AWARD NUMBER: W81XWH-19-1-0800

TITLE: Comparative Effectiveness of Upper Limb Prostheses and Component Effects

PRINCIPAL INVESTIGATOR: Dr. Linda Resnik, PhD, PT

CONTRACTING ORGANIZATION: Ocean State Research Institute, Providence, RI

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

Purpose: This application will provide data to guide prosthesis prescription by comparing effectiveness of upper limb prostheses and components and evaluating heterogeneity of treatment effects for key sub-groups. This proposal focuses on the function, form, and interface of upper limb prostheses. The data we collect will be rich and multi-faceted, enabling us to test a multitude of clinically relevant hypotheses.
Scope: 1) Compare the effectiveness of prosthesis type (body powered, myoelectric/hybrid) by amputation level; 2) Quantify the impact of prosthesis form (e.g., weight and shape) on outcomes; 3) Compare the effectiveness of prosthesis suspension method, controlling for potential confounding by prosthesis level, prosthesis type, and prosthesis weight.
Findings/Progress: This reporting period focused on maintaining regulatory approvals; preparing staff and maintaining study coordination; continuing participant recruitment and enrollment activities; conducting preliminary analyses and drafting a manuscript which has will be submitted for publication in early November. Data collection is ongoing. 100 study participants were enrolled as of 10/26/2023.

15. SUBJECT TERMS
Upper limb amputation; upper limb amputee; quality of care; Evidence-Based Clinical Practice Guidelines; prosthetic device; care satisfaction; amputation rehabilitation; amputation outcomes.

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1. **INTRODUCTION:**

Many upper limb prosthesis and componentry options are clinically available; however, it is unclear how to best match an individual amputee with a particular device type and configuration. The inconclusive results of recent systematic reviews comparing body powered to myoelectric prostheses underscore the need for studies that address comparative effectiveness of these devices and components as well as comparative effectiveness for specific sub-groups of patients. Without a body of evidence quantifying the relative benefits of specific devices and components for sub-groups of patients, the clinician has only expert opinion and experience and manufacturers' testimonials, but insufficient research evidence, to inform clinical decision-making. This study will provide data to guide prosthesis prescription by comparing effectiveness of upper limb prostheses and components and evaluating heterogeneity of treatment effects for key sub-groups. It focuses on the function, form, and interface of upper limb prostheses. The data we collect will be rich and multi-faceted, enabling us to test a multitude of clinically relevant hypotheses.

2. **KEYWORDS:**

Keyword summary: Upper limb amputation; upper limb amputee; quality of care; Evidence-Based Clinical Practice Guidelines; prosthetic device; care satisfaction; amputation rehabilitation; amputation outcomes.

3. **ACCOMPLISHMENTS:**

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

There are 3 major goals/aims in the approved statement of work (SOW) for this project:

Aim 1: Compare the effectiveness of prosthesis type (body powered, myoelectric/hybrid) by amputation level.

Aim 2: Quantify the impact of prosthesis form (e.g., weight and shape) on outcomes.

Aim 3: Compare the effectiveness of prosthesis suspension method, controlling for potential confounding by prosthesis level, prosthesis type, and prosthesis weight.

The table below shows the major tasks associated with this study, the target completion date, the actual completion date and percent complete.

Task	Target Completion Date	Completion Date	Percent Complete, End of Year 4
Obtained Regulatory Approvals	Month 1	Complete	100%
Maintain regulatory approvals	Ongoing	Ongoing	100%
Prepare Study Staff	Ongoing	Ongoing	100%
Maintain Study Coordination	Ongoing	Ongoing	85%
Begin Participant Recruitment	Month 1	Complete	100%
Continue Participant Recruitment	Month 24	Month 24	100%
Resume data collection which had been paused due to COVID 19	Month 25	Month 27	100%
Complete Participant Recruitment	Original: Month 24 Revised: Month 56		49%
Complete data collection and data entry	Original: Month 25 Revised: Month 57		49%
Continue Preliminary Data Analysis	N/A	Ongoing	30%
Data Analysis	Month 57-60	Not started	0%
Dissemination	Month 50-60	Not started	0%

- **What was accomplished under these goals?**

During Year 4 (9/30/2022-9/29/2023), we continued study recruitment and enrollment at three study sites: Richmond VA, ISR-San Antonio (DoD Site) and Tampa VA.

