

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 examine electrode selectivity in the human upper extremity. Subjects were recruited from patients undergoing upper extremity nerve repair procedures. The nerves were stimulated through four individual contacts located radially around the nerve with varying parameters. Data was recorded to estimate stimulation threshold and determine selectivity. Thresholds appeared to be higher than anticipated based on previous cat data. Preliminary selectivity was demonstrated on several nerves.

1. 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 muscle based electrodes. Second, a C4 level injury results in partial denervation of key shoulder 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. This increases the importance of activating all viable fibers. 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.

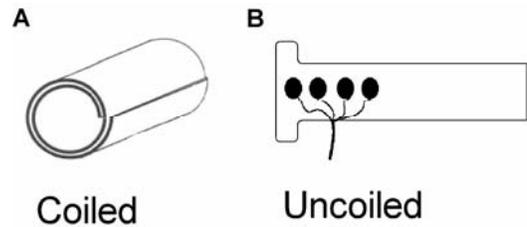


Fig. 1. Schematic of spiral cuff electrode. A. Electrode coiled, resulting in two full wraps. B. Uncoiled to show contact layout

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 [4] 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.

It has been shown [1] that it is possible to control multiple muscles or actions with a single multi-contact electrode in a cat model. 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 is 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.

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.

2. METHODS

Subjects were recruited from patients scheduled to undergo upper extremity nerve repair surgery. During these procedures, surgeons assess 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 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 in one to four target muscles innervated by the test nerve. 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 8-14 was collected using custom Matlab software that generated recruitment curves from the area under the EMG twitch response. The threshold was defined as 10% of the maximum EMG response (the maximum seen 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. Percent selectivity was found by determining the percent activation of one muscle before any other muscle reached threshold (10%).

3. RESULTS

3.1. Stimulation Thresholds

Fourteen 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 0.01 nC to 0.27 nC.

3.2. Selectivity

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.

TABLE 1
 STIMULATION THRESHOLDS ACROSS SUBJECTS

Sub #	Injury/Condition	Threshold***				Data Type	Stim Pos
		Nerve	PW μ s	PA mA	Q nC		
1	Brachial plexus avulsion	Phrenic	100	1.7	0.17	EMG	WC
			500	0.3	0.15	EMG	WC
		Spinal Acc.	100	1	0.1	EMG	WC
50	1.7		0.09	EMG	WC		
2	Partial amp 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 avulsion	No cuff data due to technical problems					
5	Brachial plex avulsion	Only SSEP, difficult to determine threshold					
6	Partially cut median nerve Healthy ulnar	Median	200	0.9	0.18	EMG	WC
		100	2.7	0.27	EMG	3	
7	Median nerve compression	Ulnar	50	0.6	0.03	EMG	1
			Median	100	1	0.1	EMG
8	Ulnar nerve compression	Ulnar	200	1	0.2	EMG	WC
			200	1	0.2	EMG	WC
9	Radial nerve compression	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 plex exploration	Ulnar	50	2	0.1	REC	WC
			150	0.5	.08	REC	4
		Median	176	0.5	0.09	REC	3
14	Median nerve exploration	Ulnar	10	3	0.3	REC	3
			100	.1	0.01	REC	2

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, BPP – bipolar probe.

***Threshold values 1-7 are the lowest recorded value that resulted in a response at the stimulation position indicated.

Selective activation of individual muscles was also seen in the upper trunk and ulnar nerves of subject 3, on the median nerve of subject 13 and the ulnar nerve of subject 11 and subject 14. In each of these cases, one muscle was recruited before the other(s) but the reverse relationship was not found.

4. DISCUSSION AND CONCLUSIONS

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 primarily evaluated in subjects 11-14 since recruitment curves were available for the analysis. Preliminary selectivity was demonstrated in 4 of the 6 nerves with intact muscle response.

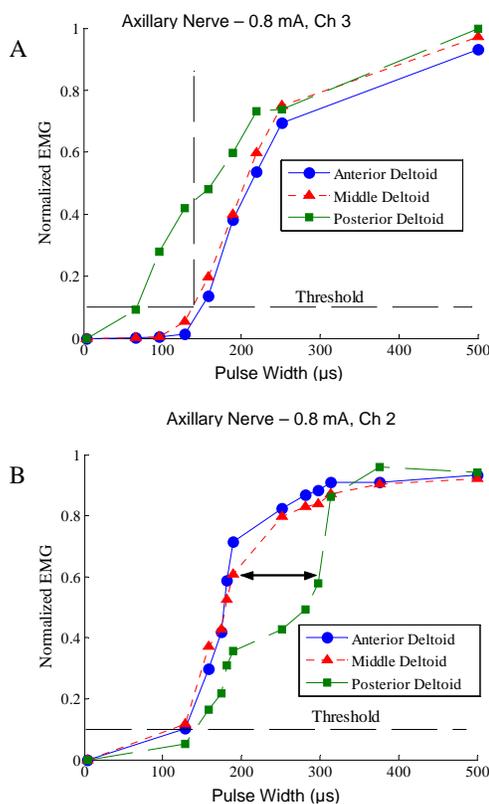


Figure 2: Pulse width modulation from the axillary nerve of subject 12. (A) Posterior deltoid is recruited to 45% activation before 10% activation of anterior and middle deltoid. (B) Anterior and middle deltoid are recruited from 45-80% activation while the posterior deltoid remains about 50% activation

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 [1,2,5]. Some increase in threshold is expected since cat nerve axons have a larger diameter than humans and thus a lower threshold [3]. 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. 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 result in higher threshold values than would be expected in a correctly fitting electrode.

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.

This study is the first to demonstrate selective stimulation by cuff electrodes on human upper extremity 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.

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