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MULTIFUNCTION PROSTHESIS CONTROL USING **I**MPLANTED **M**YO**E**LECTRIC **S**ENSORS (IMES)

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I. INTRODUCTION

Persons with recent hand amputations expect modern hand prostheses to function like intact hands. Current state-of-the-art electric prosthetic hands are generally single degree-of-freedom (opening and closing) devices that are controlled using only two muscle signals. As a result, most state-of-the-art devices fail to meet user's expectations and tend to be under-utilized or rejected. [2]. In this paper we describe the development of implantable myoelectric sensors (IMES) that will allow us to record myoelectric signals from up to 32 muscle sites. Most of the eighteen extrinsic muscles of the hand remain intact following hand amputation. The goal of this work is to develop the means to control for a multi-degree-of-freedom prosthetic hand that is capable of true dexterous manipulation. The development of IMES allows us to create many more control sources than has been possible in the past, greatly increasing the number of degrees-of-freedom we can control in a prosthetic system.

II. TESTING

Testing was conducted at a number of levels to both validate the design specifications and to demonstrate the ability of the IMES system to measure muscle activity (EMG signals) *in vivo*. A progression of experiments - bench tests, in vitro tests, acute in vivo experiments, and chronic *in vivo* experiments provided this validation and demonstration of the IMES capabilities. The bench tests were performed to validate the various IMES system components and design specifications. An *in vitro* experiment demonstrated that the magnetic and radio frequency link functioned correctly when an IMES was placed in muscle tissue, a necessary precursor to implanting IMES in cats. The animal experiments consisted of both a series of acute *in vivo* experiments to show the ability of the IMES system to accurately acquire physiologically generated EMG, and a series of chronic *in vivo* experiments show the ability of the IMES to provide live EMG data reliably over time. In all experiments the IMES implants are powered magnetically via the inductive link and telemetry is acquired via the reverse telemetry bands.

Protocols

1) **Validation.**

An IMES system consisting of a Telemetry Controller, integrated magnetic drive with RF receiving antenna coil, and an IMES implant was validated on the bench against design specifications. A set of sine wave test signals, varying logarithmically from 1 Hz to 10 KHz, was used to characterize the system. IMES data was recorded via a custom LabVIEW 7.1 (National Instruments, TX) virtual instrument configured to interface with the Sigenics IMES telemetry server. The test signal set was created using a LabVIEW 7.1 virtual instrument and output via a National Instruments NI-6221 A/D board. Samples were generated at a minimum rate of 50 samples per epoch

2) **System Comparison.**

The IMES system was compared to a Noraxon TeleMyo 2400 (Noraxon, AZ) wireless EMG system. The Noraxon TeleMyo is a commercially available sixteen channel EMG acquisition system. The system response of the Noraxon system was determined by passing a sine wave test signal set through one channel of the TeleMyo 2400. The gain, high and low filter cut off frequencies were determined as above. Using the system response characteristics of both systems, a set of setup parameters was chosen to most closely match the setup for the two systems. This was done because we were interested in determining how closely the IMES response would match that of the Noraxon System for a given set of setup parameters. Both

systems then recorded an alternating series of positive and negative step functions n=100 occurring at 1Hz to provide an estimate of the step response of both systems**.** The low frequency of the step function allowed both EMG recording systems to return to steady state after being perturbed.

3) **In Vitro**

Once the bench tests were completed and as a precursor to testing the IMES system with live animals the IMES system was evaluated in an *in vitro* model. This in vitro model consisted of a shank of lamb complete with bone. A shank of lamb was chosen because it has muscle tissue surrounding a longitudinal long bone(s), and cross-sectional area similar to that of a human forearm. A 15 mm long incision was made 12 mm deep oriented parallel to the long bone of the lamb shank. An IMES implant was placed into the incision and sutured closed. A stimulating monopole electrode was placed 5 mm from each of the IMES endcaps, to the same depth as the IMES, oriented along the axis of the implant. A pair of fine wire electrodes were implanted to the same depth as the IMES directly beside the implant, and connected to the Noraxon system for system comparison. A series of individual short duration (100-1000uS) monophasic stimulus pulses were input across the monopole electrode pair and recorded by the EMG recording devices.

