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TITLE: Women with Amputation: The Unique Needs of an Underserved Population

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14. ABSTRACT There is a growing population of women living with amputations, specifically in the VA and DoD healthcare system, yet little research has been performed to understand the unique needs of this population, which limits evidentiary support for clinical decision making. This investigation aims to conduct a 3-year national exploratory needs assessment that will focus on the unique physical, psychological and social needs of women living with amputations. The investigation is a collaborative effort between the VA, DoD, and civilian sector. To ensure a heterogeneous population of respondents, a convenience sample of 100 male and 100 female Veterans, Servicemembers, and civilians will be recruited from across the nation to participate. The participants will be asked to complete an online computer adaptive survey regarding their physical health, quality of life, prosthetic use and needs, and psychosocial experiences. Surveys will be completed anonymously and electronically without individually identifiable information.					
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1. INTRODUCTION:

Due to the historic number of women serving in combat related positions, more women have experienced amputation of one or more limbs during the most recent conflicts. During the most recent conflicts, more than 135 American servicewomen gave their lives, over 600 were injured, and 27 have experienced traumatic limb amputation. In 2016, the Veterans Health Administration (VHA) served 1,805 female Veterans with amputations. Despite these numbers, females with amputation are studied less than their male counterparts in prosthetic and amputee rehabilitation research, which limits evidentiary support for clinical decision making in this demographic. While research on this demographic has been limited in scope, it has been shown that women with lower limb amputations face physical challenges. For example, women generally require smaller prosthetic components due to their smaller bone structure and muscle mass. Commercially available prosthetic components tend not to be gender-specific and are designed with male anthropometry and biomechanics, which leads to greater dissatisfaction with prosthetic fit and appearance for women living with amputation. Challenges with prosthetic fit stemming from the lack female specific components and heavy prosthetic weight can lead to skin integrity problems, pistoning, and an increased risk for secondary comorbidities. As such, women living with amputation are at a significantly higher risk for developing osteoarthritis in the contralateral limb compared to men. Women living with amputation also face unique psychosocial challenges. One in five female Veterans screen positive for military sexual trauma and female Veterans are 22% more likely to be diagnosed with a mental health condition compared to male Veterans. There is a significant need to fill this critical gap in knowledge of the unique needs of women living with amputation. As such, this investigation will aid in the determination of these unique needs and improve the evidentiary support needed for this expanding population. This study will help determine gaps in research, as well as commercially available products, which will guide appropriate treatment strategies.

2. KEYWORDS:

Amputation, Women with amputation, Physical, Psychological, Social, Prosthetics needs assessment

3. ACCOMPLISHMENTS:

What were the major goals of the project?

The overall goals for study OP160081 include:

1. To determine the difference in physical needs of females living with amputation compared to males living with amputation, and to classify this difference.
2. To determine the differences in psychosocial needs of females living with amputation compared to males

Major Task 1: Survey and Website development IRB Submission	% Completion	Completion Date	Expected Completion
Subtask 1: Survey/Website Development		-	
Finalize surveys and guided questions	100%	5/2018	-
Purchase of website, server space	100%	10/2018	-
Creation of the survey decision tree	100%	6/2018	-
Testing, Debugging, and Optimizing electronic survey	100%	12/2018	-
Final edits and Live Launch	100%	1/2019	-
<i>Milestone Achieved: Creation of electronic survey and decision tree</i>	100%	5/2/2018	-
<i>Milestone Achieved: Launch of website/online survey</i>	100%	1/2019	-
Subtask 2: Prepare IRB Documents and Research Protocol		-	
Coordinate with Sites for CRADA* submission	100%	ongoing	-
Refine eligibility criteria, exclusion criteria, screening protocol	100%	12/15/2017	-
Finalize human subjects protocol	100%	12/2017	-
Submit Central IRB** initial submission	100%	05/18/2018	-

