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TITLE: Needs, Preferences and Functional Abilities of Veterans and Service Members with Upper Limb Amputation

PRINCIPAL INVESTIGATOR: Dr. Linda Resnik, PhD, PT

CONTRACTING ORGANIZATION: Ocean State Research Institute, Providence, RI

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14. ABSTRACT

Purpose: The purpose of this project was to provide comprehensive cross-sectional and longitudinal data on function, needs, preferences, and satisfaction of Veterans and service members with major upper limb amputation.
Scope: 1) Describe patterns of prosthesis use and abandonment in the VA and DOD; identify the impact of amputation and prosthesis use on self-reported function, activities, and participation; and identify unmet prosthetic needs; 2) Conduct a one-year follow-up study to examine changes in satisfaction with care and prosthetic services, self-reported function, and quality of life; and 3) Assess the dexterity and activity performance in upper limb amputees. Findings/Progress: This is the final report (covering the period 30 September 2016 - 29 September 2022) which summarizes the accomplishments of the study. In brief, we completed 808 Aim 1 surveys, 585 Aim 2 surveys, 127 Aim 3 Visit 1 study visits, and 64 Aim 3 Visit 2 study visits. We published 15 manuscripts and 1 paper is under review.

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:**

Quality gaps in care of military and Veterans with upper limb amputation have been reported. In 2008, amputees receiving prosthetic care in the VA were reported to be less satisfied than counterparts receiving care in the private sector. In 2011, reported widespread dissatisfaction amongst combat Veterans with upper limb loss led to calls for efforts to evaluate needs of Veterans with traumatic upper limb amputations to improve satisfaction. Major efforts to improve quality of prosthetic care have been made since these studies were conducted. In 2009, the VA reorganized its amputation system of care, and in 2014 the VA and DoD released the Evidence-Based Clinical Practice Guidelines (CPGs) for the rehabilitation of persons with upper limb amputation. A comprehensive study to assess the current state of quality and outcomes of amputation rehabilitation for upper limb amputees and to track quality and outcomes over time was needed. Our objective was to provide comprehensive cross-sectional and longitudinal data on function, needs, preferences, and satisfaction of Veterans and service members with major upper limb amputation.

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

1. Describe patterns of prosthesis use; identify the impact of amputation and prosthesis use on function, activities, and participation; and identify unmet prosthetic needs.
2. Conduct a one-year longitudinal follow-up survey to examine changes in satisfaction with care and prosthetic services, physical performance, self-reported quality of life and physical function to assess the implementation of new clinical practice guidelines (CPGs).
3. Quantify physical function using a battery of performance-based tests.

The table below shows the major tasks associated with each aim/goal, the original and revised target completion date, the actual completion date (if relevant) and percent complete.

Aim	Activities	Target Completion Date	Revised Target Completion date	Completion Date	Percent Complete
Aims 1&2	Regulatory approvals	Month 3	Month 3	May 2017	100%
	Prepare study staff for survey administration	Month 9	Month 9	April 2017	100%
	Prepare study data (VA sample)	Month 7	Month 7	May 2017	100%
	Prepare study data (DoD sample)	Month 7	Month 39	December 2019	100%
	Conduct surveys (Aim 1)	Month 19	Month 19	June 2018	100%
	Conduct Aim 1 survey (DoD sample)	Month 19	Month 42	March 2020	100%
	Conduct surveys (Aim 2)	Month 31	Month 31	June 2019	100%
	Data analysis (Aims1 & 2)	Month 33	Month 60	September 2022	100%
	Dissemination	Month 36	Month 60	Completed September 2022, except for one paper still under review (See Table 2)	99%
Aim 3	Regulatory approvals	Month 8	Month 8	July 2017	100%
	Prepare study staff	Ongoing	Ongoing	---------	100%
	Study coordination	Month 33	Month 42	March 2020	100%
	Data collection (Visit 1)	Month 21	Month 35	August 2019	100%
	Data collection (Visit 2)	Month 33	Month 42	March 2020	100%
	Data Analysis	Month 36	Month 72	September 2022	100%
	Dissemination	Month 36	Month 72	September 2022	100%

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

1 & 2: Specific objectives and major activities

Specific objectives and major activities accomplished during the project (30th September 2016 – 29th September 2022) are described below:

Aims 1 & 2

1. Maintain regulatory approvals (fully met)
2. Identify Aim 1 & 2 sample (fully met)
3. Complete Aim 1 data collection (fully met)
4. Begin Aim 2 data collection (fully met, VA sample)

5. Complete Aim 2 data collection (fully met, VA sample)
6. Begin Aim 1 data analysis (fully met, VA sample and DoD sample)
7. Complete Aim 1 data analysis (fully met VA sample, fully met DoD sample)
8. Disseminate Aim 1 results (99% met, VA sample) See Table 2 & 3 for details
   - 11 manuscripts were published (Aims 1 & 2)
   - 1 manuscript is under review (Aims 1)
   - 4 conference abstracts were presented
   - 2 posters were presented
   - 1 conference manuscript was published
   - 1 conference symposium was presented
9. Complete Aim 2 data analysis (complete)
10. Disseminate Aim 2 results (partially met, VA sample)*:*
    - 3 manuscripts were published (Aims 1 & 2) See Table 2 & 3 for details

Aim 3

1. Maintain regulatory approvals for data collection sites (fully met)
2. Complete Aim 3 Visit 1 data collection (fully met)
3. Complete Aim 3 Visit 2 data collection (fully met)
4. Continue Aim 3 analysis (fully met)

5.Complete dissemination of Aim 3 results (fully met) See Table 2 & 3 for details
   - 5 manuscripts were published
   - 5 conference abstracts were presented
   - 5 conference manuscripts were published
   - 1 conference symposium was presented

3) Significant Results or Key Outcomes

Data was collected for a very large sample of persons with upper limb amputation.

