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An Implantable Wireless System for Muscle Afferent Recording from the Sciatic Nerve during Functional Electrical Stimulation

Kang-Il Song, Ahnsei Shon, Jun-Uk Chu, Kuiwon Choi, Dosik Hwang, and Inchan Youn

Abstract— **An implantable wireless system was developed for recording muscle afferent activity and stimulating peripheral nerves with cuff electrodes. The proposed system was fabricated into the nerve cuff electrode, neural amplifier, neural stimulator, and wireless communication system with battery power. The nerve cuff electrode and neural amplifier were designed to improve the signal-to-interference ratio and signal-to-noise ratio. The wireless communication system was designed based on the medical implant communication service regulations to be suitable for implantation. The main function of this system was to extract muscle afferent activity from peripheral nerve during functional electrical stimulation. The cuff electrodes were chronically implanted on the sciatic nerve for recording and on the tibial and peroneal nerves for stimulation. When the extension and flexion movements of ankle joint were elicited from alternative electrical stimuli, the corresponding neural signals and ankle angles were recorded simultaneously. The muscle afferent activity was then extracted from the recorded neural signal through a simple blanking process. The experimental results showed that the ankle movements could be detected from the extracted muscle afferent activity.**

I. INTRODUCTION

Functional electrical stimulation (FES) systems have been used to restore damaged motor functions in spinal cord injury (SCI) patients [1]. Currently, closed-loop controlled FES systems are studied to improve the regulation of the muscle activation. In terms of closed-loop control, robust feedback signals are needed to ensure correct timing of the applied stimulation. Feedback signals can be obtained from either artificial sensors or natural sensors. Artificial sensors have been widely used but they have limitations such as cosmetic problems and re-calibration due to environmental interference. As an alternative means, natural sensors can also provide useful information on specific targeted sensory or motor organs. For examples, cutaneous afferent activities generated by exteroceptive sensors in the skin have been used for the control of grasp [2] and for the correction of foot drop [3], while muscle afferent activities generated by proprioceptive sensors in the muscle spindle have been used for the control of ankle joint [4]. However, such natural sensors require transcutaneous wires for connection with external devices. The use of wires increases the risk of infection and degrades signal quality by noise interference. Additionally, the patients' movement is restricted by the wires and external devices. Therefore, it is necessary to develop an implantable wireless system for long-term chronic recording of neural signals and electrical stimulation on nerves and muscles.

In this paper, an implantable wireless system according to the medical implant communication service (MICS) regulations is proposed (Fig. 1). The proposed system was composed of the nerve cuff electrode, neural amplifier, neural stimulator and wireless communication system with battery power. The performance of the proposed system was evaluated using a rabbit animal model by recording muscle afferent activity from the sciatic nerve during functional electrical stimulation upon the tibial and peroneal nerve.

II. MATERIALS AND METHODS

A. Nerve Cuff Electrode

The recording cuff electrode was designed based on the revised quasi-tripole (rQT) configuration [5]. In order to improve the signal-to-interference ratio (SIR), two middle electrodes were placed at the center of the cuff as shown in Fig. 2. To obtain maximal amplitude of the electroneurogram (ENG) signals, the length of cuff electrode should approximate the wavelength of ENG signals to the extent possible [6]. The wavelength ranges from 30 to 40 mm for large myelinated axons. Considering the limited space available at the implant site, the recording cuff electrode was designed as long as possible with an inner diameter of 1.6 mm and a length of 20 mm. Additionally, the stimulation cuff electrode was designed with an inner diameter of 1.5 mm and a length of 10 mm. The cuff electrodes were constructed on

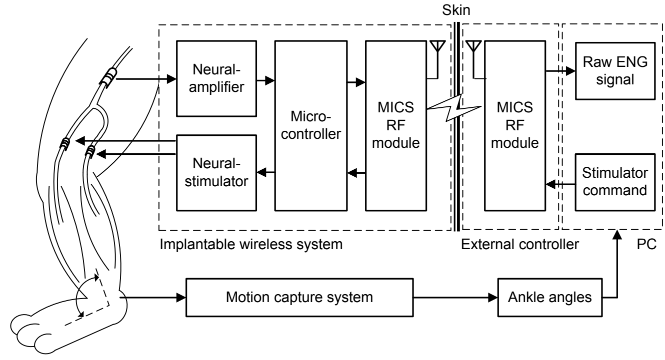

Fig. 1. Block diagram of the proposed wireless implantable system.

