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

REPORT DATE: October 2021

TYPE OF REPORT: Annual Report

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

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
October 2021	Annual	30Sep2020-29Sep2021

4. TITLE AND SUBTITLE
Comparative Effectiveness of Upper Limb Prosthesis and Component Effects

5a. CONTRACT NUMBER
W81XWH-19-1-0800

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER
0011406602

5e. TASK NUMBER

5f. WORK UNIT NUMBER

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

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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)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

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 (30 September 2020 - 29 September 2021) focused on maintaining regulatory approvals; preparing staff and maintaining study coordination; preparing for Study Restart Meetings and restarting participant recruitment activities in September 2021. Enrollment was temporarily halted due to COVID 19.

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.

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

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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 2
Obtained Regulatory Approvals	Month 1	Complete	100%
Maintain regulatory approvals	Ongoing	Ongoing	100%
Prepare Study Staff	Ongoing	Ongoing	100%
Maintain Study Coordination	Ongoing	Ongoing	50%
Begin Participant Recruitment	Month 1	Complete	100%
Continue Participant Recruitment	Month 24	Uncertain due to recruitment delay caused by COVID 19	7%
Complete data collection and data entry	Month 25	Uncertain due to data collection delay caused by COVID 19	5%
Data Analysis	Month 25	Not started	0%
Dissemination	Month 36	Not started	0%

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

1 & 2) Specific objectives and major activities

Specific objectives and major activities accomplished during the Year 2 reporting period (30th September 2020 – 29th September 2021) are described below:

Specific Objective 1: Obtain regulatory approvals (fully met)

Specific Objective 2: Maintain regulatory approvals

Major Activities:

- Submitted PI-SC Amendment 27 to the VA CIRB and received approval to add Dr. Ethan Balk / Brown University to the protocol as data analysis only site
- Submitted PI-SC Amendment 28 to the VA CIRB and received approval to add a VINCI data pull for recruitment purposes and a new measure (P.A.M) to the protocol
- Submitted Seattle LSI Amendment 2 to the VA CIRB and received approval to change the LSI to Dr. Rebecca Speckman
- Submitted Tampa LSI Amendment 4 to the VA CIRB to change the LSI to Dr. Jeffrey Heckman. Awaiting approval.
- Requested CIRB permission to close the San Antonio VA site (no longer needed now that ISR site is open). Received approval and notified HRPO

- Ensured that all staff maintain research training certification
- Obtained continuing review approval from the VA CIRB, USF IRB & ISR IRB
- Submitted all study modifications and continuing reviews to HRPO

Specific Objective 3: Prepare study staff

Major Activities:

- Held meetings with LSI sites to discuss timeline for getting back into the field
- Worked with LSI sites to schedule Study Restart Meetings
- Updated study policy & procedure manual for data collection sites in preparation for Study Restart
- Updated data collection forms and a testing manual in preparation for Study Restart

Specific Objective 4: Maintain Study Coordination

Major Activities:

- Worked with LSI teams to prepare local amendments and continuing review submissions
- Weekly PVAMC team meetings to ensure tracking of study deliverables
- Executed Year 2 subcontract awards for 3 VA sites (Seattle, Richmond, Tampa), Center for the Intrepid, University of South Florida and Brown University

Specific Objective 5: Begin Participant Recruitment (fully met)

Specific Objective 6: Continue Participant Recruitment

Major Activities:

- Participant recruitment was paused for most of Year 2, but recruitment activities resumed in September 2021, as sites prepared to restart data collection in October 2021.
- Developed study participant referral lists
- Screened potential study participants

Specific Objective 7: Began Data Collection and Data Entry

Major Activities:

- Data collection was paused during Year 2 due to the COVID-19 pandemic

3) Significant Results or Key Outcomes

Nothing to report at this time

4) Other Achievements

Infrastructure development

- Executed Year 2 subcontract awards for the 3 VA sites (Seattle, Richmond, Tampa), Institute for Surgical Research, University of South Florida and Brown University

- Revised Study Policy and Procedure Manual and Testing Manual (containing Data Collection Forms and Instructions) to ensure study fidelity

- Prepared for Study Restart Meetings to review all aspects of the study with local site PIs, Assessors and Coordinators. These meetings will be conducted in October 2021

- Maintained regular communications to facilitate coordination and to ensure study fidelity, including:
  - Regular phone meetings held with the overall Study Coordinator and Staff at data collection sites

- Identified 2 potential new data collection sites that are a part of Arm Dynamics, a company offering comprehensive, upper-limb-focused prosthetic rehabilitation
  - Secured funding from our Center for Neurorestoration & Neurotechnology (CfNN), VA Providence Healthcare System, to cover the costs of the additional sites.
  - VA contract now being prepared for Arm Dynamics.
  - We hope that the addition of these new data collection site will help us achieve our recruitment goals in a timely manner.
  - IRB submission will be submitted, once the VA contract is approved.
  - We discussed the potential new sites with Allison Mclean at HRPO. We will submit the modification to add these new sites to HRPO, once the IRB submission has been approved.