- Aim 1 (VA sample): 808 subjects
- Aim 1 (DoD sample): 5 subjects
- Aim 2 (VA sample): 585 subjects
- Aim 3 Visit 1: 127 subjects
- Aim 3 Visit 2: 64 subjects

Study results were widely disseminated: 15 manuscripts published (one additional manuscript is under review) and 10 presentations were made at scientific conferences. Full citations for the manuscripts are listed in Section 7. Products

Table 2: All Manuscripts								
Author	**Title**	**Aim 1**	**Aim 2**	**Aim 3**	**Under construction**	**Under review (journal/date)**	**In press (journal)**	**Published (journal/date)**
1. Resnik L, Benz H, Borgia M, Clark MA	Patient Perspectives on Benefits and Risks of Implanatable Interfaces for Upper Limb Prostheses: A National Survey	X						Expert Review of Medical Devices Jul 2019
2. Resnik L, Benz H, Borgia M, Clark M	Patient Perspectives on Osseointegration: A National Survey of Veterans with Upper Limb Amputation	X						Physical Medicine and Rehabilitation Jul 2019
3. Resnik, L. Borgia, M, Clark M.	Function and Quality of Life of Unilateral Major Upper Limb Amputees: Effect of Prosthesis Use and Type	X						Archives of Physical Medicine and Rehabilitation.
4. Resnik L, Borgia M, Heinemann A, Clark M	Prosthesis Satisfaction in a National Sample of Veterans with Upper Limb Amputation.	X						Prosthet Orthot Int. 2020 Jan
5. Resnik, L, Borgia, M, Clark, MA	National Survey of Prosthesis Use in Veterans with Major Upper Limb Amputation: Comparisons by Gender	X						Physical Medicine and Rehabilitation 2020 Feb 27
6. Resnik, L, Borgia, M, Clark, M.	The Prevalence and Impact of Back and Neck Pain in Veterans with Upper Limb Amputation. American Journal of Physical Medicine and Rehabilitation	X	X					Physical Medicine and Rehabilitation E.pub: 1/11/2021
7. Resnik, L, Borgia, M., Highsmith, J, Randolph, BJ, Webster, J.	Amputation Care Quality and Satisfaction with Prosthetic Limb Services: A Longitudinal Study of Veterans with Upper Limb Amputation	X	X					Federal Practitioner 3/1/2021
8. Resnik, L, Borgia, M, Clark, M.	Contralateral Limb Pain is Prevalent, Persistent and Impacts Quality of Life of Veterans with Unilateral Upper Limb Amputation	X	X					Journal of Prosthetics and Orthotics 5/26/21

9. Resnik, L, Borgia M, Cancio, J, Delikat, Ni, P.	Longitudinal Study of Prosthesis Use in Veterans with Upper Limb Amputation		X					Prosthetics and Orthotics International 9/7/2020
10. Resnik, L, Borgia, M., Cancio, J, Heckman, J, Highsmith, J, Phillips, S, Levy, C, Webster, J.	Dexterity, Activity Performance, Disability, Quality of Life and Independence in Upper Limb Prosthesis Users: A normative study.			X				Disability and Rehab. 10/18/2020
11. Balakhanlou, E, Webster, J, Borgia, M, Resnik, L.	Frequency and Severity of Phantom Limb Pain in Veterans with Major Upper Limb Amputations: Results of a National Survey	X						PM&R. 9/8/2020
12. Resnik, L**,** Borgia M, Delikat, J, Cancio, J, Delikat, J, Ni, P.	Psychometric Evaluation of the Southampton Hand Assessment Procedure in a Sample of Upper Limb Prosthesis User			X				Journal of Hand Therapy E-pub: 7/7/2021
13. Resnik, L, Borgia, M., Cancio, J, Heckman, J, Highsmith, J, Levy, C, Webster, J.	Upper Limb Prosthesis Users: A Longitudinal Cohort Study			X				Prosthetics & Orthotics International E-pub: 8/31/21
14. Resnik, L, Borgia, M, Cancio, J, Heckman, J, Highsmith, MJ, Phillips, S, Webster, J.	Understanding Implications of Residual Limb Length, Strength, and Range of Motion Impairments of Veterans with Upper Limb Amputation			X				Physical Medicine and Rehabilitation E.pub: 8/3/21
15. Webster, J, Webster, N, Borgia, M, Resnik, L**.**	Frequency, Severity, and Implications of Shoulder Pain in Persons with Major Upper Limb Amputation Who Use Prostheses: Results of a National Study			X				Physical Medicine and Rehabilitation E.pub: 7/4/21
*****Webster, J, Witt, O, Borgia, M, Resnik, L.	Outcomes Associated with Concomitant Lower Limb Amputation in Persons with Major Upper Limb Amputation: Results of a National Study	X				**X (Under Review)**		