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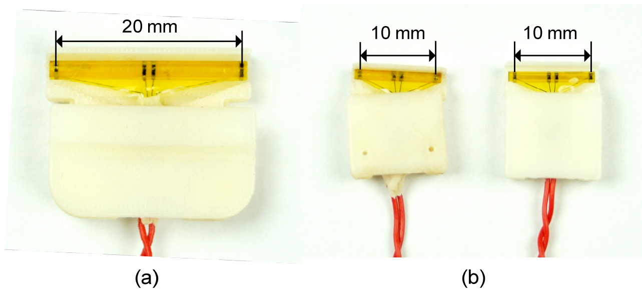

Fig. 2. The proposed nerve cuff electrodes: (a) cuff electrode for recording muscle afferent activity from the sciatic nerve, (b) cuff electrodes for stimulating the tibial and peroneal nerve.

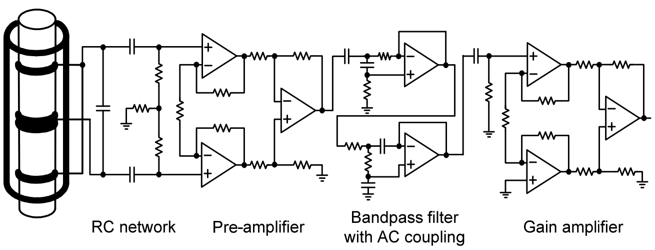

Fig. 3. Block diagram of the proposed neural amplifier.

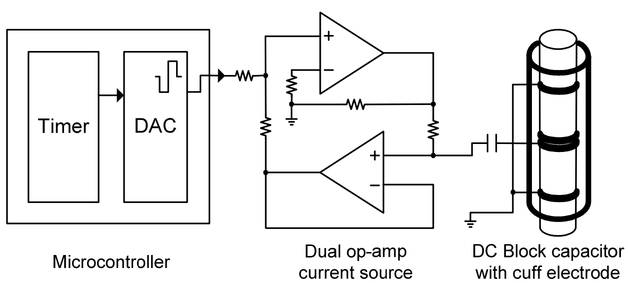

Fig. 4. Block diagram of the proposed neural stimulator.

polyimide substrate with platinum electrode contacts. The cuff electrode and lead wires were enveloped by a closure for strain relief. The ENG signals will be lost in the noisy, ion-based electric fluctuation of the surrounding electrolyte media if the electrode impedance is not sufficiently low [7]. Therefore, the electrode impedance was controlled constantly as low as 1 kΩ in the frequency range of 300-5000 Hz, where the dominant energy of the ENG signals was concentrated.

B. *Neural Amplifier*

For the neural signal amplifier, a low-noise differential amplifier, INA118 (Texas Instruments, Dallas, TX, USA) was selected as a pre-amplifier. The gain was set to 40 dB to minimize the input referred voltage noise and to amplify the ENG signals to the desired level. An RC network with a bandwidth of 159-50000 Hz was located between the cuff electrode and the pre-amplifier so as to prevent saturation by offset voltage and to suppress meaningless frequency components (Fig. 3). A noise analysis was performed to test the signal-to-noise ratio of the pre-amplifier. Since the multiple noise sources are uncorrelated, the total RMS noise can be expressed as a square root of the sum of the average mean square values of the individual sources, including the thermal noise due to the source resistance, the input referred voltage noise and input bias current noise of the pre-amplifier [8]. As a result, the total RMS noise was obtained as 677 nV and the signal-to-noise ratio was maximally calculated as about 14 dB. A bandpass filter and gain amplifier subsequently follow the pre-amplifier. The bandpass filter was composed of second-order Butterworth highpass filter with a 300 Hz cutoff frequency in cascade with second-order Butterworth lowpass filter with a 5000 Hz cutoff frequency. In addition, the gain amplifier with a gain of 20 dB was located at the output port.

C. *Neural Stimulator*

The neural stimulator was designed to generate biphasic current pulse ensuring net charge balancing at the electrode-electrolyte interface. As shown in Fig. 4, the charge-balanced biphasic voltage pulse was generated from a 12-bit digital-to-analog converter embedded on a microcontroller, MSP430F1611 (Texas Instruments, Dallas, TX). Then, it was converted to current pulse from a voltage-controlled current source composed of dual op-amps, OPA2340 (Texas Instruments, Dallas, TX) [9]. The stimulation frequency and pulse width were controlled on the basis of a 10-bit timer with a resolution of 10 μs. Even though the charge-balanced biphasic pulse was induced to ensure zero net charge, an offset voltage was occurred at the electrode-electrolyte interface by excess charge accumulation. To resolve this problem, a blocking capacitor was disposed in the path of stimulation current to avoid DC offset current.