4) In Vivo (acute)

Performance of the IMES *in vivo* was evaluated in both an acute and chronic animal preparation. The goal of the acute experiments was to investigate how well the IMES system measures a natural EMG signal, which was elicited with the cross-extension reflex [1] in a decerebrated cat preparation. The crossed extension reflex is by definition a natural form of activation, producing normal recruitment and rate modulation [3]**.** Cats were chosen because the calf muscles of the cat are similar in size and orientation to the small muscles of the human forearm [3]**.** In this experiment three IMES implants were implanted into the ankle extensor muscle group in the cat (calf muscles); Lateral Gastrocnemius (LG), Medial Gastrocnemius (MG), and Soleus (S).

The deeply anesthetized (1-3% isoflurane) animals (n = 3) were mounted to a rigid stereotaxic frame (*Kopf Instruments*). The extensor muscle group was surgically exposed, leaving all major nervous and vascular structures intact. A cuff electrode was placed around the tibial nerve before the branching plexus of the nerve to form the medial gastrocnemius and lateral gastrocnemius-soleus nerves. Each IMES was implanted by means of a surgical cut-down into the belly of the target muscle with the long axis of the IMES oriented parallel to the muscle fibers. This orientation was chosen to minimize the predicted pick-up volume of the IMES [4]. A set of bipolar fine wire electrodes were implanted into each of the muscles, parallel to and to the same depth as the IMES implant for use with the Noraxon system. The skin was stapled shut over the surgical site to prevent dehydration of the tissues. The Power/Telemetry coil was placed around the hind limb, and oriented concentric with the implant location; the implant(s) were powered and tested to confirm they were intact. The animal was decerebrated as per [5]**.** Gaseous anesthesia was then discontinued, and the animal was allowed to breathe room air.

Direct stimulation EMG was elicited by stimulation of the nerve directly via the nerve cuff using a Grass stimulator (PSIU6) (200uS pulse width, 10Hz, 10 pulses). Stimulation consisted of several trains of monophasic pulses with stimulus intensity ranging from threshold to four times threshold, as determined for each animal. Separate recordings were made for each level of stimulus intensity. EMG was then elicited via the crossed extension reflex. The crossed extension reflex was activated by administering painful stimuli to the contra-lateral hind paw of the animal or by direct electrical stimulation consisting of high-frequency monophasic pulses to

the tibial nerve of the contra-lateral hind limb. Multiple crossed extension events were recorded for each animal.

Cross talk and IMES field sensititivity were evaluated by severing the MG branch of the tibial nerve which was identified previously. Direct stimulation and crossed-extension elicited EMG were both acquired again, per above. Severing the MG branch of the tibial nerve eliminates the myoelectric activity of the MG.

5) In Vivo (chronic)

Evaluation of chronic IMES system function was performed by inserting IMES implant(s) into the Tibialis Anterior (TA) and lateral gastrocnemius (LG) of three cats and allowing the implantation site to completely heal. The TA and LG are agonist-antagonistic lower hindlimb muscles (i.e., ankle flexor vs. ankle extensor); as such they tend to be excited out of phase with each other during normal walking – allowing us to measure two independent signals and at the same time to see the level of cross talk the IMES would pick up between these two muscles.

Implantation was performed in a sterile surgical suite under a general anesthetic (isoflurane). A small incision was made in the lower hind limb, and the implants were placed into the muscle tissue via small incisions and sutured closed as in the acute procedure, but with absorbable suture (4.0 Vicryl). The IMES were powered and ordered to transmit their numeric identifier to confirm function. The skin incision was then closed, and the animal allowed to heal. A custom jacket (*Harvard Scientific)* was modified with a set of elastic straps to contain a small, silicon encased power/telemetry coil. The cats are acclimated to the jacket and coil apparatus for a period of two weeks prior to implantation, and re-acclimated for a minimum of two days post recovery. EMG was acquired during natural walking, encouraged by enrichment toys and food rewards. Data was acquired at 6050 Sample/second per implant. IMES internal filter corner frequencies are set at 4Hz and 6,600Hz respectively.

