

AWARD NUMBER: W81XWH-17-1-0431

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

PRINCIPAL INVESTIGATOR: James Colvin MS

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

REPORT DATE: January 2023

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release;
Distribution Unlimited.

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE*Form Approved*
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

1. REPORT DATE January 2023		2. REPORT TYPE Final		3. DATES COVERED 29Sep2017-28Sep2022	
4. TITLE AND SUBTITLE Comparative Effectiveness of Various Interface Designs and Control Methodologies for Myoelectric Prostheses				5a. CONTRACT NUMBER W81XWH-17-1-0431	
				5b. GRANT NUMBER	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) James Colvin, MS; Matt Wernke, PhD E-Mail: jim.colvin@willowwood.com; matt.wernke@willowwood.com				5d. PROJECT NUMBER 0011039163	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) The Ohio Willow Wood Company 15441 Scioto Darby Rd Mt. Sterling, OH 43143				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Development Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S) DoD	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
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 Unclassified	18. NUMBER OF PAGES 39	19a. NAME OF RESPONSIBLE PERSON USAMRDC
a. REPORT Unclassified	b. ABSTRACT Unclassified	c. THIS PAGE Unclassified			19b. TELEPHONE NUMBER (include area code)

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

TABLE OF CONTENTS

	<u>Page</u>
1. Introduction	1
2. Keywords	1
3. Accomplishments	1
4. Impact	15
5. Changes/Problems	16
6. Products	17
7. Participants & Other Collaborating Organizations	18
8. Special Reporting Requirements	18
9. Appendices	20

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 goal of this research was to evaluate 20 transradial amputee subjects completing a randomized crossover study including three conditions; 1. Traditional control with electrodes embedded into a rigid socket (Direct), 2. Pattern recognition control with electrodes embedded into a rigid socket (PR), 3. Pattern recognition with electrodes integrated in a gel liner (PR+Liner).

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: Complete training of the test center personnel to ensure consistent execution of the study design across every facility.

Results: A 1-day training course was designed to educate the test centers on the myoliner as well as the specific details related to study execution and to practice the AMULA. The details relating to study execution covered subject inclusion/exclusion criteria, the flow of the study, the timing of data collection, where and when data will be saved, how study compensation will work, and expectations from WillowWood and the sites. On July 24th 2018 all study sites had completed the training seminar.

Following this training, the study sites were able to complete the study procedures. The initial enrollment target for the study was 20 subjects. Due to subject dropout, primarily in response to the Covid-19 pandemic, the sites together recruited a total of 21 subjects (Table 1). A total of 16 subjects completed data collection for all three study conditions. The breakdown for enrollment and retention is as follows:

Site # 1: Handspring POA – 10 total subjects. Subjects participated from their Middletown, NY office (9 of the 10 subjects) and Salt Lake City, UT office (1 of the 10 subjects). Eight of the ten subjects completed all three conditions. One of the two subjects that did not complete the entire study, did attempt all three conditions. However, the team was unable to deliver one of the conditions successfully, therefore no data was collected. The team excluded this from the data analysis.

Site #2: Optimus – 4 total subjects. All subjects participated from their Dayton, OH office. Three of the four subjects completed all three conditions.

Site #3: Ability – 4 total subjects. Subjects participated from their Exton, PA office (2 of the 4 subjects) and Frederick, MD office (2 of the 4 subjects). Two of the four subjects completed all three conditions.

Site #4: Motus – 3 total subjects. All subjects participated from their Indianapolis, IN office. All subjects completed all three conditions.

Major Activity 2: Determine the short- and long-term effects of interface design and control methodology on objective functional performance measures.

Results: The study included two functional outcomes measures that were scorer blinded. The primary functional outcome measure was the Activities Measure for Upper Limb Amputees (AMULA). The AMULA includes 18 tasks of daily living (Table 2). The tasks are scored on a 0-4 scale across five domains: completion of task, speed of completion, movement quality, skillfulness of prosthesis use, and independence. The lowest score in any of these domains becomes the score for that task. The scores are combined into a composite score for each condition. The PR+Liner condition (using the Control Liner) had the highest scores at both initial and final data collection points compared to the other two conditions (Figure 1). At the final data collection point, these differences were statistically significant ($p=0.001$ when compared to direct control and $p=0.01$ when compared to pattern recognition control without the Control Liner). At the initial data collection point, there was also a significant difference between the PR and PR+Liner condition ($p=0.01$). It was near significant at that data point between Direct and PR+Liner ($p=0.07$).

The AMULA results provide evidence that the biggest impact on performance was due to the interface condition as opposed to the control algorithm. This makes sense from the relatively short in-lab test that the AMULA is. The value proposition of the Control Liner is more consistent electrode contact which would directly impact the performance of this in-lab test. There may be additional differences between controllers that are not fully exposed during this test. That said, the PR condition did yield the second highest results, but these differences between Direct and PR did not reach any level of significance.

The second functional outcome measure was elbow range of motion. The maximum flexion and maximum extension angles were measured by the prosthetists using a goniometer both with and without the prosthesis. Results are reported as the range of motion with the prosthesis (pro) divided by the range of motion without the prosthesis (no pro). The results found that elbow range of motion was on average ~10% higher when using the PR+Liner condition compared to the other two (Figure 2). The Control Liner enabled some prosthetists to design the socket different than the other two conditions, neither of which had a liner, thus impacting the results and explaining why there was not much difference between the Direct and PR condition. Prosthetists reported eliminating the olecranon bar typically found in transradial prosthetic socket or replacing the rigid bar with an adjustable strap for the PR+Liner condition. Further, prosthetists reported relaxing the amount of socket volume reduction since the Control Liner provided suspension of the prosthesis. Both of these factors were the primary drivers for the difference in elbow range of motion. While these results did not hit statistical significance, they were near significant. At initial data collection, the Direct to PR+Liner comparison had a p value = 0.09 and the PR to PR+Liner had a p-value = 0.06. These same comparisons had a p-value of 0.054 and 0.08 at final data collection respectively. The team identified a large variation, where some subjects had a large reduction in elbow range of motion when using the PR+Liner condition, likely due to the fit of the socket. In these instances, socket comfort was rated lower by the subject. At the start of the study, this technology was new for many of the prosthetists. This suggests there may be a learning curve when beginning to use the Control Liner as the prosthetist should not fit the socket the same way as if they were fitting a skin fit socket. Perhaps the results of this work will help minimize the learning curve for future users.

Major Activity 3: Determine the short- and long-term effects of interface design and control methodology on subjective outcome measures.

Results: The study included six subjective outcomes measures. Four sections of the Orthotic and prosthetic User Survey (OPUS) were used. These include the Upper Extremity Functional Scales, the Health Quality of Life, Satisfaction with Device (Primary subjective outcome), and Satisfaction with Services sections. The McGann Feedback form was also included as it mirrored the primary section of the OPUS and thus should provide some similarity in results. Lastly, the socket comfort score was recorded.

The results indicated no significant difference between any of the conditions for all surveys (Figures 3-8). The primary survey, the Satisfaction with Device did not follow a similar trend as the McGann Feedback Form, which asks similar questions. Although the Satisfaction with Device survey indicated the highest satisfaction for the PR+Liner condition, the McGann Feedback Form found the highest scores for Direct condition. There was also no consistency between initial and final data collection points. Other surveys such as Health Quality of Life and Satisfaction with Services did not have much change in the score for any condition or data collection point, indicating the control method and interface design did not impact these areas greatly.

Major Activity 4: Determine the impact on socket fitting, fabrication and training time for each study condition.

Results: Study prosthetists at each site completed surveys at the final data collection for each condition. The results indicated that the PR+Liner condition resulted in the least hours spent fitting the socket (Figure 9), the highest rating for ease of socket fitting (Figure 10), and the fewest number of check sockets needed to achieve the final socket shape (Figure 11). 57% of the time, the PR+Liner condition only required 1 check socket whereas the other two conditions only accomplished this 29% of the time. The PR+Liner condition never required more than 2 check sockets, but the other two conditions did, including as many as 9 check sockets. In addition, clinicians reported that the PR+Liner condition was easier to modify the positive limb mold 93% of the time (Figure 12). It was never rated harder than the other conditions. On the other side, Direct and PR conditions were only rated easier to modify the positive mold 18% and 25% of the time respectively (Figure 12). Also, the ease of fabrication was rated highest for the PR+Liner condition (Figure 13). When using PR, the ease of selecting myosites was higher than the Direct control condition (Figure 14). Note, the data sets were not equal for all conditions. Two factors impacted this. First, if the subject had an existing socket for one of the conditions that was functional and comfortable, it was used in the study and therefore the hours spent fitting the socket or the ease of fabrication may have been lost to history. Second, at times the clinicians used an outside Central Fabrication facility to fabricate the condition and in those instances did not answer questions if they didn't know the answer.

Training of the conditions was most favorable for the Direct condition. The results indicate the lowest number of training sessions (Figure 15) and the shortest amount of cumulative time spent training (Figure 16) for the Direct condition. It should be noted however that a majority of the subjects in the study were existing Direct users so they needed little training for the Direct condition, whereas PR was new to them.

Study Conclusion

The completed study represents one of the largest prospective studies on an upper extremity prosthesis population known to the team. The combined results indicate that the addition of the Liner provided the biggest difference in performance and clinician feedback. This is evident because of the bigger differences between the PR+Liner condition relative to the other two and the smaller differences between conditions without the liner. This is likely due to the reduction in electrode lift off that would have been consistent in the non-liner conditions. The survey results provided inconclusive results and may point to the need for new surveys to be validated for the comparison of technologies. Currently no surveys were originally constructed for this purpose, and this could explain the large variations in results.

Table 1: Subject demographics.

ID	Sex	Age	Prosthesis Side	Clinic	Existing Condition	Completed all Conditions
TR01	M	53	Left	Optimus	Direct	Yes
TR02	M	60	Left	Optimus	Direct	No
TR03	M	68	Left	Optimus	PR	Yes
TR04	F	62	Right	Handspring	Direct	Yes
TR05	M	41	Right	Handspring	Direct	Yes
TR06	M	23	Left	Ability	PR	No
TR07	F	18	Left	Handspring	Direct	Yes
TR08	F	50	Right	Handspring	PR	Yes
TR09	F	54	Left	Ability	PR	No
TR10	M	56	Left	Optimus	PR	Yes
TR11	M	41	Right	Ability	PR	Yes
TR12	M	63	Left	Handspring	Direct	Yes
TR13	M	47	Right	Motus	Direct	Yes
TR14	M	46	Left	Handspring	Direct	No
TR15	F	32	Left	Motus	Direct	Yes
TR16	M	54	Right	Ability	PR	Yes
TR17	F	54	Left	Handspring	Direct	Yes
TR18	M	63	Left	Handspring	Direct	Yes
TR19	M	32	Left	Handspring	Direct	Yes
TR20	M	27	Let	Motus	Direct	Yes
TR21	M	33	Left	Handspring	PR	No

Table 2: AMULA tasks and the number of substeps defined for task completion.

