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Intraoperative Demonstration of Selective Stimulation of the Common Human Femoral Nerve with a FINE

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Abstract— **We have tested the hypothesis that the Flat Interface Nerve Electrode (FINE) can selectively stimulate each muscle innervated by the common femoral nerve of the human, near the inguinal ligament in a series of intraoperative trials. During routine vascular surgeries, an 8-contact FINE was placed around the common femoral nerve between the inguinal ligament and the first branching point. The efficacy of the FINE to selectively recruit muscles innervated by the femoral nerve was determined from electromyograms (EMGs) recorded in response to electrical stimulation. At least four of the six muscles innervated by the femoral nerve were selectively recruited in all subjects. Of these, at least one muscle was a hip flexor and two muscles were knee extensors. Results from the intraoperative experiments were used to estimate the potential for the electrode to restore knee extension and hip flexion through Functional Electrical Stimulation (FES). Normalized EMGs and biomechanical simulations were used to estimate joint moments and functional efficacy. Estimated knee extension moments exceed the threshold required for the sit-to-stand transition.**

I. INTRODUCTION

NERVE electrodes provide an alternative approach to muscle-based electrodes. Epimysial and intramuscular electrodes have restored short duration standing and stepping function to select individuals with paraplegia [1-3]. However, these systems require multiple surgical approaches to deploy electrodes in multiple muscles. A single multi-contact nerve cuff electrode could reduce surgery time by requiring only a single implant for multiple functions. Often muscle-based electrodes only partially recruit large muscles with multiple nerve entry points. Complete recruitment of a large muscle, such as those of the upper leg used during gait, is challenging [4]. Due to a nerve electrode's proximity to the axons innervating a target muscle, it has the potential to fully recruit that muscle.

Nerve cuff electrodes have been tested on the human femoral nerve. A multicontact spiral nerve cuff electrode was implanted around distal branches innervating knee extensors [5]. An additional electrode needed to be implanted to selectively activate hip flexors. To investigate the ability to selectively recruit knee extensors or hip flexors with a single electrode, a spiral cuff electrode was tested intraoperatively on the proximal common femoral nerve but was unable to separate knee extensors from hip flexors [6].

The FINE is an attractive neural interface because the target region of the nerve proximal to branching is broad and flat. The FINE has selectively recruited muscles in animals [7-9]. Simulations indicated that sufficient selective stimulation could be obtained if a FINE had an opening height of 1.5 mm and contained eight stimulating contacts (four on top, four on bottom) [10]. Based on these simulations, the hypothesis of this study is that a FINE placed proximally on the common femoral nerve will selectively activate at least four of the six muscles innervated by the femoral nerve and can separate knee extensors from hip flexors.

II. METHODS

Seven subjects were recruited. All surgeries were conducted at the LSCDVAMC in Cleveland, OH. The Institutional Review Board of the LSCDVAMC approved the study and the subjects provided consent.

A. EMG Recording Procedures

A reference electrode was placed over the patella contralateral to the leg undergoing surgery. The surgeon placed EMG needle electrodes into the six muscles innervated by the femoral nerve [11, 12] (Fig. 1). Each pair of EMG electrodes was attached to a differential pre-amplifier. A bank of programmable amplifiers further amplified the EMG response, producing an overall gain of 1,155 to 1,155,000. Gain was selected such that the twitch response to a supramaximal stimulus was maximized without saturating the amplifiers. A laptop interfaced with the amplifiers, stimulator, and A/D data acquisition board.

B. FINE Stimulating Procedures

The FINE, a silicone nerve cuff electrode, had eight platinum contacts: four on the upper inner surface and four on the lower inner surface (Fig. 2). Upper surface contacts

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were offset from those on the lower surface.

During surgery, a 2 cm section of the femoral nerve was exposed distal to the inguinal ligament but proximal to nerve branching. The surgeon positioned the FINE on the femoral nerve and a return electrode near the incision (Fig. 1). Charge-balanced, biphasic, cathodic-phase first, square pulse stimulus was delivered to the FINE. Amplifiers were blanked (clamped near 0 V) for 3 ms during and after stimulation to prevent saturation.

