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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.					
15. SUBJECT TERMS Amputation, Women with amputation, Quality of life, Physical health, Prosthetic use, Prosthetic needs					
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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	100%	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	-
Coordinate with Non-VA site for IRB** protocol submission	100%	Walter Reed site: 11/15/2018 NYU site: 10/23/2019	-
Coordinate with Sites for Military 2 nd level IRB** review (ORP/HRPO)	100%	NYHHS: 11/9/2018 JJPVAMC: 5/13/2019 DC VA: 8/27/2019 Cleveland: 8/27/2019 Tampa: 9/30/2019 Philadelphia: 10/17/2019 Denver: 10/17/2019 Walter Reed: 02/21/2019 NYU: 03/03/2021	-
<i>Milestone Achieved: Central and Local IRB** approval</i>	100%	-	-
<i>Milestone Achieved: HRPO** approval for all protocols</i>	100%	-	-
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>	95% of Men; 121% of Women overall, but seeking 30 more female Veterans/ Service Members		
<i>Milestone Achieved: All subjects have completed the research protocol</i>	100% overall (but 40% of targeted female Veterans/Service Members have completed)		

What was accomplished under these goals?

Major Activities and specific objectives for Year 4 include:

Survey Status

As of 10/22/2021, 219 participants have completed the survey. Of those, 123 are female, 95 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 398 participants: 219 subjects (55.03%) have completed the survey, 52 (13.07%) were ineligible based on inclusion/exclusion questions, 122 participants (30.65%) started the survey but did not complete it and 5 participants (1.26%) were over quota. Due to the length of the survey, we expected approximately 20-25% would not complete the survey after starting it. We are likely seeing an increase in non-completions because more patients are now taking the survey from home due to COVID without full knowledge of the time commitment. During recruitment in person, the time commitment was fully explained. Furthermore, participants were given the opportunity to complete the survey on site.

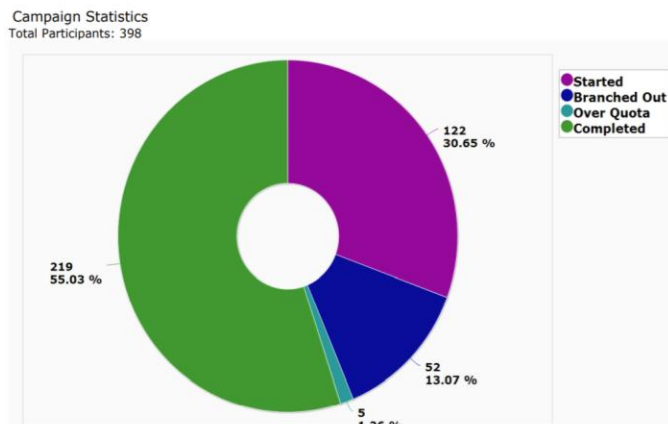


Figure 1: Survey statistics. 219 subjects have completed the survey, 52 were ineligible based on inclusion/exclusion questions, 122 participants have started the survey but did not complete it and 5 were over quota.

Figure 2 outlines the participants by military status (current/previous service or never served) and identified gender

milaffil. Which one of the following describe your current service in the United States Armed Forces?

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	52	101	0	0	0	0	0	153
	% by Col	54.7%	82.1%	0.0%	0.0%	0.0%	0.0%	0.0%	69.9%
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	2.1%	0.8%	0.0%	0.0%	0.0%	0.0%	0.0%	1.4%
I have served in the Armed Forces in the past	Count	41	20	0	1	0	0	0	62
	% by Col	43.2%	16.3%	0.0%	100.0%	0.0%	0.0%	0.0%	28.3%
Prefer not to answer	Count	0	1	0	0	0	0	0	1
	% by Col	0.0%	0.8%	0.0%	0.0%	0.0%	0.0%	0.0%	0.5%
Total	Count	95	123	0	1	0	0	0	219.0
	% by Col	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Figure 2: Military and gender identification status of participants. Currently, 21 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

A data use agreement between VA and Army Public Health Center (APHC) for sharing raw data with the statistical analysis team was completed on 03/31/21. Preliminary analysis of collected data occurred. Below are the results for a sample size of 114 women, 93 men and 1 transgendered female who completed the survey.

Research Question 1: Is there a difference in physical needs of females living with amputation compared to males living with amputation?

Independent sample t-tests with gender (male/female) as the grouping variable and physical needs variables as the dependent variables were conducted. For both upper and lower extremity amputation, women were less satisfied with appearance compared to men. Women with lower limb loss reported worse residual limb health compared to men, but with no gender differences for those who had lost an arm. This is likely due to sample size (e.g., df = 8 and 10). Women with lower limb loss reported less aesthetic, functional, and overall satisfaction compared to men with limb loss.

Research Question 2: Is there a difference in functional needs of females living with amputation compared to males living with amputation?

Independent sample t-tests with gender (male/female) as the grouping variable and functional needs variables as the dependent variables were conducted. Women with lower extremity limb loss reported significantly fewer activity restrictions than men. Women reported less satisfaction with the usefulness/reliability of their lower extremity prosthesis compared to men. There were no other differences in functionality between men and women.

