Proceedings of the 2nd International IEEE EMBS
Conference on Neural Engineering
Arlington, Virginia · March 16 - 19, 2005

Intraoperative Testing of Selectivity of Spiral Nerve Cuff Electrodes

Katharine H. Polasek[1], Harry A. Hoyen[1,3], Michael W. Keith[1,3], Robert F. Kirsch[1,2,3], Dustin J. Tyler[1,2,3]
[1]Department of Biomedical Engineering, Case Western Reserve University, Cleveland, OH, USA
[2]Louis Stokes Cleveland Department of Veteran Affairs Medical Center, Cleveland, OH, USA
[3]Department of Orthopedics, Metrohealth Medical Center, Cleveland, OH, USA

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. Data was recorded to estimate stimulation threshold and determine selectivity data. Thresholds appeared to be higher than anticipated based on previous cat data. Preliminary selectivity was demonstrated on several nerves.**

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.

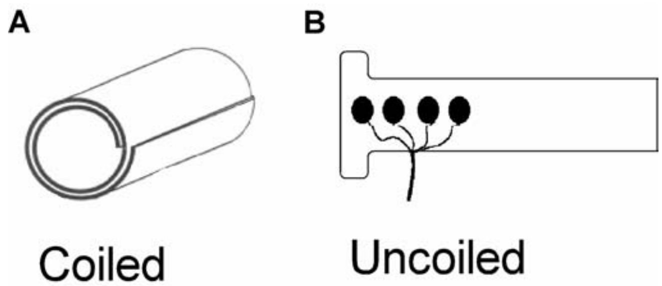

Fig. 1. Schematic of spiral cuff electrode. A. Spiral electrode coiled, resulting in two full wraps. B. Electrode uncoiled to show contact layout

The multiple contacts around the nerve can be activated individually. Stimulating a single contact should activate 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. Selective stimulation with peripheral nerve electrodes in the human upper extremity has not previously been demonstrated. The purpose of intraoperative testing is to prepare for chronic implantation of nerve cuff electrodes in a subject with high tetraplegia. The hypothesis is that individual muscles and/or muscle groups can be controlled selectively from a proximal nerve cuff electrode in human subjects.

II. Methodology

Subjects were recruited from patients scheduled to undergo upper extremity nerve repair surgery. During these procedures, surgeons asses the extent of nerve injury by measuring somatosensory evoked potentials (SSEP) proximally and evoked electromyograms (EMG) distally. Typically, a hand-held, bipolar, stimulating probe is used to stimulate the nerves. For this study the CWRU spiral nerve cuff electrode was used, as well as the traditional probe. 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. SSEP data and EMG data for subjects 1-7 was collected using a commercially available clinical evoked potential system (Epoch 2000, Axon Systems, Hauppauge NY). Threshold values were obtained by increasing the stimulation intensity until a response was seen. EMG data for subjects 8-12 was collected using custom Matlab software that facilitated generation of recruitment curves. The threshold was defined as 10% of the maximum activation for each muscle across all trials.

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.

III. Results

A. Stimulation Thresholds

Thirteen subjects have participated in this study. There was significant variability between subjects based on the condition of the nerves being tested. In five of the thirteen subjects, no muscle activity was present due to distal nerve damage. Threshold data (Table 1) ranged from 0.03 nC to 0.27 nC.

TABLE 1
STIMULATION THRESHOLDS ACROSS SUBJECTS

Subj Num	Injury/Condition	Threshold*** Nerve	PW µs	PA mA	Q nC	Data Type	Stim Pos
1	Brachial plexus avulsion	Phrenic	100	1.7	0.17	EMG	WC
		Spinal Acc.	500	0.3	0.15	EMG	WC
			100	1	0.1	EMG	WC
			50	1.7	0.09	EMG	WC
2	Partial amputation at elbow	Median	100	1	0.1	SSEP	WC
		Ulnar	100	1	0.1	SSEP	WC
3	C4 SCI – nerve transfer	Upper Trunk	190	1.1	0.21	EMG	7
			200	1.1	0.22	EMG	7
		Ulnar	200	1	0.2	EMG	4
			300	0.5	0.15	EMG	5
			250	0.5	0.13	EMG	6
			275	0.5	0.14	EMG	7
4	Brachial plex avul	No cuff data due to technical problems					
5	Brachial plex avul	Only SSEP, difficult to determine threshold					
6	Partially cut median nerve, ulnar healthy	Median	200	0.9	0.18	EMG	WC
			100	2.7	0.27	EMG	3
		Ulnar	50	0.6	0.03	EMG	1
7	Median n. compression	Median	100	1	0.1	EMG	Probe
			200	1	0.2	EMG	WC
8	Ulnar n. compress	Only SSEP, difficult to determine threshold					
9	Radial n. comp	Only SSEP, difficult to determine threshold					
10	Brachial plex stab	Only SSEP, difficult to determine threshold					
11	Central cord injury	Ulnar	140	0.3	0.04	REC	4
12	SS nerve exploration	Musc	125	0.5	0.06	REC	3
		Axillary	70	0.8	0.06	REC	3
13	Brachial plexus exploration	Median	50	2	0.1	REC	3
		Median	176	0.5	0.09	REC	4

Legend: *PW* = Pulse width
PA = Pulse amplitude
Q = Total Charge injected (PA*PW/1000)
Data Type refers to the data recorded. SSEP – no EMG recorded; EMG – EMG response from discrete locations; REC – full recruitment curves
Stim Position contains a number that refers to the cuff stimulation position on the nerve. WC – whole cuff
***Threshold values 1-7 are the lowest recorded value that resulted in a response at the stimulation position indicated.

