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Intraoperative Testing of Selectivity of Spiral Nerve Cuff Electrodes

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Abstract—**Nerve cuff electrodes were used intraoperatively to stimulate peripheral nerves to test electrode selectivity in the human upper extremity. Subjects were recruited from patients undergoing upper extremity nerve repair procedures. The nerves were stimulated through different contacts in the cuff and with varying parameters. Estimates of threshold and selectivity data were recorded. The stimulation thresholds found were an order of magnitude higher than prior animal studies using the spiral nerve cuff electrode. Preliminary selectivity was found on the ulnar nerve and the upper trunk of the brachial plexus of one subject. The biceps and pectoralis major were selectively activated by a single cuff placed proximally, on the upper trunk; the flexor carpi ulnaris and first dorsal interosseous were selectively activated by a single cuff placed on the ulnar nerve.**

Keywords—**Electrical stimulation, electrodes, neural prosthesis, neural stimulation, peripheral nerve, spinal cord injury**

I. Introduction

The overall objective of this research is to extend the benefits of Functional Electrical Stimulation (FES) and neuroprostheses to individuals with C3/C4 level tetraplegia. An injury at this level introduces additional technical and medical problems compared to C5/C6 individuals that have been the subjects of past clinical work. First, there are more paralyzed muscles than in lower level injuries, requiring many more electrodes. Second, a C4 level injury results in partial denervation of functionally important muscles. Since the denervated portions of the muscles cannot be stimulated, the number of motor units and potential force output of these muscles is reduced. Third, many of the muscles that need to be stimulated are broad and experience large motions over bony prominences. Muscle based electrodes are sewn near or on the muscle and activate the fibers in the immediate vicinity of the electrode. To fully recruit broad and partially denervated muscles, several muscle electrodes would be required.

Nerve cuff electrodes have the potential to solve many of these problems. Cuff electrodes are placed on the nerve trunk proximal to the muscle. The cuff electrode can fully activate all remaining innervated muscle fibers, thereby achieving the maximum possible muscle force output. Similarly, cuff electrodes can fully activate the broad shoulder muscles with a single electrode.

The CWRU self-sizing spiral nerve cuff electrode [1] is being used in this project. This electrode is a self-sizing coil (fig. 1) with four contacts evenly spaced around the nerve. The natural coiling of the electrode results in an intimate fit between the nerve and the contacts while still allowing the nerve to swell. The cuff electrodes are approved for investigational use (IDE #G950116).

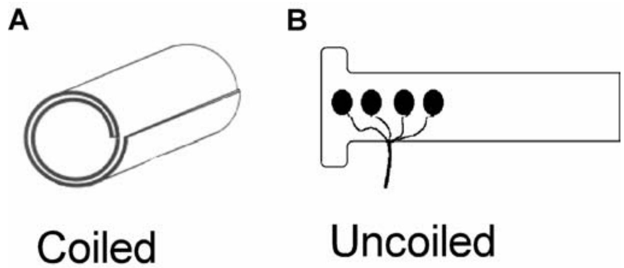

Fig. 1. Schematic of spiral cuff electrode. A. Spiral electrode coiled, resulting in two full wraps. B. Electrode uncoiled to show contact layout

The multiple contacts that wrap around the nerve can be activated individually. Stimulating a single contact activates the portion of the nerve near that contact and may selectively recruit a single muscle or synergistic muscle group. With multiple selective contacts, it could be possible to control multiple muscles or actions with a single electrode. This would reduce the total number of electrodes to be implanted, shortening the length of the surgical procedure and decreasing the number of implanted lead cables. It has been shown [2] that it is possible to control multiple muscles or actions with a single multi-contact electrode in a cat model. The purpose of this study is to test the hypothesis that individual muscles and/or muscle groups can be controlled independently from a proximal peripheral nerve cuff electrode in human subjects. These studies are the final preparation for the chronic implantation of nerve cuff electrodes in a subject with high tetraplegia.

II. Methodology

Subjects were recruited from patients scheduled to undergo upper extremity nerve repair surgery. During these procedures, surgeons tested the viability of potentially injured nerves by measuring somatosensory evoked potentials (SSEP) proximally and evoked electromyograms (EMG) distally. For this study the CWRU spiral nerve cuff electrode was used in place of a two-ball hook electrode. Recording electrode pairs were placed over the cervical spinal cord, brainstem, cortex and Erbs point to record SSEPs. Needle recording electrodes were placed within up to four target muscles. Data was collected using a

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commercially available clinical evoked potential system (Epoch 2000, Axon Systems, Hauppauge NY).

The nerve cuff electrode was placed around each nerve using a custom implant tool. The multiple contacts on the cuff electrode allowed the surgeon to stimulate in several places around the nerve and evaluate the nerve's function. Stimulation of individual contacts was used to demonstrate selectivity.

