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TITLE: A Pilot Trial to Assess Implantable Myoelectric Sensors (IMES) to Improve Prosthetic Function for Transhumeral Amputees with Targeted Muscle Reinnervation

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CONTRACTING ORGANIZATION: Henry M. Jackson Foundation for Advancement of Military Medicine
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14. ABSTRACT
The overall project goal is to investigate the functional performance of transhumeral amputees who have received targeted muscle reinnervation with EMG signals measured intramuscularly using a fully wireless implant. During this year we completed design and testing of the both implant and base-station to show that the final form factors couple the required energy for normal operation and to show that data can be telemetered at the required data rate. Final system testing of 8 implants being wirelessly powered and transmitting data was verified within a transhumeral socket filled with simulated tissue was completed and the data were added to a FDA IDE submission.

15. SUBJECT TERMS
Recruitment, infrastructure, patient identification

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1. Introduction

The inadequacies of current prosthetic technologies severely limit rehabilitative options for upper limb amputees and contribute to the disability caused by upper limb loss. TMR presents new possibilities for control of upper limb prostheses, and, building on this success, our team has developed innovative technologies to address key remaining challenges in the design and control of advanced prosthetic systems. The overall objective of this grant is to improve functional independence for individuals with transhumeral amputees, who have had TMR using implantable MyoNodes. Our hypothesis is that chronic implants within reinnervated muscle will provide stable EMG recordings that will allow intuitive, simultaneous control of 3 DOF prosthesis system. Furthermore, we hypothesize that this technology will result in significant functional improvements for users as measured through the ACMC, SHAP, clothespin relocation, Jebsen Hand task, and box-and-block tasks.

Aim 1: Obtain a feasibility study investigational device exemption for the MyoNode system.
Extensive preliminary work has already been conducted to develop and test the MyoNode prototype, with demonstration of successful wirelessly powered and telemetered data from a tissue depth of 10 cm in an animal model. All design files have been transferred to Cirtec Medical Systems to create final form factor devices under GMP and are working with Med Institute Inc., to obtain a feasibility Investigational Device Exemption (IDE) from the FDA. The engineering, fabrication, and regulatory team has extensive experience in developing implantable medical devices.

Aim 2: Assess the accuracy with which transhumeral amputees can control isolated and simultaneous movements of a three DOF myoelectric prosthesis utilizing the MyoNode system after successful TMR surgery.

TMR has proven very useful for enhancing prosthesis control. However, to date, subjects have been limited to using surface EMG signals to control a prosthesis. Surface EMG is often corrupted by muscle cross-talk and instability in the skin-electrode interface necessitates frequent recalibration of controllers. We will recruit three individuals with transhumeral amputations and who have had TMR surgery. As our basic control platform, we will use natively innervated biceps and triceps to provide direct proportional control of the elbow, and we will try both direct control and pattern recognition of EMG from reinnervated muscles to control the wrist and hand. Subjects will complete 3-DOF Fitt's Law virtual testing to measure throughput of discrete and simultaneous measurements. We will also measure subjects' control of a physical prosthesis as they complete movements which require discrete and simultaneous movements. A commercially available prosthesis with an elbow, a wrist rotator, and a hand will be used in conjunction with commercially available pattern recognition software (Coapt LLC). The only variable will be the input signals; allowing us to compare performance using IM and/or surface EMG signals, and with data from other transhumeral TMR subjects using the pattern recognition controller with surface EMG (W81XWH 12-02-0072).

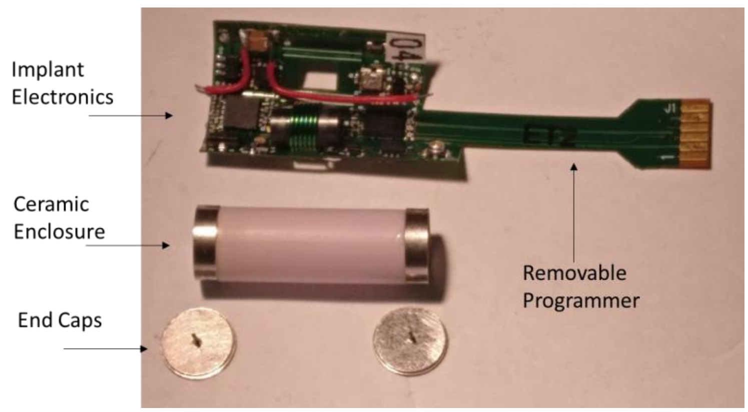
Aim 3: Determine the ability of transhumeral amputees to successfully perform functional activities using a three DOF myoelectric prosthesis control by the MyoNode system and TMR.

