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First permanent human implant of the Stimulus Router System, a novel neuroprosthesis: preliminary testing of a polarity reversing stimulation technique

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Abstract— Neuroprostheses (NPs) are electrical stimulators that help to restore sensory or motor functions lost as a result of neural damage. The Stimulus Router System (SRS) is a new type of NP developed in our laboratory. The system uses fully implanted, passive leads to "capture" and "route" some of the current flowing between pairs of surface electrodes to the vicinity of the target nerves, hence eliminating the need for an implanted stimulator. In June 2008, 3 SRS leads were implanted in a tetraplegic man for restoration of grasp and release. To reduce the size of the external wristlet and thereby optimize usability, we recently implemented a polarity reversing stimulation technique that allowed us to eliminate a reference electrode. Selective activation of three target muscles was achieved by switching the polarities of the stimulus current delivered between pairs of surface electrodes located over the pick-up terminals of the implanted leads and reducing the amplitude of the secondary phases of the stimulus pulses.

I. INTRODUCTION

Neuroprostheses (NPs) are electronic stimulators that can restore or substitute functions lost after neural trauma such as brain or spinal cord injury (SCI) by artificially activating the remaining intact, peripheral nerves. Currently existing motor NPs include surface and implanted systems, which each have their advantages and disadvantages [1]. Surface NPs electrically stimulate the target nerves via pairs of surface electrodes that are placed on the skin using external stimulators. While these systems are noninvasive and relatively inexpensive, they are often poorly selective due to lack of proximity of the stimulating electrodes to the target nerves. Stimulation through the skin at the levels required to activate the targeted muscles can co-activate non-targeted muscles and cutaneous sensory nerves, resulting in user discomfort or pain. Daily donning and doffing of the surface electrodes can be time consuming and difficult in subjects with disabilities. With implanted NPs, hermetically sealed stimulators with leads terminating in epimysial or nerve cuff electrodes are fully enclosed in the body. External coils and control units are used to deliver command signals to the implanted stimulator. Selectivity is improved and complexity of daily donning is avoided in these systems. However, these systems are invasive, inaccessible for repair or maintenance and can be relatively expensive.

The Stimulus Router System (SRS) is a new type of NP developed in our laboratory. The system uses fully implanted, passive leads to "capture" and "route" some current flowing between pairs of surface electrodes to the vicinity of the target nerves, hence eliminating the need for an implanted stimulator. The SRS lead consists of an insulated wire with a conductive terminal on each end, one being a "pick-up" terminal that is implanted subcutaneously under one of the surface electrodes and another a "delivery" terminal that is implanted on the target nerve.

Previous animal studies have shown that the SRS is safe and reliable as a long term NP and can selectively activate deep-lying nerves [2, 3]. Human proof-of-principle of the SRS was also shown during an acute human intra-operative procedure [4]. In 2008, a 3-channel SRS was implanted in a tetraplegic man for restoration of hand opening and closing [5] (Fig.1). A full length paper reporting our findings in the first year after the implantation is in revision. In this report, we describe the implementation of a polarity reversing stimulation technique that eliminates the reference electrode previously used.

II. METHODS

A. Participant

The participant was a 52-year-old man who experienced C6/7 level incomplete SCI in 1998 due to a sports injury. He had some voluntary control of the shoulder, elbow and wrist movements that provided him with the ability to reach and produce a tenodesis grasp and release. In May 2008, he agreed to participate in the SRS study and chose to have the system implanted in his right, less functional arm for restoration of grasp and release. In June 2008, he was implanted with 3 SRS leads for activation of 1) his finger extensors, 2) finger flexors and 3) thumb flexor.