Task	No. of Substeps Defined
Brush/Comb Hair	4
Put on T-Shirt	4
Remove T-Shirt	5
Button Shirt with Front Buttons	5
Attach End of Zipper and Zip Jacket	4
Put on Socks	3
Tie Shoelaces	5
Drink from a Paper Cup	5
Use a Fork	4
Use a Spoon	4
Pour from a 12oz Can	5
Write the Word "LETTER" legibly	4
Use a Pair of Scissors	5
Turn a Round Door Knob	4
Dial a Touch Tone Phone	3
Use a Hammer and Nail	5
Fold a Bath Towel	3
Reach Overhead	4

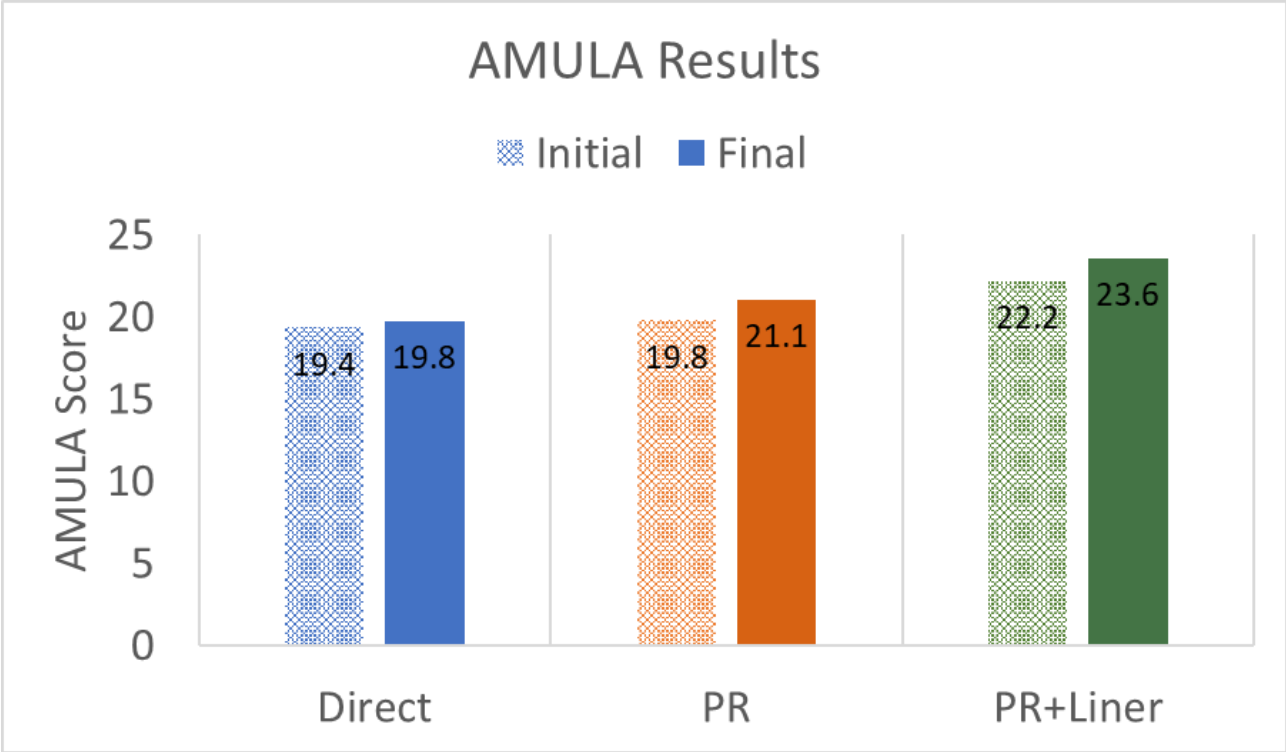


Figure 1: AMULA results from the study.

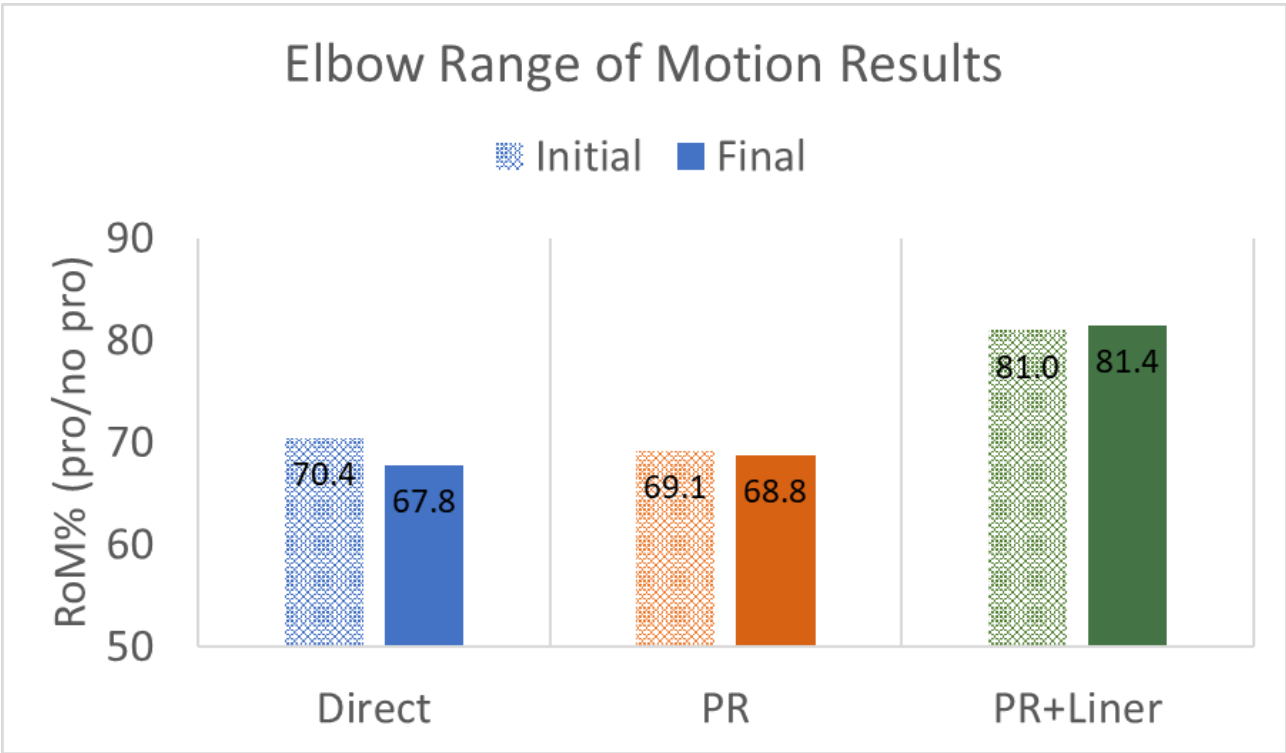


Figure 2: Elbow range of motion results from the study.

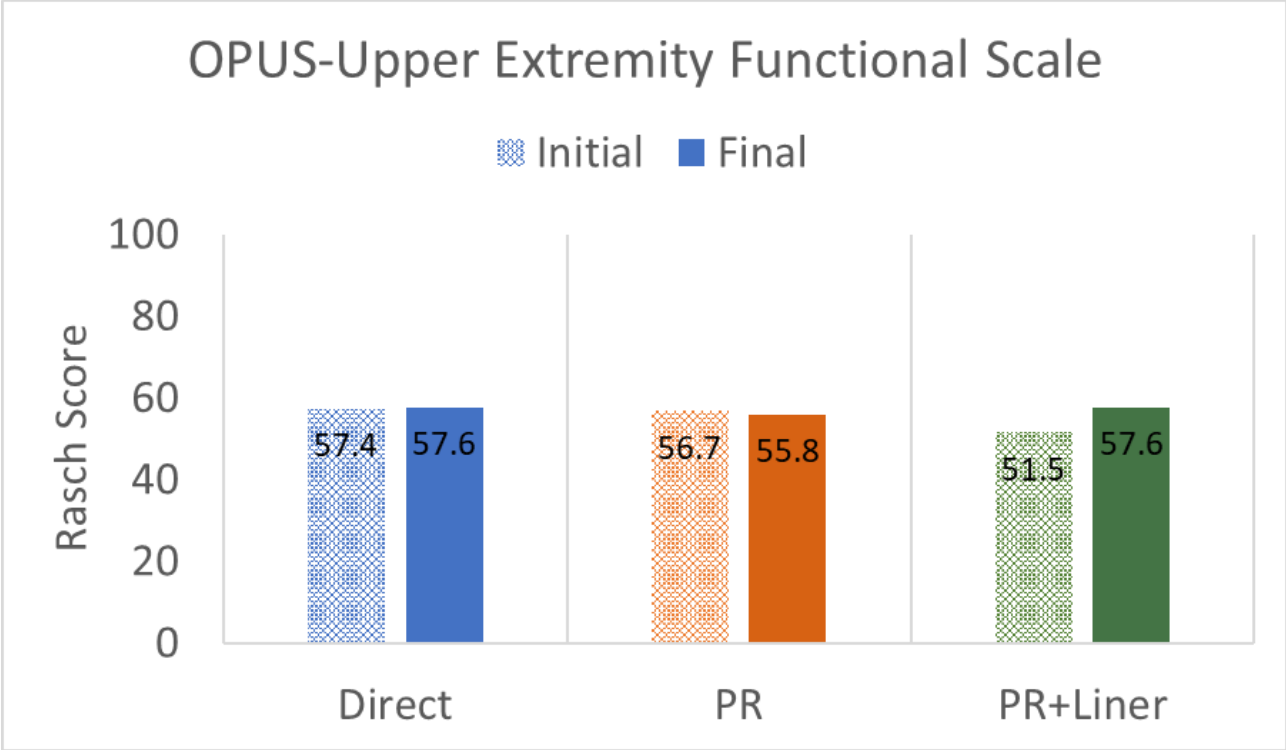


Figure 3: OPUS Upper Extremity Functional Scale results for the study.

