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Implantable Multichannel Wireless Electromyography for Prosthesis Control

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Abstract— **We have developed a prototype implantable device for recording multiple independent channels of EMG and sending those signals wirelessly to an external receiver. This design records multichannel EMG signals for providing simultaneous multi-axis control of prosthetic limbs. This proof-of-concept study demonstrates benchtop performance of the bioamplifier in dry and soaked in saline configurations, as well as system performance in a short-term in vivo study in six dogs. The amplifier was shown to have an input-referred noise of 2.2 μV$_{RMS}$, a common mode rejection ratio greater than 55 dB, and neighboring channel isolation averaging 66 dB. The prototype devices were constructed of an amplifier ASIC along with discrete components for wireless function. These devices were coated in silicone and implanted for at least one week in each dog. EMG recorded from each animal as it walked down a hallway had very low noise and swing/stance phases of gait were clearly shown. This study demonstrates this device design can be used to amplify and transmit muscle signals.**

I. Introduction

The challenge for controlling electronic prosthetic arm and hand systems is that a small number of control signals must be used to control multiple degrees of freedom in the limb. Commercially available myoprostheses use a pair of surface myoelectric signals detected from residual muscles to control serial motions of individual joints. Prosthesis motion is slow and poorly controlled, which patients cite as a leading factor in myoprosthesis rejection [1]. These limitations have also become increasingly relevant as newer prostheses with more sophisticated capabilities have been introduced.

Multichannel surface electrode arrays have been widely investigated as a means for extracting richer command signals from the muscles of the residual limb. For example, methods for recognition of discrete muscle patterns have been used to control transition between sets of characteristic hand grips in the prosthesis [2]. Surface array recordings can also be used with continuous signal processing to provide simultaneous proportional control of a limited number of degrees of freedom in the limb [3]. However, electrode array approaches are also inherently limited by the inability of surface electrodes to reliably record activity from deeper muscles and inconsistent signal quality due to varying skin conditions in the prosthesis socket. Moreover, the impact of these issues can increase in relation to the complexity of the information derived from the electrodes. These practical challenges have limited the development and translation of these advanced methods into commercial clinical devices.

Implantable sensors have been explored as a means of avoiding the problems associated with surface recordings. The Implantable Myoelectric Sensor (IMES) system proposed by Weir et al [4] uses small muscle recording implants injected into individual muscles of the residual limb. The implants receive power from a large telemetry coil placed around the limb, and transmit data back to the telemetry coil through reflected impedance modulation. The use of inductive powering allows the implants to draw power from the supply of the prosthesis, rather than requiring the complexity and limited device lifetimes associated with implanted batteries. Prototype versions of this system have been used to record multiple independent channels of muscle activity for prosthesis control [5]. However, the large inductive power fields created by the external coil present practical difficulties for overall efficiency. In addition, the implants must be parallel to and completely enclosed by the external coil, and this limits flexibility for surgical placement.

To overcome the challenges of surface electrodes and the limitations associated with the IMES system, we have developed a prototype multichannel EMG system using a centralized implant design with close-coupled telemetry. In this design the implanted transmitter receives inductive power from the external transceiver. The implant records muscle signals via electrode pairs implanted on individual muscles, and the device transmits data wirelessly back to the external receiver through reflected impedance signaling. This approach allows the flexibility to place and align the electrodes in various muscles independent of the telemetry component location.

In order to demonstrate the basic feasibility of this approach, we have developed a complete prototype version for short-term, in vivo testing. This system uses large implanted and external modules based on commercial, discrete components and ASIC (Application Specific Integrated Circuit) analog amplifiers. This prototype provides early validation prior to miniaturization required for a final clinical system.