We conducted bi-monthly phone meetings with individual site coordinators to review recruitment and enrollment and to discuss site-specific issues. The Richmond, San Antonio and Tampa study staff have been working diligently to meet study recruitment and enrollment goals. We continue to work with each site to improve enrollment. While recruitment and enrollment were challenging during the first half of this year, we saw improvement in Quarters 3 and 4.

We reached out to over 359 Amputee Support Groups in states surrounding our enrollment sites. We shared CIRB approved recruitment materials and made follow-up phone calls to those who expressed interest in the study. Dr. Resnik gave a presentation about the study to clinicians and persons with Upper Limb Amputation (ULA) on September 19, 2023.

We partnered with Hanger Clinic to send recruitment materials to 700 of their clients with upper limb difference in states surrounding our enrollment sites. We received a good response to this mailing and have the local sites scheduled study visits for those who responded.

We held an All Staff Meeting on April 6, 2023. The purpose of this meeting was to discuss the study recruitment status, brainstorm strategies to improve recruitment and to present preliminary data analysis. In preparation, we analyzed data from the first 64 participants and prepared a slide deck for the April 6th meeting. We discovered that we have had five study participants with osseointegration (OI) and decided to prepare a case series on these participants to fully describe them. Given the dearth of literature on OI, we believe that this case series will make a novel and important contribution to the literature. The study team met monthly during Quarters 3 and 4 to collaborate on this project which is almost complete. The resulting manuscript, Outcomes in Transhumeral Upper Limb Amputation with Osseointegration and Targeted Muscle Reinnervation: A Preliminary Observational Cohort Study has been invited for a Special Issue of Frontiers in Rehabilitation and will be submitted in early November.

Another outcome of the All Staff Meeting was the suggestion to expand eligibility criteria to allow participants from Aim 3 - our previous study (Needs, Preferences and Functional Abilities of Veterans and Service Members with Upper Limb Amputation – Award Number: W81XWH-16-2-0065) to participate in the current study. The rationale for this change was that we believed that many of the Aim 3 participants may have new prostheses and that we are collecting some novel data not collected in Aim 3. This revision was approved by the VA CIRB and OHRO. In Year 4, we enrolled 16 participants who previously participated in Aim 3.

Our Tampa Site Coordinator staffed a recruitment table at the Amputee Coalition National Conference in Orlando, Florida that was held on August 2-5, 2023. Team members who attended this meeting and presented at sessions also highlighted our research study and let audience members know that the study is actively recruiting. We recruited 5 study participants at this conference.

Specific Year 4 activities include the following:

<u>1 & 2) Specific objectives and major activities</u>

Specific objectives and major activities accomplished during the Year 4 reporting period (30th September 2022 – 29th September 2023) are described below:

Specific Objective 1: Obtain regulatory approvals (fully met)

Specific Objective 2: Maintain regulatory approvals
Major Activities:

- Ensured that all staff maintain research training certification.
- Submitted and received approval for Amendment 31 which:

– Removed the exclusion criteria that did not allow Aim 3 participants (those who were enrolled in our previous study Needs, Preferences and Functional Abilities of Veterans and Service Members with Upper Limb Amputation Award Number: W81XWH-16-2-0065) to enroll in Aim 5 (our current study).
- Clarified language in the Screening Guide to make it easier to use.

- Submitted and received approval for Amendment 32 which:
  - Modified Aim 5 by inviting a small subset of Aim 5 participants (up to 8 persons) to utilize wearable sensors (accelerometers) during the study visit and at home for a 7- day period. (The wearable sensors study component is being funded by the VA RR&D Centers for Neurorestoration and Neurotechnology.)
  - Submitted a revised informed consent/HIPAA document for Aim 5.
  - Revised the protocol and the Aim 5 consent form to reflect the additional compensation for the wearable sensor portion of the study.
  - Added the Aim 5 Activity Diary for the wearable sensors portion of the study.
  - Added a new study aim, Aim 6, which is being funded by the VA Office of Rehabilitation Research and Development. It is not related to E00981.1 – Proposal Log Number OP180030, therefore we will not summarize the VA CIRB protocol changes associated with Aim 6.
- Obtained continuing review approval from the VA CIRB, USF IRB & ISR (San Antonio) IRB.
- Submitted all study modifications and continuing reviews to OHRO.