Data

- Nothing to report.

Stated goals not met

1. Continue participant recruitment
   a. Goal – Month 24; Actual: Uncertain. Recruitment was temporarily halted due to the COVID 19 pandemic for most of Year 2. We resumed participant recruitment in September 2021, in preparation for restarting data collection activities in October 2021.

2. Complete data collection and data entry
   a. Goal- Month 25; Actual Uncertain. The temporary halt to study activities due to COVID 19, will also impact our data collection and data entry goals. With data collection restarting for our original sites in October 2021 and the potential of adding 2 new data collection sites to the study, we hope to make steady progress towards achieving these goals.

- **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 (Year 3), 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 • Twice a month meetings with each site • Monthly study coordinators meetings • Assessors meetings as needed	Ongoing
Submit regulatory approvals to HRPO	Ongoing
Continue recruitment activities	Recruitment activities were restarted in September 2021. Goal Completion Date is uncertain due to the delay caused by COVID 19
Conduct Study Restart training meetings with all data collection sties	October 2021
Restart data collection activities	Data collection activities will restart in October 2021. Goal Completion Date is uncertain due to the delay caused by COVID 19
Restart data entry activities	Data entry activities will restart in October 2021. Goal Completion Date is uncertain due to the delay caused by COVID 19

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

  We temporarily halted study activities beginning in March 2020 (Month 6) and throughout Year 2 due to the COVID 19 pandemic and the related safety concerns for potential study participants and our study staff. Now that vaccines are available and COVID 19 infection rates have dropped at our local sites, we feel it is safe to resume study activities as described above.

  We anticipate that we will need to request a No Cost Extension at the end of Year 3 and will need to extend the project timeframe for data collection, analysis and dissemination activities. At this time, we are uncertain whether we will be constrained financially, and if we will have sufficient funds to achieve our data collection goals. We have sought (and received) a commitment of funds from the VA to support the addition of two Arm Dynamic sites. We hope that the addition of these sites will help us accrue subjects in a timely manner.

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

  The temporary halt of study activities decreased our project expenditures for Year 2 significantly. Research Coordinator effort was reduced to 5%. This conserved funds and allowed us to maintain regulatory requirements and communication with local sites. No funds were expended related to data collection.

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 at this time.

- **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):	
Nearest person month worked:	1.0
Contribution to Project:	Dr. Resnik has performed work in the area of overall study oversight and oversight for the work of Ms. Small 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:	.05
Contribution to Project:	Ms. Small has performed work in the area of study coordination, providing technical support to local site coordinators in regulatory document preparation and submission. In addition, she maintained the overall study budget and associated tasks.
Funding Support:	*n/a*

Name:	John Davey
Project Role:	Senior Research Assistant
Researcher Identifier (e.g., ORCID ID):	n/a
Nearest person month worked:	.03
Contribution to Project:	Mr. Davey has performed work in the area of developing participant referral lists, revising Policy and Procedure and Testing manuals and preparing materials for the Study Restart meetings.
Funding Support:	*n/a*

Name:	Meghan Rosenbrock Kern
Project Role:	Research Assistant/Coordinator (Tampa)
Researcher Identifier (e.g., ORCID ID):	
Nearest person month worked:	.09

Contribution to Project:	Ms. Rosenbrock has coordinated required regulatory submissions for this site and restarted recruitment activities.
Funding Support:	*n/a*

Name:	Matthew Jerrell
Project Role:	Research Assistant/Coordinator (Seattle)
Researcher Identifier (e.g., ORCID ID):	
Nearest person month worked:	.09
Contribution to Project:	Mr. Jerrell has coordinated required regulatory submissions for this site and restarted recruitment activities.
Funding Support:	*n/a*

Name:	Mandeesha Singh
Project Role:	Research Assistant/Coordinator (Richmond)
Researcher Identifier (e.g., ORCID ID):	
Nearest person month worked:	.09
Contribution to Project:	Ms. Singh has coordinated required regulatory submissions for this site and restarted recruitment activities.
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 some changes to active support for the PI and some senior/key personnel. These changes are listed below. None of these changes have impacted level of effort on this project.