II. Methods

A. Implant Design

In these prototypes each implant can be connected to four differential recording electrodes, along with a shorter electrode for ground equalization. The implant is constructed entirely on a double-sided, ceramic-filled printed circuit board with hard gold plating over copper. A 30 mm diameter telemetry coil is directly printed on the substrate as a twelve-

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turn, two-layer spiral coil with center tap. A 4.2 Mhz carrier frequency was used in the prototype for practical resonant operation with the larger prototype telemetry coils. As the implant and coils are reduced in size, the carrier will moved to the 6.78 Mhz ISM (Industry-Scientific-Medical) band. Power recovery is provided by a rectification and filtering network with regulation and comparators supply monitoring and power-on reset. All logic in the implant is implemented with a single Xilinx Coolrunner II CPLD (Complex Programmable Logic Device). Electrode leads are connected to the amplifier, filter, and multiplexer ASIC (Intan RHA2216 wire bonded die) through a RF pre-filter network. Amplified signals are digitized by a 12-bit A/D converter (AD7887) at 2000 samples per second, and control of the ASIC and A/D converter is managed by the CPLD. The CPLD encodes each set of four channel samples into a data packet with alignment and error checking bits. The serial telemetry data are encoded with differential Manchester coding for DC balance and used to drive the impedance modulation of the power circuits at 280 kbps. The prototype implant is shown below.

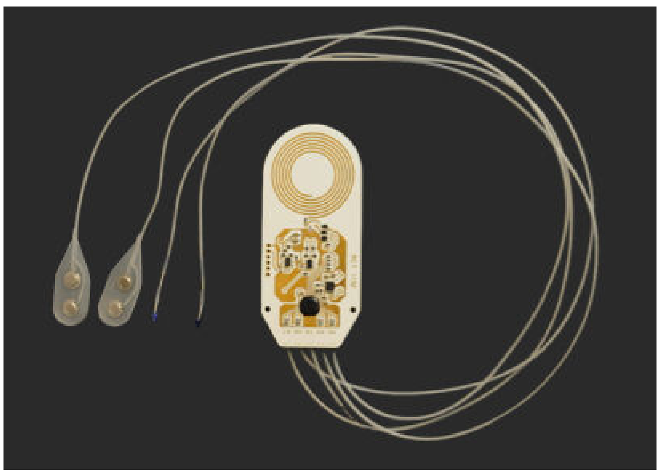

Figure 1. Prototype implant used for the preliminary *in vivo* validation study included discrete components for telemetry function, an ASIC amplifier, and four pairs of electrodes .

We used electrodes and leads similar to those developed at Case Western Reserve University (Cleveland, OH) for stimulation and recording from muscles for clinical myoelectric neuroprosthetic applications. The leads consist of a pair of multi-stranded stainless steel (316SS) wires helically coiled and wrapped in a 1.27-mm silicone tube. The band electrode configuration has a polypropylene tined fixation tip for insertion within a muscle and a pair of 4-mm coiled stainless steel wire band electrodes separated by 6 mm. The disc electrode configuration records from two 4-mm platinum alloy discs separated by 1 cm. The surrounding reinforced silicon suture apron was fixed at three points to the underlying muscle. We also used microwire electrodes made by exposing 5 mm of the stainless steel lead wire. The lead pairs were implanted into the muscle approximately 1 cm apart.

For encapsulation, the electronic components and ASIC die are plasma cleaned and coated with a conformal polymer sealant (Loctite FP4450). The electrodes are soldered to the board, and the entire assembly is coated in silicone (Nusil MED-4244) along with a polyethylene surgical mesh 3 mm larger than the implant perimeter to provide suture fixation points. An accelerated lifetime soak test was performed on each to confirm moisture resistance prior to implantation. No evidence of destructive water ingress was observed in the implants.