C. Selectivity

The muscle response to each stimulus was quantified as the rectified and integrated EMG. The integration window captured the m-wave. The measure of a muscle to a given stimulus was presented as the percentage activation that that muscle exhibited relative to the maximum response observed for that muscle over all trials.

Selectivity, S_i, for a muscle of interest *i* was defined as the recruitment benefit minus the average recruitment cost. The recruitment benefit, RB_i, was the normalized twitch response or activation level of target muscle *i.* The recruitment cost, $RC_{i,j}$, was the normalized twitch response of muscle *j* when targeting muscle *i.* Selectivity ranged from -1.0 to 1.0. A selectivity of -1.0 indicated that the stimulus parameters did not activate the target muscle but fully activated all other muscles. A selectivity of 1.0 indicated that the stimulus parameters resulted in full activation of the target muscle only. Based on prior work, a cost threshold was defined as 10% of the maximum activation observed for any non-target muscle [9, 13, 14], which has been shown to correspond to the first visible or palpable muscle twitch [13]. The maximum selectivity for each muscle was found when all costs remained below this threshold.

S_i was also calculated with respect to joint motion: knee extension or hip flexion. $RC_{i,j}$ was a function of the twitch response of non-agonist muscles but not the agonists. For knee extension, agonists were considered to be the three vasti (vastus lateralis, vastus intermedius, vastus medialis). For hip flexion, the agonists were considered to be the rectus femoris, sartorius, and pectineus.

D. Estimated Joint Moments

Measurement of muscle moment was not possible during intraoperative trials. Therefore, moments and the functions they would produce were estimated using a SIMM (Software for Interactive Musculoskeletal Modeling, Musculographics Inc., Santa Rosa, CA) biomechanical model [10, 15-19]. To estimate the joint moment generated as a result of stimulation, the maximum moment produced by the muscle as predicted by the model was scaled by its activation level represented by the percentage of the maximum EMG elicited. This is an indirect estimate of the expected functional response to an implanted FINE.

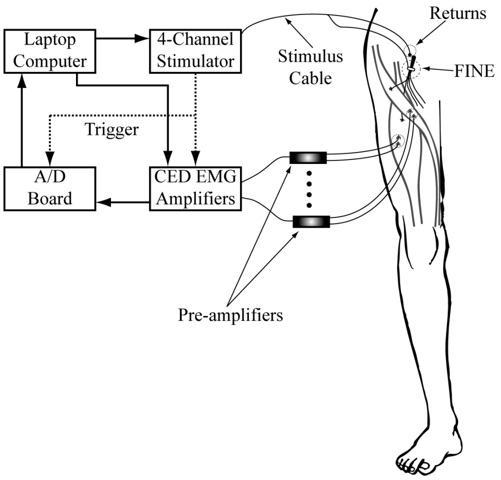

Fig. 1. Experimental setup for testing the FINE on the femoral nerve. A 4-channel stimulator is used to deliver the stimulus to one of the eight contacts in the FINE. The cable connecting the stimulator to the FINE must be switched between two cables to control the contacts either on the top or the bottom of the electrode, respectively. Differential EMG is collected from the six innervated muscles.

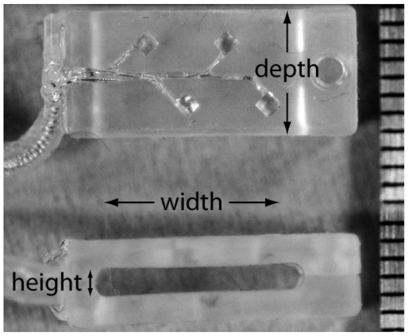

Fig. 2. A FINE similar to the one used in intraoperative experiments. Dimensions: 10 mm wide, 1.5 mm tall, 7 mm deep. Offset contacts maximized the spatial volume that was stimulated. Scale (right) in mm.

III. RESULTS

A. Subject Recruitment

Seven subjects consented to the study from whom valid data were collected for the last four. Technical software and hardware problems during the first experiment prevented collection of data from all muscles. The second subject had a high stimulus threshold as confirmed with a handheld stimulator independent of the FINE. High thresholds prevented investigation of stimulation parameters that were within the charge density safety limits of the FINE. In the third subject, the nerve was found to be embedded in scar tissue from previous surgeries and the surgeon elected to remove the subject from the study.