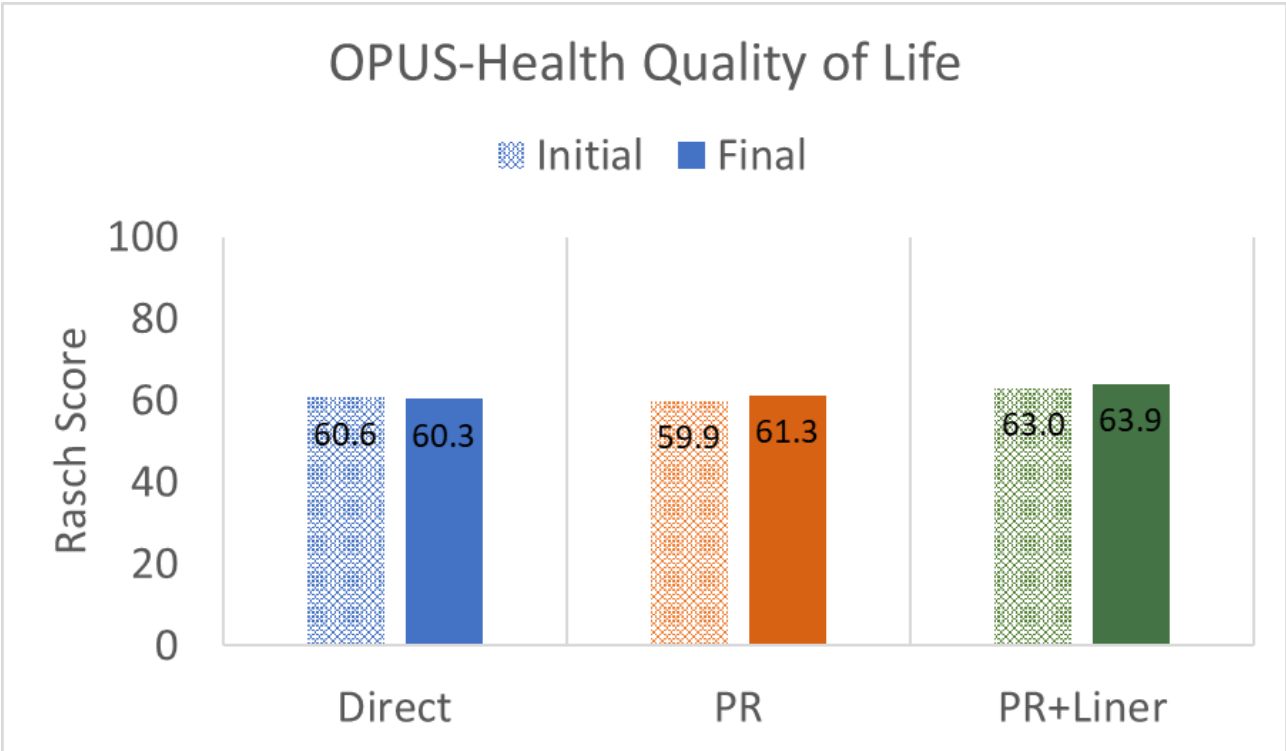


Figure 4: OPUS Health Quality of Life results for the study.

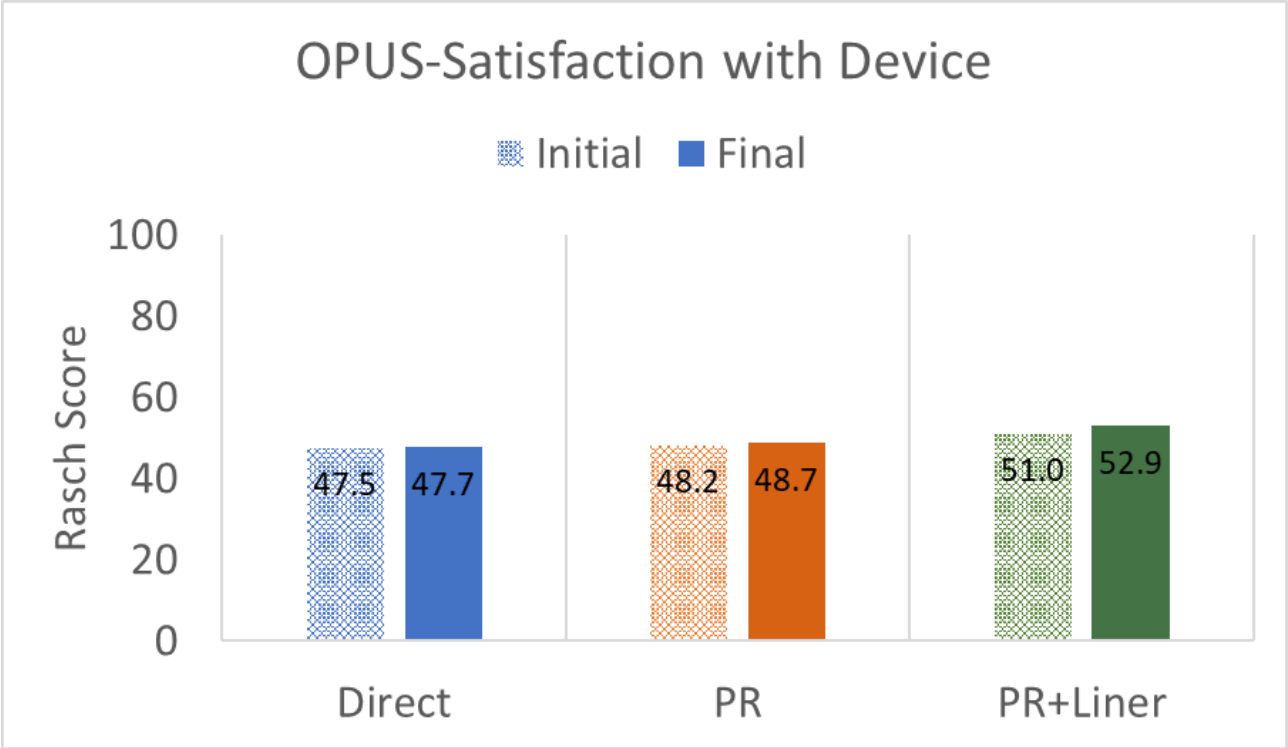


Figure 5: OPUS Satisfaction with Device results for the study.

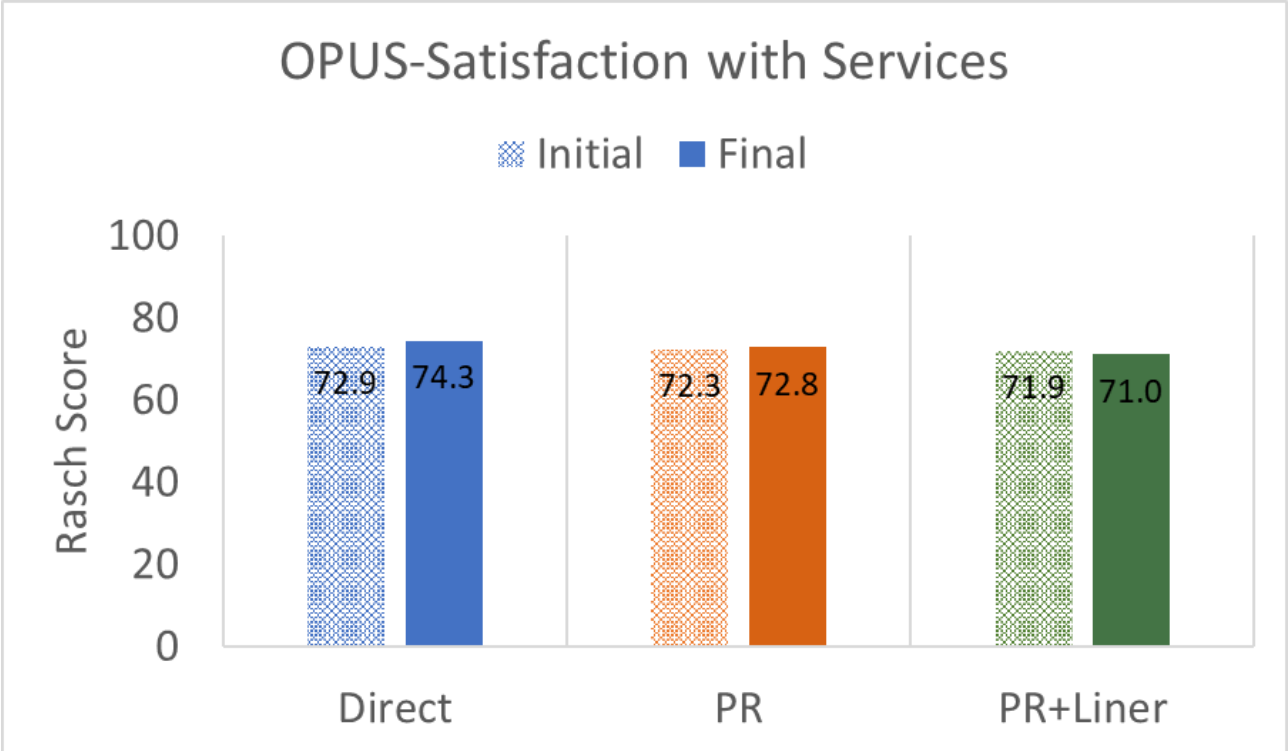


Figure 6: OPUS Satisfaction with Services results for the study.

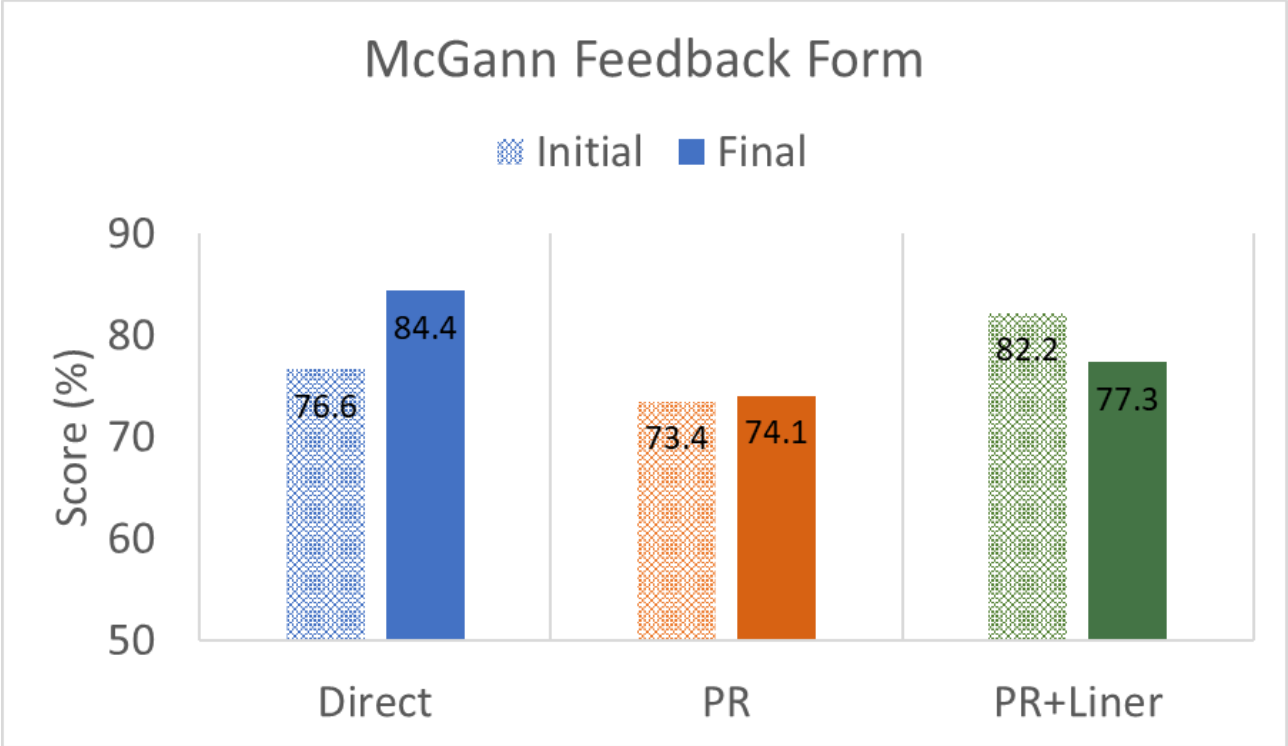


Figure 7: McGann Feedback Form results for the study.