Coordinate with VA Sites for Central IRB**LSI submission	88%	NYHHS: 12/4/2018 JJPVAMC: 2/27/2019 Washington DC: 6/24/2019 Cleveland: 6/24/2019 Tampa: 6/24/2019 Philadelphia: 8/22/2019 Denver: 8/22/2019 Augusta: ongoing	11/2020
Coordinate with Non-VA site for IRB** protocol submission	75%	Walter Reed site: 11/15/2018; NYU site: Pending	11/2020
Coordinate with Sites for Military 2 nd level IRB** review (ORP/HRPO)	88%	NYHHS: 11/9/2018 JJPVAMC: 5/13/2019 Washington DC: 8/27/2019 Cleveland: 8/27/2019 Tampa: 9/30/2019 Philadelphia: 10/17/2019 Denver: 10/17/2019 Augusta: ongoing	11/2020
<i>Milestone Achieved: Central and Local IRB** approval</i>	88%	-	11/2020
<i>Milestone Achieved: HRPO** approval for all protocols</i>	78%	-	11/2020
Major Task 2: Coordinate Study Staff for Recruitment/Enrollment			
Subtask1: Hiring and Training of Study Staff		-	
Coordinate with VA, DoD, and Private Sector for job description	100%	10/30/2017	-
Advertise and interview for project related staff	100%	11/15/2017	-
Coordinate with Sites for hiring, training, supervision and, fidelity checks as needed for attrition.	100%	3/2018	-
Recruit Point of Contact (POC) at each VA Polytrauma site and Regional Amputation Center (RAC)	100%	10/15/2017	-
<i>Milestone Achieved: POC of contact for recruitment identified at each RAC and Polytrauma site</i>	100%	10/15/2017	-
<i>Milestone Achieved: Project Research staff hired and trained</i>	100%	12/11/2017	-

Major Task 3: Participant Recruitment			
Subtask 1: Subject recruitment			
Coordinate with Prosthetics and Rehabilitation Clinic for Subject Recruitment as well as each POC at all RAC and Polytrauma Sites	100%	12/3/2019	
Develop flyers with survey information	100%	06/14/2018	
Complete local pilot study	100%	07/02/2019	
<i>Milestone Achieved: Study begins</i>	100%	1/10/2019	
<i>Milestone Achieved: First subject consented, screened and enrolled</i>	100%	1/10/2019	
Major Task 4: Data Collection			
Subtask 1: Set up web-based data management system	100%		
Maintain website and server	100%		
Subtask 2: Conduct Study			

Collect electronic survey data according to the project timeline	Ongoing		
<i>Milestone Achieved: All subjects have been recruited, consented, screened, and enrolled</i>	88% of Men; 103% of Women, but need 37 more female Veterans/ Service Members		
<i>Milestone Achieved: All subjects have completed the research protocol</i>	83%		

What was accomplished under these goals?

Major Activities and specific objectives for Year 3 include:

Survey Status

As of 10/29/2020, 192 participants have completed the survey. Of those, 103 are female, 88 are male, and 1 is a transgender woman. Our goal is to have a minimum of 200 completed surveys, including 100 female participants and 100 male participants. Figure 1 depicts general campaign statistics. To date, there have been 311 participants: 192 subjects (61.74%) have completed the survey, 33 (10.61%) were ineligible based on inclusion/exclusion questions, and 86 participants (27.65%) started the survey but did not complete it. Due to the length of the survey, we expected approximately 20-25% would not complete the survey after starting it.