Table 3: All Abstracts / Conference Manuscripts

Author	Title	Aim 1	Aim 2	Aim 3	Submitted	Accepted	Presented
Webster, N, Webster, J, Borgia, M, Resnik, L	Frequency and Severity of Shoulder Pain in Persons with Major Upper Limb Amputation Who Use Prostheses: Results of a National Study			X		AAPMR 2020 Assembly	Abstract presented November, 2020
Cancio, JM, Borgia, M., Cancio, LC, Resnik, L.	The Impact of Burn Injury on Upper Extremity Prosthesis Users. American Burn Association National Conference			X		American Burn Association	Abstract presented at ABA National Conference in April, 2021
Witt, O, Webster, J, Borgia, M, Resnik, L.	Outcomes Associated with Concomitant Lower Limb Amputation in Persons with Major Upper Limb Amputation: Results of a National Survey	X				VCU Research Day	Abstract presented June 2021
Witt, O, Webster, J, Borgia, M, Resnik, L.	Outcomes Associated with Concomitant Lower Limb Amputation in Persons with Major Upper Limb Amputation: Results of a National Survey	X				AAPMR 2021 Assembly	Abstract presented November, 2021
Resnik, L, Highsmith, J, Webster, J.	Exploring the Relationship between Residual Limb Length, Strength and Range of Motion Impairments of Veterans with Upper Limb amputation			X		ISPO 18th World Congress 2021	Abstract presented November, 2021
Resnik, L, Borgia, M, Cancio, J, Delikat, M, Ni, P.	Alternative Scoring and Psychometric Evaluation of a Briefer Version of the Southampton Hand Assessment Procedure (SHAP)			X		ISPO 18th World Congress 2021	Abstract presented November, 2021
Resnik, L, Highsmith, J, Webster, J.	Exploring the Relationship between Residual Limb Length, Strength and Range of Motion Impairments of Veterans with Upper Limb amputation			X		ISPO 18th World Congress 2021	Conference Manuscript published November 2021
Webster, J, Highsmith, M, Resnik, L.	Pain Conditions in Persons with Upper Limb Amputation: New Findings from the U.S. Department of Veterans Affairs			X		ISPO 18th World Congress 2021	Conference Manuscript published November 2021
Resnik, L, Borgia, M, Cancio, J, Delikat, M.	Alternative Scoring and Psychometric Evaluation of a Briefer Version of the Southampton Hand Assessment Procedure (SHAP)			X		ISPO 18th World Congress 2021	Conference Manuscript published November 2021

Highsmith, M, Webster, J, Resnik, L.	Comparing Dexterity, Activity Performance, Disability, and Quality of Life, of Body Powered and Myoelectric Upper Limb Prosthesis Users			X		ISPO 18th World Congress 2021	Conference Manuscript published November 2021

4) Other Achievements

This was a multi-site study that required coordination efforts for scientific and operational management.

Infrastructure development

- All subcontract awards were fully executed
- Maintained regular communications with local sites to facilitate coordination and to ensure study fidelity, including:
    - Biweekly meetings with local sites (enrollment sites) to monitor progress and provide support with recruitment and study protocols and procedures
    - Regular meetings with study Assessors to monitor and promote fidelity to testing protocols
    - Regular PVAMC Team meetings for study coordination and tracking

Data

- Data was used in numerous publications and presentations as described above.

Stated goals not met

1. Complete dissemination for Aims 1, 2 & 3
   Goal – Month 36; Actual: September 2022 (Month 72)
   One publication is still under review. We may need to revise and resubmit in response to reviewer comments and will not be complete until any additional papers are accepted for publication.

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

Oksana Witt, a medical resident at the Richmond VA, worked with the research team on the analysis of data related to outcomes associated with concomitant lower limb amputation in persons with major upper limb amputation. She presented two conference abstracts and is first author of the manuscript still under review.

Ellie Balakanlou, a medical resident at the Richmond VA, worked with the study team, to examine the epidemiology of pain in our sample. She was first author of a paper on phantom limb pain.

Natalie Webster, an undergraduate student from George Macon University, worked with the research team to conduct data analyses and prepare dissemination materials. She presented a conference abstract and was co-author of a peer-reviewed manuscript.

- **How were the results disseminated to communities of interest?**
  Please see Table 3 for details.

4. **IMPACT:**

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

Many of our findings have important implications that may impact regulatory policy and clinical care.

- We reported data that indicated widespread interest of Veterans in exploring osseointegration, and surgeries to restore sensation and improve motor function. This data will be useful to the FDA in reviewing risk/benefit for experimental surgeries.

- We found that a substantial proportion of Veterans did not receive amputation related care at the VA, and many had never been to a VA amputation clinic, suggesting an opportunity to increase access to VA care for persons with upper limb amputation.

- We found that amputees who do not use a prosthesis reported more difficulty in activities, greater overall disability, and lower physical function compared to amputees that use any type of active prosthesis. Additionally, those that do not use a prosthesis are more likely to need help with ADLs compared to those who use a body powered prosthesis. These findings demonstrated the value of active prostheses in improving quality of life and highlight the clinical imperative to encourage prosthesis use by addressing factors such as early prosthetic training to improve satisfaction with devices and reduce abandonment.

- The manuscript resulting from the in-person component of this study reported normative values for dexterity, activity performance, prosthesis satisfaction disability, HRQoL and community integration in persons with upper limb amputation by amputation level and prosthesis type. These never before published data will inform clinicians and researchers and help them create benchmarks for these standardized measures by amputation level and prosthesis types.

- **What was the impact on other disciplines?**
  Amputation care is transdisciplinary, and our research has application to fields of prosthetics, occupational therapy, physical therapy, physical medicine and rehabilitation and research.

- **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**

Nothing to report.

- **Changes that had a significant impact on expenditures**
  Not applicable.

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:**

Publications, conference papers, and presentations

- **Journal publications.**
  Please see Table 2. A copy of all published manuscripts will be included in Appendix A.

- **Books or other non-periodical, one-time publications.**
  Nothing to report.

- **Other publications, conference papers, and presentations.**
  Please see Table 3.