Research Aim 3: Is there a difference in healthcare of females living with amputation compared to males living with amputation?

Independent sample t-tests with gender (male/female) as the grouping variable and the two healthcare composites and individual items as the dependent variables were conducted. There were no differences between men and women in either of the healthcare composites, or at the item level for healthcare.

Research Question 4: Is there a difference in psychosocial needs of females living with amputation compared to males living with amputation?

Independent samples t-tests with gender (male/female) as the grouping variable and psychosocial needs variables as the dependent variables were conducted. Women with lower limb loss reported a higher level of being bothered at people looking at their prosthesis. Women with lower limb loss also reported lower levels of overall satisfaction with their prosthesis compared to men. Women reported being less comfortable with people they were sexually attracted to compared to men. Women reported less ease in social situations, less change for the better in social situations after amputation, more anxiety, depression, and worse body image perception compared to men. Women with upper extremity limb loss reported more general adjustment compared to men, but the sample sizes are not generalizable.

Dissemination of our findings will include presentations at leading conferences in 2022, as well as the development of several journal manuscripts.

Regulatory Approvals

Table 1 outlines the regulatory status of each collaborating site. Other regulatory updates include:

- HRPO concurrence with determination of exemption for NYU was received on 03/03/21.
- Continuing Review Approval granted by VA Central IRB for overall study on 09/10/2021.
- HRPO acknowledgement of the Continuing Review Documents for all sites received by 10/04/2021.

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. Crescenz 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
New York University Langone	Local IRB EXEMPT, HRPO concurred	Local IRB (exemption granted): 10/23/2019 HRPO Concurrence With Determination of Exemption for the Protocol: 03/03/2021	Enrolling

Goals Not Met:

All goals have not been met for Y4. Due to the ongoing COVID-19 pandemic, recruitment of female Veterans and Service Members remains less than anticipated.

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 regular 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.

How were the results disseminated to communities of interest?

Nothing to report currently. There are plans to submit abstracts to leading conferences for 2022. 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 5, we plan to:

- Coordinate recruitment efforts at collaborating sites, including leveraging virtual telehealth appointments.
- Complete enrollment of at least 30 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?

This investigation stands to have a significant impact on the care of female Veterans and Service Members with amputation. Preliminary results (outlined above) already indicate several differences between men and women with upper and/or lower extremity amputation. By understanding the physical and psychosocial differences between men and women with amputation, the amputation care team will be able to provide a more personalized care plan for this growing population of women with limb loss. This study will help determine gaps in research, current treatment plans, as well as commercially available products, which will guide appropriate treatment strategies.

What was the impact on other disciplines?

Findings from this study can directly influence the Clinical Practice Guidelines utilized for amputation care in this population and potentially impact the care provided by the amputation care team, including occupational and physical therapists, physiatrists, and prosthetists. Furthermore, healthcare providers for women with amputation must evolve healthcare delivery and research practices and work jointly with industry in order to meet the needs of this population. As such, it is critical to understand both the physical and psychosocial needs of women with amputation in order to provide evidentiary support for cross-disciplinary clinical decision making in this demographic.

What was the impact on technology transfer?

Nothing to Report

What was the impact on society beyond science and technology?

The Clinical Practice Guidelines associated with amputation care for female Veterans and Service Members with amputation may be updated based on the outcomes of this research study. It is necessary for clinicians to understand the unique physical and psychosocial needs of women with amputation. By understanding these unique needs, clinicians can use this “toolbox” of information to provide a customized healthcare plan that can address their needs and concerns to return our female Veterans and Servicemember to their highest levels of physical and psychosocial function. While the VA/DoD lower limb amputation Clinical Practice Guidelines provide guidance on critical decision points in the rehabilitation healthcare plan, results from this novel research have the potential to directly impact the healthcare provided to both Veterans and Service Members by the VA and DoD, as the new information will allow for more evidence-based prescription of services. Information gained from this study will allow VA and DoD to more adequately address the healthcare needs of this growing population, helping them to live higher quality lives.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

Due to the ongoing, global pandemic, in-person recruitment at local prosthetic clinics remained limited for year 4. Furthermore, recruitment at national amputation conferences and events has also been suspended due to VA travel restrictions. 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 ongoing COVID-19 pandemic has limited in-person recruitment since March 2020. We have continued to recruit participants whenever possible to take the 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 Y4Q4 to meet our enrollment goals, as well as to perform data analysis and dissemination.

Changes that had a significant impact on expenditures

As anticipated, expenses increased when the statistical analysis team was engaged. Expenditures are expected to continue to return toward the projected budget with the approved year 5 extension.

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 JJP VAMC
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:	Heidi Klingbeil, MD
Project Role:	Co-I at JJP VAMC
Nearest person month worked:	1
Responsibilities/ Contributions:	Study overview

Name: Josef Butkus, MS, OTR/L
Project Role: 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 oversight at Walter Reed

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.

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

Dr. Heidi Klingbeil was added as Co-I for study oversight at the JJPVAMC. 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