In Subjects 4 through 7, the stimulus charge required to elicit a muscle contraction was 21±18 nC. This value was not significantly different from the 25±17 nC found during chronic studies with a spiral nerve cuff electrode implanted on upper extremity nerves in humans (p=.25, one-sided *t*-test) [13], from the 18±12 nC obtained during intraoperative evaluation of the spiral electrode on the human femoral nerve (p=.38, one-sided *t*-test) [20], or from the 23±8 nC obtained in chronic studies with a spiral nerve cuff electrode implanted on the distal femoral nerve in humans (p=.38, respectively, one-sided *t*-test) [5]. Thresholds for activation were significantly less than that required for intramuscular stimulation of the quadriceps (p<.001, one-sided *t*-test) [21].

B. Selectivity

The maximum selectivity obtained for each muscle in each subject when costs were a function of all non-target muscles was plotted (Fig. 3, dark bars). Under these criteria, 18 of the 23 recorded muscles and at least four muscles in each subject were selectively recruited above threshold.

When recruiting a muscle, spillover to an agonist facilitates the desired function. The maximum selectivity obtained for each muscle in each subject when costs were a function of non-agonist muscles was plotted (Fig. 3, light bars). Under these criteria, 19 of the 23 recorded muscles and at least four muscles in each subject were selectively recruited above threshold. Average costs associated with spillover to non-target muscles were 0.02±0.01. Under this cost constraint, either the number of subjects in which the muscle was selectively recruited, the degree to which the muscle was selectively recruited, or both increased for five of the six target muscles in all subjects. In Subject 6, recruitment of the vastus lateralis required simultaneous recruitment of the vastus medialis and the latter was nearly fully activated only when the former was simultaneously activated.

C. Estimated Joint Moment

The maximum estimated knee extension moment for each subject was found while varying the acceptable hip flexion moment across all stimuli applied to each contact (Fig. 4). When the estimated knee extension moment was maximized while restricting hip flexion moment to no more than 5 Nm – approximately 10% of the maximum moment produced by simultaneous contraction of the hip flexors – knee extension moment averaged 82±48 Nm. Knee extension moment exceeded the estimated 35 Nm sit-to-stand transition threshold [21-23]. 35 Nm is approximately 16% of the maximum moment produced by simultaneous contraction of knee extensors.

When costs were limited to 10%, an estimated 5 Nm of hip flexion, or approximately 17% of that required for gait, could be obtained in all subjects (Fig. 4). The maximum estimated hip flexion moment exceeded the estimated 30 Nm required for gait [24, 25] in one subject but required excessive knee extension.

IV. DISCUSSION

This study presents data from the first human trials using a FINE. When non-target muscles could not be activated above threshold, at least four of the six muscles were selectively activated in all subjects and all six muscles were selectively activated in one subject. In all subjects, at least half of the muscles were selectively activated to or above 0.24. Knee extensors were separable from hip flexors in each subject. In two subjects each head of the quadriceps could be selectively activated. These results were obtained over a short period of time during which only a small portion of the stimulus space was explored. A thorough exploration of stimulus and the addition of field shaping techniques [26] should result in even higher selectivity.

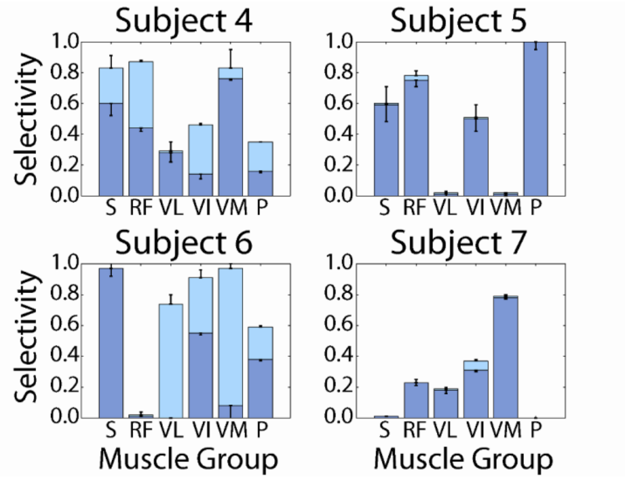

Fig. 3. The selectivity within each subject when costs were a function of all non-target muscles and did not exceed 10% for any non-target muscle (dark bars) and when cost were a function of all non-agonist muscles and did not exceed 10% for any non-agonist muscle (light bars).