Campaign Statistics
Total Participants: 311

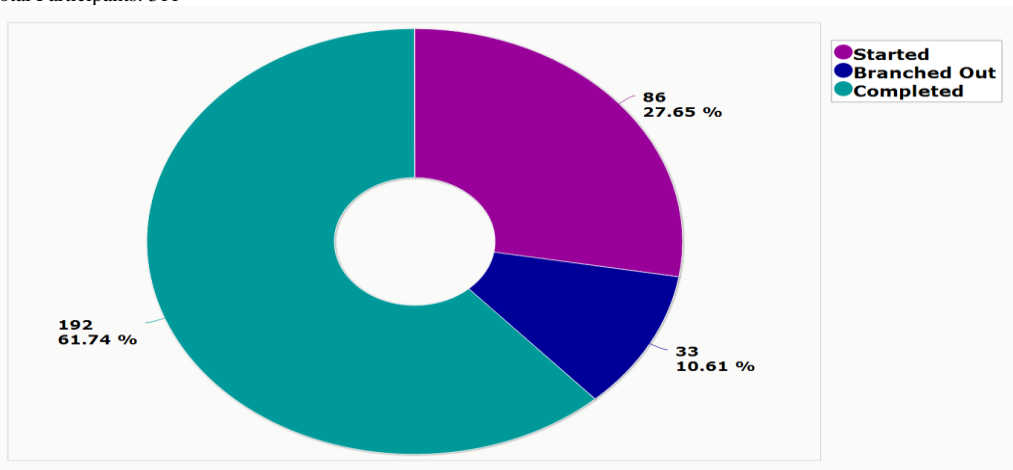


Figure 1: Survey statistics. 192 subjects have completed the survey, 33 were ineligible based on inclusion/exclusion questions, and 86 participants have started the survey but did not complete it.

milaffil. Which one of the following describe your current service in the United States Armed Forces?		gender. Which gender do you currently identify as?							Total
		Male	Female	Transgender Male	Transgender Female	Gender Queer	Other	Prefer not to answer	
I have never served in the United States Armed Forces	Count	50	90	0	0	0	0	0	140
	% by Col	56.8%	87.4%	0.0%	0.0%	0.0%	0.0%	0.0%	72.9%
I currently serve in the United States Armed Forces as Active Duty, National or National Air Guard Unit, in a Reserve Unit	Count	2	1	0	0	0	0	0	3
	% by Col	2.3%	1.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1.6%
I have served in the Armed Forces in the past	Count	36	11	0	1	0	0	0	48
	% by Col	40.9%	10.7%	0.0%	100.0%	0.0%	0.0%	0.0%	25.0%
Prefer not to answer	Count	0	1	0	0	0	0	0	1
	% by Col	0.0%	1.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.5%
Total	Count	88	103	0	1	0	0	0	192.0
	% by Col	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Figure 2: Military status of participants. This illustrates the military and gender status of participants who completed the survey. Currently, 12 female Veterans or Service Members and one transgender female veteran has completed the survey. One female participant preferred not to answer military status question. Our goal is to have at least 50 female Veterans/Service Members complete the survey.

Statistical Analysis

We have identified a statistical analysis team and reviewed the data analysis plan. Statistical analysis will begin upon completion of a data use agreement between VA and Army Public Health Center (APHC) for sharing raw data with the statistical analysis team. Once this is accomplished, analysis of collected data to date will occur. Dissemination of our findings will include presentations at leading conferences in 2021, as well as the development of several journal manuscripts.

Regulatory Approvals

Local Research & Development Committee approval and HRPO approval for all sites are detailed in Table 1. Approval for NYU and the Charlie Norwood VA Medical Center is ongoing. Active recruitment will resume at all approved sites upon further guidance from VA ORD.