III. RESULTS AND DISCUSSION

a) General Notes

A time synchronization algorithm was used to calculate the normalized continuous RMS voltage levels for both records and make use of the maximum cross-correlation point to allow for time synchronization. All signals are post processed with a 25Hz-1000Hz 3rd order Butterworth band pass filter to eliminate low frequency motion artifacts in the Noraxon data channel. All EMG data is normalized to allow for processing and comparison. Cross correlation and MSC were used as measures of signal similarity.

b) Validation and System Comparison.

High and low corner frequency fidelity was determined by plotting signal amplitude against frequency and calculating frequencies at which the amplitude of the measured signal dropped to -3dB of the maximum measured signal amplitude. System parameters of the TeleMyo 2400 system were calculated in the same manner. To determine the step response of both systems, a 50 second segment of each record was divided into five second windows for averaging purposes. The mean n=10 of the maximum cross correlation values is 0.850. This degree of cross-correlation shows that the IMES system will produce responses similar to that of an EMG system which is currently in clinical use, suggesting that the IMES system is able to measure EMG accurately.

c) In Vitro.

The mean n=5 of the maximum cross correlation values is 0.767 which indicates that there may be a small degree difference in detected signals. This may be associated with the conformation of the IMES device endcaps vs. the fine wire recording electrodes; producing different spatial filtering properties [6]. This shows a high degree of coherence at low frequencies, with the correlation in frequency falling off as the frequency increases, which would be expected with varying spatial filters [8].

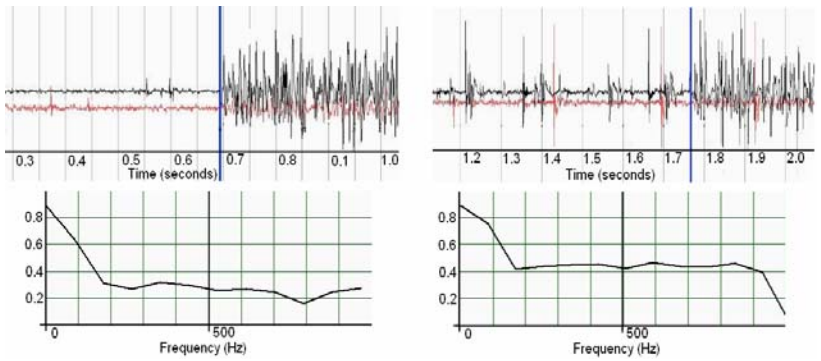

Fig. 2: Left: Intact medial gastrocnemius nerve. Right: medial gastrocnemius de-enervated. Both graphs show onset of crossed extension reflex. Normalized (voltage) raw EMG (top) black is soleus, red is medial gastrocnemius. Vertical bar indicates reflex onset. Magnitude

d) In Vivo (acute)

One second of each reflex event containing both pre- and post-onset EMG data was processed. Maximum cross correlation between signals does not exceed 0.080 which is to be expected from devices which are measuring composite stochastic signals from multiple sources. Evaluation of the pick up field of the IMES was accomplished by comparing the RMS voltage of the detected signal in the medial gastrocnemius before and after the medial gastrocnemius was denervated. Average RMS voltage measured in the medial gastrocnemius during a crossed reflex extension decreases to less than 5% of the RMS voltage measured in the Soleus (average of 27mm separation between implants) during the same reflex event. This corresponds to the levels predicted by Lowery *et al* [4]. One can also see (Fig. 2.) the increase in MSC of the detected IMES signals indicating that cross talk now accounts for a larger percentage of the total signal detected in the medial gastrocnemius. Decrease in the RMS of the signal coupled with an increase in coherence **(see Fig. 2.)** suggest the detected signal is composed of cross-talk from the adjacent muscles while at the same time being within the absolute limits predicted by Lowery *et al* [6].

e) In Vivo (chronic)

One second of data chosen at random during the course of normal walking was used for comparison**.** Both signals were normalized and post processed with a 25Hz-1000Hz 3rd order Butterworth bandpass filter to remove motion artifacts. The acquired EMG from the chronic *in vivo* experiments shows a maximum cross correlation of 0.09. MSC between the two measured signals does not exceed 0.40 and for most of the recording spectrum coherence is lower than 0.10**.** These coherence and cross correlation values show a distinct independence between signals attesting to the ability of the IMES system to make focal EMG measurements from multiple muscles in close proximity without picking up excessive cross-talk.