Specific Objective 3: Prepare study staff

Major Activities:

- Held Assessors Meetings on November 14, 2022, March 6, and September 16, 2023, to review performance testing protocols, provide feedback from video tape quality control reviews and discuss overall study progress.
- Held an All Staff Meeting on April 6, 2023, to discuss study recruitment status, brainstorm strategies to improve recruitment and to present preliminary data analysis.
  - We decided to amend our protocol to allow for recruitment of Aim 3 study participants for our current Aim 5 study.
  - PIs agreed to prepare a case series on the study participants with osseointegration and targeted muscle reinnervation (TMR) (see #3 Significant Results below).

Specific Objective 4: Maintain Study Coordination

Major Activities:

- Weekly PVAMC team meetings to ensure tracking of study deliverables.
- Executed Year 4 subcontract awards for 2 VA sites (Richmond, Tampa), Institute for Surgical Research – San Antonio, University of South Florida, and Brown University.
- Bi-monthly, plus as needed, phone meetings with individual Site Coordinators to discuss recruitment, enrollment and regulatory issues and address questions.

- Worked with the 3 study site teams to prepare local amendments and continuing review submissions.

Specific Objective 5: Begin Participant Recruitment (fully met)

Specific Objective 6: Continue Participant Recruitment
Major Activities:

- Continued to develop study participant referral lists.
- Hanger Clinic sent our recruitment materials to 700 patients living in states adjacent to our 3 study sites (June 2023).
- Staffed a recruitment table at the Amputee Coalition National Conference in Orlando, FL (August 2-5, 2023). Recruited 5 study participants at the conference.
- Recruited 16 Aim 3 study participants for the current study.
- Study presentation by Dr. Resnik to clinicians and persons with ULA on September 19, 2023
- Screened potential study participants.
- Scheduled potential study participants for study activities.

Specific Objective 7: Continue Data Collection and Data Entry
Major Activities:

- Data collection continued
- Data entry and data quality control continued

3) Significant Results or Key Outcomes

- Data collection is ongoing.
- 100 participants were enrolled as of 10/26/23 (the date of this report)
- To date, there are 4 study visits scheduled for the first quarter of NCE Year 5.
- A manuscript titled, Outcomes in Transhumeral Upper Limb Amputation with Osseointegration and Targeted Muscle Reinnervation: A Preliminary Observational Cohort Study has been drafted and was invited for submission to a special issue in Frontiers in Rehabilitation Sciences. It will be submitted in early November. This paper used an observational matched cohort design to identify and describe characteristics of cases with OI and TMR (cases), a control group without OI or TMR, and a control group with TMR but no OI.

4) Other Achievements

- Nothing to report

Infrastructure development

- Executed Year 4 subcontract awards for the 2 VA sites (Richmond, Tampa), Institute for Surgical Research, University of South Florida, and Brown University

- Maintained regular communications to facilitate coordination and to ensure study fidelity, including:

- Bi-monthly - plus as needed - phone meetings with individual Site Coordinators to discuss recruitment, enrollment and regulatory issues and address questions.
- Held multiple Site Assessors Meetings to review performance testing protocols, provide feedback from video tape quality control reviews and discuss overall study progress.

Data

- Nothing to report

Stated goals not met

1. Complete participant recruitment – Goal – Month 24; Revised – Month56
   As mentioned in previous reports, the year long pause in study activities due to COVID 19 and the slow restart because of the Delta and Omicron waves impacted our recruitment, in part due to hesitancy of potential participants to travel to study sites. Recruitment was challenging during Year 4 Quarters 1 and 2 but has improved significantly in Quarters 3 and 4.

2. Complete data collection and data entry - Goal- Month 25; Revised – Month 57
   Due to recruitment issues described above, data collection and data entry goals have not been met. We are hopeful that the improvement in recruitment and enrollment seen in the last 2 Quarters of Year 4, will continue in Year 5. Please see Section 5 Changes/Problems for more details.