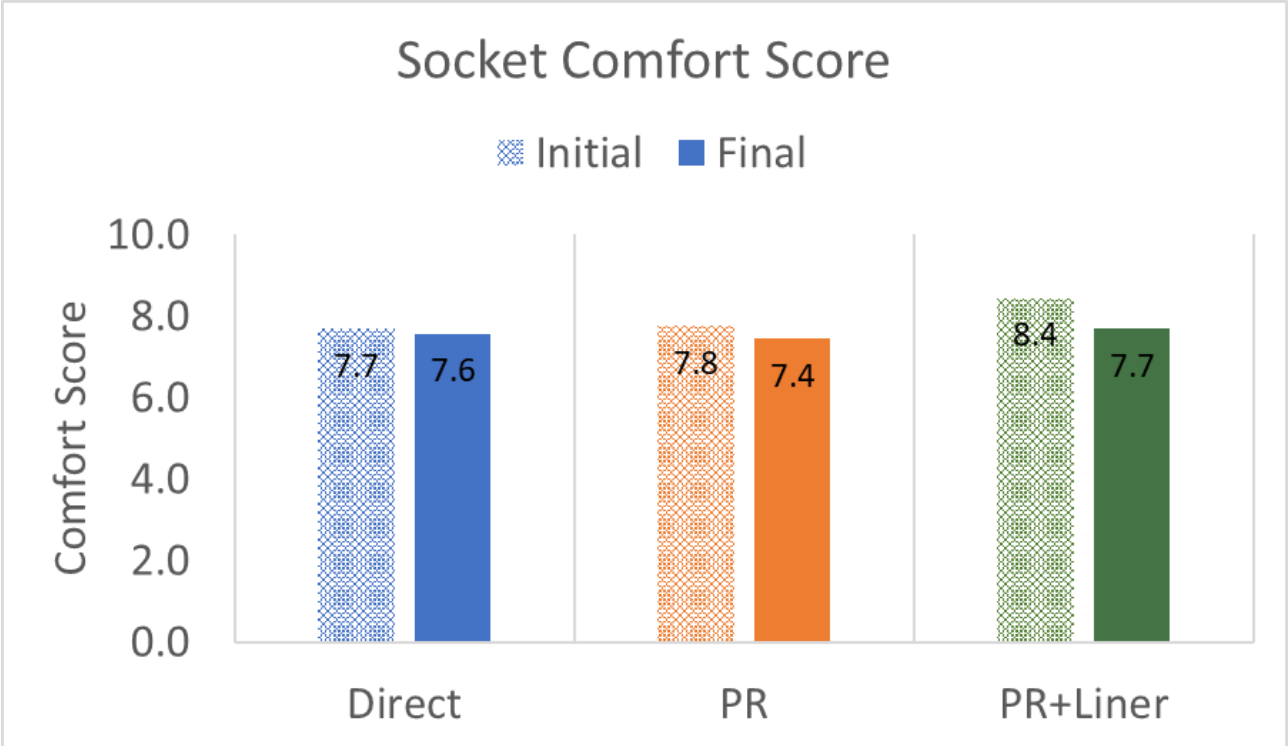


Figure 8: Socket Comfort Score results for the study.

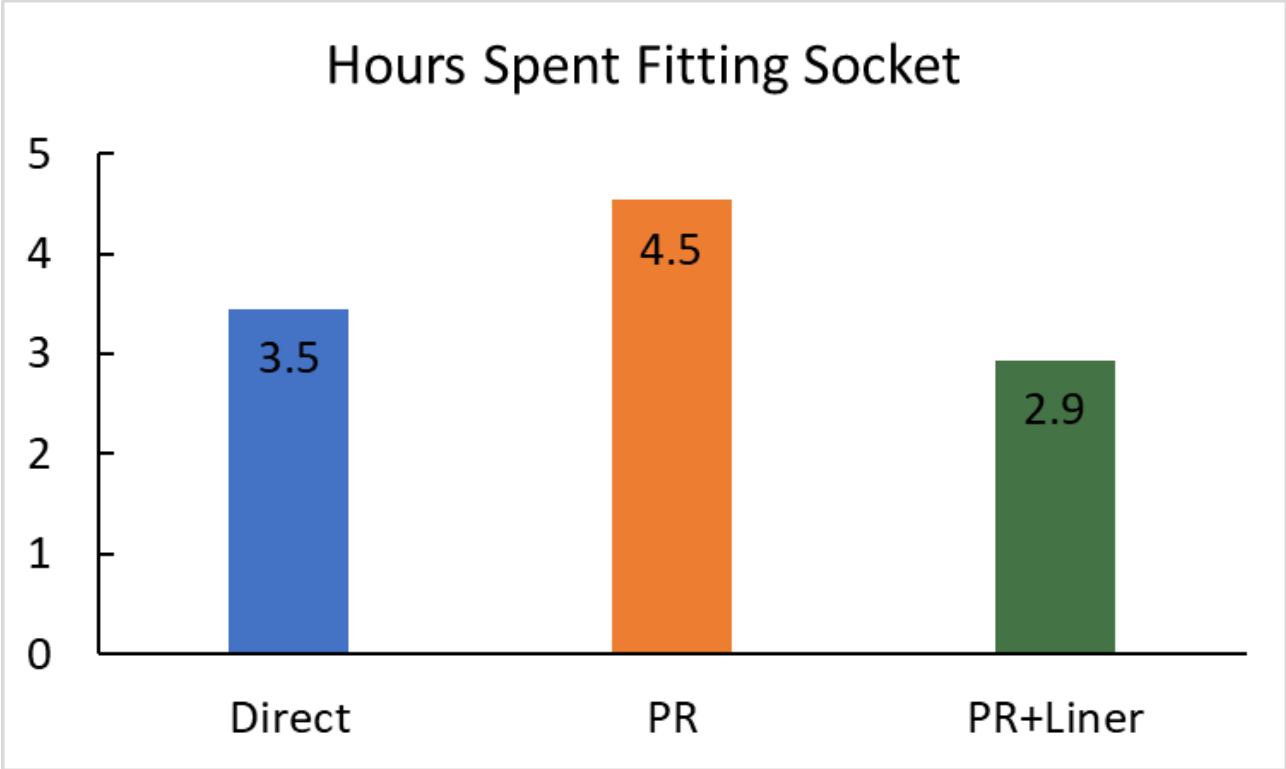


Figure 9: Clinician-report hours spent fitting the socket.

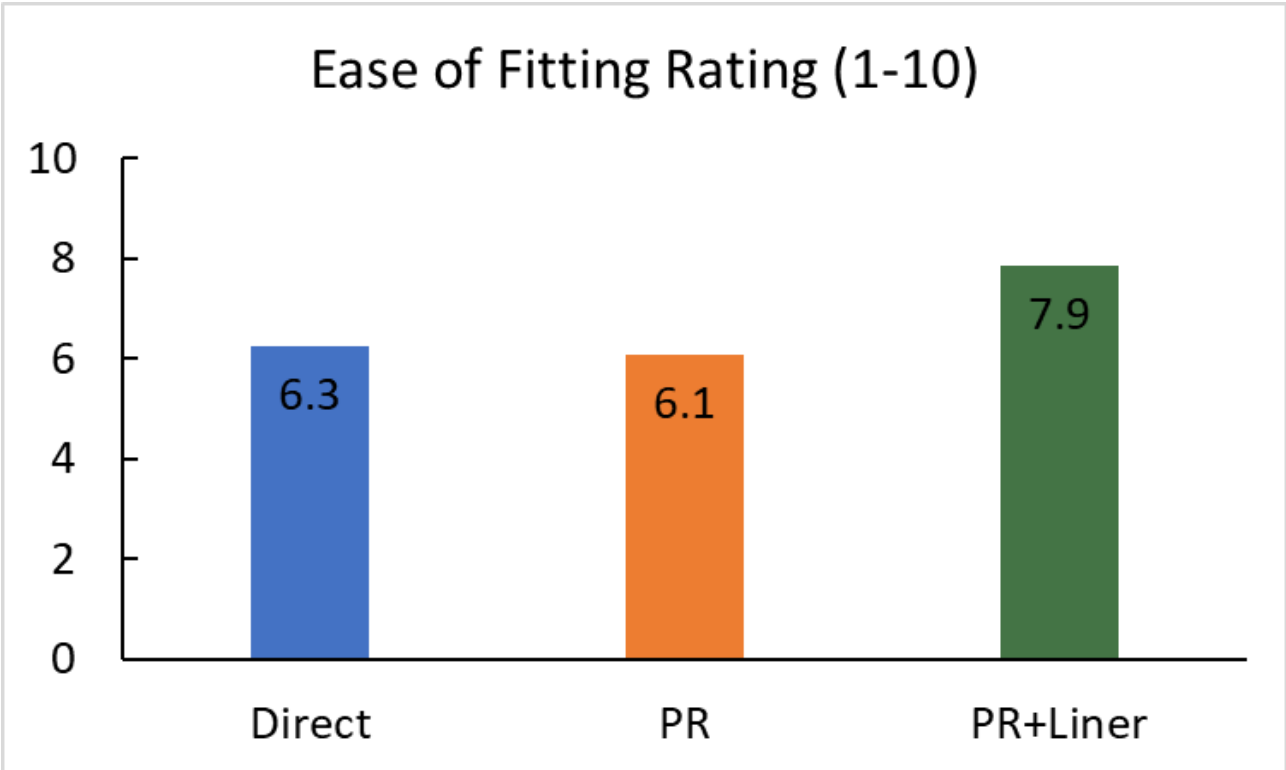


Figure 10: Clinician-rated ease of fitting condition. 10 indicates the easiest possible fitting.

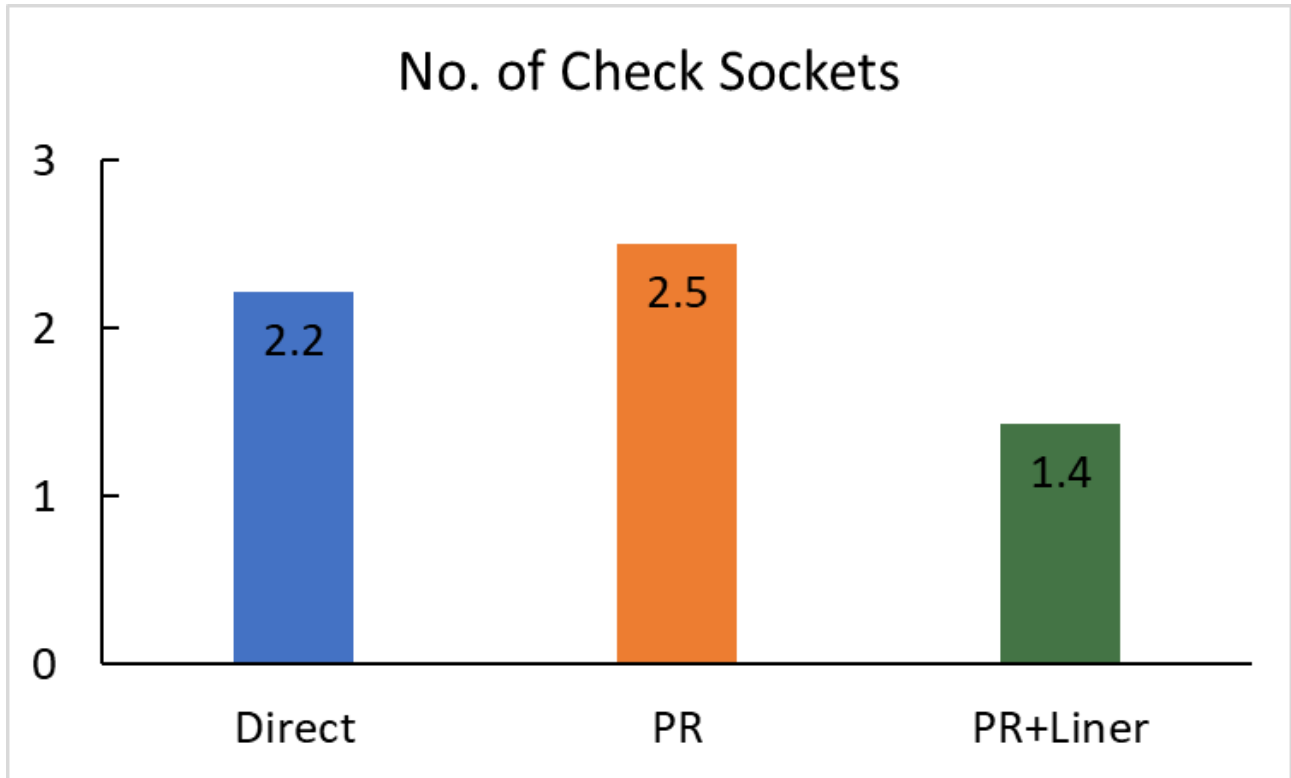


Figure 11: Clinician-reported number of check sockets to achieve proper fit.