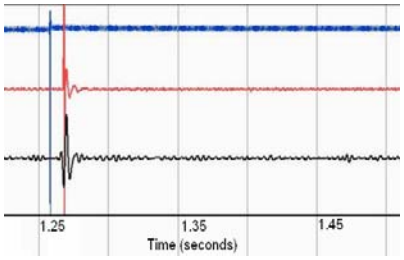

Fig.1. Characteristic normalized (voltage) impulse response of both systems through tissue. Timescale in seconds. Black trace, IMES 2520 sps. Red trace Noraxon 3000 sps. Blue trace input signal 3000 sps.

f) General Discussion

During the course of these experiments a number of issues had to be addressed. The nature of the USB interface necessitated the development of signal processing techniques which allow accurate comparison of signals acquired from disparate sources. This synchronization relies on the presence of distinct time stamps in both data streams. These time stamps were either impulse or step responses in the bench top experiments, or single motor unit action potentials in the acute cat experiments. It is important to remember that this synchronization is only necessary when trying to correlate signals acquired by the IMES with signals from a 2nd data acquisition system; data acquired from multiple IMES remains synchronous. Another issue that had to be addressed was due to the nature of the phase locked loop in the IMES implants. The resonant frequency of the class-E oscillator can be influenced by the presence of ferrous materials in or near the magnetic field. This frequency shift propagates through all aspects of the IMES system operation.

To address the effect the frequency shift has on sampling rate; all recorded signals were resampled to the nominal sampling frequency via spline interpolation. The frequency shift also affects the nominal reverse telemetry frequency, and can increase the amount of bit error the system sees due to shifting the reverse telemetry frequency outside of the range of frequencies the antenna and associated circuitry is designed to accommodate. This has been partially addressed by altering the filter corner frequencies on the receiving antenna circuitry to accommodate a larger range of frequencies. A thorough examination of the ASIC design revealed a pair of positive temperature biased transistors in the phase loop circuitry which were out of specifications, leading to larger than predicted frequency shifts when the implants were operating at body temperature. To address this issue, the nominal operating frequency of the IMES system was decreased to compensate for the slight increase in the carrier of the reverse telemetry signal. This has been remedied in the newest revision of the implant ASIC; which uses pair of matched positive and negative temperature biased transistors to maintain a reliable telemetry frequency independent of temperature.

2) Ongoing work

We are continuing to monitor the three chronic animals for signs of implant migration and to provide data for the analysis of data over time, with which we plan to address the consequences of device encapsulation on both data and signal quality. To date, we have not seen signs of implant migration or a decrease in the quality of telemetry signal and have not seen a qualitative decrease in the EMG data but are awaiting the conclusion of the study period to perform a quantitative analysis of the chronic EMG data. We are additionally in the process of performing an in depth quantitative analysis of all of our data in order to address the reliability and consistency in regards to the data acquisition abilities of the IMES system.

IV. CONCLUSION

The IMES system is capable of measuring focal intramuscular EMG comparable in both the time and frequency domain to commercially available clinical EMG systems. The use of implantable sensors in place of percutaneous wires makes the IMES system a reliable and robust platform for any EMG measurement application where a coil, flat or circular, can be accommodated on the body, such as a flat coil over the pectoralis or a cylindrical coil around a residual forearm. The IMES system is not limited to upper-limb prosthesis control and has application in lower-limb prosthetics as more powered components enter that field. In addition, IMES systems have application in experimental research where intramuscular recordings need to be made over long periods of time [7]. Using IMES obviates the need for percutaneous wires,

and can be viewed as a platform technology for making long-term intramuscular recordings. We have demonstrated the functionality and reliability of the system on the bench and we have fully operational systems that have been tested both acutely and chronically in cats. Six out of six chronic implants are completely operational 10 months after implantation. Clinical experience with implantation indicates minimal difficulty in implantation and minimal discomfort. Future research will include evaluation of the IMES system for multifunction prosthesis control.

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