- **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**

- During the last year of the study (2nd NCE), the following individuals 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 provided overall study oversight, data quality monitoring, data analysis, manuscript preparation and oversight for the work of Mr. Borgia, Ms. Small and Mr. Davey
Funding Support:	*n/a*

Name:	Melissa Clark
Project Role:	Co-Investigator
Researcher Identifier (e.g., ORCID ID):	
Nearest person month worked:	0.6
Contribution to Project:	Dr. Clark has assisted Dr. Resnik with data interpretation, manuscript development and other dissemination activities.
Funding Support:	*n/a*

Name:	Eileen Small
Project Role:	Program Manager
Researcher Identifier (e.g., ORCID ID):	n/a
Nearest person month worked:	4.0

Contribution to Project:	Ms. Small provided study coordination. She maintained the overall study budget and related tasks. In addition, Ms. Small was responsible for regulatory document preparation and submission. Ms. Small has also assisted with manuscript preparation.
Funding Support:	*n/a*

Name:	Matthew Borgia
Project Role:	Biostatistician/Analyst
Researcher Identifier (e.g., ORCID ID):	n/a
Nearest person month worked:	4.0
Contribution to Project:	Mr. Borgia prepared study data for analysis and completed analyses for Aims 1, 2 & 3. He assisted Dr. Resnik with manuscript preparation.
Funding Support:	n/a

Name:	John Davey
Project Role:	Senior Research Assistant
Researcher Identifier (e.g., ORCID ID):	n/a
Nearest person month worked:	4
Contribution to Project:	Mr. Davey maintained study databases study data, assisted with data cleaning and manuscript preparation
Funding Support:	*n/a*

- **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:** Appendix A – Copies of published manuscripts

- 15 manuscripts were accepted for publication.

Needs, Preferences and Functional Abilities of Veterans and Service Members with Upper Limb Amputation

PI: Linda Resnik, PT, PhD **Org:** Providence VA Medical Center **Award Amount:** $2,497,440

Study/Product Aims

1. Describe patterns of prosthesis use; identify the impact of amputation and prosthesis use on function, activities and participation; and identify unmet prosthetic needs.
2. Conduct a one-year longitudinal follow-up survey to examine changes in satisfaction with care and prosthetic services, physical performance, self-reported quality of life and physical function to assess the implementation of new clinical practice guidelines (CPGs)
3. Quantify physical function using a battery of performance-based tests.

Approach

This 3-part study provided cross-sectional and longitudinal survey and performance data. Data was collected through surveys and functional performance testing. Part 1 was a cross-sectional survey. Part 2 was a one-year longitudinal follow-up survey of respondents from Part 1. Part 3 was an in-person study to collect performance-based measures of physical function at two time points, about one year apart.

Accomplishments: Data collection for **Aim 1** (**N=808 VA**, **N=5 DoD**), **Aim 2** (**N=585**) and **Aim 3** (**Visit 1 (N=127)** & **Visit 2 (N=64)**) was completed. **16 manuscripts** have been published to date. Seven reported on Aim 1, 3 reported on Aims 1 & 2, 1 on Aim 2 only; and 5 on Aim 3 results. An additional manuscript using Aim 1 data is still under review.

Timeline and Cost

Activities - Project Year (PY)	Year 1	Year 2	Year 3	Year 4
Identify sampling frame and train interviewers				
Data collection – Part 1				
Data collection – Part 2				
Data collection – Part 3				
Data analysis/dissemination				
Actual Expenses	**$404,526**	**$810,622**	**$679,432**	**$602,860**

Goals/Milestones

PY1 Goals – All goals met

PY2 Goals – Data collection and early analysis

- ✓ Part 2 surveys administered
- ✓ Conducted analyses Aim 1, and preliminary analyses Aim 2

PY3 Goals – Data collection, preliminary analysis and dissemination

- ✓ Completed all data collection (Aims 1, 2 & Aim 3 Visit 1)
- ✓ Analyzed data Aims 1, 2 and 3
- ✓ Submitted abstracts and manuscripts

PY4 (NCE Goals) – Data, analysis and dissemination

- √ Completed remainder of data collection (Aim 3 Visit 2)
- √ Completed data analysis for Aims 1, 2 and 3
- √ Completed dissemination for Aims 1 & 2 (*1 manuscript still under review)
- √ Completed dissemination for Aims 3 results

Appendix A Cover Sheet

List of Published Manuscripts

1. Patient Perspectives on Benefits and Risks of Implanatable Interfaces for Upper Limb Prostheses: A National Survey (Resnik L, Benz H, Borgia M, Clark MA)

2. Patient Perspectives on Osseointegration: A National Survey of Veterans with Upper Limb Amputation (Resnik L, Benz H, Borgia M, Clark MA)

3. Function and Quality of Life of Unilateral Major Upper Limb Amputees: Effect of Prosthesis Use and Type (Resnik, L. Borgia, M, Clark M.)

4. Prosthesis Satisfaction in a National Sample of Veterans with Upper Limb Amputation (Resnik L, Borgia M, Heinemann A, Clark M)

5. National Survey of Prosthesis Use in Veterans with Major Upper Limb Amputation: Comparisons by Gender (Resnik, L, Borgia, M, Clark, MA)

6. The Prevalence and Impact of Back and Neck Pain in Veterans with Upper Limb Amputation. American Journal of Physical Medicine and Rehabilitation (Resnik, L, Borgia, M, Clark, M.)

7. Amputation Care Quality and Satisfaction with Prosthetic Limb Services: A Longitudinal Study of Veterans with Upper Limb Amputation (Resnik, L, Borgia, M., Highsmith, J, Randolph, BJ, Webster, J.)

8. Contralateral Limb Pain is Prevalent, Persistent and Impacts Quality of Life of Veterans with Unilateral Upper Limb Amputation (Resnik, L, Borgia, M, Clark, M.)

9. Longitudinal Study of Prosthesis Use in Veterans with Upper Limb Amputation (Resnik, L, Borgia M, Cancio, J, Delikat, Ni, P.)

10. Dexterity, Activity Performance, Disability, Quality of Life and Independence in Upper Limb Prosthesis Users: A normative study (Resnik, L, Borgia, M., Cancio, J, Heckman, J, Highsmith, J, Phillips, S, Levy, C, Webster, J.)

11. Frequency and Severity of Phantom Limb Pain in Veterans with Major Upper Limb Amputations: Results of a National Survey (Balakhanlou, E, Webster, J, Borgia, M, Resnik, L.)

12. Psychometric Evaluation of the Southampton Hand Assessment Procedure in a Sample of Upper Limb Prosthesis User (Resnik, L**,** Borgia M, Delikat, J, Cancio, J, Delikat, J, Ni, P.)