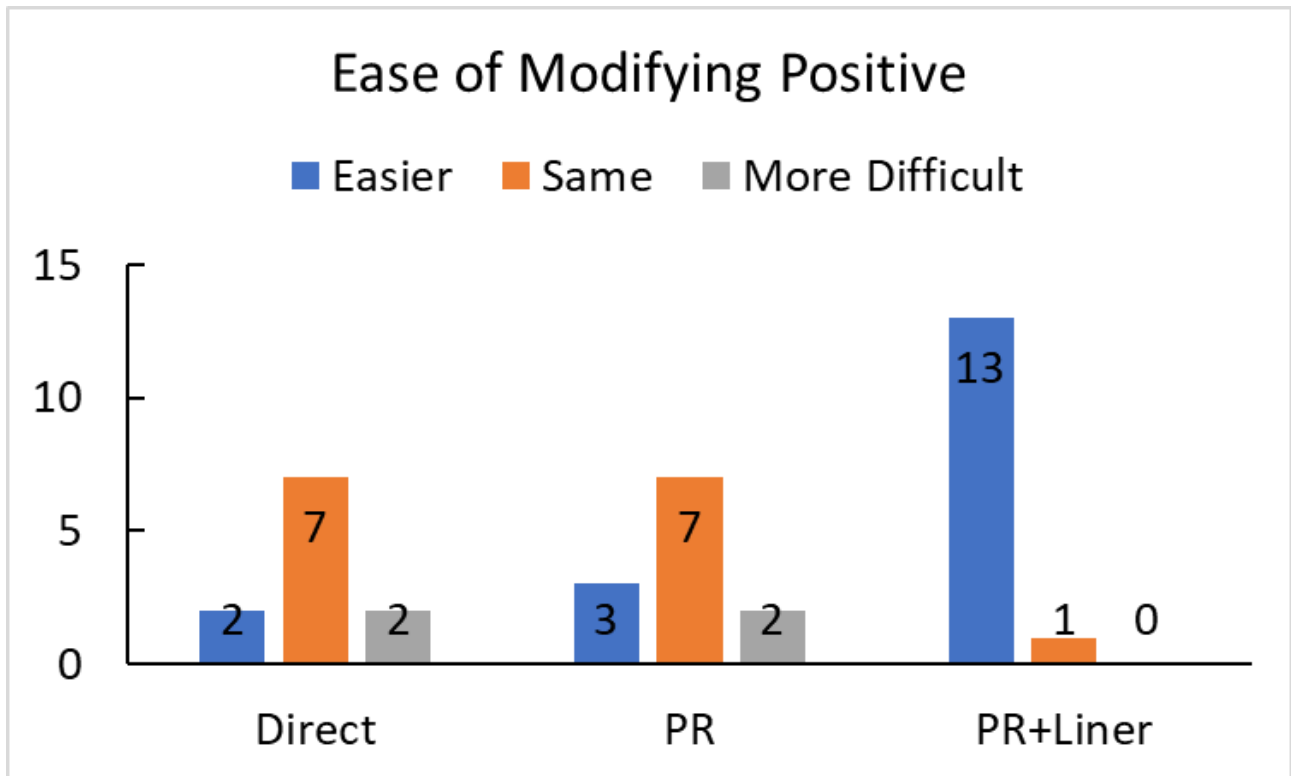


Figure 12: Clinician-reports ease of modifying the positive model.

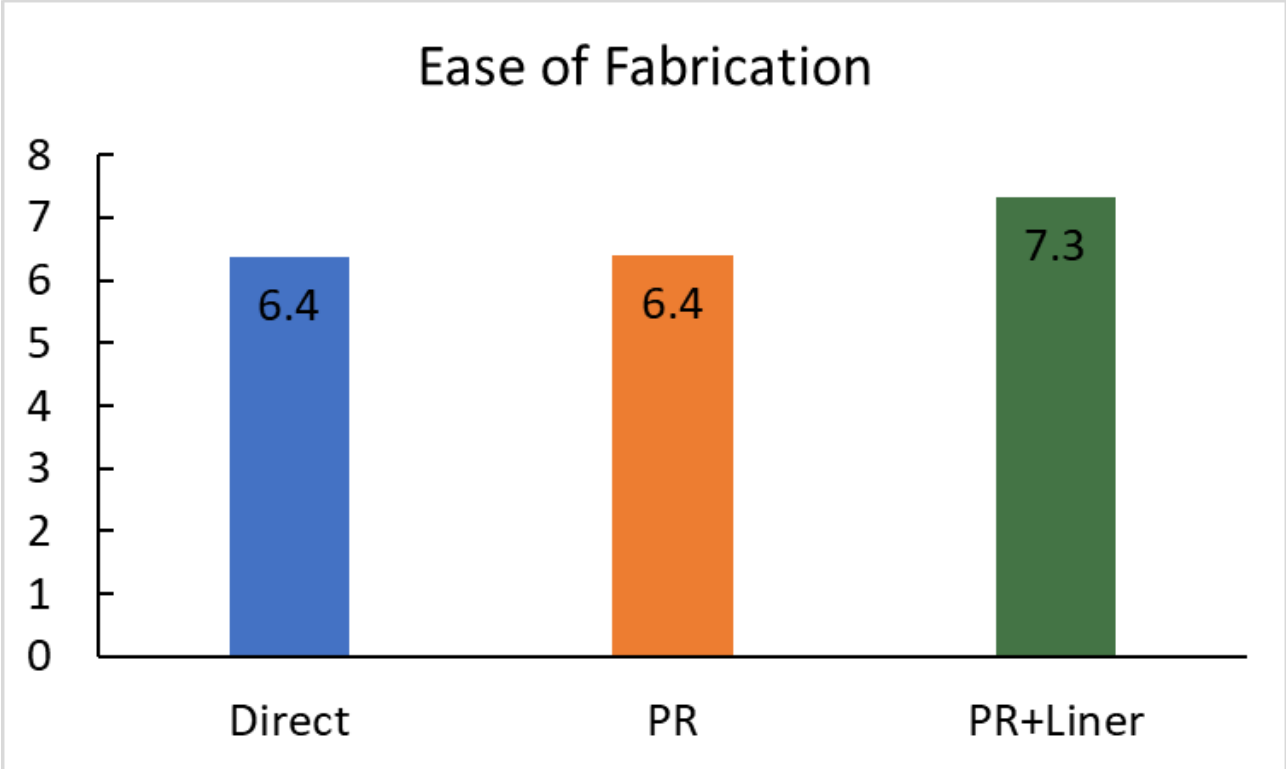


Figure 13: Clinician-reported ease of fabrication.

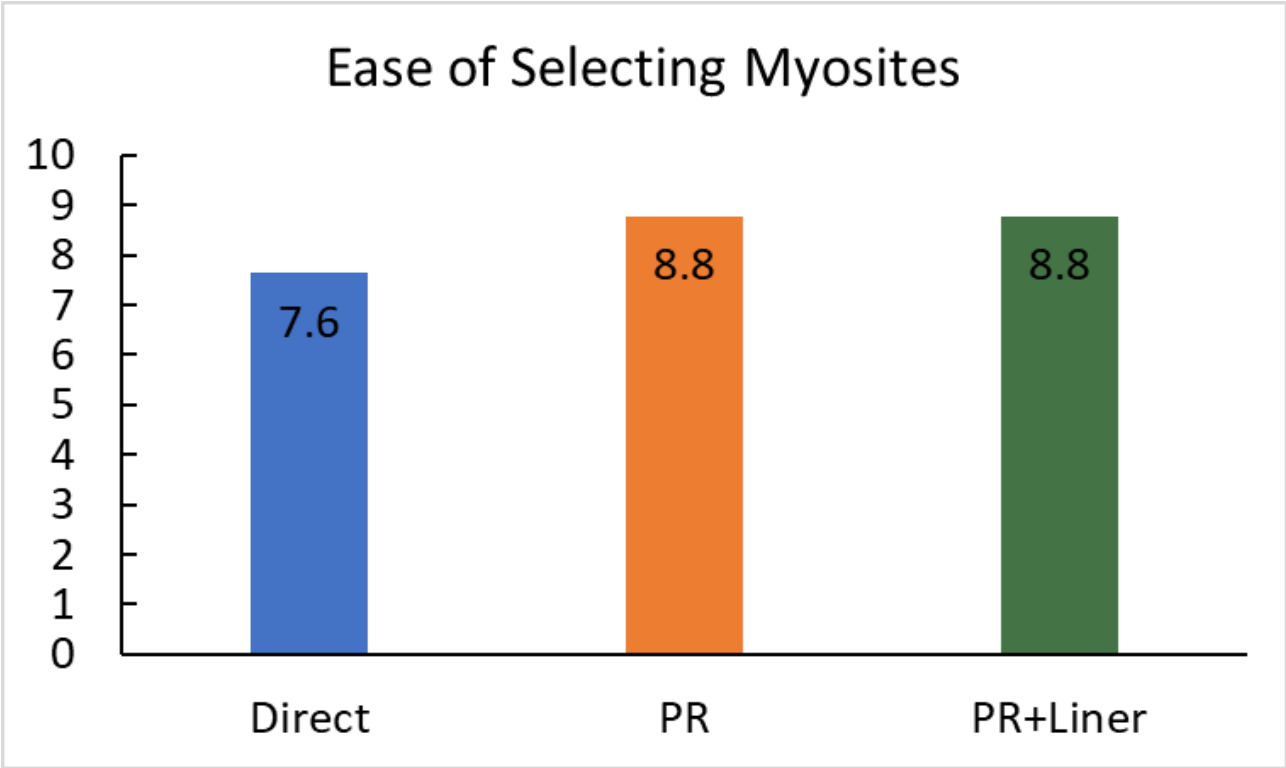


Figure 14: Clinician-reported ease of selecting myosites.

