, it inserted into the opened FPC connector easily, with an additional spacer used to ensure good contact.