3. Data analysis - Goal – Month 25; Revised – Month 57-60
   Due to the delay in reaching data collection and data entry goals, there was not sufficient data to begin analysis in Month 25. We did begin preliminary data analysis in Month 42 and plan dissemination of the OI/ TMR manuscript in Month 50.

4. Dissemination – Goal – Month 36; Revised – Month 60
   The original goal for dissemination was the last month of Year 3. The revised goal is now Months 50-60+.

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

  Nothing to report

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

  We are not at a point in the study to disseminate results.

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

During the next reporting period (NCE Year 5), we anticipate accomplishing the following activities to meet the project goals and objectives:

Project Activity	Goal Completion Date
Maintain regulatory approvals	Ongoing
Maintain communication with local sites • Bimonthly and as needed meetings with each site • Assessors Meetings as needed • Annual All Staff Meeting	Ongoing
Submit regulatory approvals to OHRO	Ongoing
Continue recruitment activities	Ongoing
Complete Participant Recruitment	Month 56
Complete data collection and data entry	Month 57
Complete Preliminary Data Analysis	Month 52
Begin Data Analysis	Month 57
Begin Dissemination • Publish Osseointegration / TMR manuscript	Month 50-60

4. **IMPACT:**

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

  Nothing to report

- **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:**

- **Changes in approach and reasons for change**

  Nothing to report.

- **Actual problems or delays and actions or plans to resolve them**

Delayed Enrollment with resulting delays in data collection, date entry, data analysis and dissemination:

As reported in the Year 2 & Year 3 Annual Progress Reports and in our 1st and 2nd No Cost Extension requests, the COVID 19 pandemic, beginning in March 2020 (Month 6) and continuing through the end of Year 2 (Month 24), has had a tremendous negative impact. Our study activities were temporarily paused during this prolonged period due concerns for study participant safety and staff safety.

Recruitment was challenging during the first 2 quarters but improved significantly in Quarters 3 and 4 due to the successful recruitment strategies described in Section 1. We will continue to employee these strategies in Year 5.

Although recruitment and enrollment improved in Quarter 4, the delayed notification of the Year 5 No Cost Extension disrupted our research activities during this period. Given the uncertainty regarding the NCE, our subcontracted sites (VA Richmond and Tampa and ISR San Antonio) had to put recruitment on hold. They were unable to schedule or book travel because they did not want to incur changes until they had assurance these funds would be reimbursed. Furthermore, the Research Assistant at the ISR was reassigned to another research study as of September 29th, because the Henry Jackson Foundation did not know if funds for his salary would be reimbursed. Therefore, he was unable to work on our study until the matter was resolved.

On October 4th, Ms. Simmons informed OSRI Executive Director, Mary Ford, that she could send Intent to Fund letters for NCE Year 5. Our sites were promptly notified and resumed recruitment and data collection activities. As of the date of this report, we have completed data collection on 100 participants and have 4 additional participants scheduled for study visits. We are continuing efforts to recruit participants from prior studies, through a second Hanger Clinic mailing, advertising at conferences and through networks, and social media posts.

Anticipated Problems/Issues

With this extended 12-month timeframe afforded by the Year 5 NCE, we will be able to continue to enroll study participants through the end of the Month 57. Since enrollment will not be completed until the end of Month 57, we will only have 3 months to complete data analysis and dissemination. It is likely these tasks will extend beyond the study's completion date (Month 60).

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

  - Less money was expended for participant travel and compensation than anticipated. These funds will be reallocated to the NCE Year 5 budget.