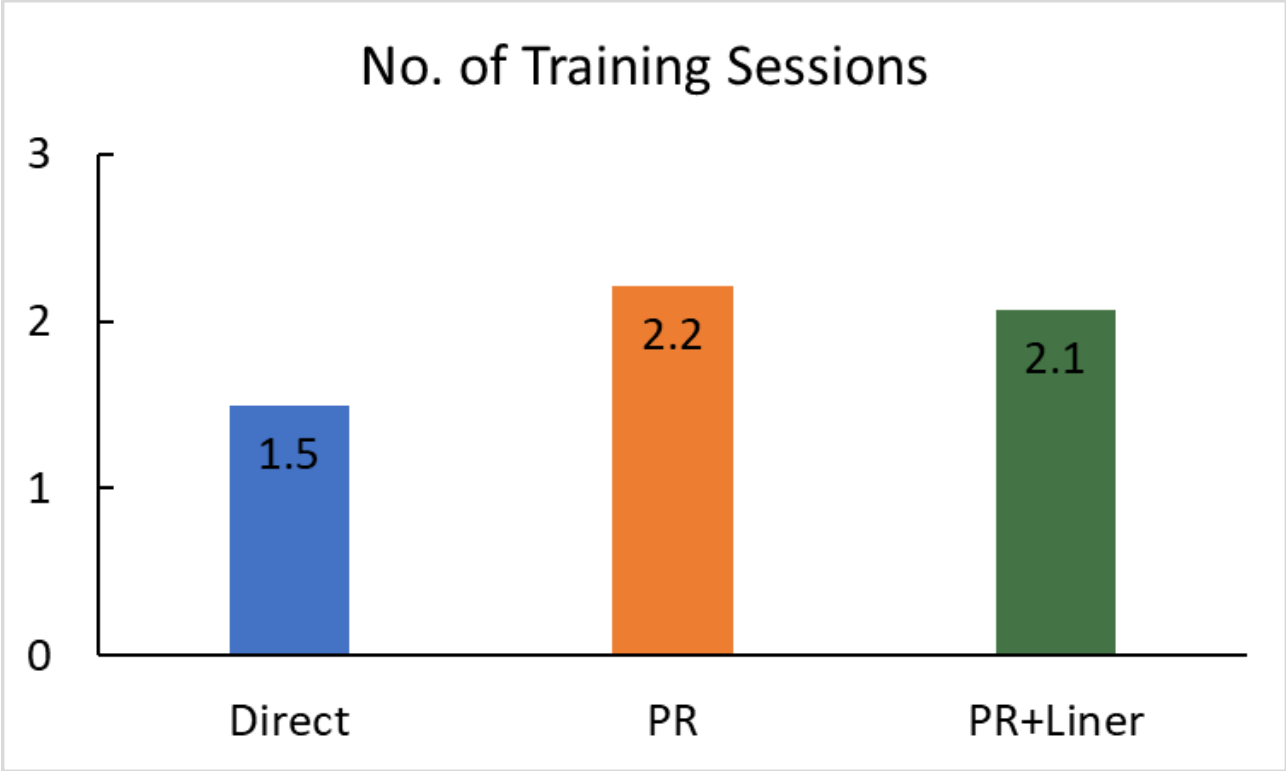


Figure 15: Number of training sessions for each condition.

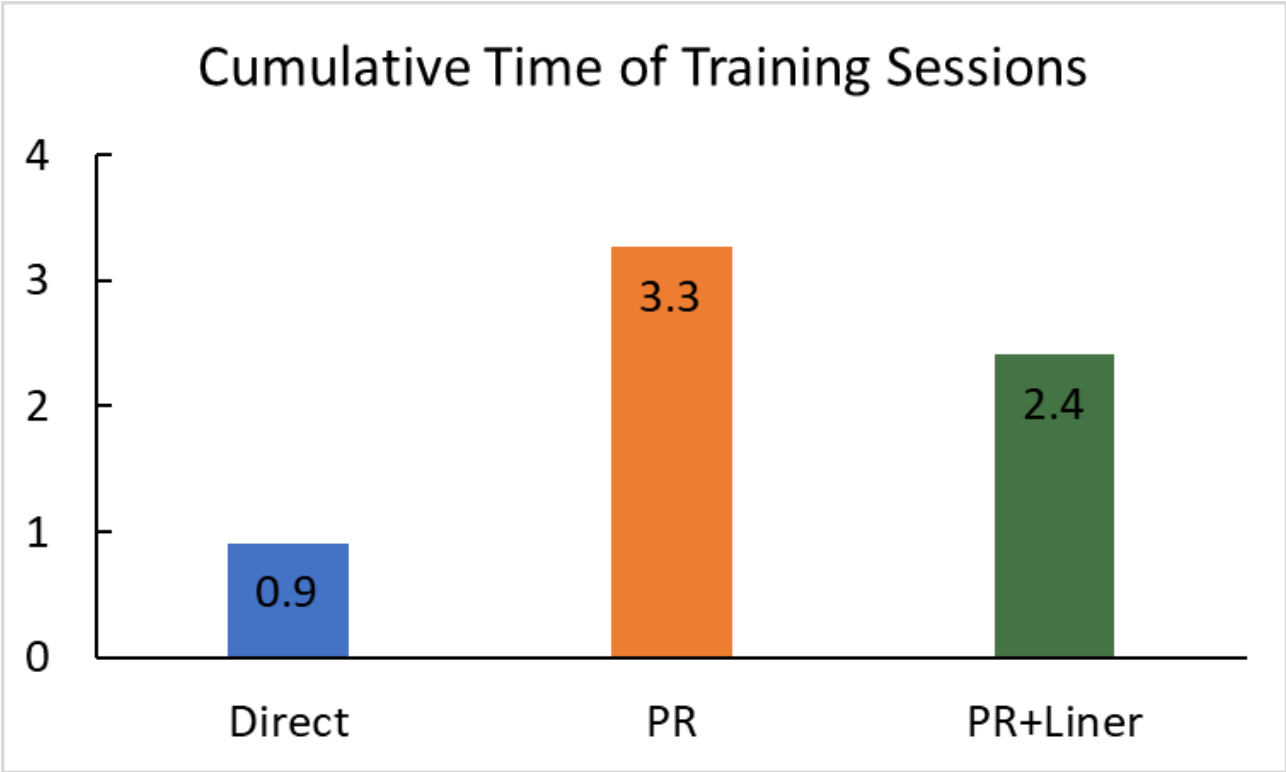


Figure 16: Total time reported engaging in training sessions with the subjects.

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

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

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

How were the results disseminated to communities of interest?

During the course of the project, the team has presented at various conferences as follows:

1. Wernke et al. Advances in Upper-Limb Control Technologies: The Myoliner. Part of an Organized Session at AOPA National Meeting 2018.
2. Wernke et al. Performance and Satisfaction with the Alpha Control Liner. Podium Presentation. AAOP National Meeting. 2020.
3. Wernke et al. Comparison of Upper Extremity Myoelectric Interface and Control Methodologies: A Preliminary Report from the First Five. Podium Presentation. AOPA National Meeting. 2020.
4. Wernke et al. Comparison of Upper Extremity Myoelectric Interface and Control Methodologies: A Preliminary Report from the Halfway Point. Podium Presentation. AAOP National Meeting. 2021.
5. Wernke et al. Comparison of Upper Extremity Myoelectric Interface and Control Methodologies: A Preliminary Report from the First Fifteen. Podium Presentation. AOPA National Meeting. 2022.
6. Wernke et al. Comparison of Upper Extremity Myoelectric Interface and Control Methodologies: A Preliminary Report from the First Sixteen. Podium Presentation. MHSRS Meeting. 2022.
7. Wernke et al. Comparison of Upper Extremity Myoelectric Interface and Control Methodologies: A Preliminary Report from the First Sixteen. Podium Presentation. AOPA National Meeting. 2022.

Note, there were also two abstracts accepted for presentation at the 2020 and 2021 MHSRS conference but due to Covid-19 the conferences were cancelled.

The team is currently working on a final conference presentation and a journal manuscript to be submitted in the upcoming 2 months.

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

Nothing to Report.

4. IMPACT::

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

The Control Liner Technology is the first prosthetic liner with integrated electronics. The results of the study indicate how this interface technology has affected prosthetic care in comparison with other standards of care.

Further, this was a first time for clinicians in the field to utilize this technology. As such, clinicians at each site had different approaches to how the socket should be designed and fit, and many of these clinicians adapted their techniques as the study continued. The lessons learned when fitting this technology will help with future educational materials published by WillowWood when using the Control Liner to avoid potential pitfalls when fitting the socket over the Control Liner to enable the best clinical outcomes.

Additionally, this study is one of the largest prospective studies ever completed in upper extremity prosthetic research. The framework developed here can have an impact for future studies trying to complete similar research with a host of clinical support facilities.

What was the impact on other disciplines?

Nothing to report.

What was the impact on technology transfer?

The Control Liner technology was previously licensed by WillowWood from Rehabilitation Institute of Chicago prior to the start of the award. Since then, WillowWood filed for additional IP prior to the start of the award. The Alpha Control Liner is an FDA cleared Class II device that will be commercially available in 2023.

What was the impact on society beyond science and technology?

Nothing to report.

5. CHANGES/PROBLEMS:

The Covid-19 pandemic caused significant issues. As a result of the delays, we received two 1-year No Cost Extension for the project in order to complete the project goals. Fear of the pandemic did result in a few subjects dropping out of the study.

Actual or anticipated problems or delays and actions or plans to resolve them

Nothing to report.

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

All sites modified procedures to comply with local laws surrounding the pandemic in order to see patients in clinic. This included wearing a mask and checking temperatures prior to engaging in the research.

Significant changes in use or care of vertebrate animals

Nothing to report.

Significant changes in use of biohazards and/or select agents

Nothing to report.

6. PRODUCTS:

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

Journal publications.

The team is currently drafting a manuscript on the full results for peer-review. The team is initially focusing on the journal Prosthetics and Orthotics International (POI). The manuscript will recognize the funding support from the Department of Defense as defined in the award contract.

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

Nothing to report.

Other publications, conference papers and presentations.

The conference presentations are noted above in the dissemination section.

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

Nothing to report.

- **Technologies or techniques**

Here the team completed one of the largest prospective studies of subjects who utilize an upper extremity prosthesis. The techniques to create a network of clinics and have them execute the study can become a model for future efforts in a tough to recruit population.

- **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>Role</i>	<i>Contribution</i>	<i>Person Month Worked</i>
James Colvin	PI	Developing consultant agreements. Developed training materials. Coordinated site trainings. Generate reports	4.3
Matthew Wernke	Co-PI	Coordinated with study sites to correct IRB. Develop training materials. Executed Site Training Generate reports	10.7

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

Mr. Colvin was awarded a Phase II NIH SBIR award in 2019 but his total time commitment remained under 12 calendar months.

WillowWood was awarded a small Phase I NIH SBIR subcontract on which key personnel may spend less than 100 hours but their total time commitment remained under 12 calendar months.

What other organizations were involved as partners?

The clinical testing sites were involved as consultants on the award and were reimbursed based on the completion of study conditions. These clinical sites include Handspring, Optimus, Ability, and Motus.

8. SPECIAL REPORTING REQUIREMENTS

QUAD CHARTS:

See next page.