B. *External Transceiver Design*

The telemetry supply consists of a Class C driver powered by a small, adjustable switching regulator, allowing the transmitted power level to be adjusted. A four-turn, 45mm-diameter Litz-wire coil is driven by the power transmitter, with series resistance added to adjust the Q of the transmitter. All logic and control in the transceiver is provided by a Xilinx Spartan FPGA (Field Programmable Gate Array). The FPGA recovers, decodes, and parses the data packets from the implant and relays the digitized myoelectric signal data to a Ripple Grapevine data acquisition system. The data are then displayed and stored in the Grapevine Trellis software and imported to MATLAB for analysis and figure generation.

The housing for the external transceiver was designed to withstand the rugged use of an unrestrained, large dog. The transceiver housing was built from plates of acrylic fitted to shield the circuit board and coil with strain relief features for the data acquisition cable. For an eventual medical device the external transceiver be will re-designed to be much more compact.

C. *Input-Referred Noise*

Baseline implant input-referred noise was measured on all four inputs of a representative sample device under wireless power with inputs grounded. To conservatively measure the background noise of the complete system in saline along with noise contributions of different electrodes, a representative encapsulated device was evaluated with band and disc electrodes and a fine wire (75 µm) EMG stainless steel electrode pair with 5 mm electrode exposure.

D. *Common Mode Rejection Ratio*

Common Mode Rejection Ratio (CMRR) was measured on all four inputs of a representative sample device under wireless power with unused channels grounded. Input test signal was a 400mV$_{Pk\text{-}Pk}$ sine wave over the frequency range of 20 to 300 Hz. This CMRR was measured again as an *in vitro* simulation by constructing a saline bath with signal source electrodes at the ends of the bath to provide a gradient across the bath. The same band, disc, and wire electrodes were used as describe for the *in vitro* noise test. The implant body and ground electrode were placed in one side of the bath, and the electrodes under test were placed at the other side. The differential electrodes were oriented to be perpendicular to the axis of the test signal gradient. A second telemetry amplifier was used to adjust the source signal voltage so that the amplitude of the signal across the bath between the implant ground and electrodes under test was maintained at 10 mV$_{Pk\text{-}Pk}$. Test signals were recorded and cycle averaged for precision.

E. *Neighboring Channel Isolation*

For the neighboring isolation tests, a 400 mV sine wave was injected (common mode WRT ground) into each channel pair of a representative sample device under wireless power. Unused channels were connected to a 100 ohm impedance to ground and the recorded signals were measured at frequencies between 20 and 300 Hz. An *in vitro* isolation test was performed similar to the dry isolation test, but with band, disc, and wire electrodes connected to a representative implant assembly immersed in saline. Electrodes to be driven were individually removed from the saline and connected to the signal generator while comparison electrodes and a ground reference electrode remained in saline.

F. Surgical Implantation

We validated the implant design in a short-term chronic *in vivo* study in six dogs (50-60 kg) at the University of Utah Comparative Medicine Center. In the first animal a single, four-channel device was implanted unilaterally, and in the remaining five animals four-channel devices were implanted bilaterally.

Anesthesia was induced with propofol (6mg/kg, IV), an endotracheal tube placed and inhalation Isoflurane anesthesis (0.5-5%) was established. Anesthesia was monitored by evaluation of ECG, heart rate, temperature, SpO2, eye blink and ear flick reflex. IV access was established via a cephalic vein and saline solution administered during surgery. The skin over the incision sites was clipped and prepped for the sterile procedure.

To reduce potential surgical complications, the devices were implanted in the forelimb, instead of the hindlimb as outlined in the proposal. Loose skin around the shoulder blades is more accommodating for displacement by the implant than the skin around the hips. The 7 cm x 3.5 cm electronics package was implanted subcutaneously approximately 3 cm caudal to the scapula, and the potted circuit board was sutured into place at three reinforced fixation points. Electrodes were routed subcutaneously to the deltoideous and triceps muscles. In dogs, the triceps muscle extends the elbow during the stance phase of gait to propel the animal forward, and the deltoideous muscle raises the humerus during the swing phase. We implanted two channels of electrodes on to the deltoideous muscle, a channel of the lateral head of triceps, and a channel on the long head of triceps.