13. Upper Limb Prosthesis Users: A Longitudinal Cohort Study (Resnik, L, Borgia, M., Cancio, J, Heckman, J, Highsmith, J, Levy, C, Webster, J.)

14. Understanding Implications of Residual Limb Length, Strength, and Range of Motion Impairments of Veterans with Upper Limb Amputation (Resnik, L, Borgia, M, Cancio, J, Heckman, J, Highsmith, MJ, Phillips, S, Webster, J.)

15. Shoulder Pain in Persons with Major Upper Limb Amputation Who Use Prostheses: Results of a National Study (Webster, J, Webster, N, Borgia, M, Resnik, L**.)**

EXPERT REVIEW OF MEDICAL DEVICES
2019, VOL. 16, NO. 6, 515–540
https://doi.org/10.1080/17434440.2019.1619453

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ORIGINAL RESEARCH

Check for updates

Patient perspectives on benefits and risks of implantable interfaces for upper limb prostheses: a national survey

Linda Resnik[a,b], Heather Benz[c], Matthew Borgia[a] and Melissa A. Clark[d]

[a]Research Department, Providence VA Medical Center, Providence, RI, USA; [b]Health Services, Policy and Practice, Brown University, Providence, RI, USA; [c]Center for Devices and Radiological Health, US Food & Drug Administration, Silver Spring, MD, USA; [d]Department of Quantitative Health Sciences, University of Massachusetts Medical School, Worcester, MA, USA

ABSTRACT

Objective: Patient perspectives on benefits and risks of implantable interfaces for prostheses are needed.

Methods: A telephone survey was administered to 808 Veterans. Multivariate logistic regression identified factors associated with willingness to consider surgery to restore touch and better movement control. Risk and benefit ratings were compared.

Results: 41.8% of unilateral and 40.6% of bilateral amputees were willing to consider surgery for touch; 49.0% were willing to consider surgery for control. Persons 65–75 years and >75 were 0.42 (p= 0.0009) and 0.19 (p< 0.0001) as likely as those 18–45 to consider surgery for touch, those with better mental health (MH) were 0.47 (p= 0.0005) as likely as those with worse, and those with infection etiology were 1.7 (p= 0.03) as likely as those without. Persons 65–75 and >75 were 0.28 and 0.12 as likely as those 18–45 to consider surgery for control (p's<0.0001). Myoelectric users were 2.16 (p= 0.006) as likely as body-powered users and persons with better MH were 0.61 (p= 0.03) as likely as those with worse to consider surgery for control. Long-term risks were most unacceptable. Durability, comfort, and improved functional abilities were most important.

Conclusions: There is substantial interest in prosthetic interfaces to gain a sense of touch and greater movement control.

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Haptic feedback; patient perspectives; prosthesis control; upper limb prostheses

1. Background

Until recently, upper-limb prostheses did not involve implanted componentry, and most were not subject to Food and Drug Administration (FDA) review prior to marketing in the United States (US) [1]. Emerging prosthetic technologies, developed in part to address widespread dissatisfaction with devices and high prosthesis rejection rates [2–4], involve new types of human-prosthesis interfaces. New technologies and procedures such as implanted myoelectric sensors, peripheral nerve implants, targeted muscle reinnervation, brain computer interfaces [5–9], and implanted stimulators [5–17] offer promising new and improved capabilities. These and other types of prosthetic technologies involve the use of surgeries and implantable devices, and may also raise new questions about safety and effectiveness.

The FDA weighs probable benefit to health from the use of a medical device against any probable risk of injury or illness when reviewing new medical device marketing applications [18]. In addition to pre-clinical and clinical evidence, the FDA may also consider patient perspectives on these benefits and risks, acknowledging that there may be patients who will tolerate a risk to achieve a probable benefit, especially if the medical device may improve quality of life [19,20]. The Medical Device Innovation Consortium, a public–private partnership that includes the FDA, has identified the value of collecting and using patient perspectives to ensure medical product development and evaluation is patient-centric [21]. The FDA and medical device industry's recognition of the value of patient input is aligned with a growing movement in medicine to ensure medical care meets patients' needs and priorities [22].

Patient input may include a range of information and perspectives, including testimony at Advisory Committee Panel meetings, opinions expressed publicly, responses to qualitative ad hoc surveys, and quantitative measurements of patient-reported outcomes. These patient perspectives may provide the FDA with an understanding of the impact of a condition on patients and assist in identifying outcomes most important to patients [19,23]. While earlier surveys of individuals with limb loss focused on identifying factors contributing to prosthesis satisfaction and abandonment [2,3,24], more recent surveys have responded to technological developments by eliciting patient perspectives on interest in novel prosthetic control techniques and factors associated with such interest [25,26]. In recognition of the risks and burdens associated with more complex devices, patients have also been asked about concerns associated with novel prosthetic devices [27].

Because patient perspectives may be informative for decision-making about novel prostheses and prosthetic interfaces,

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Article highlights

- A telephone survey of Veterans with upper limb amputation asked about willingness to consider surgery to restore touch and better movement control of upper limb prostheses.
- 42% of unilateral and 41% of bilateral amputees were willing to consider surgery to restore touch, while 49% of all amputees were willing to consider surgery for better movement control.
- Younger age and poorer mental health were associated with increased interest in both types of surgery. Infection as a cause of amputation was associated with increased interest in surgery to restore a sense of touch.
- Long-term surgical risks were considered the most unacceptable risks and device durability, comfort, and ability to perform more activities were rated the most important benefits.

we developed a survey about the benefits and risks of these technologies to elicit patient perspectives and administered the survey to individuals with upper limb loss. The results of this survey may inform prosthesis developers, medical professionals, and regulators, and may contribute to the design of future patient preference surveys. The purposes of this manuscript are to (1) describe the stages of development and pilot testing of the patient perspective survey, (2) quantify benefit-risk perspectives of a nationally representative sample of Veterans with upper limb amputation, and (3) identify patient-level factors associated with variation in benefit-risk perspectives.