- **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**

  Nothing to report

6. **PRODUCTS:**

   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?**

Name:	Linda Resnik
Project Role:	Principal Investigator
Researcher Identifier (e.g., ORCID ID):	n/a

Nearest person month worked:	1.0
Contribution to Project:	Dr. Resnik has provided overall study oversight and data quality monitory. She is responsible for oversight of the work of Ms. Small, Mr. Borgia and Mr. Davey.
Funding Support:	*n/a*

Name:	Eileen Small
Project Role:	Program Manager
Researcher Identifier (e.g., ORCID ID):	n/a
Nearest person month worked:	6.0
Contribution to Project:	Ms. Small has performed study coordination across all sites, including providing technical support to local site coordinators in regulatory document preparation and submission. In addition, she was responsible for maintaining the overall study budget, reporting requirements, conducting quality control reviews and other administrative tasks as required.
Funding Support:	*n/a*

Name:	Matthew Borgia
Project Role:	Analyst
Researcher Identifier (e.g., ORCID ID):	n/a
Nearest person month worked:	3.0
Contribution to Project:	Mr. Borgia was responsible for coordinating VINCI data pulls in preparation for recruitment mailings and updating DART requests as needed.

Funding Support:	*n/a*

Name:	John Davey
Project Role:	Deputy Project Coordinator
Researcher Identifier (e.g., ORCID ID):	n/a
Nearest person month worked:	7.0
Contribution to Project:	Mr. Davey has developed participant referral lists and prepared materials for the Study Restart meetings. He was also responsible for maintenance of study data bases, data cleaning, providing technical support to local site coordinators in data collection and data entry procedures. Mr. Davey also conducted quality control reviews.
Funding Support:	*n/a*

Name:	Jeffrey Heckman
Project Role:	Local Site Investigator (Tampa VA)
Researcher Identifier (e.g., ORCID ID):	n/a
Nearest person month worked:	1.2
Contribution to Project:	Dr. Heckman has provided oversight for the Tampa VA Site and oversight for the work of Ms. Kern and Ms. Delikat.
Funding Support:	n/a

Name:	Meghan Kern
Project Role:	Research Assistant/Coordinator (Tampa)

Researcher Identifier (e.g., ORCID ID):	n/a
Nearest person month worked:	3.6
Contribution to Project:	Ms. Kern has coordinated data collection activities for the Tampa site, including subject recruitment, travel, reimbursement tracking, data collection and data entry. In addition, she has coordinated required regulatory submissions for the Tampa Site.
Funding Support:	*n/a*

Name:	Jemy Delikat
Project Role:	Assessor (Tampa)
Researcher Identifier (e.g., ORCID ID):	n/a
Nearest person month worked:	2.4
Contribution to Project:	Ms. Delikat is the Assessor for the Tampa Site. She has participated in Assessors Meetings and collected functional performance data.
Funding Support:	*n/a*

Name:	Joseph Webster
Project Role:	Local Site Investigator (Richmond VA)
Researcher Identifier (e.g., ORCID ID):	n/a
Nearest person month worked:	1.2
Contribution to Project:	Dr. Webster provided study oversight for the Richmond VA Site and oversight for the work of Ms. Singh.

Funding Support:	

Name:	Mandeesha Singh
Project Role:	Research Assistant/Coordinator (Richmond)
Researcher Identifier (e.g., ORCID ID):	n/a
Nearest person month worked:	6.0
Contribution to Project:	Ms. Singh has coordinated data collection activities for the Richmond Site, including subject recruitment, travel, reimbursement tracking, data collection and data entry. In addition, she has coordinated required regulatory submissions for the Richmond Site.
Funding Support:	*n/a*

Name:	Jill Cancio
Project Role:	Local Site Investigator & Assessor (ISR – San Antonio)
Researcher Identifier (e.g., ORCID ID):	n/a
Nearest person month worked:	2.4
Contribution to Project:	Dr. Cancio has provided study oversight for the ISR San Antonio Site and oversight for the work of Mr. Bohanon. She is also the Site Assessor and has participated in Assessors Meetings and collected functional performance data.
Funding Support:	*n/a*

Name:	Markese Bohanon
Project Role:	Research Assistant/Coordinator (ISR – San Antonio)
Researcher Identifier (e.g., ORCID ID):	n/a

Nearest person month worked:	6.0
Contribution to Project:	Mr. Bohanon has coordinated data collection activities for the ISR San Antonio Site, including subject recruitment, travel, reimbursement tracking, and data collection.
Funding Support:	*n/a*

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

There have been changes to active other support for investigators. These changes are listed below and do not impact levels of effort on this project.

