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

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CONTRACTING ORGANIZATION: The Ohio Willow Wood Company, Mt. Sterling, OH

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6. AUTHOR(S)

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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

The Ohio Willow Wood Company
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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

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12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

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.

15. SUBJECT TERMS
None listed.

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	11	19b. TELEPHONE NUMBER *(include area code)*

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1. INTRODUCTION:

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:

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: 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 2020, the team has completed recruitment and enrolled the final subjects. This addition brings the total enrollment to 20 subjects as 2 subjects dropped out of the study during the previous year. Current enrollment at each site is as follows:

- Ability P&O = 4 subjects
- Handspring = 9 subjects
- Motus = 3 subjects
- Optimus = 4 subjects

Completion of the data collection procedures continues to progress. Condition A data collection has been completed for 19 subjects, Condition B data collection has been completed for 17 subjects, and 13 subjects have completed the entire study. The remaining subjects are being fit and trained with the appropriate study condition. Blinded data analysis continues on the collected data.
No further data summary has been completed at this time beyond the summary of 10 subjects presented in Year 4 Quarter 2 report. The next planned analysis is after 15 subjects have completed the entire study.

Major Activity 2: Investigate the effect of study conditions on subjective and objective data.
Specific Objectives: Disseminate results.
Results: Data from the first 10 subjects to complete the study was analyzed and presented virtually at the 2021 American Academy of Orthotists and Prosthetists
(AAOP) annual meeting in May.

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.

The myoliner platform has also given engineering interns at WillowWood the opportunity to learn about PCB board design and manufacturing process while producing systems for the study subjects.

How were the results disseminated to communities of interest?

A virtual presentation was given to the 2021 AAOP annual meeting in May based on data from the first 10 subjects.

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

In the next reporting period, we plan to complete Condition A data collection for all study subjects. Further, we plan to complete the entire study for the first 15 subjects. The data from the first 15 subjects will be scored and unblinded for reporting.

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. Further, many prosthetists have seen the team's presentation and have inquired further about use of the myoliner for their patients.

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:

The pandemic halted human subject testing in March of 2020, which caused a delay in testing. It also resulted in the drop out of one subject due to concerns about leaving isolation. These challenges have persisted much longer than originally anticipated and are in part exacerbated by a backlog of patients outside of the research study that require the practitioners' attention.

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

An anticipated problem is continuing progress on the project given the challenges with the pandemic and the length of the study. The WillowWood team is communicating regularly with the study sites and all partners continue to have high commitment to the study. The team will continue to work together to ensure subjects complete the study procedures. As a result of the delays caused by the pandemic, we secured a 1-year No Cost Extension for the project in order to complete the project goals.

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:

- **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.

Wernke M, Katzenberger L, Schober G, Denune J, Haynes M, Tollett A, Colvin J. Comparison of Upper Extremity Myoelectric Interface and Control Methodologies: A Preliminary Report from the Halfway Point. 2021 AAOP Virtual National Assembly. May 7.

Wernke M, Katzenberger L, Schober G, Denune J, Haynes M, Tollett A, Colvin J. Comparison of Upper Extremity Myoelectric Interface and Control Methodologies: A Preliminary Report from the First Five. 2020 AOPA Virtual National Assembly. Sept 10.

- **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?

Name:	*James Colvin*
Project Role:	*PI*
Nearest person month worked:	*4.0*
Contribution to Project:	*Mr. Colvin has led the grant effort, overseeing communications with the test facilities, executing agreements, and participating in the site training preparation and execution.*
Name:	*Matt Wernke*
Project Role:	*Co-I*
Nearest person month worked:	*7.4*
Contribution to Project:	*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.*

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)

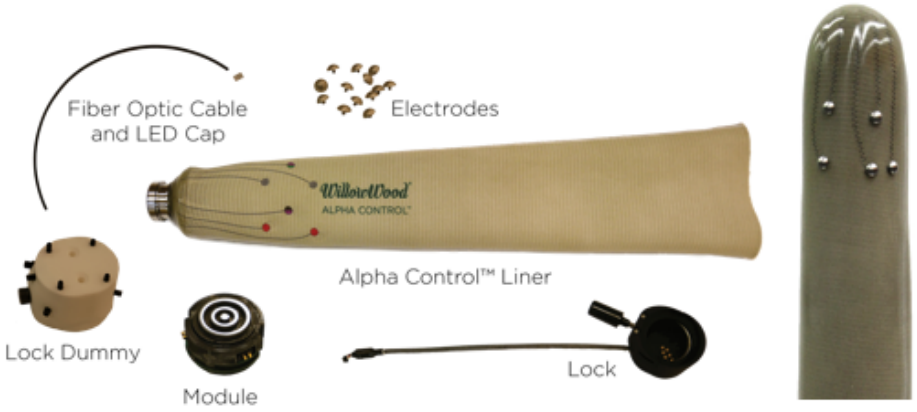
PI: James Colvin, MS **Org:** The Ohio WillowWood Company **Award Amount:** $1,067,854

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 magnetic electronic connection.

Timeline and Cost

Activities / CY	17	18	19	20	21	22
Complete Training (Aim 1)						
Functional Performance (Aim 2)						
Subjective Responses (Aim 3)						
Time of Socket Delivery (Aim 4)						
Estimated Budget ($K)	**$15.5**	**$121**	**$371**	**$192**	**$282**	**$86**

Updated: October 11th, 2021

Goals/Milestones

CY17 Goals – Obtain human subject testing approval
☑ Obtain IRB approval
CY18 Goal – 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
CY20 Goal – Continue comparative effectiveness study
☑ Complete first 5 subjects and present preliminary results
☑Complete recruitment
CY22 Goal – Complete comparative effectiveness study
☐ Complete data collection and data analysis and report final results

Comments/Challenges/Issues/Concerns

- None.

Budget Expenditure to Date

Projected Expenditure: $ 1,067,854
Actual Expenditure: $945,805.57