G. Wireless EMG Recording

Approximately one week after implantation (5-9 days) EMG signals were recorded while the animals walked down a 30-m hallway. To allow the animals to walk freely it was necessary to construct a backpack to carry a battery-powered data acquisition system (DAQ). Ripple has developed a portable battery-powered configuration of our Grapevine Neural Interface Processor that streams data to a flash drive. This seven-pound portable DAQ configuration was mounted to a commercially available backpack for large dogs. The remaining exposed surface of the backpack was covered with Velcro to allow the ready attachment of the transceivers directly over the implanted device. Synchronized video recordings were used to confirm swing/stance motions with the EMG signals recorded from the implant.

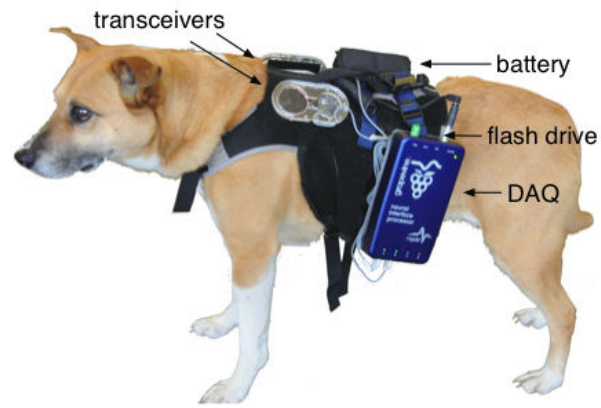

Figure 2. External transceiver/data acquisition system used for preliminary study. This prototype system is optimized for robust telemetry performance, and the eventual clinical device will be substantially reduced in size to fit all external components within a small section of the socket.

III. Results

A. Telemetry Performance

The implant and external transceiver prototypes provided robust power and data transfer with telemetry coil distances up to 5 cm and alignment offsets up to 2 cm. The transceivers were also tolerant of tilts up to 30 degrees. Overall power consumption for the system was under 300mW for most alignments. Power efficiency will be optimized in subsequent iterations of the system with new coil geometries.

B. Input-referred noise

Average noise referred to input across the four-channel device was 2.22 ± 0.03 μV_{RMS} (mean ± stdev) in a dry configuration. This is consistent with similar devices and ASIC amplifiers [4-5] and well within a minimum criterion of less than 5 μV_{RMS}. In the saline test, measured noise referred to input was 2.23 μV_{RMS} (band), 2.22 μV_{RMS} (disc), and 2.6 μV_{RMS} (wire). The noise was also unaffected by lead proximity to the telemetry inductive field and even consistent when the leads were wrapped around the telemetry coil area of the implant. This qualitatively demonstrates a high level of robustness of the prototype to EMI and other RF interference.

C. Common Mode Rejection Ratio

The CMRR in the dry and wet conditions for each electrode tested in the 20 to 300 Hz range was greater than 55 dB. To provide functional control input signals for a myoprosthesis it is necessary that CMRR must be greater than at least 40 dB.

D. Neighboring Channel Isolation

In the dry and wet measured isolation values at all frequencies were above the minimum criterion limit of > 40 dB. The average isolation was 67 ± 8 dB (mean ± stdev). No significant difference was measured between the dry configuration vs. band, disc, and wire electrodes in the wet