Principal Investigator
Linda Resnik, PT, PhD
The following changes have been made to Dr. Resnik's other support:

Completed
Title: Intelligent Spine Interface
Role: Co-Investigator
Time commitments: 0.60 Calendar Months
Supporting agency: Defense Advanced Research Projects AgencyR21AG059120-0 (Borton)
Performance period: 09/06/20 –09/24/22 (NCE)
Level of funding:
Project goals: The project proposes to build an Intelligent Spine Interface (ISI) capable of reading and writing simultaneously to, and from, the human spinal cord both above and below the site of spinal cord injury (SCI).

Title: Evaluating Medicare's New Skilled Nursing Facility Payment System
Role: Co-Investigator
Time commitments: 0.30 Calendar Months
Supporting agency: Warren Alpert Foundation (Rahman, Grabowski)
Performance period: 11/01/19 – 10/31/22
Level of funding:
Project goals: This study will examine the impact of the PDPM on SNF quality of care and overall spending for admissions to SNFs in RI and MA.
Title: The Role of Impaired Physical Function during Midlife on Predicting Future ADRD
Role: Co-Investigator
Time commitments: 0.12 Calendar Months
Supporting agency: NIA R03AG070668 (Bardenheier)
Performance period: 03/01/21 – 02/28/23 (NCE)
Level of funding:
Project goals: The study will ascertain the extent to which self-reported impairment in physical function during midlife, predicts future ADRD, thereby offering a new,

efficient mechanism for early identification of ADRD.

New
Title: Assessing the Lasting Impact of the Pandemic on US Nursing Homes
Role: Co-Investigator
Time commitments: 0.12 Calendar Months

Supporting agency: Sub to Harvard/Warren Alpert Foundation (Grabowski)
Performance period: 12/2022-11/2025
Level of funding:
Project goals: Brown University will be integral in the design and evaluation of all the study aims.

Title: The Center for Neurorestoration and Neurotechnology (CfNN)
Role: Director, Focus Area on Restoring Limb and Sensory Function
Contingent Upon VA RR&D A9264-S
Time commitments: 0.05 Calendar Months
Supporting agency: VA RR&D N9228C
Performance period: 07/1/2012- 05/31/2023 (Renewal 6/1/2023- 5/31/2028)
Level of funding:
Project goals: CfNN unifies distinguished researchers and clinicians to advance and translate neurotechnology to restore lost function. Research in Restoring Limb and Sensory Function aims to advance rehabilitation and develop and investigate new technologies for individuals following upper limb amputation. Investigations on restoring limb function provide new hope to Veterans and other persons with amputation and mobility limitations, and include collaborations with clinicians and investigators across the United States toward deployment of new techniques, therapies, and devices

Title: Advancing measurement of physical function in upper limb amputation
Role: Principal Investigator
Contingent Upon VA RR&D A9264-S
Time commitments: 3.00 Calendar Months
Supporting agency: VA RR&D A4775-R
Performance period: 10/1/2023 to 9/30/2027
Level of funding:
Project goals: The overall aim of this proposal is to advance the measurement of physical function in upper limb amputation by refining two measures: the UEFS-P and the custom PROMIS-UE SF as well to provide tools to facilitate implementation of the measures.

Title: Patient-specific requirements of upper limb prosthetic technology
Role: Co-Investigator
Contingent Upon VA RR&D A9264-S
Time commitments: 0.15 Calendar Months
Supporting agency: CDMRP – HT94252310114 (Gracyzk)
Performance period: 9/15/2023-9/14/2025
Level of funding:

Project goals: The primary objective of this proposal is to produce a theoretical model explaining how patient-specific needs, expectations, psychosocial factors, and care experiences interact with prosthetic device features to drive prosthesis acceptance.

Key Personnel

Jill Cancio, OTD, OTR/L, CHT

The following change has been made to Dr. Cancio's other support:

New

Title: Interplay of Physiological, Psychosocial, and Functional Outcomes in Burn Survivors.
Role: Associate Investigator (Site PI),
Time commitments: 2.4 Calendar Months
Supporting agency: National Institute on Disability, Independent Living, and Rehabilitation Research (Suman) Project # TBD
Performance period: 09/27/2023-09/26/2026
Level of funding:
Project goals: The overall objective of this study is to characterize various physiological assessments of physical function and then determine relationships and associations with the psychosocial information gathered by the NIDILRR BMS PROMIS 29 Questionnaire at discharge, 6 months, and 12 months post-burn.