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

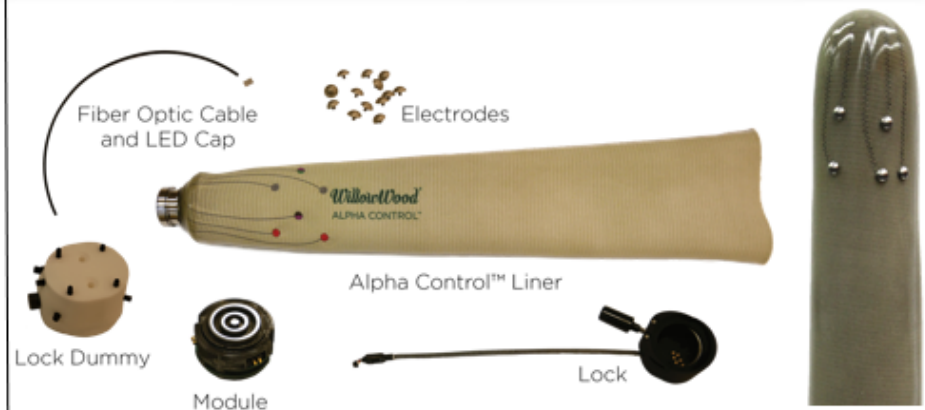
Award Amount: \$1,067,854

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: January 18th, 2023

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: \$1,067,854

APPENDIX I: Data Collection Form

Comparative Effectiveness of Various Interface Designs and Control Methodologies for Myoelectric Prostheses Test Protocol

NEEDS:

- Printed Questionnaire: OPUS Upper Extremity Functional Status
- Printed Questionnaire: OPUS Health Quality of Life Index
- Printed Questionnaire: OPUS Satisfaction With Device and Service
- Printed Questionnaire: McGann Feedback Form
- Printed Questionnaire: Socket Comfort Score
- Printed Questionnaire: Clinician Survey (If Final Visit Only)
- Goniometer
- Supplied AMULA Test Material Bag
- A Full Unopened Soda Can (12 fl oz)
- Table and Chair
- Access to Shelf
- Camera and Video Camera or Smartphone
- Tripod (Optional)

Comparative Effectiveness of Various Interface Designs and Control Methodologies for Myoelectric Prostheses Test Protocol

Subject ID: _____ **Condition:** A or B or C **Time point:** Initial or Final

Protocol:

- Have Subject Complete 3 OPUS Sections
- Have Subject Complete McGann Feedback Form
- Have Subject Complete Socket Comfort Score

If 0 represents the most uncomfortable socket fit you can imagine and 10 represents the most comfortable socket fit, how would you score the comfort of the socket fit of your artificial limb at the moment? **Score:** _____

- Prosthetist Completes Clinician Survey if Final Visit Only
- Take Pictures of the Subjects Residual Limb
 - Anterior
 - Posterior
 - Medial
 - Lateral
 - Distal End

Collect Elbow Range of Motion:

RoM Without Prosthesis	
Extension	degrees
Flexion	degrees

RoM With Prosthesis	
Extension	degrees
Flexion	degrees

- Have Subject Don Sleeve to Blind Scorer
- Have Subject Perform AMULA Procedures (see directions on following pages)
- Scan This Page and Upload to Basecamp (Filename: SubjectID_Condition[A or B or C]_[Initial or Final]_DataForm) *Example = TR01_A_Initial_DataForm*
- Upload Residual Limb Photos to Basecamp (Filename: SubjectID_Condition[A or B or C]_[Initial or Final]_[Anterior or Posterior or Medial or Lateral or Distal]) *Example = TR01_A_Initial_Medial*
- Upload OPUS sections to Basecamp (Filename: SubjectID_Condition[A or B or C]_[Initial or Final]_[OPUS]) *Example = TR01_A_Initial_OPUS*
- Upload McGann Feedback Form to Basecamp (Filename: SubjectID_Condition[A or B or C]_[Initial or Final]_[McGann]) *Example = TR01_A_Initial_McGann*
- Upload AMULA Videos to Basecamp (Filename: SubjectID_Condition[A or B or C]_[Initial or Final]_AMULA) *Example = TR01_A_Initial_AMULApart1*

Note: AMULA videos can be uploaded in multiple videos. If so, just add part1, part2, etc to end of filename

Administering the AMULA

AMULA Introduction Statement:

“I want to see how you do some everyday activities. Please use your prosthetic arm to do these activities. Please use your sound arm only on those activities that require 2 hands.”

1. Brush/Comb Hair (Unilateral) □

“Please take this comb and, while grasping it, run it through your hair (or over the top of their head if bald). Then put the comb down. Try to use **only** your prosthesis to do this task.”

- *Subject is seated behind table with brush/comb on table. Place camera directly in front of subject and ensure hand/comb stay in field of view when brushing hair. Ensure when the subjects grasps and releases the comb/brush it is in the field of view of the camera. Task ends when subject releases grasp of brush/comb and places it on table.*

2. Drink From a Paper Cup (Unilateral) □

“Pick up this paper cup from the table, bring it all the way to your mouth, and pretend to drink from it. Then put the cup back on the table. Try to use **only** your prosthesis to do this task.”

- *Subject is seated behind table with cup on table. Place camera directly in front of subject and ensure upper body (table to above head) stay in field of view of the camera while drinking from the cup. Task ends when subject releases grasp of the cup.*

3. Use a Fork (Unilateral) □

“Please grasp this fork and bring it to your mouth as if you were going to take a bite of food from it. Then put the fork back on the table. Try to use **only** your prosthesis to do this task.”

- *Subject is seated behind table with fork on table. Place camera directly in front of subject and ensure upper body (table to above head) stay in field of view of the camera while using the fork. Task ends when subject releases grasp of the fork.*

4. Use a Spoon (Unilateral) □

“Please grasp this spoon with your prosthesis and bring it to your mouth as if you were going to take a bite of food from it. Then put the spoon back on the table. Be sure to use your prosthesis while doing this.”

- *Subject is seated behind table with spoon on table. Place camera directly in front of subject and ensure upper body (table to above head) stay in field of view of the*

camera while using the spoon. Task ends when subject releases grasp of the spoon.

5. Pour From a 12oz Can

“Please pick up the soda can from the table with 1 hand and grasp the cup with your other hand. Then pour the soda from the can into the cup. When finished set the can and cup (if necessary) down on the table. Be sure to use your prosthesis while doing this.”

- *Subject is seated behind table with cup and soda can on table. Place camera directly in front of subject and ensure upper body (table to above head) stay in field of view of the camera while pouring the can. Task ends when the subject releases cup and soda can.*

6. Write the word “LETTER” Legibly (Unilateral)

“Please grasp this pen with your prosthesis and write the word “LETTER” on the blank sheet of paper on the clipboard. Then set the pen down on the table. Try to use only your prosthesis to do this task.”

- *Subject is seated behind table with pen and paper on table. Place camera directly in front of subject and ensure upper body (table to above head) stay in field of view of the camera while they write. Task ends when the subject releases grip of pen and paper. Show the paper to the camera at the end so the scorer can see the written word.*

7. Use a Pair of Scissors

“Please take this blank piece of paper and, grasping scissors in 1 hand and with the paper in the other, make at least 3 cuts in the paper. Then place the cut paper and scissors on the table.”

- *Subject is seated behind the table with the scissor and paper on the table. Place camera directly in front of subject and ensure upper body (table to above head) stay in field of view of the camera while using the scissors. Cut the paper they just wrote the word letter on. Task ends when the subject releases grip of paper and scissors.*

8. Dial a Touch Tone Phone

“Please take this cell phone and dial a phone number with it. Be sure to use your prosthesis while doing this.”

- *Subject is seated behind table with phone of the table. Place camera directly in front of subject and ensure upper body (table to above head) stay in field of view*

of the camera while dialing phone. Task ends when the subject has pretended to dial number.

9. Put on Socks

“Please take this sock and put it on, pull the sock over your heel and pull it up all the way so that it fits well. Then remove the sock from your foot. Be sure to use your prosthesis while doing this.”

- *Subject is seated with sock on a table next to subject. Place camera directly in front of subject and foot, sock and prosthesis ensure lower body stay in field of view of the camera while putting on the sock. Task ends when the subject pulls the sock over their heel so it fits properly.*

10. Tie Shoelaces

“Please take this shoe-lace board (place on the floor) and tie the laces. Grasp a lace in each hand, criss-cross the laces, making loops, and tie the bow tight. Be sure to use your prosthesis while doing this.”

- *Subject is seated with shoe-lace board on floor in front of them. Place camera directly in front of subject and ensure shoe-board and prosthesis stay in field of view of the camera while they tie the shoe. Task ends when the subject releases grip of the laces.*

11. Put on T-Shirt

“Please put this t-shirt on. I want you to grasp the t-shirt, thread your head through the neck opening, thread your arms through the arm holes, and pull the shirt down over your body. Be sure to use your prosthesis while doing this.”

- *Subject is standing behind table with t-shirt on table. Place camera directly in front of subject and ensure whole body and shirt stay in field of view of the camera while putting on the shirt. Make sure camera can see subject grasp the shirt off the table initially and pull it over their head. Task ends when the shirt is pulled down to fit properly.*

12. Remove T-Shirt

“Now I’d like you to remove the t-shirt. While grasping the t-shirt, lift it over your head, remove your arms from the sleeves, and place the shirt on the table. Be sure to use your prosthesis while doing this.”

- *Subject is standing behind table wearing t-shirt. Place camera directly in front of subject and ensure whole body and shirt stay in field of view of the camera*

while taking off the shirt. Make sure camera can see subject remove the shirt and release the t-shirt to the table at the end of the task.

13.Button Shirt with Front Buttons □

“Please put on this button-up shirt (therapist may help don shirt) and then button 3 buttons by putting the buttons through the holes and pulling them out the other side. Be sure to use your prosthesis while doing this.”

- *Subject is standing behind table. Place camera directly in front of subject and ensure subject (roughly mid-thigh to above head) and shirt stay in field of view of the camera while buttoning the shirt. Task ends when subject releases grasp on shirt.*

14.Attach End of Zipper and Zip Jacket □

“Please put this vest on (therapist may help don vest), start the zipper, and pull it at least two-thirds of the way up. Then unzip the zipper. Be sure to use your prosthesis while doing this.”

- *Subject is standing behind table. Place camera directly in front of subject and ensure subject (roughly mid-thigh to above head) and vest stay in field of view of the camera while zipping up the vest. Task ends when the subject unzips vest and releases grasp.*

15.Use a Hammer and Nail □

“Please pick up the hammer in 1 hand and the nail in the other. Position the nail vertically on the piece of wood and use the hammer to drive the nail into it. Remove your hand that was holding the nail and continue hammering the nail into the wood. Then put the hammer down.”

- *Subject is standing behind table with a block of wood, nail, and hammer on the table. Place camera directly in front of subject and ensure upper body (table to above head) stay in field of view of the camera while hammering the nail. Task ends when the subject releases grasp of nail, possible hammering nail a few more blows to ensure it stays in the wood and releases grasp on hammer. No need to hammer nail until the head is flush with the wood surface.*

16.Fold a Bath Towel □

“Please grasp the ends of this bath towel, bringing the ends of the towel together to fold it twice. Then place the folded towel back on the table. Be sure to use your prosthesis while doing this.”