TABLE 1: Regulatory Status of Collaborating Sites

Site/HRPO Site #	IRB Status	Most recent Approval Dates	Study Stage
VA New York Harbor (New York, NY) A-20481.a	cIRB, local R&D, HRPO approved	cIRB: 08/27/2020 HRPO Acknowledgement: 10/21/2020	Enrolling
Walter Reed National Military Medical Center A-20481.b	Local IRB, HRPO approved	Local IRB (exemption granted): 11/15/2018 HRPO: 2/21/2019	Enrolling
James J. Peters VA Medical Center (Bronx, NY) A-20481.c	cIRB, local R&D, HRPO approved	cIRB: 08/27/2020 HRPO Acknowledgement: 10/05/2020	Enrolling
Washington DC VA Medical Center A-20481.d	cIRB, local R&D, HRPO approved	cIRB: 08/27/2020 HRPO Acknowledgement: 10/02/2020	Enrolling
VA Northeast Ohio Healthcare System (Cleveland, OH) A-20481.e	cIRB, local R&D, HRPO approved	cIRB: 08/27/2020 HRPO Acknowledgement: 09/24/2020	Enrolling
James A. Haley VA Medical Center (Tampa, FL) A-20481.f	cIRB, local R&D, HRPO approved	cIRB: 08/27/2020 HRPO Acknowledgement: 09/18/2020	Enrolling
Corporal Michael J. Crescenzo VA (Philadelphia, PA) A-20481.g	cIRB, HRPO approved	cIRB: 08/27/2020 HRPO Acknowledgement: 09/24/2020	Enrolling
VA Eastern Colorado Healthcare System (Denver, CO) A-20481.h	cIRB approved, HRPO approved	cIRB: 08/27/2020 HRPO Acknowledgement: 10/01/2020	Enrolling
Charlie Norwood VA Medical Center (Augusta, GA)	Pending cIRB approval		Pending cIRB approval
New York University Langone	Local IRB approved	Local IRB: 10/23/2019	Pending HRPO approval

Goals Not Met:

All goals have not been met for Y3. Due to the ongoing COVID-19 pandemic, the VA Office of Research and Development (ORD) placed an administrative hold on all non-essential research patient visits. While protocol

activities involving online survey completion have been permitted to continue, in-person recruitment has been suspended for most of year 3. Only recently have collaborating sites began reopening outpatient clinics, but only to a percentage of Pre-COVID levels. As such, the ongoing pandemic has limited the ability of the local clinics for in-person recruitment. For example, as of October 2020, VA New York Harbor Healthcare System remains at about 10-15% of pre-COVID in-person clinic visits. While over 100 women have completed the survey, recruitment of female Veterans and Service Members is less than expected. We plan to enroll 37 more female Veterans/Service members to reach our recruitment goal. To help reach this goal, the study team will continue in-person recruitment where possible, as well as leverage virtual telehealth patient visits for basic prosthetic care to share study flyers with female Veterans and Service Members to increase recruitment during this pandemic.

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

While this investigation is not designed for training or professional development, the study team holds monthly calls with Co-Investigators, as well as quarterly calls with local sites, to provide study updates, promote successful recruitment strategies, discuss any problems, and review data to-date. The next meeting with the local site investigators is scheduled for November 2020.

How were the results disseminated to communities of interest?

Nothing to report at this time. There are plans to submit abstracts to leading conferences for 2021. Furthermore, we expect to develop several manuscripts by the conclusion of the grant performance period.

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

To accomplish the goals and objectives for Year 4, we plan to:

- Obtain IRB/HRPO approval and complete all regulatory requirements for the remaining local sites.
- Coordinate recruitment efforts at collaborating sites, including leveraging virtual telehealth appointments.
- Complete enrollment of 200 completed surveys, include 50 female Veterans/Service Members.
- Analyze results.
- Submit abstracts to leading conferences to present our results.
- Manuscript preparation and submission.
- Proposal development for continued funding

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

Due to the ongoing, global pandemic, in-person recruitment at local prosthetic clinics remained suspended for most of year 3. Furthermore, recruitment at national amputation conferences and events has also been suspended. Recruitment will continue in-person where feasible, as well as through video telehealth appointments.

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

The administrative hold due to the COVID-19 pandemic has limited in-person recruitment since March 2020. We have continued to recruit participants whenever possible to take the online survey, but recruitment was lower than expected. Outpatient clinics continue to slowly reopen to pre-COVID levels for many of our collaborators, which will help in-person recruitment. Furthermore, we will leverage virtual prosthetic telehealth appointments to educate female Veterans and Service Members about the online survey. A one-year, no cost extension has been granted during Y3Q4 to meet our enrollment goals, as well as to perform data analysis and dissemination.

Changes that had a significant impact on expenditures

Due to the ongoing pandemic, expenses are less than projected. We expect expenditures to increase as we engage the statistical analysis team and begin dissemination of results.