D. *Wireless Communication System*

The wireless communication system was developed based on the medical implant communication service (MICS) regulations to be suitable for implantation. The system consisted of an external device and implantable device. The external device was composed of a microprocessor, MSP430F1611 (Texas Instruments, Dallas, TX) to control the entire system, an USB module to connect PC, and an RF module to communicate with the implantable device. The implantable device was composed of the same microprocessor used in the external device and an RF module for data exchange with the external device. For the RF modules, ZL70102 and ZL70120 (Zarlink, CA, USA) were used according to the MICS standard. Therefore, the wireless communication system achieved a low power consumption of 15 mW and a data transfer rate of 800 kbit/s. Fig. 5(a) shows the developed implantable device, including the neural amplifier for recording the ENG signals, two neural stimulators for electrical stimulation, and the loop-type antenna for data exchange with external device. The implantable device was implemented on a printed circuit board using SMD components with the dimension of 35 mm x 45 mm x10 mm (Fig. 5(b)), and encapsulated with a hermetic case to render it during long-term subcutaneous implantation (Fig. 5(c)).

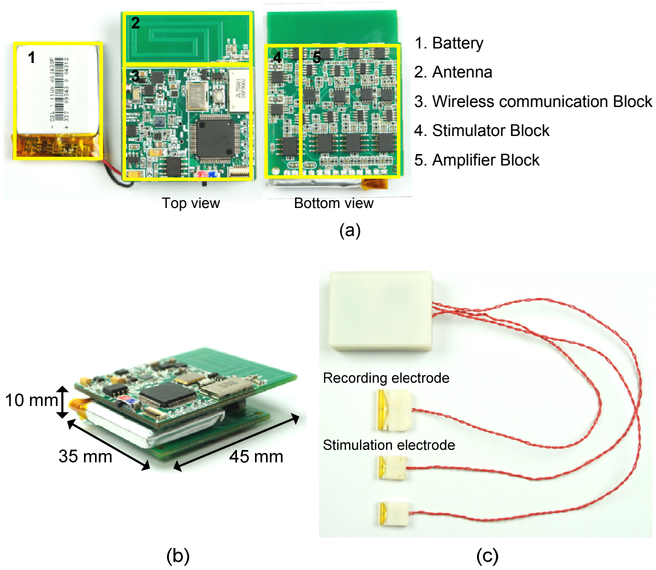

Fig. 5. Pictures of the proposed implantable wireless system: (a) components (b) dimensions, and (c) packaging.

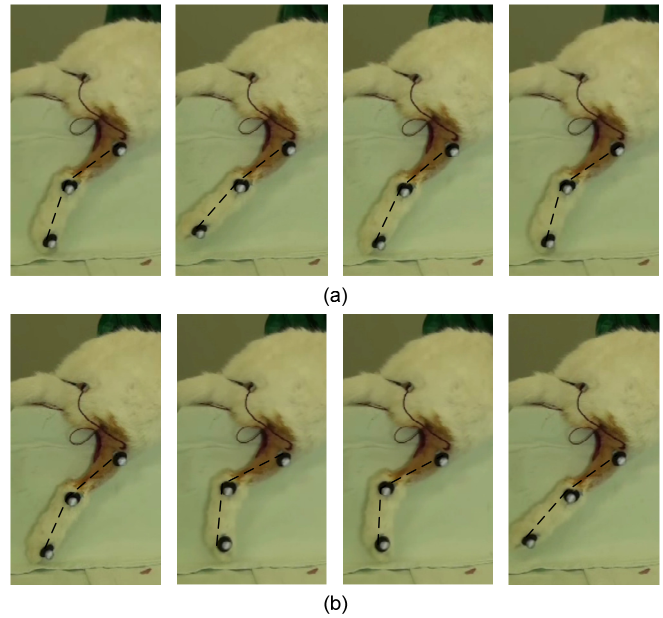

Fig. 6. Movements of the ankle joint during FES: (a) plantar flexion, (b) dorsiflexion.