B. SRS leads

The leads (Fig. 2) were made of unisulated platinum-iridium wires loosely coiled inside 1.2mm diameter silicone

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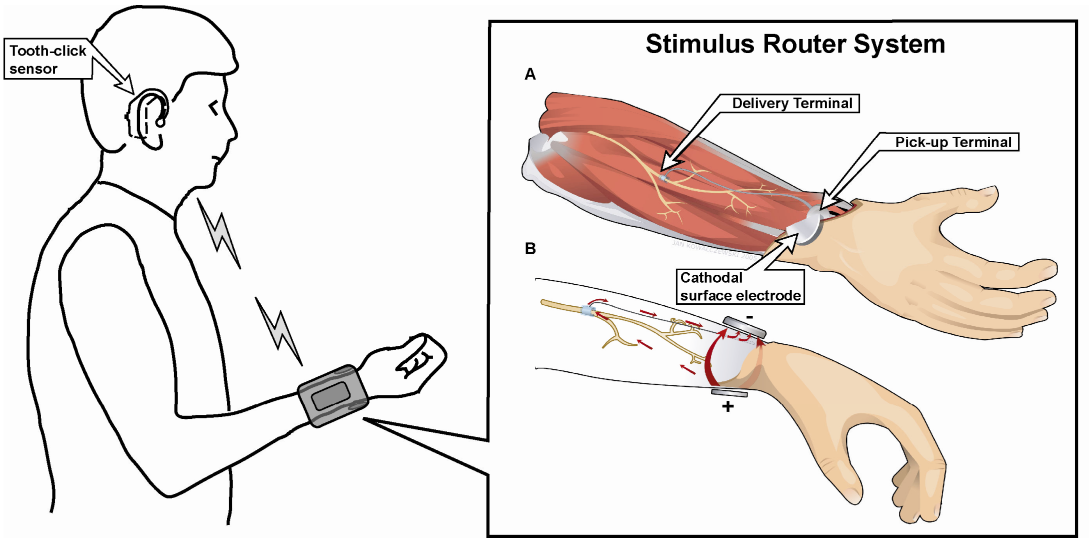

Figure 1: Application of the stimulus router system (SRS) as a neural prosthesis (NP) for restoration of hand opening and closing. A wristlet containing a surface stimulator and surface electrodes is worn on the forearm. Stimulation is triggered by small tooth clicks produced by the user that are detected by a wireless sensor worn behind the ear. The schematic of the SRS on the right shows: A) a cutaway view, showing surface electrodes, implanted lead with subcutaneous pick-up terminal at one end and nerve cuff at the other; B) a cross-sectional view of current flowing between the surface electrodes, some being diverted through the implanted conductor to the nerve cuff and returning via forearm tissues.

tubing. The wires protruding from the tube at both ends were tightly wound back onto the surface of the tube to form electrically conductive terminals. The pick-up terminal was 15mm in length and the delivery terminal was 5mm in length. A silicone strip with a structure similar to a tie-wrap was attached to the delivery terminal to form a nerve cuff. This design allowed for custom sizing of the nerve cuff to the target nerve [6]. Small silicone rectangular strips (tie downs) were attached to the leads to allow for anchoring of the lead to the surrounding connective tissues.

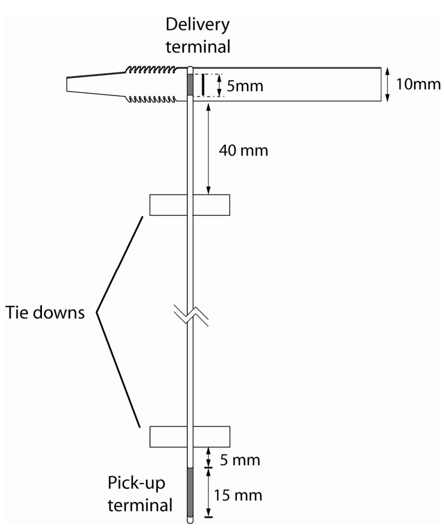

Figure 2. The schematic of the SRS lead.

C. External stimulator and surface electrodes

The external stimulator and electrodes were incorporated into a custom designed Neoprene garment. The stimulator was a custom-built, 3-channel stimulator that produced asymmetric, biphasic, constant-current pulses (250us primary phase duration, 33 pulses/s). Moistened pad electrodes of 2.5cm and 5cm diameter were placed on the inner surface of the garment so as to contact the skin over the implanted pick-up terminals.

