## Proceedings of the 28th IEEE EMBS Annual International Conference New York City, USA, Aug 30-Sept 3, 2006 Spiral Nerve Cuff Electrodes for an Upper Extremity Neuroprosthesis

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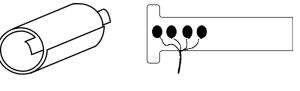
Abstract— Four nerve cuff electrodes were implanted in the shoulder and arm of one subject with high tetraplegia. Stimulation produced shoulder abduction, elbow flexion and extension, and wrist and finger extension. Recruitment properties were quantified using twitch EMG recruitment curves and tetanic moment measurements. The chronic qualitative 'function' of each channel of stimulation could be predicted from the intraoperative data collection. The average threshold was  $11.3 \pm 9$  nC and stabilized to this value over the 35 weeks of testing. The moment production of most muscles increased over the testing period due to exercise of the atrophied muscles. No muscle decreased its moment and most appeared to plateau after 15 weeks. Sensation was also evaluated since this subject had an incomplete injury and nerve stimulation was not found to painful throughout the range of muscle activation. Nerve electrodes have been shown to be a stable, effective means of activating muscles for neuroprosthetics.

*Index Terms*—Electrical stimulation; electrodes; neural prosthesis; neural stimulation; peripheral nerve; spinal cord injury

# I. INTRODUCTION

Functional electrical stimulation (FES) is used to elicit contractions in paralyzed muscles and increase the independence of paralyzed individuals. Most existing FES systems consist of muscle based electrodes, where a single electrode controls a single muscle. As neuroprosthetic designs increase in complexity, requiring activation of more muscles and increasing the degrees of freedom, different types of electrodes will be required. One type of electrode that may simplify neuroprosthetic implementation is the nerve cuff electrode.

In general, nerve cuff electrodes wrap around the nerve and stimulate axons leading to all muscle fibers innervated by that nerve. This may be an effective method to fully activate broad or pinnate muscles that are difficult to stimulate using muscle based electrodes. Since nerve electrodes are in direct contact with the nerve, less current is required to activate muscles than when using muscle based electrodes. Additionally, many nerve cuff electrodes have the capability to stimulate different portions of the nerve selectively and potentially activate different functions and/or muscles individually. In a neuroprosthetic application, this would reduce the number of electrodes needed and may decrease the length and complexity of surgery. Because of the number of muscles to be stimulated and the large size of many shoulder muscles, a neuroprosthetic for high tetraplegia is a suitable platform to implement nerve electrodes clinically.



Coiled

Uncoiled

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

The Case self-sizing spiral nerve cuff electrode [1] was chosen for initial clinical implementation because it has demonstrated selectivity and stable chronic nerve activation in cats [1-8] and had been implanted on the human optic nerve [9]. These electrodes are self-sizing coils (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.

Prior to this study, the thresholds and selectivity of the spiral electrode were evaluated intraoperatively [10]. These preliminary results justified a more thorough study involving chronic implant in a human subject with nerve cuff electrodes.

This paper addresses three hypotheses. First, the recruitment properties and moment production stabilize and plateau after implant. Second, functional forces and movements are produced by stimulating using nerve cuff electrodes. Third, the sensation produced by stimulating through a nerve with mixed motor and sensory fibers does not elicit pain in the range used for muscle stimulation.

# II. METHODOLOGY

Four percutaneous spiral nerve cuff electrodes were implanted in one subject with a motor complete, sensory incomplete C1 injury of the right arm. Spiral nerve cuff electrodes were implanted on four upper extremity nerves. Single-contact electrodes were placed on the axillary and suprascapular nerves to stimulate the deltoid, infraspinatus and supraspinatus. Four-contact electrodes were placed on the radial and musculocutaneous nerves to stimulated the biceps, brachialis, triceps, wrist extensors, finger extensors, supinator and some thumb muscles. The MetroHealth Medical Center IRB approved the study and the subject gave informed consent prior to study participation.

TABLE 1        Schedule of Testing for Subject #1														
Week		6	7	8	9	10	11	12	13	14	15	16	35	
Monopolar EMG recruitment	X							x			X	X	х	
Tetanic moment measurements		X	x		x			x	x	x	x			

## A. Electromyography Recordings

Surface and percutaneous EMG recordings were used to evaluate recruitment and selectivity of each nerve. Surface twitch recruitment curves were generated using single channel, square, biphasic stimulation at different values of pulse width and pulse amplitude modulation. Curves were collected at different times (Table 1) and compared to evaluate the stability of the recruitment properties (threshold, maximum). Additional recruitment curves were generated after the percutaneous phase of testing at 35 weeks post implant.