Jeffrey T. Heckman, DO

The following change has been made to Dr. Heckman's other support:

New

Title: LASER Pilot Project: Laser Therapy in Amputee Skin Care to Enhance Rehabilitation. A Preliminary Investigation
Role: Principal Investigator
Time commitments: 0.6 Calendar Months
Supporting agency: VA Rehabilitation Research & Development SPIRE Program I21RX004110-01A1
Performance period: 10/01/23 - 9/30/25
Level of funding:
Project goals: To evaluate the impact of laser therapy treatments for individuals with limb loss with residual limb scarring and fibrosis on range of motion, prosthesis use and quality of life.

M. Jason Highsmith, PhD, PT, DPT

The following changes have been made to Dr. Highsmith's other support:

Completed

Title: Enhanced Auto-Diagnostic Adaptive Precision Trainer for Myoelectric Prosthetic Users (eADAPT-MP)
Role: Principal Investigator
Supporting agency: Design Interactive
Performance period: 01/23/2019-09/29/2021 (no cost extension)
Level of funding:
Project goals: Evaluate a novel training method for users of upper limb myoelectric prostheses and the resulting effects on prosthesis use, return to work, and quality of life.

Title: Enhanced Auto-Diagnostic Adaptive Precision Trainer for Myoelectric Prosthetic Users (eADAPT-MP) matching grant
Role: Principal Investigator
Supporting agency: FL High Tech Corridor
Performance period: 01/23/2019-09/29/2021 (no cost extension)
Level of funding:
Project goals: Evaluate a novel training method for users of upper limb myoelectric prostheses and the resulting effects on prosthesis use, return to work, and quality of life.

- **What other organizations were involved as partners?** Nothing to report.

8. **SPECIAL REPORTING REQUIREMENTS**

- **COLLABORATIVE AWARDS:** Not applicable.

- **QUAD CHART:** See attached.

9. **APPENDICES:** None

Comparative Effectiveness of Upper Limb Prostheses and Component Effects

PI: Linda Resnik, PT, PhD **Org:** Ocean State Research Institute **Award Amount:** $1,493,676

Study/Product Aims

1. Compare the effectiveness of prosthesis type (body powered, myoelectric/hybrid) by amputation level
2. Quantify the impact of prosthesis form (e.g., weight, shape) on outcomes
3. Compare the effectiveness of prosthesis suspension method, controlling for potential confounding by prosthesis level, prosthesis type, and prosthesis weight

Approach

This is a multi-site comparative effectiveness study with an observational, cross-sectional design. Data collection will be done through in-person assessment and functional performance testing. The study will involve multiple data collection sites and a coordinating site. Each participant will complete one study visit.

Figure 1. A variety of upper limb prostheses.

Timeline and Cost

Activities – Project Year	Year 1	Year 2	Year 3	Year 4	Year 5
Start up activities: IRB approvals and staff training					
Data Collection					
Data Analysis					
Dissemination					
Actual Expenses – Years 1-4 (Estimated Expenses Year 5)	**$133,931**	**$73,964**	**$307,713**	**$391,852**	**$586,215**

Goals/Milestones

PY1 Goals – Project launch and data collection

x Submit and obtain all regulatory approvals for study activities
x Kick off meeting planned and held
x Begin participant recruitment
x Begin data collection - *study was paused due to Covid-19 in Year 1

PY2 Goals – Recruitment, data collection, preliminary data analysis

x Resumed recruitment activities in September 2021
x Maintained regulatory approvals

PY3 / PY4 (NCE)Goals – Data Collection and preliminary data analysis

x Continue data collection
- 100 study participants enrolled as of 10/26/23

x Continue preliminary data analysis

Budget Expenditure to Date

Actual Expenditure: Cumulative Y1 = $133,931 + Y2 = $73,964 + Y3 = $307,713 + Y4 = $391,852***** **Total Expenditure to date: $907460***

***As of 10/26/23 – Awaiting final Y4 invoices.**