We hypothesize that the MyoNode implant system will improve control of the prosthesis, and that this will subsequently improve functional activities. We will measure functional performance prior to implantation and during training with the MyoNode system, using the SHAP, ACMC, a clothespin relocation task, the Jebsen task, and the box and blocks task. We will also provide the subjects with a questionnaire for subjective feedback at the end of the study.

In our original project plan, The MyoNode System was planned to be ready for implantation by March 2016, allowing for adequate time for FDA approval and to complete the three aims within the 4 year trial period. However, delays in project start date due to the contracting process has delayed our plan. Fortunately, we were able to complete significant technology development during the contracting delays as part of other ongoing work so that the overall project schedule impact should be minimized.

2. Body

Over the past year, we primarily worked to address feedback that we received from our FDA IDE presubmission meeting and the ensure that we address appropriate concerns in FDA draft guidance for development of implanted neuroprostheses that was released earlier this year. We first fabricated and performed system testing on 2 implant designs. Both implants used the same core operating principles and off-the-shelf electronics; however they differed in their component placement and manufacturing processes. The first implant used a foldable and flexible printed circuit board, with the power coupling coil located in the center of the design (Figure 1). When folded, this could be placed inside of a ceramic enclosure and attached to 2 electrodes (Figure 2).



1)

Figure 1: The components required to assemble the MyoNode Implant.

Figure 2: Folder Implant Design

When received, the implant is programmed with the required firmware, and the inputs to the amplifiers are attached to the electrodes that are incorporated into the ceramic enclosure. Next, the programming tab is removed, and the implant is folded and inserted into the ceramic enclosure, and then the end caps are attached to the implant. This implant was placed into a socket with the geometry of a transhumeral amputee that had a power coupling coil embedded into the construction (Figure 3).

Figure 3: Socket sized for a large transhumeral amputee with an embedded powering coil.

A testing apparatus was built so that the implants could be positioned to spatially sample to volume enclosed by the socket. We systematically measured the energy coupled into the implant and measured the quality of the data telemetry link through free-space and simulated tissue.

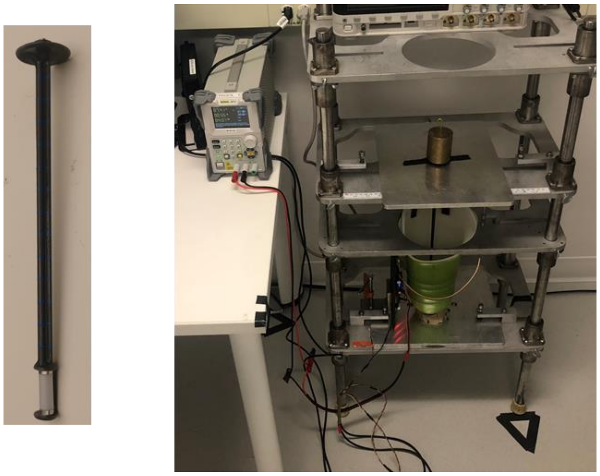


Figure 4: On the left, the implant is attached to a test fixture. The right shows the test apparatus used in the depth power transfer test.

As a result of these tests we determined that the wireless energy coupling circuitry worked as expected and the implant could be powered on when placed in the socket; however, we noted that the data telemetry link functioned poorly within certain locations. Further analysis of the anomaly pointed to one of 2 root causes: 1) the folding of the printed circuit board around the 2.4 GHz telemetry antenna was attenuating the signal, or 2) the firmware did not include sufficient error-correction in the data telemetry protocol.

As a result of these tests, we completed a revision of the implant to move away from reliance on the folded printed circuit board. Instead, we moved to a flat, 2 sided printed circuit board that attached to the powering coil at the distal end. We also created a larger version of the implant, which we refer to as the implant development board, to ensure that the firmware could be tested to ensure reliable data telemetry. This is functionally equivalent to the implant, but is easier to program, debug, and perform verification testing. We again fabricated a set of implants according to this new layout and replicated similar testing as described above (Figures 5-7).