## B. Moment Measurements

Tetanic stimulation (12.5 Hz) was used to measure the moment capabilities of the muscles at four pulse width values. To remove passive moments from each joint, the moment produced without stimulation was subtracted from the moment produced during stimulation. To measure elbow, wrist, and finger moments, the subject was placed in a device consisted of 4 individual four bar linkage transducers, one for the elbow and wrist and one for each of the first two fingers. For these measurements, the shoulder was abducted 55° and horizontally flexed 60°, the elbow was flexed 90°. The wrist and fingers were straight in line with the forearm.

To measure shoulder moments, the subject was placed in a setup consisting of a JR3 force and moment transducer attached to the endpoint of the humerus with the elbow bent to 90°. The shoulder was position at 45° of abduction and 0° of horizontal flexion. When measuring shoulder moments, axillary and suprascapular nerves were stimulated together obtain a more realistic measurement of functional abduction using both the deltoid and the rotator cuff muscles

### C. Sensory

Since the subject tested had sensation on the area innervated by the radial and musculocutaneous nerves, one experimental session of sensory stimulation was performed. First, the dermatomes were mapped by stimulating below the motor threshold and asking the subject where and what was felt. Then, tapping, brushing, squeezing or pushing stimulus was applied over the dermatomes while recording from the nerve electrode.

## III. RESULTS

## A. Stimulation Thresholds

The stimulation threshold (10% maximum EMG) was calculated for each EMG recruitment curve (fig. 2). The average threshold at 5 weeks was  $35.2 \pm 26$  nC. At 35 weeks post implant, the thresholds for most channels decreased and the variability between channels decreased. The average threshold at 35 weeks was  $11.3 \pm 9$  nC.

#### B. Electrode Positional Stability

To determine if the electrodes move during and after the surgery, the recruitment curves generated intraoperatively were compared with curves generated 5 and 16 weeks post implant. At both times, stimulation of channel 1 resulted in triceps activation before the other muscles (fig. 3) while stimulation of channel 3 resulted in activation of triceps last. This indicated that intraoperative testing is a valid predictor of chronic performance.

#### **Stability of Nerve Thresholds**

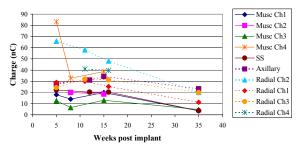


Fig. 2. Threshold charge over time from 5 to 35 weeks post implant for each electrode contact. The thresholds for each channel converge after 35 weeks.

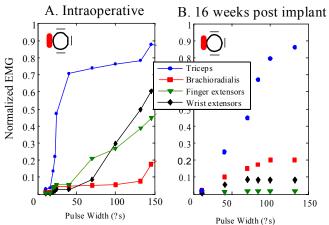


Fig. 3. Comparison of radial nerve electrode recruitment from intraoperative testing to 16 weeks post implant. Each recruitment curve was generated using pulse width modulation with a pulse amplitude of 0.8 mA. The schematic in the upper left hand corner of each plot visually depicts the channel used for simulation. Channel 1 activates triceps first in both cases.

#### C. Moment Production

The maximum moments from each electrode were recorded at three different sessions between 7 and 15 weeks. The deltoid strength significantly (p<0.05) increased from with exercise while the infraspinatus and supraspinatus together produced horizontal flexion moments that were not significantly different (p=0.35) and abduction moments that were significantly lower (p<.02) than the values recorded at 7 weeks. When the axillary and suprascapular nerves were stimulated together, an abduction moment of 340 N-cm was recorded.

Musculocutaneous nerve stimulation did not result in a significant increase in elbow flexion moment over the 5 weeks tested. The maximum flexion moment produced was  $432 \pm 14$  N-cm from contact 1.

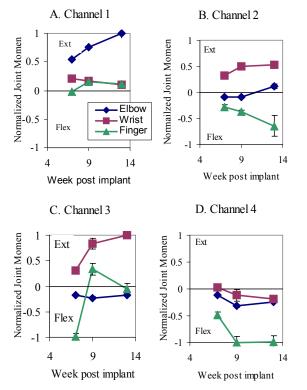


Fig. 4. Moment production for the elbow, wrist and fingers generated by stimulating through channels 14 of the radial nerve cuff electrode.