- *Subject is standing behind table with a towel on the table. Place camera directly in front of subject and ensure upper body (table to above head) and towel stay in*

field of view of the camera while folding the towel. Task ends when subject releases grasp on towel after two folds.

17. Turn a Round Door Knob (Unilateral) □

“Please reach for this door knob (use a round door knob), grasp the knob, and turn it until the latch is released. Then release the knob. Try to use **only** your prosthesis to do this task.”

- *Subject is standing with the mini door placed on a table. Use clamps to secure table if needed. Place camera behind and to the side (prosthesis side) of the subject. Ensure camera view can see the terminal device grasp the handle and turn it. Task ends when the subject releases grasp of the knob after unlatching door.*

18. Reach Overhead (ie, to the top of refrigerator door) (Unilateral) □

“Using your prosthetic side, reach up to this overhead shelf and grasp the object (a lightweight cup) on the shelf, now lower your arm and hand the object to me. Try to use **only** your prosthesis to do this task.”

- *Subject is standing in front of overhead shelf or refrigerator with a cup on top. Place camera behind and to the side (prosthesis side) of the subject. Ensure camera view can see the terminal device grasp the object overhead and place it on the lower shelf. Task ends when the subject brings down prosthesis with object in hand.*

APPENDIX II: AMULA Scoring Sheet

Grade	Completion of Sub-tasks	Speed of Completion (as Compared to Non-disabled)	Movement Quality	Skillfulness of Prosthesis use	Independence
0 Unable	Less than all	N/A	N/A	No prosthetic use	N/A
1 Poor	All	Very slow to slow	Very awkward, many compensatory movements	Inappropriate choice of grip for task (if choice is available) Loses grip multiple times during task, lack of proportional control (if available) Multiple unintentional activation of a control Prosthesis only used as a stabilizer during bimanual activities, ie, there is no active use or use of grip, but arm or terminal device used to stabilize during the task	May or may not use assistive device
2 Fair	All	Slow to medium	Some awkwardness or compensatory movement	Sub-optimal choice of grip for task (if choice is available) Use of prosthesis as an assist for bimanual activities or prime mover unilateral activities Loses grip once during task More than 1 attempt needed to pre-position object within grasp and/or more than minimal awkwardness in pre-positioning object One incidence of unintentional activation of a control Fair proportional control	May or may not use assistive device
3 Good	All	Medium-fast to normal	Minimal to no awkwardness or compensatory movement	Skilled use of prosthesis as an assist for bimanual activities or as a prime mover for unilateral activities Quick and easy pre-positioning of object within grasp No unintentional loss of grip Optimal choice of grip for task (if choice is available)	May or may not make use of assistive device
4 Excellent	All	Equivalent to nondisabled	Excellent movement quality, no awkwardness or compensatory movement	No inadvertent loss of grip or unwanted movement Optimal choice of grip for task (if choice is available) Sound side NOT used to pre-position object within grasp	No assistive device use

APPENDIX III: Surveys



Patient ID#

Date / /

OPUS UPPER EXTREMITY FUNCTIONAL STATUS

I. Please indicate your affected limb(s). Left arm Right arm Both arms
 II. How many hours per day do you currently wear your prosthesis or orthosis?

III. Using the scale to the right, please indicate how easily you perform the following activities.	Very easy	Easy	Slightly difficult	Very difficult	Cannot perform activity	Not applicable	IV. Do you usually perform this activity using or not using your prosthesis or orthosis?	
							Using	Not using
1. Wash face	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Put toothpaste on brush and brush teeth	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Brush/comb hair	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Put on and remove t-shirt	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Button shirt with front buttons	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. Attach end of zipper and zip jacket	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. Put on socks	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. Tie shoe laces	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. Drink from a paper cup	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. Use fork or spoon	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. Cut meat with knife and fork	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. Pour from a 12 oz can	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. Write name legibly	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. Use scissors	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



Patient ID#

--	--	--	--	--	--

OPUS UPPER EXTREMITY FUNCTIONAL STATUS

III. Using the scale to the right, please indicate how easily you perform the following activities.	Very easy	Easy	Slightly difficult	Very difficult	Cannot perform activity	Not applicable	IV. Do you usually perform this activity using or not using your prosthesis or orthosis?	
							Using	Not using
15. Open door with knob	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16. Use a key in a lock	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17. Carry laundry basket	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18. Dial a touch tone phone	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
19. Use a hammer and nail	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
20. Fold bath towel	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
21. Open an envelope	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
22. Stir in a bowl	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
23. Put on and take of prosthesis or orthosis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
24. Open a bag of chips using both hands	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
25. Twist a lid off a small bottle	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
26. Sharpen a pencil	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
27. Peel potatoes (or fruit) with a knife/peeler	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
28. Take bank note out of the wallet	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



Client ID

OPUS: Health Quality of Life Index

Note: For the questions below, the term "physical condition" refers to the reason you use an orthotic or prosthetic device.	Not at all	A little	A fair amount	A great deal	Excessively
1. How much do you keep to yourself to avoid people's reactions to a missing body part or your need for a device?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. To what extent do you find that people's attitudes toward your physical condition are insulting?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. To what extent are you prevented from doing what you want to do because of social attitudes, the law, or environmental barriers?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. How much does pain interfere with your activities (including both work outside the home and household duties)?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. To what extent do you accomplish less than you would like because of your physical condition?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. To what extent do you accomplish less than you would like because of emotional problems?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. How much does your physical condition restrict your ability to run errands?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. How much does your physical condition restrict your ability to pursue a hobby?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. How much does your physical condition restrict your ability to do chores?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. How much does your physical condition restrict your ability to do paid work?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. To what extent have you cut down on work or other activities because of your physical condition?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. To what extent have you cut down on work or other activities because of emotional problems?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



Client ID

OPUS: Health Quality of Life Index

<u>During the past week, how often have you...</u>	All the time	Most of the time	Some of the time	A little of the time	None of the time
13. felt full of life?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. felt calm and peaceful?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. had a lot of energy?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16. been happy?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17. been very nervous?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18. felt so down in the dumps that nothing could cheer you up?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
19. felt downhearted and depressed?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
20. felt worn out?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
21. felt tired?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
22. been easily bothered or upset?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
23. had difficulty concentrating or paying attention?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



20094

Client ID

OPUS: Satisfaction With Device and Services

Please mark the response that most closely reflects your opinion.

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree	Don't Know / Not Applicable
1. My prosthesis / orthosis fits well.....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. The weight of my prosthesis / orthosis is manageable.....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. My prosthesis / orthosis is comfortable throughout the day.....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. It is easy to put on my prosthesis / orthosis.....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. My prosthesis / orthosis looks good.....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. My prosthesis / orthosis is durable.....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. My clothes are free of wear and tear from my prosthesis / orthosis.....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. My skin is free of abrasions and irritations.....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. My prosthesis / orthosis is pain free to wear.....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. I can afford the out-of-pocket expenses to purchase and maintain my prosthesis / orthosis.....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. I can afford to repair or replace my prosthesis / orthosis as soon as needed.....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. I received an appointment with a prosthetist / orthotist within a reasonable amount of time.....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. I was shown the proper level of courtesy and respect by the staff.....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. I waited a reasonable amount of time to be seen.....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. Clinic staff fully informed me about equipment choices.....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16. The prosthetist / orthotist gave me the opportunity to express my concerns regarding my equipment.....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17. The prosthetist / orthotist was responsive to my concerns and questions.....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18. I am satisfied with the training I received in the use and maintenance of my prosthesis / orthosis.....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
19. The prosthetist / orthotist discussed problems I might encounter with my equipment.....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
20. The staff coordinated their services with my therapists and doctors.....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
21. I was a partner in decision-making with clinic staff regarding my care and equipment.....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



MCGANN FEEDBACK FORM MODIFIED – Upper Limb Prosthetics

Name: _____ Date: _____

Prosthesis: _____

Date of Delivery: _____ Training Week # _____

Current Wear Schedule: # _____ sessions/day; # _____ hours/session; # _____ days/week

Rate your satisfaction with the following on a scale of 0 (very dissatisfied) to 2 (very satisfied)

	0	1	2	N/A	COMMENTS
Ease of Donning					_____
Position of Sensors					_____
Weight of Prosthesis					_____
Length of Prosthesis					_____
Control of Terminal Device					_____
Control of Wrist					_____
Control of Elbow					_____
Control of Shoulder					_____
Comfort of Socket					_____
Comfort of Harness					_____
Skin Integrity					_____
Ease of Doffing					_____
Battery Life					_____
Reliability					_____
Appearance					_____
Overall Endurance					_____
Pain: Involved Side					_____
Pain: Uninvolved Side					_____
Ability to Complete ADL's					_____
Comfort with Public Use					_____
Answer Questions - Family					_____
Answer Questions - Strangers					_____
TOTAL (each column)					

Calculation: $\frac{\text{Total Yellow} + (\text{Total Green} \times 2)}{(\text{Total Red, Yellow \& Green}) \times 2} \times 100 = \% \text{ Satisfaction } _____\%$

3x Bimanual Tasks: _____

Clinician Survey

Subject ID: _____ Condition: A or B or C

1. In general practice, what is your normal upper extremity socket technique (ie ¾ style, pin-lock, anatomical, etc)?

2. Did you use a different socket design than stated in Question 1? If yes, how did it differ?

3. Approximately how many hours did you spend in front of the subject fitting the socket for this condition? _____ hrs

4. Rate the ease of fitting the socket using the scale below.

1	2	3	4	5	6	7	8	9	10
Hardest									Easiest
Possible									Possible

5. How many check sockets did it require before a definitive socket was created for this condition?

_____ check sockets

6. How would you describe the process of modifying the positive model for check socket creation compared to normal socket modifications?

Same as Normal Easier than normal More difficult than normal?

Please explain _____

7. Rate the ease of fabrication of the socket and prosthesis using the scale below. If a CFab was used, please skip this question.

1	2	3	4	5	6	7	8	9	10
Hardest									Easiest
Possible									Possible

Data Collection Form

8. How many training sessions did you complete with this condition prior to the initial data collection? _____sessions

9. Approximately what was the cumulative time spent during those training sessions?
_____hrs

10. How many training sessions did you complete between the initial and final data collection? _____sessions

11. Approximately what was the cumulative time spent during those training sessions?
_____hrs

12. Rate the overall ease of training the subject on this condition.

1	2	3	4	5	6	7	8	9	10
Hardest									Easiest
Possible									Possible

13. Rate the ease of selecting myoelectric sites for this condition.

1	2	3	4	5	6	7	8	9	10
Hardest									Easiest
Possible									Possible

14. How much time did you spend finding myoelectric sites for this condition?
_____hrs

15. Rate the ease of incorporating the electronics into the prosthesis for this condition. If a CFab was used, please skip this question.

1	2	3	4	5	6	7	8	9	10
Hardest									Easiest
Possible									Possible

16. What was the most difficult aspect of fitting and delivering this condition?

17. At the end of this condition, do you feel the interface and control methodology provides a change, positive or negative, regarding myoelectric potential? This may include the addition/subtraction of components, increase/decrease in controlled degrees of freedom, etc. Please Explain. _____