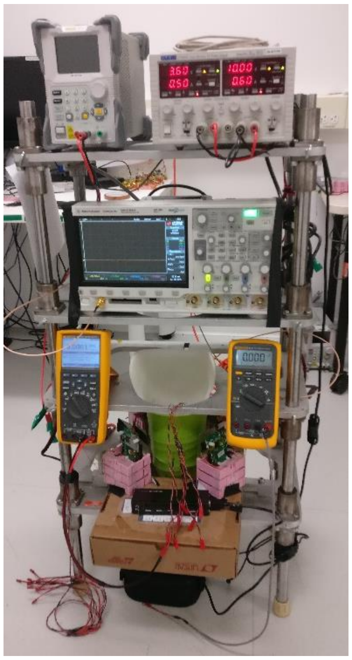


Figure 5: General Setup. Green socket in center contains the inductive coil.

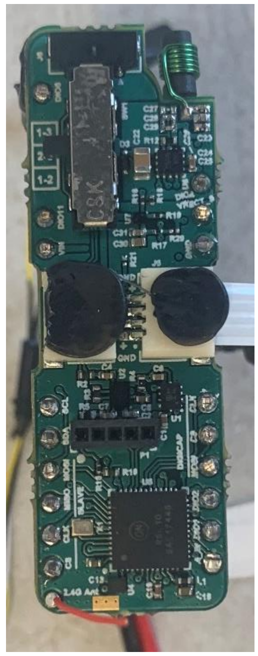


Figure 6: Implant Development Board

Figure 7: Implant and Ceramic Housing

The result of testing this implant again showed excellent power coupling within the volume encompassed by the socket, through free air, and simulated tissue, even when the implant was tilted by up to 30 degrees off the alignment axis. We implanted a custom Bluetooth low-energy data telemetry protocol to take advantage of the error-correction aspect of the Bluetooth communication protocol. When the paired 1 or 2 implants were paired with a single receiver chip on the base-station we noticed excellent throughput; however, when 1 received chip on the base-station was paired with 8 implants, we noticed performance drops. Consequently, we made the design decision to add 8 receiver chips on the base-station. This will not be a problem as they are addressable over the SPI communication bus, small (<2.5 mm x 2.5 mm chip-size) and power efficient (<10 mW of power consumption). As a result of these tests, we locked in the implant design and released drawings to the manufacturer for construction of the implants.

Finally, with the final implant package completed and testing verified, we were able to complete design of the base-station. We prioritized a base-station that was self-contained, meaning that we do not want the users to need to carry any additional componentry, or use a tether to power/control the resulting Myonode System. The resulting base-station design in shown in Figure 8.