Radial nerve stimulation produced moments at the elbow, wrist and fingers. Fig. 4 shows the normalized moment for each channel. The maximum moments are as follows: 511 N-cm from the elbow; 116 N-cm from the wrist; and 12.9 N-cm from the index finger. Channel 1 produced predominantly elbow extension and the force significantly increased (p<0.05) across the 5 weeks tested (fig. 4A). Channel 2 produced wrist extension and finger flexion with very little elbow moment (fig. 4B). Channel 3 produced predominantly wrist extension with some elbow flexion (brachioradialis) and the wrist moment significantly increased (p<0.05) across the 5 weeks (fig. 4C). Channel 4 produced finger, wrist, and elbow flexion (fig. 4D).

## D. Sensation

Sensation due to motor stimulation was not reported to be painful between threshold and supramaximal stimulation. If the stimulation levels were increased significantly beyond supramaximal, the subject would report a painful sensation. During motor threshold stimulation of the musculocutaneous nerve, the subject felt pressure over most of her forearm that increased with increasing pulse amplitude. Smaller areas of sensation could not be localized by stimulation.

#### IV. DISCUSSION

Four spiral nerve cuff electrodes were implanted in one human subject and tested for 16 weeks with one follow up test at 35 weeks. Threshold, position and moment production stabilized over the testing period.

The thresholds recorded at the initial session 5 weeks post implant had considerable variation but were still within the range expected based on intraoperative testing of this electrode. Over the course of the trail, the varied slightly from week to week but after 35 weeks appear to converge. This is not unexpected since tissue encapsulation should reduce the relative stabilize the electrode on the nerve and prevent movement of the electrode relative to the nerve between measurement sessions.

To estimate the functionality of the shoulder abductors, the total abduction force was compared to inverse model simulations run with the Delft shoulder and elbow model [11] in the same position. The model predicted that 430 N-cm were required from the deltoid to maintain the arm at 45° of abduction. The measured deltoid abduction was 300 N-cm. However, between 9 and 14 weeks, this abduction moment increased by 50%. Additional increases are expected as the subject continues to exercise and loosen the joint. The unconstrained abduction should also increase with stimulation of the serratus anterior which was implanted on November 8, 2005. The serratus anterior improves scapular stability as well as rotating the scapula, which should allow for easier abduction.

The elbow moments obtained were sufficient to functionally flex and extend the elbow. Stimulating the musculocutaneous nerve was sufficient to fully flex the elbow against gravity. Stimulating the radial nerve fully extended the elbow in a neutral plane.

Very little finger extension was recorded in these trials. This was because these measurements were made with the fingers nearly fully extended. Additional measurements will be performed to record accurate finger extension moments but, visually there was sufficient finger extension to open the hand and grasp a normal sized cup.

The radial nerve predominantly innervates extensors, including extensors of the elbow, wrist and fingers. It also innervates the brachioradialis (elbow flexor), the supinator, and various thumb muscles. When stimulating the radial nerve of this subject, significant wrist and elbow flexion was seen on several channels (fig. 4). Part of this large moment was due to the fact that these measurements were made with the fingers nearly fully extended, in a position where the flexors produce maximum moment. However, finger and wrist flexion (and ulnar deviation) was seen when the hand was free of the measurement apparatus as well. The reason for this flexion is unknown. There are no published anastamoses from the ulnar or median nerves (the nerves responsible for finger and wrist flexion) to the radial nerve and it is not probable that stimulation could spill over from the radial nerve to the ulnar or median nerves since they are not located close to each other in the part of the arm where the electrode is located.

#### V. CONCLUSION

This study is the first to demonstrate chronic nerve stimulation in the human upper extremity. The recruitment properties of the electrodes were stable over the 16 weeks of percutaneous testing and further converged to the 35 week follow-up test with no painful sensation. Intraoperative testing of electrodes is a predictor of chronic performance. Also, muscle force production was stable or increasing with exercise, indicating no adverse physiological consequences of the electrode implanted on the nerve.

Additional electrodes have been implanted in the shoulder, arm and hand of this subject to provide functional movements. The goal is to have the subject control her paralyzed arm using voluntary neck EMG signals.

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