2. Methods

2.1. Development and pilot testing of the patient perspective survey

Development of the patient perspective survey occurred in three phases as shown in Figure 1: development of an initial item set, prioritization of the survey content, and cognitive and pilot testing. All aspects of this study were approved by appropriate institutional review boards. All participants gave informed consent.

Stage A consisted of semi-structured interviews with seven participants. The purpose of this stage was to understand the desired improvements in prosthetic technology that might motivate persons to incur risks to obtain new devices. This stage resulted in lists of challenges and limitations related to function and quality of life, as well as desired improvements in prosthetic technology [28]. The results of this stage were used by co-author HB to draft a set of items addressing these benefits and risks.

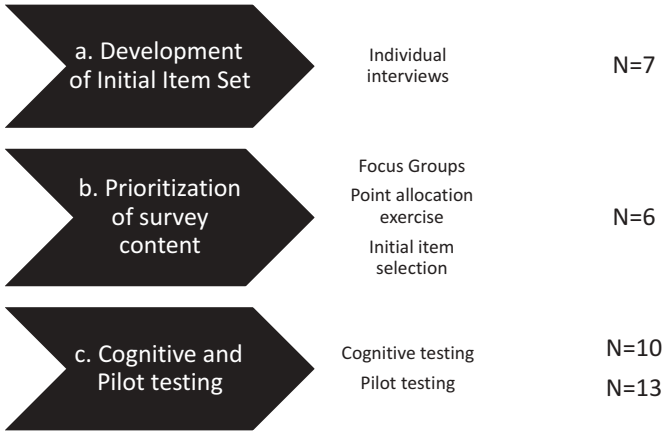

Figure 1. Benefit factor ratings for those who would consider surgery to have a prosthesis that could restore a sense of touch (yes/maybe): unilateral and bilateral amputees.

In Stage B, participants with upper limb difference were asked to prioritize items from the lists of benefits and risks using a point allocation exercise. This was followed by a focus group in which participants discussed challenges they had experienced with amputation or limb difference, what they liked and disliked about the prostheses they had used, their experiences with pain, and what they would like to see in prostheses. They also discussed their responses to a survey on consumer priorities reported elsewhere [27]. During the focus group, participants were asked to explain their responses to the prioritization exercise. Findings from this stage were used to refine items for inclusion in the benefit-risk survey.

In Stage C, cognitive and pilot testing were used to test participants' understanding of the item sets produced in Stage B and to refine the items. During cognitive testing, participants were asked to think out loud as they attempted to answer the survey items and to mention any words or items that were confusing or difficult for them to answer. Survey items were iteratively refined as a result. The benefit-risk survey was then pilot tested by telephone by trained interviewers. During the telephone-administered pilot interviews conducted by a professional survey research team, additional refinements were made to instructions to ensure that items were well understood.

Stage C resulted in the version of the survey employed in the national study. The final survey contained yes/no screening questions to ascertain participants' willingness to consider undergoing surgery to obtain one of the three benefits: (1) restore sense of touch, (2) provide more control over several types of prosthesis device movement, or (3) eliminate the need for a prosthetic socket and harness through surgery for osseointegration. The survey then asked those who answered yes to the screening questions about their willingness to undergo specific risks associated with surgery. The final version of the survey sections related to restoration of touch and more control is shown in Appendix A. Details on the development of the benefit-risk items as well as the results of benefit-risk questions about surgery for osseointegration are reported elsewhere [29].

2.2. Recruitment

The sampling frame consisted of all Veterans with a diagnosis of major upper limb amputation who had received care in the Veterans Administration (VA) between 2010 and 2015 (N = 5639) as identified from VA Corporate Data Warehouse sources. Major limb amputation was defined as an amputation at the wrist level or above. A total of 2288 persons were excluded (1479 deceased and 601 missing valid addresses and/or phone numbers). Recruitment letters with opt out cards were sent to the remaining 3559 persons. Up to 10 phone call attempts were made to reach those who did not opt out of participation (N = 408) or inform us that they did

not meet eligibility criteria (N = 208). The 1893 Veterans who were reached by phone were screened for eligibility.

2.3. Data collection

Respondents were administered a comprehensive survey (described elsewhere) [30] which contained the benefit-risk questions and items related to demographics, amputation level, laterality and etiology, prosthesis use, as well as a standardized measure of health-related quality of life (HRQoL), the VR-12. The VR-12 is a Veteran version of the SF-12 Health Survey that produces the Physical Component Summary (PCS) and Mental Component Summary (MCS) [31,32]. All surveys were telephone administered with no additional details explaining the survey or surgeries provided.

2.4. Data analyses

We described the demographics, amputation characteristics, and prosthetic use for respondents and examined the proportion of respondents who indicated yes, no or not sure of their willingness to consider surgery to restore a sense of touch or obtain greater prosthesis control. We evaluated responses by laterality of amputation (unilateral vs. bilateral), amputation level, prosthesis type, gender, age group, categories of Health-related Quality of Life (HRQoL), and etiology of amputation. Due to smaller sizes in some categories, we categorized amputation level as shoulder (SH) if the amputation was at the forequarter or shoulder disarticulation level, as transhumeral (TH) if the amputation was at the elbow disarticulation or transhumeral level, and as transradial (TR) if the amputation was at the wrist disarticulation or transradial level. We categorized mental and physical HRQoL by separately grouping VR-12 PCS and MCS scores into three groups (low, medium, and high). Because the MCS and PCS have a population mean of 50 with a standard deviation (sd) of 10 (normative values), we categorized respondents in the low category if their scores were more than 1 sd below the mean on each scale. Respondents in the medium category had scores within 1 sd of the mean, and those with more than 1 sd above the mean were categorized in the high category.