Dr. Linda Resnik - The following changes have been made to Dr. Resnik's support*:*
New

Title: Intelligent Spine Interface (PI: _Borton)

Sponsor: Defense Advanced Research Projects Agency
Role: Co-Investigator
Time Commitment: 0.6 CM (Brown)
Period of Performance: 09/06/2020 – 09/24/2022 (NCE)
Amount Funded:
Project Goals/Specific Aims: 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: The Role of Impaired Physical Function during Midlife on Predicting Future ADRD (PI: Bardenheier)
Sponsor: NIA 1R03AG070668-01
Role: Co-Investigator
Time Commitment: 0.24 CM (Brown)
Period of Performance: 03/01/2021 – 02/28/2023
Amount Funded:
Project Goals/Specific Aims: 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

Completed

Title: Needs, Preferences and Functional Abilities of Veterans and Service Members with Upper Limb Amputation – Female Supplement
Sponsor: VA RR&D A2707-1
Contingent Upon VA RR&D A9264-S
Role: Principal Investigator
Time Commitment: 0.0 CM (VA Appt)
Period of Performance: 05/01/2017 – 04/30/2021
Amount Funded:
Project Goals/Specific Aims: The objective of this study is to provide comprehensive cross-sectional and longitudinal data on function, needs, preferences, and satisfaction of Veterans and service members with major upper limb amputation. This supplement will include a robust sample of female Veterans and allow comparisons of findings by gender.

Dr. Jeffrey Heckman: The following change have been made to Dr. Heckman's support*:*
New

Title: Resolving the Burden of Low Back Pain in Military Service Members and Veterans: A Multi-Site Pragmatic Clinical Trial
Time commitments: 0.6 Calendar Months
Supporting agency: NIH-DoD-VA Pain Management Collaboratory, W81XWH-18-2-0007
Contracting/Grants Officer contact info: Mai Apriyanto, mapriyanto@hjf.org
Performance period: 9/28/2020-5/31/2024

Level of funding:
Project goals: The objective of this study is to provide a framework necessary for widespread dissemination and implementation of physical therapy (PT) Clinical Practice Guidelines (CPG) recommendations for patients with low back pain (LBP) across DoD and the VA.

Dr. M. Jason Highsmith - The following changes have been made to Dr. Highsmith's support*:*
New

Title: RESOLVE: Resolving the Burden of Low Back Pain in Military Service Members and Veterans: A Multi-Site Pragmatic Trial
Performance Period: 05/15/2019-05/14/2022
Role: Co-Investigator
Level of Funding:
Project Goals: Evaluate the rehabilitative standard of care for patients with low back pain compared to alternatives using a step wedge, pragmatic study design in real outpatient clinics within the VA and DOD.

Completed

Title: Prosthetic Smart Socket Technology to Improve Patient Interaction, Usability, Comfort, Fit and Function
Supporting Agency: U.S. Department of the Army
Performance Period: 09/15/2015-09/29/2021 (no cost extension)
Role: Principal Investigator

Title: The IM ABLE Study: A Cross-Sector, Multi-Site Initiative to Advance care for Warriors and Veterans following Neuromusculoskeletal Injury of the Lower Limb
Supporting Agency: Department of the Army - USAMRAA
Performance Period: 10/1/2016-9/29/2021 (no cost extension)
Role: Principal Investigator
Level of funding:
Project Goals: Determine if advanced (ADV) ankle foot orthoses (AFOs) will enable users to achieve greater levels of physical and self-reported function compared with conventional (CONV) AFOs for those ambulating at or above the independent community level of ambulation.

Dr. Joseph Webster - The following change have been made to Dr. Webster's support*:*
New

Title: Improving Acceptability and Outcomes for Upper Extremity Transplantation in Service Members and Veterans
Supporting Agency: Congressionally Directed Medical Research Programs FOA #W81XWH-19-RTRP-QRA. Reconstructive Transplantation Research Translational Research Award
Performance Period: 7/01/2021-7/01/2023
Prime Institution: Johns Hopkins University School of Medicine
Level of funding: TBD

Role: Site Principal Investigator
Time Commitment: 1.2 CM

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

  Nothing to report

8. **SPECIAL REPORTING REQUIREMENTS**

- **COLLABORATIVE AWARDS:** Nothing to report, 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 Aim(s)

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 will be 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 5 data collection sites and a coordinating site. Each participant will complete one study visit. Data collection activities will be completed in 2 years.

Figure 1. A variety of upper limb prostheses.

Timeline and Cost

Activities – Project Year	Year 1	Year 2	Year 3
Start up activities: IRB approvals and staff training			
Data collection			
Data analysis			
Dissemination			
Actual Expenses (Y1 & Y2) **Projected expenses (Y3 w/ NCE)**	**$ 133,931**	**$73,696**	**$1,286,049**

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 Resume recruitment activities in September 2021
- x Maintain regulatory approvals

PY3 Goals – Data analysis and preliminary data analysis
- ❑ Restart data collection in October 2021, NCE anticipated end of PY3
- ❑ Begin preliminary data analysis

Budget Expenditure to Date

Actual Expenditure: Cumulative Y1 = $133,931 + Y2 = $73,696
Total Expenditure to date: $207,627)