

**AWARD NUMBER:** W81XWH-17-1-0431

**TITLE:** Comparative Effectiveness of Various Interface Designs and Control Methodologies for Myoelectric Prostheses

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# REPORT DOCUMENTATION PAGE

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| <b>13. SUPPLEMENTARY NOTES</b>  |  |   |   |  |   |
| <b>14. ABSTRACT</b><br>The purpose of this project is to better understand the clinical impact of various upper extremity myoelectric prosthesis control methodologies and socket interface designs to improve evidence-based practice. |  |   |   |  |   |
| <b>15. SUBJECT TERMS</b><br><br>NONE LISTED   |  |   |   |  |   |
| <b>16. SECURITY CLASSIFICATION OF:</b>  |  |   | <b>17. LIMITATION OF ABSTRACT</b><br><br>Unclassified | <b>18. NUMBER OF PAGES</b><br><br>11               | <b>19a. NAME OF RESPONSIBLE PERSON</b><br>USAMRMC |
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**1. INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

Despite the advancements in upper extremity myoelectric prosthesis interface and control methodology, little evidence exists to help the practitioner determine the most effective system combination for their particular patient. Further, advanced technologies continue to be reimbursed using miscellaneous L5999 Medicare codes, thus limiting the widespread use of the new technology given the current reimbursement climate. The purpose of this study is to evaluate and compare the short- and long-term effectiveness of existing and emerging interface designs and control methodologies to provide objective and subjective data to guide evidence based practices, as well as to present the latest research to third-party payers in order to make the best technologies available to those most in need. The research will include 20 transradial amputee subjects completing a randomized crossover study including three conditions; 1. Traditional control with electrodes embedded into a rigid socket, 2. Pattern recognition control with electrodes embedded into a rigid socket, 3. Pattern recognition with electrodes integrated in a gel liner (myoliner).

**2. KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

Myoliner, myoelectric prosthesis, pattern recognition, direct control, conventional control

**3. ACCOMPLISHMENTS:**

**What were the major goals of the project?**

1. Complete training of the test center personnel to ensure consistent execution of the study design across every facility.
2. Determine the short- and long-term effects of interface design and control methodology on objective functional performance measures.
3. Determine the short- and long-term effects of interface design and control methodology on subjective outcome measures.
4. Determine the impact on socket fitting, fabrication and training time for each study condition.

## What was accomplished under these goals?

Major Activity 1: Obtain IRB and HRPO approval.

Specific Objectives: Submit protocol and facilities information to Chesapeake IRB. Once approved, submit the approved documents to HRPO for review and approval.

Results: After the first year of the award, the team had CIRB and HRPO approval for 4 clinical sites which include Ability P&O, Optimus Prosthetics, Handspring, and Motus. The team also had CIRB approval from the Shirley Ryan Ability Lab and Sampsons P&O. During the past year, HRPO approval was acquired for these two sites.

Major Activity 2: Execute subcontracts with the various clinical sites.

Specific Objectives: Review and sign agreements.

Results: In addition to the subcontracts executed in Year 1, the team executed a subcontract with Ability P&O at the beginning of this performance period.

Major Activity 3: Investigate the effect of study conditions on subjective and objective data.

Specific Objectives: Recruitment of subjects and data collection

Results: Since the end of September 2018, the team has recruited and enrolled an additional 9 subjects. This addition brings the total enrollment to 16 subjects. Current enrollment at each site is as follows:

- Ability P&O = 3 subjects
- Handpring = 6 subjects
- Motus = 2 subjects
- Optimus = 5 subjects

Completion of the data collection procedures continues to progress. So far, Condition A data collection has been completed for 10 subjects, Condition B data collection has been completed for 3 of those subjects with an additional 4 through the initial data collection for Condition B, and 2 subjects have completed the initial collection for Condition C. The remaining subjects are being fit and trained with the appropriate study condition. Blinded data analysis continues on the collected data.