We conducted chi-square tests to examine bivariate relationships between key patient-related variables (age category, unilateral/bilateral amputation, amputation level, type of prosthesis used, gender, laterality of amputation, etiology of amputation) and willingness to consider surgery. We categorized the type of prosthesis used as body powered, myoelectric or hybrid, cosmetic, or none. For bilateral amputees, we used the prosthesis type reported on the dominant side. We combined the categories of yes and not sure for the willingness to consider surgery because we believed that respondents who might consider a surgery were different than those who clearly would not consider surgery. We performed multiple comparison tests for variables using the COMPROP macro, a Tukey-type method in SAS [33] to examine differences between sub-groups containing three or more categories. We then created two separate multivariate logistic regression models for willingness to consider surgery for (1) restoration of sensation and (2) better movement control. These models contained amputation level as well as all variables that were significant in the bivariate analyses at $p < 0.10$. We added amputation level because in prior studies, it has been strongly associated with functional limitation and prosthesis abandonment and thus was a proxy for the need for improvements in prosthesis care.

We examined ratings of importance of obtaining potential benefits (e.g. natural touch, better speed of movement control, ability to do more activities) given specific risks (e.g. overnight hospital stay, infection requiring antibiotics, infection requiring device removal) for those respondents who indicated that they were or might be willing to consider each type of surgery. We then described the proportion of persons who were willing to accept each of the specific risks. For sub-groups in which respondents indicated that they were willing to accept specific risks, we calculated the proportion who indicated that each of the specific benefits was important, somewhat important, or not important. We then analyzed these data graphically for each type of surgery to determine whether patterns of importance ratings varied by the willingness to accept each type of risk. Lastly, we compared ratings of benefit importance for each of the risks for prosthesis users and non-users, and by amputation level. Comparisons were performed graphically and using Wilcoxon rank-sum and Kruskal–Wallis tests.

3. Results

3.1. Sampling frame and response rate

Eighty-three percent (N = 808) of those screened to be eligible were recruited into the study (Figure 2). The survey response rate and cooperation rate were 47.7% and 63.3%, respectively, as calculated using the American Association for Public Opinion Research methodology [34].

3.2. Demographic, amputation-related and prosthetic use characteristics

Participants included 776 unilateral amputees and 32 bilateral amputees, median age 67.0 years (range 25 to 95). The entire interview was completed by 788 persons, and an additional 20 persons completed a portion of the interview. Characteristics of the participants are shown in Table 1. Briefly, 764 participants (97.4%) were male and 20 (2.6%) were female. Amongst unilateral amputees, 36.1% had transradial (TR) amputation, 30.4% transhumeral (TH), 16.2% wrist joint, 9.2% shoulder disarticulation (SD), 5.2% elbow disarticulation (ED), and 3.0% forequarter amputation (FQ). The majority of the sample was white (75%), and 8.6% Hispanic or Latino. Respondents had lost their limbs on average 31.2 (sdL 18.3) years prior to participating in the study. The most common etiology of limb loss was classified as ‘accident’ (62.1% unilateral, 62.5% bilateral), followed by ‘other’ (54% unilateral, and 71.9% bilateral), and combat injury (35.5% unilateral, 28.1% bilateral). Burns were the cause of amputation for 40.6% of respondents with bilateral amputation. Prostheses were used by the majority of respondents (60% unilateral, 84% bilateral).

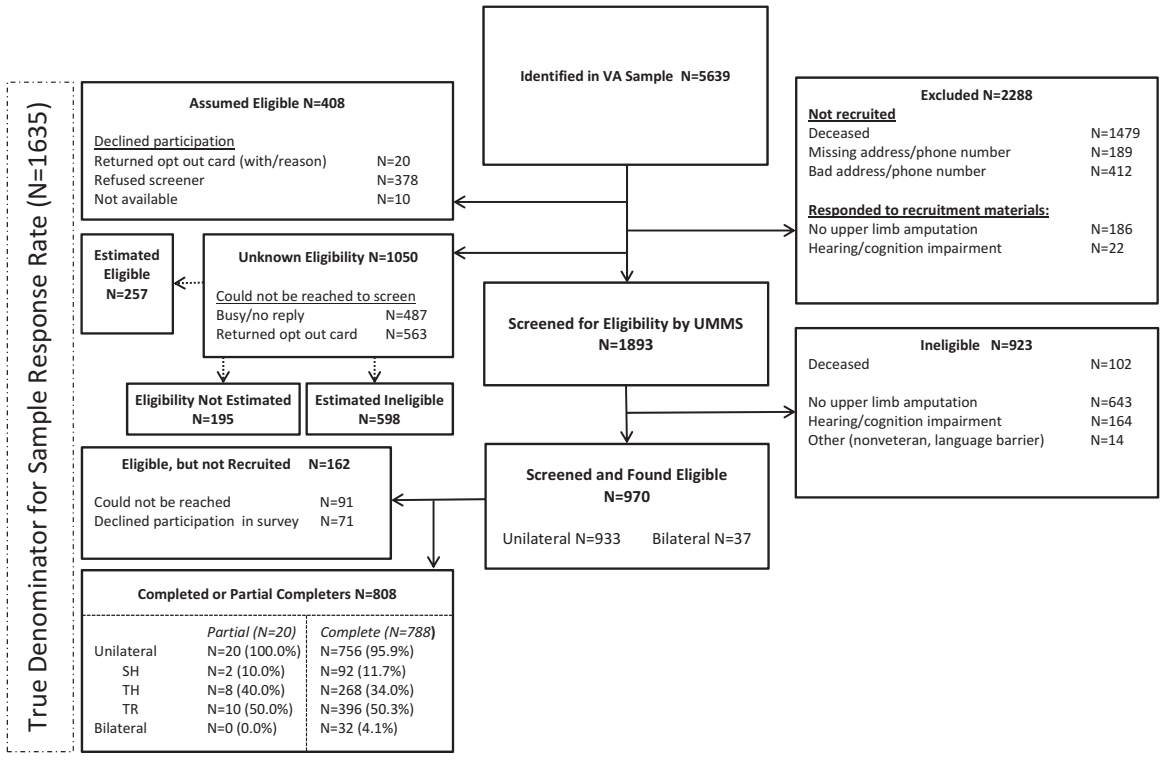

Figure 2. Benefit factor ratings for those who would consider surgery to have a prosthesis that gives more control over finger movements, grasps or wrist motions (yes/maybe): unilateral and bilateral amputee.