B. Selectivity

Selective activation of individual muscles was seen in subject 4. Stimulating the upper trunk of the brachial plexus with a pulse width of 200 µs and pulse amplitude of 1 mA resulted in biceps stimulation and no response from deltoid, supraspinatus and pectoralis major. Conversely, stimulating with a pulse width of 500 µs and pulse amplitude of 0.5 mA resulted in pectoralis major stimulation and no response from the other three muscles. Also on subject 4, similar selective activation was found on the ulnar nerve while recording from flexor carpi ulnaris, flexor digitorum profundus, and the first dorsal interosseous.

Selective activation of the axillary nerve was found in subject 12 (fig. 2). When stimulating on channel 3, the posterior deltoid is recruited first and reached nearly 50% activation before 10% middle deltoid activation (fig. 2A). When stimulating on channel 2, all three muscles were recruited together over the first half of the range, then the anterior and middle deltoid activations increased while posterior deltoid remained at approximately 50% activation.

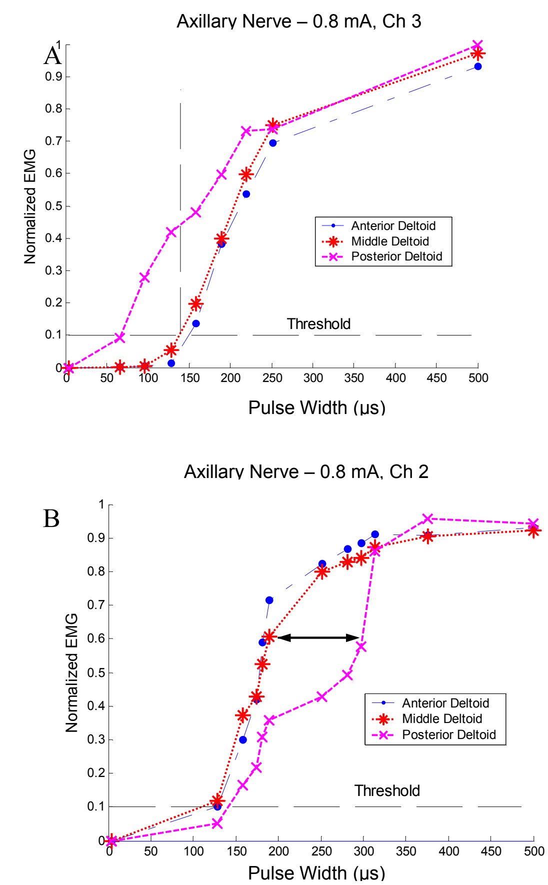

Figure 2: Pulse width modulation from the axillary nerve of subject 12. (A) Posterior deltoid is recruited to 45% activation before 10% activation of anterior and middle deltoid. (B) Anterior and middle deltoid are recruited from 45-80% activation while the posterior deltoid remains about 50% activation

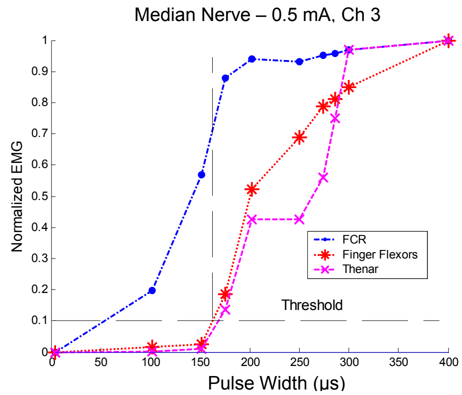

Figure 3: Pulse width modulation from the median nerve of subject 13. The flexor carpi radialis (FCR) was recruited to 70% activation before the other muscles reached 10% activation.

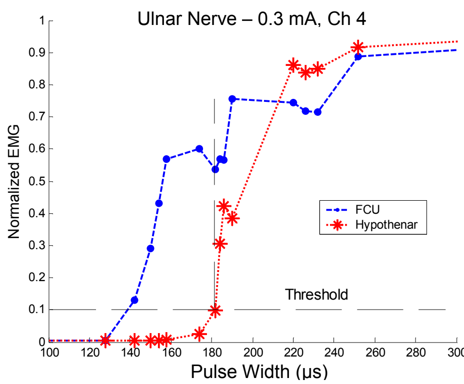

Figure 4: Pulse width modulation from the ulnar nerve of subject 11. The flexor carpi ulnaris was recruited to 60% activation before hypothenar reach 10% activation.