Time constraints of intraoperative testing did not always allow for a complete characterization of the selectivity of the cuff electrodes. As many pulse width/pulse amplitude combinations as possible in the allotted time were tested at each location and approximate threshold values were recorded. These threshold values were obtained by increasing the stimulation intensity until a response was seen. This response was recorded and the surgeon advanced to the next contact.

III. Results

A. Stimulation Thresholds

Four subjects have participated in this study. For three of the four subjects, almost no EMG data were recorded due to distal nerve damage. SSEP data were recorded for all patients. Rough threshold data are recorded in Table 1.

B. Selectivity

EMG responses were recorded in response to stimulation of the upper trunk of the brachial plexus and the ulnar nerve in subject #3: Each was stimulated at approximately 9 different points around the nerve. While stimulating the upper trunk, EMG signals were recorded from the biceps, pectoralis major, deltoid and supraspinatus. Low stimulation at position 7 selectively activated the biceps (fig. 2). Increasing the stimulation recruited the pectoralis major and deltoid as well.

TABLE I
SUMMARY OF INTRAOPERATIVE TESTING DATA

Subj #	Injury/ Condition	Time Post Injury	Threshold***		Stim Pos
			Nerve	Stim Params	
1	Brachial plexus avulsion	3 weeks	Phrenic	100 μs, 1.7mA	WC
			Spinal Acc.	500 μs, 0.3 mA	WC
				100 μs, 1.0 mA	WC
				50 μs, 1.7 mA	WC
2	Partial amputation at elbow	3.5 weeks	Median	100 μs, 1.0 mA	WC
			Ulnar	100 μs, 1.0 mA	WC
3	C4 SCI – nerve transfer	2 years	Upper Trunk	190 μs, 1.1 mA	7
				200 μs, 1.1 mA	WC
				200 μs, 1.0 mA	7
			Ulnar	300 μs, 0.5 mA	4
				250 μs, 0.5 mA	5
				275 μs, 0.5 mA	6
				300 μs, 0.5 mA	7
				500 μs, 0.5 mA	1
4	Brachial plexus avulsion	9 weeks	Ant. C5	200 μs, 2.0 mA	WC

Legend: WC – whole cuff; Stim Position contains a number that refers to the cuff rotation around the nerve and a letter that refers to the contact on the cuff.
***Threshold values are the lowest recorded value that resulted in a response at the stimulation position indicated.

During ulnar nerve stimulation, EMG signals were recorded from the flexor carpi ulnaris (FCU), flexor digitorum profundus (FDP) and first dorsal interosseous (FDI). Stimulation at position 5 resulted in activation of FCU alone (fig. 3A). Stimulating at a different position (position 1) with low pulse amplitude, high pulse width resulted in FDI alone (fig.3B). Time did not allow for further detailed testing to selectively activate the flexor digitorum profundus (FDP).

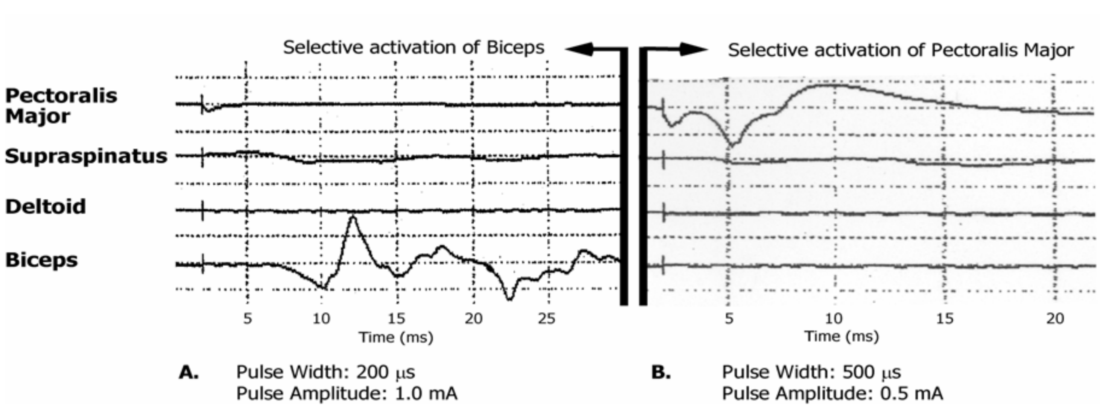

Fig. 2. Selective activation demonstrated on upper trunk of brachial plexus. EMG signals were recorded from pectoralis major, supraspinatus, deltoid, and biceps. Stimulating at different positions around the nerve resulted in selective activation of biceps (stim. position 7) and pectoralis major (simultaneous stim. positions 4-7).