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

There have been no significant changes in use or care of human subjects.

Significant changes in use or care of vertebrate animals

N/A

Significant changes in use of biohazards and/or select agents

N/A

6. PRODUCTS:

Publications, conference papers, and presentations Journal publications.

Nothing to Report.

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

Nothing to Report.

Other publications, conference papers and presentations.

Nothing to Report.

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

The survey can be found at www.limblossmatters.com

- **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:	Roxanne Disla, OTD, OTR/L
Project Role:	PI at NYHHS
Nearest person month worked:	2
Responsibilities/ Contributions:	Responsible for overall coordination and integrity of study.
Name:	Jason Maikos, PhD
Project Role:	Co-PI at NYHHS
Nearest person month worked:	1
Responsibilities/ Contributions:	Oversaw pilot study, item-bank development, responsible for site-specific enrollment.
Name:	Michael Hyre, MS
Project Role:	Study Coordinator at NYHHS
Nearest person month worked:	1
Responsibilities/ Contributions:	Assisted with all regulatory activities at NYHHS.
Funding Support	CDMRP award number W81XWH-17-1-0568
Name:	Alison Pruziner, PT, DPT
Project Role:	Co-I at National Veterans Sports Programs and Special Events
Nearest person month worked:	1
Responsibilities/ Contributions:	Assisted pilot study analysis, item-bank development, and recruitment at National Veterans Wheelchair games
Name:	Kathryn Ellis, OTD, OTR/L
Project Role:	(Former) Site-PI at Walter Reed
Nearest person month worked:	1
Responsibilities/ Contributions:	Oversees site-specific activities, item bank development
Name:	Josef Butkus, MS, OTR/L
Project Role:	New Site-PI at Walter Reed
Nearest person month worked:	1
Responsibilities/ Contributions:	Oversees site-specific activities, item bank development
Name:	Christopher Dearth, PhD
Project Role:	Co-I at WRNMMC
Nearest person month worked:	1
Responsibilities/ Contributions:	Study overview
Name:	Tamara Bushnik, PhD
Project Role:	Site-PI at NYU
Nearest person month worked:	1
Responsibilities/ Contributions:	Oversees site-specific activities, item bank development.

Name: Theresa Jackson Santo, PhD, MPH
Project Role: Site lead at APHC
Nearest person month worked: 1
Responsibilities/ Contributions: Responsible for site efforts and coordination, including regulatory requirements.

Name: Jill Brown, PhD
Project Role: Co-site lead at APHC
Nearest person month worked: 1
Responsibilities/ Contributions: Survey item bank development and survey implementation plan development.

Name: Alyssa Coleman, MPH, CPH
Project Role: Programmer at APHC
Nearest person month worked: 1
Responsibilities/ Contributions: Survey item bank development and survey implementation plan development.

Name: Patricia Erickson, MPH
Project Role: Programmer at APHC
Nearest person month worked: 1
Responsibilities/ Contributions: Survey item bank development and survey implementation plan development.

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

Due to Dr. Ellis leaving Walter Reed, Mr. Josef Butkus, MS OTR/L has assumed the role as site-PI at Walter Reed (Site A-20481.b). Local PI change was acknowledged at the site on 10/09/2020 for the exempted protocol. A submission to HRPO for this PI change will be sent by the lead site, as soon as all documentation is in place. There are no changes to the study protocol.

What other organizations were involved as partners?

Walter Reed National Military Medical Center

8901 Wisconsin Ave Bethesda, MD 20889

Contributions to the Project: Collaboration and Facilities

NYU Langone Ambulatory Care Center

Rusk Rehabilitation

240 East 38th Street, New York, NY 10016

Health Promotion and Wellness Directorate Army Public Health Center

8977 Sibert Road

E1570, ATTN: MCHB-PH-PHA, OE103

Aberdeen Proving Ground - EA, MD 21010

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: This report covers the reporting period for both NYHHS and WRNMMC.

QUAD CHARTS: Attached.

9. APPENDICES: None