## What opportunities for training and professional development has the project provided?

The WillowWood team provided training to O&P practitioners on the use of the Myoliner, a new technology for upper extremity myoelectric prosthesis users. The practitioners learned about patient selection, sizing, fitting and delivering a socket for the myoliner, and troubleshooting any problems. In addition to the Myoliner training, these practitioners were also provided training on conducting the AMULA clinical outcome measures test. This training will be useful for the completion of the project, as well as promoting evidence based care in the future.

**How were the results disseminated to communities of interest?**

Nothing to report as the results are still blinded until subjects complete all 3 conditions.

**What do you plan to do during the next reporting period to accomplish the goals?**

In the next reporting period, we will continue to recruit addition subjects as we work to reach our goal of 20 subjects. In addition to these newly recruited subjects, we will continue the data collection procedures on all consented subjects. Blinded data analysis will continue to be performed as the data is received to avoid a backlog of data analysis near the end of the project.

**4. IMPACT:**

**What was the impact on the development of the principal discipline(s) of the project?**

We have seen an acceptance of the outcomes testing during the study as participating prosthetists gain confidence executing the data collection procedures. The groups have developed effective systems to complete the procedures. We expect these systems for data collection to grow into their everyday practice to help support clinical decisions and reimbursement.

**What was the impact on other disciplines?**

Nothing to report.

**What was the impact on technology transfer?**

Nothing to report.

**What was the impact on society beyond science and technology?**

Nothing to report.

**5. CHANGES/PROBLEMS:**

While recruitment started at a fast pace, we have seen a slower pace in recruitment progress as we near our goal of 20 subjects. We need to recruit 4 more subjects in the last year and complete the procedures for all remaining subjects. We have found the fitting and training of each condition has taken longer than expected, but this time has reduced as study sites get more comfortable with the procedures.

**Changes in approach and reasons for change  
Actual or anticipated problems or delays and actions or plans to resolve them**

An anticipated problem that may occur is trouble recruiting the 4 remaining subjects into the study. We are taking several actions to stay in front of this anticipated problem. Dr. Wernke sent an email to each study site to inform them we are entering the final year of the award and to review the status of each subject at their site. This was followed up with a telephone or in-person conversation with each investigator and a plan to complete each subject and recruit additional subjects was discussed.

**Changes that had a significant impact on expenditures**

Nothing to report.

**Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

**Significant changes in use or care of human subjects**

Nothing to report.

**Significant changes in use or care of vertebrate animals**

Nothing to report.

**Significant changes in use of biohazards and/or select agents**

Not applicable.

**6. PRODUCTS:** *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state “Nothing to Report.”*

- **Publications, conference papers, and presentations**

**Journal publications.**

Nothing to report.

**Books or other non-periodical, one-time publications.**

Nothing to report.

**Other publications, conference papers and presentations.**

Nothing to report.

- **Website(s) or other Internet site(s)**

Nothing to report.

- **Technologies or techniques**

Nothing to report.

- **Inventions, patent applications, and/or licenses**

Nothing to report.

- **Other Products**

Nothing to report.

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

### What individuals have worked on the project?

|                                     |   |
|-------------------------------------|---|
| <i>Name:</i>                        | <i>James Colvin</i>   |
| <i>Project Role:</i>                | <i>PI</i>   |
| <i>Nearest person month worked:</i> | <i>3.1</i>  |
| <i>Contribution to Project:</i>     | <i>Mr. Colvin has led the grant effort, overseeing communications with the test facilities, executing agreements, and participating in the site training preparation and execution.</i> |
| <br>                                |   |
| <i>Name:</i>                        | <i>Matt Wernke</i>  |
| <i>Project Role:</i>                | <i>Co-I</i>   |
| <i>Nearest person month worked:</i> | <i>3.3</i>  |
| <i>Contribution to Project:</i>     | <i>Dr. Wernke has led the subject testing and data analysis. He assembled the AMULA test kits and prepared study procedures, instructions, and checklists for the test facilities.</i>  |

**Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

Nothing to report.