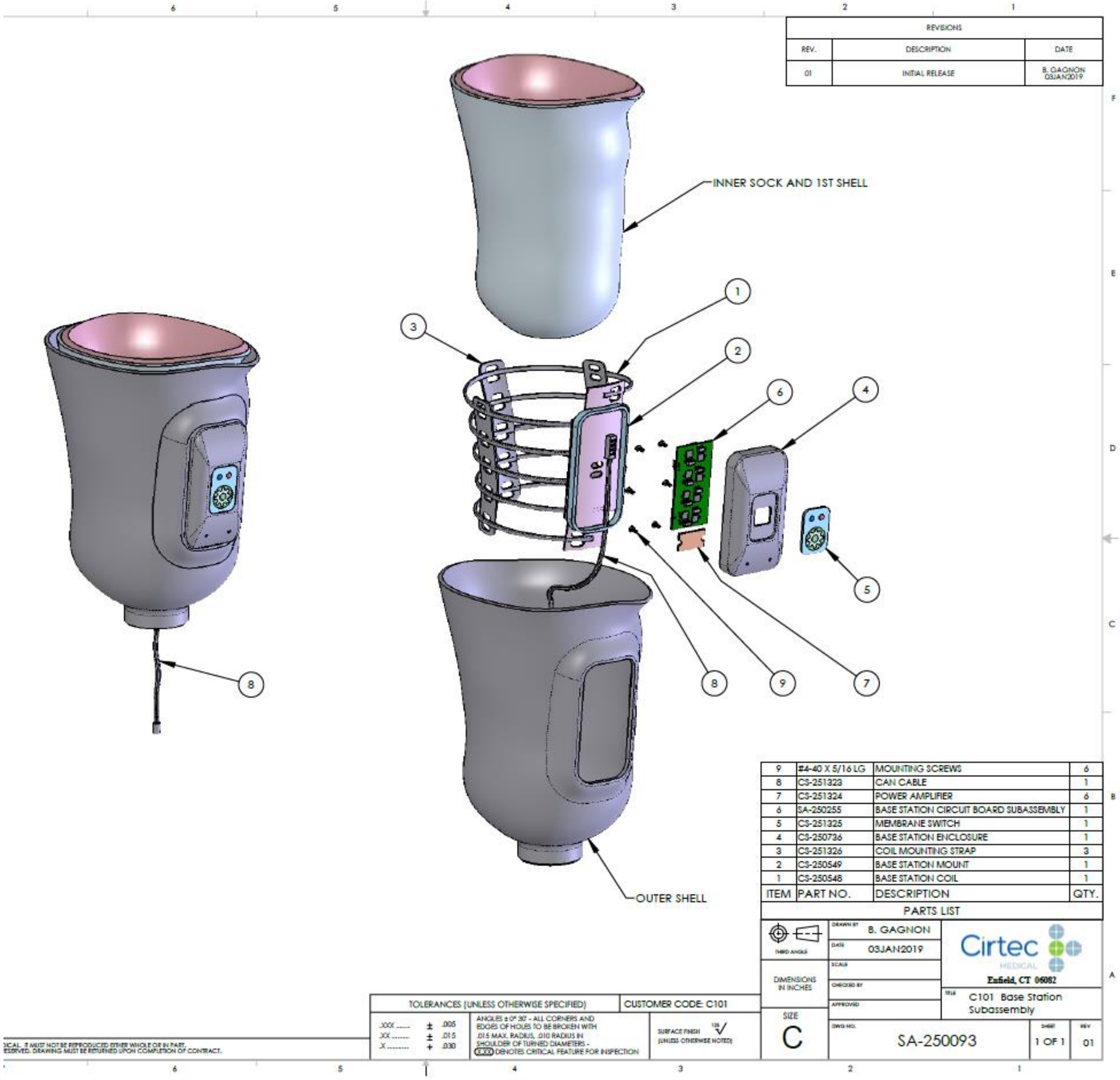


Figure 8: MyoNode base-station design.

During the base-station design process we engaged prosthetists to ensure that it would be easy to incorporate into their standard practices and verified that the design could dissipate any heat generated by the electronics systems through thermal tests. As a result of the efforts made this year, we feel that we have addressed major feedback provided by the FDA and will soon submit for an early feasibility study IDE.

3. Key Research Accomplishments

***** Performed validation and verification testing on the implant

4. Reportable Outcomes and Conclusions

The critical technical developments for the MyoNode project is now complete. The implant design is locked in and long-lead time components are now being procured. Overall, the project is still on budget but is behind schedule. There are a number of contributing factors, but the single biggest issue was in completing the testing suggested by the FDA in response to the IDE presubmission meeting. We do anticipate requiring a no-cost-extension to complete the clinical portion of the work.

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A Pilot Trial to Assess Implantable MyoNodes to Improve Prosthetic Function for Transhumeral Amputees after Targeted Muscle Reinnervation
W81XWH-16-2-0009

PI: Paul F. Pasquina, MD **Org:** Henry M. Jackson Foundation **Award Amount** $2,622,160

Study Purpose / Deliverables

Current prosthetic technologies severely limit rehabilitative options for upper limb amputees and contribute to the disability caused by upper limb loss. Targeted muscle reinnervation (TMR) presents new possibilities and the overall objective of this grant is to improve functional independence for individuals with transhumeral amputees, who have had TMR using implantable MyoNodes.

Study Aims

Aim 1: Investigational device exemption for the MyoNode system.
Aim 2: Assess the accuracy and control of a 3 DOF myoelectric prosthesis utilizing the MyoNode system after TMR surgery.
Aim 3: Determine the ability of transhumeral amputees to successfully perform functional activities using a three DOF myoelectric prosthesis control by the MyoNode system and TMR.

Accomplishments: During this quarter, verified that the changes to the PCB addressed he problems associated with data telemetry and performed wireless powering and data telemetry testing of 8 implants simultaneously inside of a socket geometry for a transhumeral amputee.

Timeline and Cost

Activities FY	16	17	18-20
Execute subaward agreements			
Complete development work			
Obtain IDE from the FDA			
Evaluate technology and publish findings			
Estimated Budget ($K)	**$2100**	**$250**	**$250**

Updated: 15 May 2019

Goals/Milestones

FY16 Goals
☑ Execute subaward agreements between institutions
☑ Technical Demonstration of MyoNode Technology

FY17 Goals
☑ Complete MyoNode Developmental Work
☐ Obtain investigational device exemption (IDE) from the FDA

FY18-20 Goals
☐ Obtain institutional review board (IRB) approval
☐ Assess the accuracy of the MyoNodes system after TMR
☐ Perform functional test with the MyoNodes system
☐ Complete the final study report and publish findings

Budget Expenditure to Date: $2,042,498
Projected Expenditure: $2,622,160