First human intra-operative testing of the Stimulus Router System

Arthur Prochazka*, Liu Shi Gan*, Jaret Olson# and Michael Morhart#
*Centre for Neuroscience and #Department of Surgery, University of Alberta, Edmonton, Alberta, Canada.

Abstract

The stimulus router system (SRS) is a novel type of neural prosthesis in which some of the current flowing subcutaneously between a pair of surface electrodes is routed to a target nerve by a passive implanted conductor. The implanted conductor connects a pick up terminal placed subcutaneously under a cathodal surface electrode to a deliver terminal placed on the target nerve. An external stimulator is connected to the surface electrodes to deliver current pulses. Recently the SRS was tested intra-operatively in a human subject undergoing nerve transfer surgery. The results suggest that the SRS can elicit strong, targeted muscles contractions without causing discomfort or pain. The first permanent SRS implant to restore hand opening and grasp in a quadriplegic man is scheduled for June 2008.

1 Introduction

The application of neural prostheses (NPs) for restoration of sensory or motor functions after brain or spinal cord injury has produced a variety of system designs catering to different clinical uses [1]. Surface NPs deliver stimulus current pulses via surface electrodes placed on the skin using external stimulators. While these devices are non-invasive and inexpensive, they are often poorly selective, sensitive to electrode positions and can activate cutaneous sensory nerves, causing pain or discomfort. With implantable NPs, stimulators, leads and sensors can be enclosed in the body. Selectivity is improved and complexity of daily donning is avoided in these systems, but costs are high and might not be justified if clinical utility is limited or uncertain.

Previous acute and chronic animal studies have suggested that the SRS is safe and offers advantages that justify human trials. In this paper, we report the results obtained from an intra-operative testing of the SRS on a human subject during a nerve graft and transfer surgery.

2 Methods

The subject was a young male who was undergoing nerve graft and transfer surgery. Prior to surgery, thresholds of sensory perception and motor responses of finger flexors and extensors elicited through pairs of surface electrodes attached to the anterior and posterior forearms were determined. The surface electrodes used were sterile, self-adhesive gel electrodes. The indifferent surface electrode (3.8x7.6cm; anode) was placed on the posterior aspect of the wrist while the stimulating surface electrodes (3.8x3.8cm; cathodes) were placed over the motor points of the finger flexors and extensors on the anterior and posterior aspects of the forearms respectively (Fig. 2). A custom built stimulator was used to deliver trains of stimulus current pulses (current controlled, biphasic, 300µs pulse duration, 30Hz) across the surface electrodes.
Prior to surgery, the sensory and motor thresholds to surface stimulation were recorded with the anode located on the posterior aspect of the wrist and the cathode located on A) the anterior forearm for finger flexion and B) the posterior forearm for finger extension. During the intra-operative testing of the SRS, the surface electrodes were positioned at the same locations as B). The delivery terminal was placed on the anterior interosseous nerve about 6 cm proximal to the wrist crease and the pick up terminal was placed subcutaneously under the cathode.

During the surgery, in a procedure lasting about 20 minutes, the anterior interosseous nerve innervating the flexor digitorium longus (finger flexors) was identified and the delivery terminal of the SRS lead, a nerve cuff, was placed snugly around it. The nerve cuff consisted of a three-segment cylindrical electrode (1mm long contacts with 1mm separations) attached to a 40 x 10 mm silicone strip. The pick-up terminal of the SRS lead was placed subcutaneously under a cathode on the posterior aspect of the forearm. The terminal was a 15 mm long “Peterson” style electrode made with a bared length of multistranded stainless steel wire (AS 632 cooner wire) coiled tightly around a piece of 1.2 mm outer diameter silastic tubing. To allow for current measurements, the terminals were provided with separate leads terminating in miniature connectors that were brought out of the incision. Current flowing through the surface electrodes (I_{total}) and SRS lead (I_{internal}) was monitored by measuring the voltage difference across two 100Ω resistors that were connected in series with the surface electrodes and the SRS terminals. The force elicited by stimulation through the SRS was measured using a proving ring strain gauge that was attached to a sling looped around the four fingers at the first interphalangeal joints. The SRS lead and surface electrodes were removed at the end of the test.

3 Results

3.1 Pre-operative measurements

The sensory perceptual thresholds to surface stimulation applied to the anterior and posterior forearm prior to surgery was 6.5mA and 7.7mA respectively. The corresponding motor thresholds for finger flexor and extensor were 11.5mA and 9.5mA.
3.2 Intra-operative measurements

The surface current pulses required to elicit just-detectable finger flexion with the SRS were 3.2 mA in amplitude. This was 45% of sensory perceptual threshold and 31% of motor threshold recorded pre-operatively. At surface current pulse amplitudes of 6.7 mA, 9.8 N of flexor force was elicited, corresponding to a firm hand grasp. Fig. 3 shows force and current measurements obtained during this procedure. Fig. 3C shows that only about 1.9% of the surface current was diverted though the SRS lead to the target nerve (I_{internal} = 130 µA). This is lower than the percentage we expected from animal experiments, nonetheless the surface current required to produce muscle contractions was still below sensory perceptual threshold. The results suggest that the SRS can activate a useful range of target muscle contractions without causing discomfort or pain in the user.

4 Discussion and Conclusions

From our animal studies, we have found that ~10% of the surface current was diverted through the SRS lead to the target nerve [2]. The percentage was much lower in this human intra-operative test. Various reasons can contribute to such difference, including the amount of extracellular fluid surrounding the target nerve and the size of surface electrodes. However, it is important to note that this percentage only provides limited indication of the total amount of surface current needed to activate the target muscles [3].

The successful intra-operative test provides proof-of-principle in a human subject of the efficacy of the SRS. The SRS was able to elicit target muscle contractions at current levels below the thresholds of sensory perception and motor responses elicited through surface electrodes in the absence of the SRS. The results suggest that the SRS can elicit strong contractions without activating the cutaneous and motor fibres lying directly underneath the surface electrodes. The animal experiments indicated that the surface current threshold to stimulate a nerve increases approximately exponentially with lateral displacement of the surface electrode from the optimal position over the pick-up terminal [2]. At 3 cm displacement from the optimal position, thresholds were typically elevated by an order of magnitude. Lead terminal spacing of 2 to 3 cm will therefore probably be required to avoid cross-talk reliably. This will limit the number of separate SRS channels to two or three when the anatomical location of the terminals is restricted in area (e.g. at the wrist of small subjects).

The SRS has the advantage of improved selectivity compared to external NPs while avoiding some of the costs and complications associated with implanted NPs. The first permanent SRS implant to restore hand opening and grasp was performed in a quadriplegic man on 10 June 2008.

5 References


6 Acknowledgements

The authors thank Mr. Jan Kowalczewski for the artwork in Figure 1 and 2. This study is supported by Alberta Heritage Foundation for Medical Research and the Canadian Institutes of Health Research.