D. Electrode configurations

In the conventional configuration used until recently (Fig. 3A), 4 surface electrodes were needed for the 3-channel system: 3 serving as cathodes and one as the common anode. Trains of biphasic pulses were delivered between each of the cathodes and the common anode in an interleaved cyclical sequence, so that each cathode delivered a current pulse to its lead at an allocated time, thus enabling independent control of stimulation strength to each muscle even during co-activation. Biphasic, partially charge-balanced pulses were used, whereby the voltage of the cathode went negative with respect to the anode in the primary phase and stayed negative even when the current reversed in the secondary phase of the pulse because of tissue capacitance.

With polarity reversing stimulation, each surface electrode served either as a cathode or an anode depending on which lead was providing its nerve with a negative voltage (Fig. 3B & C). This eliminated the need for a common anode. The polarity assignment of the SRS system with this technique is shown in Figure 3B & C.

E. Stimulation waveforms

The stimulation waveforms for conventional and polarity reversing stimulation are shown in Figure 4. In both cases, the primary cathodic ("activation") phase had a current-feedback-controlled rectangular profile. With conventional stimulation (Fig. 4A), the secondary or recovery phase was a rapid exponential discharge of all the charge stored at the

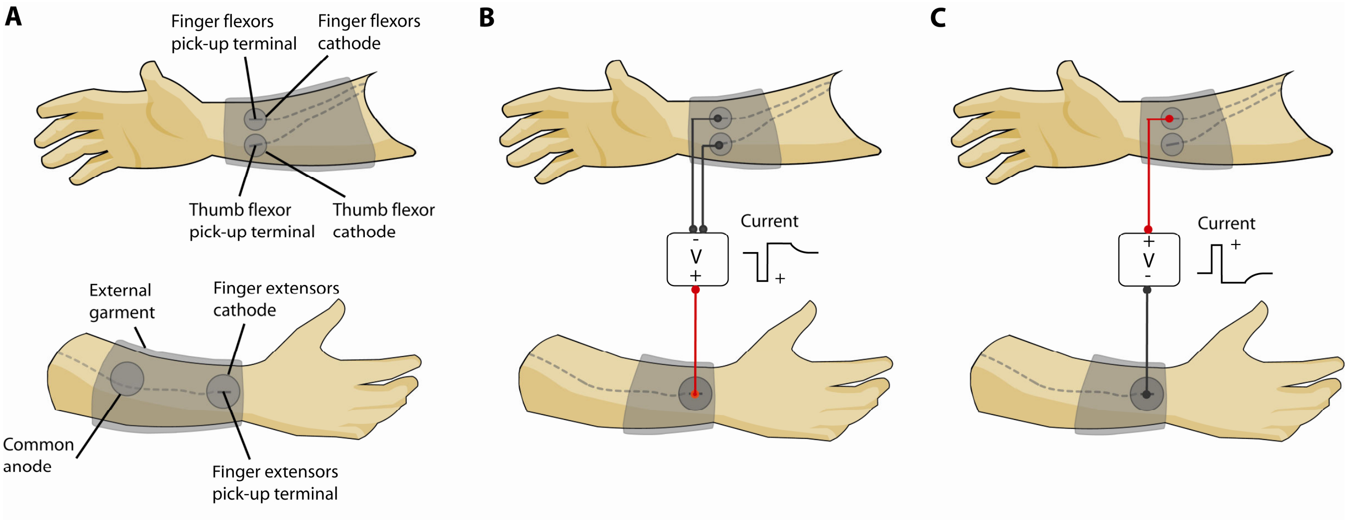

Figure 3 Electrode configurations with A) conventional stimulation, B) polarity reversing stimulation for activation of the flexors and C) polarity reversing stimulation for activation of the finger extensors. During activation of the flexors, the surface electrode over the corresponding pick-up terminal served as cathode and the surface electrode over the finger extensor pick-up terminal served as anode. During activation of the finger extensors, the surface electrode over the finger extensor pick-up terminals was the cathode and the surface electrode over the finger flexors pick-up terminal was the anode. The dashed gray lines represent the implanted SRS leads and the gray full circles represent the surface electrodes. The pick-up terminals of the two flexor nerve leads were located subcutaneously on the anterior side of the forearm proximal to the wrist and those of the extensor nerve lead was implanted on the posterior side.

surface electrode-tissue interface during the primary phase. With polarity reversing, the current during the secondary phase was limited to a low level to avoid cathodic activation via the electrode serving as the anode. This is because from the perspective of this electrode, the current in the secondary phase is cathodic. In order to preserve charge balance, the duration of the secondary phase polarity reversing was increased.