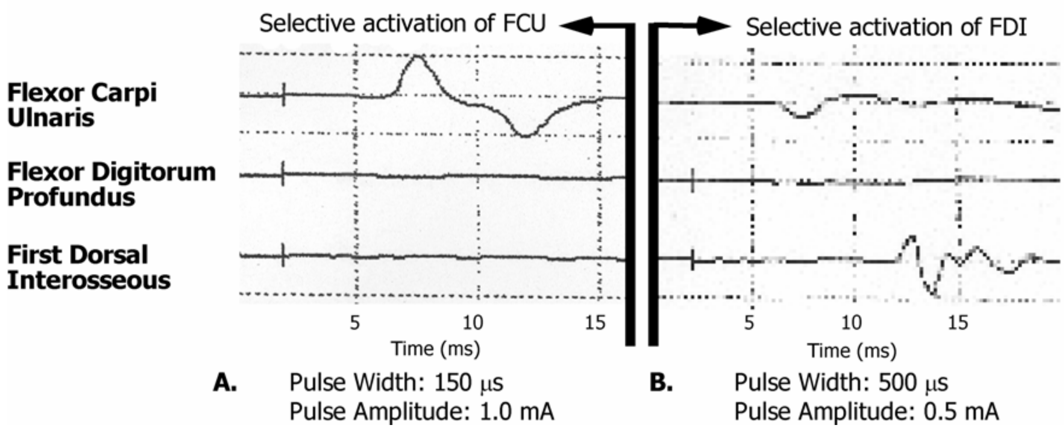

Fig. 3. Selective activation demonstrated on ulnar nerve. EMG signals recorded from flexor carpi ulnaris (FCU), flexor digitorum profundus (FDP) and first dorsal interosseous (FDI). Stimulating at different positions around the nerve resulted in selective activation of FCU (stim position 5) and FDI (stim position 1).

IV. Discussion

The CWRU spiral nerve cuff electrode was tested intraoperatively in human subjects. Threshold data was recorded when stimulating through individual contacts as well as all contacts together. Selectivity was demonstrated on two nerves in an individual with spinal cord injury. Further data is needed to adequately characterize the electrodes.

The observed thresholds were an order of magnitude higher that found in the cat model. The intraoperative thresholds were in the range of 2 mA, 200 μs, while the thresholds in cats have been reported to be approximately 0.5 mA, 10 μs [2-4]. This may be a result of the conditions of the subjects' nerves. Subjects were selected from patients undergoing nerve repair surgery, and therefore, their nerves may not have been as excitable as healthy nerves. However, the subject with spinal cord injury had no direct injury to the nerves tested and also had higher thresholds. A study using spiral electrodes on the human optic nerve [5] found threshold levels in the same range as the cat results. Conversely, in an experimental system to correct footdrop [6], the average thresholds were 220 μs and 1.01 mA, comparable to the thresholds found in the present study. The electrodes used in the footdrop system were loosely wrapped around the nerve, which could explain the higher thresholds.

The selective activation of the biceps and pectoralis major from stimulation of the upper trunk was unexpected. This electrode was placed proximal to the brachial plexus. While there appears to be mixing of fibers in the plexus, these results suggest some organization of fascicles by muscle group even at this proximal location. EMG signals were recorded from only four muscles were recorded. It is possible that activation occurred in other, uninstrumented, muscles but was not recorded.

Of the five subjects tested, selectivity data was only obtained from one. The other four subjects had nerve injuries that resulted in an inability to activate their muscles and only SSEP data were recorded. Since one quarter of patients undergoing eligible procedures have partially viable nerves, the number of subjects will be increased to the probability of obtaining data from less damaged nerves.

This study presents preliminary data. To prove that the spiral nerve cuff electrodes are capable of functional selective control of muscles, it is necessary to demonstrate that one muscle can be recruited through its full range before spillover to other muscles. An experimental setup has been developed to more fully answer this question intraoperatively. The algorithm uses a recursive binary search to characterize the twitch recruitment curves of muscles innervated by the nerve being tested. With this algorithm, the recruitment curves for each contact can be obtained in 1-2 minutes. This will increase the amount and quality of data collected by speeding up the process and reducing the arbitrary selection of stimulation parameters.

V. Conclusion

This study is the first to demonstrate selective stimulation by cuff electrodes on human peripheral nerves. These preliminary results support a chronic implant in a human subject with nerve cuff electrodes. Based on these trials, it is expected that chronically implanted nerve cuff electrodes will be able to selectively recruit individual muscles in the upper extremity, which can be used for functional restoration of hand and arm function in C3/C4 SCI subjects.

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