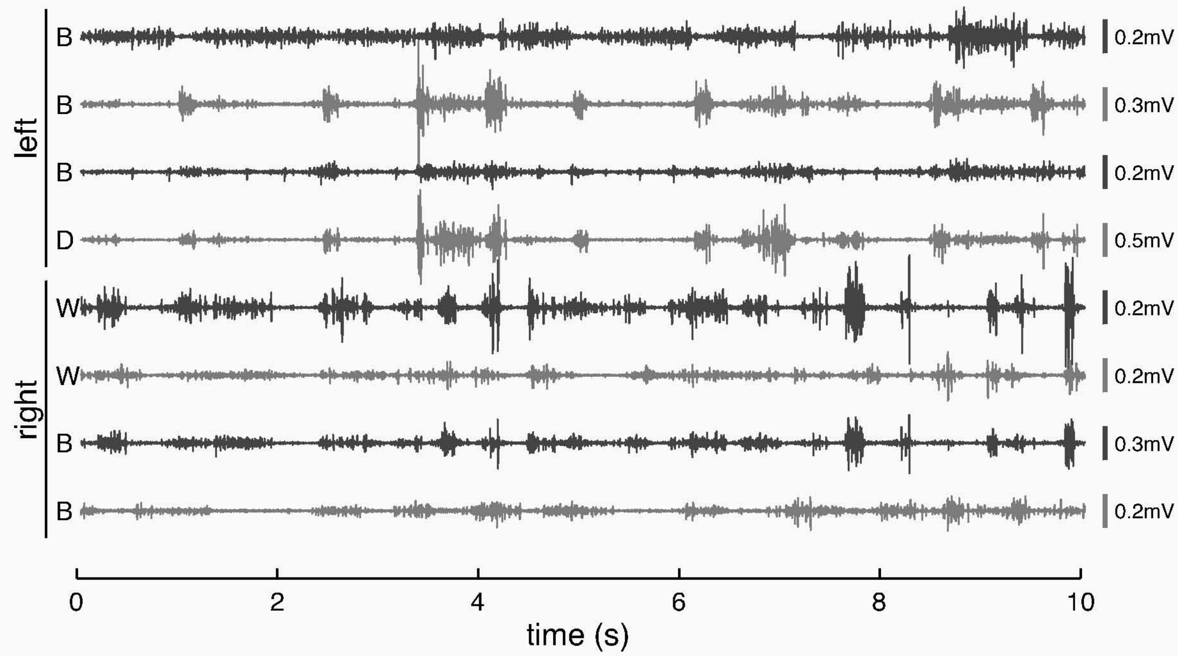

Figure 3. Sample EMG recording. electrodes recording triceps activity are indicated by the darker line; deltoideous is plotted with the lighter line. This graph indicate type of electrode by letters preceding the trace with D = disc, W = wire, and B = band. Scale bars on the right of each trace indicate amplitude scale.

configuration. This consistent performance indicates the device will not be susceptible to crosstalk from adjacent electrode leads

E. *In Vivo Study*

EMG data recorded with the device show very low noise and clearly represent characteristic sequential activity associated with swing/stance in gait. The sample EMG recording shown below demonstrates cyclical activity of bilateral deltoideous and triceps while the dog was walking. Although simultaneous multi-axis movement of a prosthetic arm will require recording the co-activation of several muscles, the example above clearly demonstrates the wireless amplifier system did not have problems with crosstalk from antagonist muscles. All 43 electrodes in 11 devices implanted in six dogs low noise EMG signals during this proof-of-concept study.

IV. Discussion

The device used in the study demonstrated low-noise recording on the benchtop in “worst-case scenario” configuration and robust performance in the *in vivo* trial. We are continuing development of this device towards the creation of an implantable medical device to control prosthetic limbs. This development will include miniaturization of the electronics package (approximately 13mm x 20mm x 3mm), verification of a long-term hermetically sealed ceramic enclosure, optimization telemetry efficiency, and accelerated lifetime testing of electrodes for a 10-year device lifetime. The external transceiver will also be miniaturized to fit in the socket of the prosthesis, and it will draw power from the myoprosthesis battery.

This device may be especially useful when used in conjunction with patients who have also had targeted muscle reinnervation (TMR) to attach peripheral nerves into the residual muscles. Electrodes could be placed to detect the reinnervated neural command signals and wirelessly transmit these multichannel data to an external receiver built into the prosthetic limb.

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