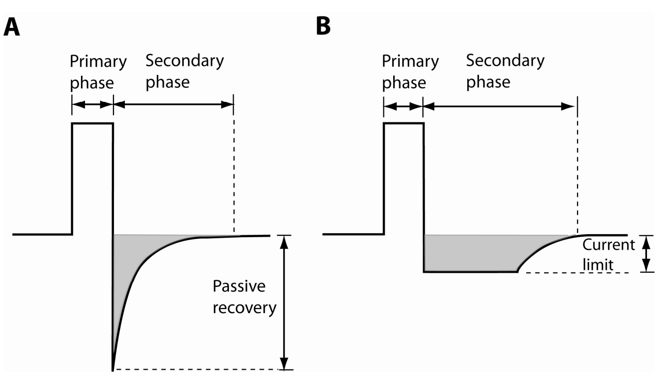

Figure 4 Stimulation waveforms for A) conventional stimulation and B) polarity reversing stimulation. The shaded areas represent the charge recovered in the secondary phase.

F. *User control*

The participant triggered stimulation with small tooth-clicks that were detected by a wireless earpiece containing a 3-axis accelerometer [7, 8]. Upon detecting a tooth-click, the earpiece transmitted a radio frequency signal to a receiver/stimulator located in the wristlet. This allowed the participant to advance the stimulator through a grip-release-relax sequence with successive toothclicks.

TABLE I
MINIMAL SURFACE CURRENT LEVELS REQUIRED TO ACTIVATE TARGET MUSCLES WITH CONVENTIONAL AND POLARITY REVERSING STIMULATION

	Conventional stimulation	Polarity reversing stimulation
Finger extensors	3.9 mA	5.1 mA
Finger flexors	2.6 mA	3.5 mA
Thumb flexor	2.8 mA	4.0 mA

III. RESULTS

Table 1 shows the minimal primary phase current levels needed to elicit a visible movement in the target muscles with conventional stimulation and with polarity reversing stimulation. The secondary phase in polarity reversing stimulation was limited to 1 mA to avoid co-contractions of the non-targeted muscles. Surface current levels needed to activate the target muscles were ~ 1mA higher with polarity reversing stimulation compared to conventional stimulation. Functional contractions of the finger extensors, finger flexors and thumb flexors were elicited at 6.0 mA, 4.4 mA and 4.9 mA. The subject did not report any discomfort or pain at these stimulation levels and activation of the non-targeted muscles was not observed. The elimination of the common anode resulted in a smaller external garment that the subject found preferable. At the time of this report, the subject has been using the new garment for 2 weeks.

IV. DISCUSSION

Selective activation of target muscles were achieved by switching the polarity of the stimulus current delivered across pairs of surface electrodes overlying separate SRS pick-up terminals. The currents needed to elicit target muscle contractions were higher with the polarity reversing stimulation than with conventional stimulation. The primary, "activating" phase of the stimulation pulses was identical in shape and duration in both configurations. However, in the polarity reversing configuration, the *change* in current at the onset of the secondary phase was less than in the conventional configuration. Also, the relative positions of the cathode, anode and delivery terminals differed in the two configurations. We have previously shown that $I_{threshold}$ was lowest when the cathode was over the pick-up terminal and the anode was over the nerve cuff [3]. $I_{threshold}$ gradually increased as the anode was moved towards the cathode and was highest when the anode was placed beyond the cathode. In the conventional configuration the anode was closer to the delivery terminals than in the polarity reversing configuration, so $I_{threshold}$ was lower.

The SRS requires wetting each electrode daily before use. The polarity reversing configuration reduces by one the number of electrodes involved. However, the reduction in size of the wristlet was a more important improvement. The participant reported that the wristlet was significantly more comfortable and easier to don and doff. In applications where only a few channels are required, further miniaturization of the stimulator could eventually result in a wristwatch-like garment that will greatly improve the usability of the SRS.

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