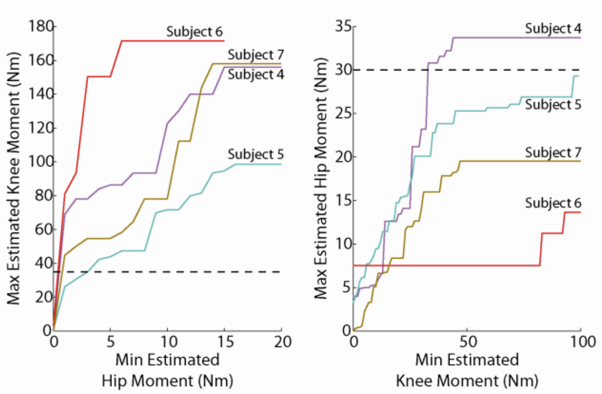

Fig. 4. The maximum estimated knee extension moment increased as the acceptable estimated hip moment increased (left). No knee extension moment was estimated without hip flexion moment. The dashed line marks the threshold for the sit-to-stand transition. The maximum estimated hip flexion moment increased as the acceptable estimated knee moment increased (right). Hip flexion was estimated to occur without knee extension in three subjects. Hip flexion sufficient for gait was marked by the dashed line. Single contact stimulation.

Relaxation of the cost constraint increased the number of muscles that were activated and the level to which they were activated. When maximum recruitment costs were relaxed from 0.10 to 0.20, at least half of the muscles were selectively activated to or above 0.40 in all subjects.

The specific criteria used to define selectivity may differ depending on the desired outcome. Activation of a non-target muscle above threshold may be acceptable when the activated muscle is synergistic with the target muscle. When spillover to agonists did not contribute to the cost calculation, the number of subjects in which the muscle was selectively recruited, the degree to which the muscle was selectively recruited, or both increased. Under this criterion, at least four muscles could be selectively recruited to a level of 0.20 in all subjects and in three subjects these muscles could be activated to at least 0.49. Therefore, in 75% of the subjects more than half of the muscles could be selectively activated to or above approximately 50% of their maximal activation when spillover to synergists was acceptable.

The data suggest that a knee extension moment sufficient for the sit-to-stand transition can be obtained with minimal hip flexion moment using a single contact. However, selectivity may be improved by using a more sophisticated stimulus paradigm involving multiple contacts. Multiple contacts existed in the FINE that were estimated to facilitate the desired outcome, indicating that the FINE is functionally redundant. The anatomically-based modeling study suggested that selectivity increased when using multiple contacts to recruit non-overlapping populations of axons innervating the same muscle [10].

It was assumed that EMG can be used to estimate moment. Normalized EMG can be used to determine the maximum isometric force contribution by a muscle assuming the maximum voluntary contraction for the muscle is known [27]. For these estimates, the maximum voluntary contraction for a muscle was based on generalized SIMM simulations. These simulations did not account for subject-specific parameters, weakened muscles, or fatigue. The moments may be over-estimated but the pattern of recruitment and selectivity are not expected to change. Others have reduced muscle strength by 50% to account for muscle atrophy in post-SCI patients [28]. The maximum estimated moment may not be achievable in a chronically implanted subject due to weakened muscles. However even with a reduction in simulated muscle strength by 50%, estimated knee extension moment exceeded 35 Nm.

V. CONCLUSION

This study indicates that a single 8-contact FINE placed on the femoral nerve selectively recruits muscles in a manner that will be sufficient for the knee extension phase of gait and can provide a supplement for the hip flexion portions of gait.

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