On the median nerve of subject 13 and the ulnar nerve of subject 11 (fig. 3 and fig. 4), one muscle was recruited before the other(s) but the reverse relationship was not found. Stimulating on channel 3 of the median nerve of subject 13 resulted in 70% flexor carpi radialis (FCR) activation before the finger flexors and thenar muscles reached 10% activation. Selective activation of the other two muscles was not found at a pulse amplitude of 0.5 mA. Stimulating on channel 4 of the ulnar nerve of subject 11 resulted in 60% activation of the flexor carpi ulnaris (FCU) before the hypothenar reached 10% activation. Similarly, selective activation of hypothenar was not found at a pulse amplitude of 0.3 mA.

IV. Discussion

V.

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. Preliminary selectivity was demonstrated in 4 of the 13 subjects tested. In five subjects, no EMG was recorded due to prior distal nerve damage. In the remaining subjects, the data acquisition method did not allow recording of sufficient data to draw any meaningful conclusions.

The observed thresholds were an order of magnitude higher than found in the cat model. The intraoperative thresholds were in the range of 1 mA, 150 μs, while the thresholds in cats have been reported to be approximately 0.5 mA, 10 μs [2-4]. Some increase in threshold is expected since cat nerve axons have a larger diameter than humans and thus a lower threshold [5]. But many of the nerves tested had a higher threshold than found when stimulating a healthy human nerve (50 μs, 0.6 mA - see ulnar nerve of subject 6 in Table 1). This may be due to the fact that the nerves being tested were injured in some way. A study using spiral electrodes on the human optic nerve [6] found threshold levels (50 μs, 1.1 mA and 100 μs, 0.8 mA) in the same range as the healthy ulnar nerve recorded from subject 6. Conversely, in an experimental system to correct footdrop [7], the average thresholds were 220 μs and 1.01 mA, comparable to the thresholds found in the present study. However, the electrodes used in the footdrop system were loosely wrapped around the nerve, which could explain the higher thresholds.

Due to the time constraints of intraoperative testing, only a limited number of stimulation parameters were attempted at each procedure. Selective recruitment of a single muscle from a nerve innervating multiple muscles was shown in several subjects. However, the ultimate goal is to selectively activate more than one muscle innervated by one nerve. A more thorough search of the parameter space is required to answer the question of selectivity. The experimental protocol is being optimized to increase the amount of data collected at each procedure but there will still be a finite amount of time.

The next stage of testing will include the chronic implant of four spiral electrodes in a paraplegic human volunteer. This will allow systematic testing of the entire parameter space. Additionally, none of the stimulation techniques for enhancing selectivity (pre-pulses, current steering, etc.) have been used intraoperatively. These methods will also be tested with the chronically implanted electrodes.

V. CONCLUSION

This study is the first to demonstrate selective stimulation by cuff electrodes on upper extremity human peripheral nerves. These preliminary results justify a more thorough study involving 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.

REFERENCES

[1] G. G. Naples, J. T. Mortimer, A. Scheiner, and J. D. Sweeney, "A spiral nerve cuff electrode for peripheral nerve stimulation," *IEEE Trans Biomed Eng*, vol. 35, pp. 905-16, 1988.

[2] W. M. Grill, Jr. and J. T. Mortimer, "Quantification of recruitment properties of multiple contact cuff electrodes," *IEEE Trans Rehabil Eng*, vol. 4, pp. 49-62, 1996.

[3] J. D. Sweeney, D. A. Ksienski, and J. T. Mortimer, "A nerve cuff technique for selective excitation of peripheral nerve trunk regions," *IEEE Trans Biomed Eng*, vol. 37, pp. 706-15, 1990.

[4] W. M. Grill and J. T. Mortimer, "Stability of the input-output properties of chronically implanted multiple contact nerve cuff stimulating electrodes," *IEEE Trans Rehabil Eng*, vol. 6, pp. 364-73, 1998.

[5] J. A. Hoffer, G. E. Loeb, W. B. Marks, M. J. O'Donovan, C. A. Pratt, and N. Sugano, "Cat hindlimb motoneurons during locomotion. I. Destination, axonal conduction velocity, and recruitment threshold," *J Neurophysiol*, vol. 57, pp. 510-29, 1987.

[6] C. Veraart, C. Raftopoulos, J. T. Mortimer, J. Delbeke, D. Pins, G. Michaux, A. Vanlierde, S. Parrini, and M. C. Wanet-Defalque, "Visual sensations produced by optic nerve stimulation using an implanted self-sizing spiral cuff electrode," *Brain Res*, vol. 813, pp. 181-6, 1998.

[7] R. L. Waters, D. R. McNeal, and J. Perry, "Experimental Correction of Footdrop by Electrical Stimulation of the Peroneal Nerve," *J. Bone Joint Surg*, vol. 57A, pp. 1047-1054, 1982.