**What other organizations were involved as partners?**

Organization Name: Ability P&O

Location of Organization: Participating offices located in Hanover, PA, Hagerstown, MD, Mechanicsburg, PA, Frederick, MD, York, PA, Rockville, MD, Exton, PA, Charlotte, NC, Asheville, NC, and Royersford, PA.

Partner's contribution to the project: Collaboration on the research. Recruitment of subjects, fit and delivery of study conditions, execute outcomes collection, upload data for analysis.

Organization Name: Optimus Prosthetics

Location of Organization: Participating office located in Dayton, OH.

Partner's contribution to the project: Collaboration on the research. Recruitment of subjects, fit and delivery of study conditions, execute outcomes collection, upload data for analysis.

Organization Name: Handspring

Location of Organization: Participating offices located in Salt Lake City, UT and Middletown, NY.

Partner's contribution to the project: Collaboration on the research. Recruitment of subjects, fit and delivery of study conditions, execute outcomes collection, upload data for analysis.

Organization Name: Motus

Location of Organization: Participating office located in Indianapolis, IN.

Partner's contribution to the project: Collaboration on the research. Recruitment of subjects, fit and delivery of study conditions, execute outcomes collection, upload data for analysis.

## **8. SPECIAL REPORTING REQUIREMENTS**

**COLLABORATIVE AWARDS:**

**QUAD CHARTS:** See attached.

## **9. APPENDICES:**

Comparative Effectiveness of Various Interface Designs and Control Methodologies for Myoelectric Prostheses  
 Quad Chart  
 W81WXH-16-OPORP-PORA (Research Level 3)



PI: James Colvin

Org: The Ohio WillowWood Company

Award Amount: \$1,067,854

**Study/Product Aim(s)**

**Aim 1:** Complete training of the test center personnel to ensure consistent execution of the study design across every facility.  
**Aim 2:** Determine the short- and long-term effects of interface design and control methodology on objective functional performance measures. **Aim 3:** Determine the short- and long-term effects of interface design and control methodology on subjective outcome measures. **Aim 4:** Determine the impact on socket fitting, fabrication and training time for each study condition.

**Approach**

The research team proposes a randomized crossover longitudinal study to compare objective functional performance measures and subjective user responses of upper-extremity amputee participants wearing different myoelectric interface designs employing different control methodologies. During each of the testing visits, a combination of objective and subjective outcome measures will be collected.



Dexterous prosthetic hands are on the market but their functionality is restricted. Pattern recognition algorithms are becoming more popular to increase functionality of these systems. The most significant challenge for pattern recognition algorithms is that they require increasingly noise-free EMG signals., which may best be achieved through a gel liner with embedded electrodes and mechanical/electrical connection.

**Timeline and Cost**

| Activities                      | CY | 17            | 18           | 19           | 20           |
|---------------------------------|----|---------------|--------------|--------------|--------------|
| Complete Training (Aim 1)       |    |               |              |              |              |
| Functional Performance (Aim 2)  |    |               |              |              |              |
| Subjective Responses (Aim 3)    |    |               |              |              |              |
| Time of Socket Delivery (Aim 4) |    |               |              |              |              |
| <b>Estimated Budget (\$K)</b>   |    | <b>\$15.5</b> | <b>\$121</b> | <b>\$550</b> | <b>\$381</b> |

**Goals/Milestones**

**CY17 Goals** – Obtain human subject testing approval

Obtain IRB approval

**CY18 Goals** – Initiate comparative effectiveness study

Obtain HRPO approval

Complete the training of all test sites

Recruit subjects and begin test procedures

**CY19 Goals** – Continue comparative effectiveness study

Continue data collection

Complete recruitment of subject

**CY20 Goals** – Complete comparative effectiveness study

Complete data collection and data analysis

Report final results

**Comments/Challenges/Issues/Concerns**

• None.

**Budget Expenditure to Date**

Projected Expenditure: \$1,067,854

Actual Expenditure: \$455,573.79

Updated: October 24<sup>th</sup>, 2019