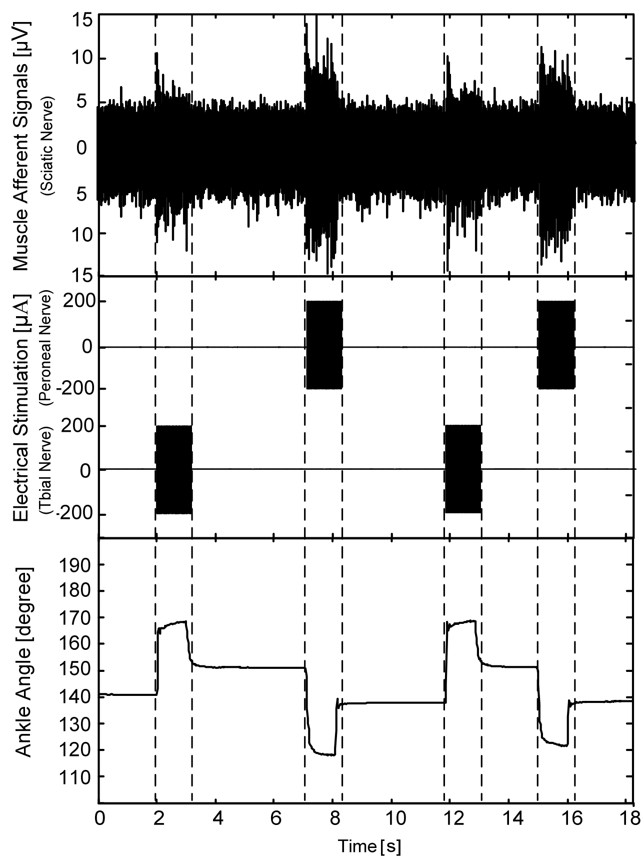

Fig. 7. Muscle afferent signals and ankle angle data during FES.

III. Results and Discussion

A. In Vivo Experiment

Animal experiments were performed using New Zealand rabbits. Animals were kept and handled in accordance with the regulations of the Institutional Animal Care and Use Committee of Korea Institute of Science and Technology (KIST). During surgical implantation, the rabbit was anesthetized with 2%–3% isoflurane in O_2 through spontaneous inhalation. The recording cuff electrode was wrapped around the sciatic nerve in the rabbit's right leg. The two stimulation cuff electrodes were implanted on the tibial and peroneal nerve branches. The proposed implantable wireless system was then located in a subcutaneous pocket on the back of the rabbit. Muscle afferent activity for ankle joint movement was elicited from the electrical stimulation upon the tibial and peroneal nerves. The electrical stimulation was applied with a pulse amplitude of 200 µA, a pulse width of 250 µs, and a frequency of 60 Hz. When the angle of the rabbit's ankle joint changed, muscle afferent activity was measured using the recording cuff electrode located on the sciatic nerve. The proposed neural amplifier was set to have a gain of 10000, and the final output of the amplifier was then digitized using a 12-bit analog-to-digital converter embedded on the microcontroller with a sampling frequency of 10 kHz. The ankle angle data were recorded simultaneously during electrical stimulation. A two-dimensional motion analysis was performed to measure the joint angle variation. The motion analyzer consisted of a digital camera, 10 mm-diameter reflective markers, and an image grabber board with a 640 × 480 pixel resolution. The digital camera (Marline F033B, AVT) was positioned perpendicular to the rabbit's right leg and recorded the images at a 60 Hz sampling rate. The ankle angle data were then obtained from marker points attached onto the skin over three anatomic landmarks on the lateral side of the hindlimb: the knee joint, the lateral malleolus, and fifth metatarsal head. The movements of the ankle joint during FES are shown in Fig. 6. When the tibial nerve was stimulated according to the electrical stimulation profile as mentioned above, the plantar-flexion was produced as shown in Fig. 6(a). For the peroneal nerve, the dorsi-flexion was induced as shown in Fig. 6(b).

B. *Muscle Afferent Activity during FES*

The recorded muscle afferent signals and ankle angle data during FES are shown in Fig. 7. As a result of the electrical stimulation, considerable interference of the stimulus artifacts, compound action potentials, and evoked electromyogram signals appeared in the recordings of the neural signals. To eliminate this interference, a blanking process synchronized to the stimulation was applied with a duration of 3 ms. The muscle afferent activity was detected only during stimulation on the tibial and peroneal nerve. When the tibial nerve was stimulated, the amplitude of muscle afferent activity was about 6 μVp-p. For the peroneal nerve, the amplitude of the muscle afferent activity was approximately 8 μVp-p.

IV. CONCLUSION

In this paper, an implantable wireless system was proposed to record muscle afferent activity during functional electrical stimulation. The implantable system was fabricated into the nerve cuff electrode, neural amplifier, neural stimulator and wireless communication system with battery power. The nerve cuff electrode and neural amplifier were designed to improve SIR and SNR making it possible to record neural signals clearly. The wireless communication system was designed to use the MICS band for subcutaneous implantation. The experimental results showed that the proposed system is suitable for recording muscle afferent activity during functional electrical stimulation.

In further study, we will record muscle afferent activity using a multichannel cuff electrode to separate the tibial and peroneal ENG signals from the sciatic ENG signal. Moreover, ankle angle will be predicted from the separated tibial and peroneal ENG signals to construct an implantable closed-loop FES system for SCI patients.

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