3.3. Willingness to undergo surgery

Table 2 shows the characteristics of respondents who indicated willingness to consider each type of surgery by subgroup characteristics. There were 41.8% of unilateral amputees and 40.6% of bilateral amputees who stated that they would consider surgery to restore a sense of touch, and 12.6% of unilateral and 3.1% of bilateral amputees who stated that they were unsure. Forty-nine percent of unilateral and bilateral amputees responded that they would consider surgery to gain more movement control, while 8.3% of unilateral and 3.1% of bilateral amputees stated that they were unsure.

The willingness to consider surgery to restore a sense of touch was fairly evenly distributed by amputation level of unilateral amputees, while interest was less prevalent for bilateral amputees (40.6% yes, 3.1% maybe). A smaller proportion of respondents who had lost their limbs due to combat injury indicated a willingness to undergo surgery to restore a sense of touch or to gain more movement control compared to persons with amputation from other etiologies. A greater proportion of respondents who had lost their limbs due to an accident indicated a willingness to undergo surgery to restore a sense of touch relative to respondents who had lost a limb due to other reasons.

3.4. Factors associated with willingness to undergo surgery: bivariate analyses

Results of the bivariate analyses comparing participant characteristics associated with willingness to undergo the surgeries (yes or unsure vs. no) for each of the major benefits are shown in Table 3. Prosthesis type ($p = 0.03$); age ($p \leq 0.0001$); mental health (MCS categories) ($p = 0.0002$); and non-combat ($p = 0.0005$), accident ($p = 0.002$), and infection ($p = 0.04$) etiologies were statistically associated with willingness to consider surgery for sense of touch. Prosthesis type ($p = 0.0002$), age ($p \leq 0.0001$), mental health ($p = 0.01$), and non-combat ($p = 0.01$) and accident ($p = 0.009$) amputation etiologies were statistically associated with willingness to consider surgery to gain more movement control.

Post-hoc analysis of the relationship of prosthesis type on willingness to consider surgery for a sense of touch revealed statistically significant differences ($p < 0.05$) only between body-powered and myoelectric device users, with body-powered users being less likely to consider surgery. Myoelectric device users were significantly more likely to consider surgery for movement control than nonusers, body-powered users, and cosmetic device users. Post-hoc analysis of the effect of VR-12 MCS on willingness to consider surgery for movement control revealed statistically significant differences only between the high and low categories, with those with better mental health being less likely to be willing to consider surgery. Post-hoc analyses between age group category showed statistically significant differences in willingness to consider either surgery between every age category except 18-≤45 and >45 ≤ 65 years old with older ages less willing to consider the surgeries.

3.5. Factors associated with willingness to undergo surgery: multivariate analyses

Multivariable logistic regression models shown in Table 4 included all variables statistically significant at $p \leq 0.10$, as well as amputation level, which was included as a clinically

Table 1. Characteristics of unilateral and bilateral amputee respondents.

	Unilateral Amputees N = 776	Bilateral Amputees N = 32	All N = 808
	Mean (sd)	Mean (sd)	Mean (sd)
Age (Years)	63.2 (14.1)	63.6 (15.3)	63.3 (14.1)
Missing (n)	n = 24	n = 0	n = 24
Years since initial amputation (either side)	31.3 (18.4)	32.8 (18.1)	31.2 (18.3)
Years since amputation (second side)	NA	29.8 (5.4, 72.3)	NA
Missing (n)	n = 21	n = 0	n = 21
	N (%)	**N (%)**	**N (%)**
Age category			
18≤ age <45	99 (13.2)	5 (15.6)	104 (13.3)
46≤ age <65	207 (27.5)	9 (28.1)	216 (27.6)
66≤ age <75	340 (45.2)	13 (40.6)	353 (45.0)
75+	106 (14.1)	5 (15.6)	111 (14.2)
Missing (n)	n = 24	n = 0	n = 24
Gender			
Male	755 (97.3)	32 (100.0)	787 (97.4)
Female	21 (2.7)	0 (0.0)	21 (2.6)
Missing (n)	n = 0	n = 0	n = 0
Race			
White	583 (77.5)	22 (68.8)	605 (74.9)
Black	86 (11.4)	3 (9.4)	89 (11.0)
Native American	5 (0.7)	0 (0.0)	5 (0.6)
Other (including mixed race)	30 (4.0)	4 (12.5)	34 (4.2)
Unknown	48 (6.4)	3 (9.4)	75 (9.3)
Missing (n)	n = 24	n = 0	n = 24
Hispanic or Latino			
Yes	62 (8.2)	5 (15.6)	67 (8.6)
No	678 (90.2)	26 (81.3)	704 (89.8)
Unknown	12 (1.6)	1 (3.1)	13 (1.7)
Missing (n)	n = 24	n = 0	n = 24
Employment			
Employed full-time	73 (9.7)	1 (3.1)	74 (9.4)
Employed part-time	31 (4.1)	13 (40.6)	31 (4.0)
Student	20 (2.7)	0 (0.0)	20 (2.6)
Retired, but employed after amputation	373 (49.6)	13 (40.6)	386 (49.2)
Retired, but not employed after amputation	152 (20.2)	5 (15.6)	165 (21.1)
On medical leave	9 (1.2)	0 (0.0)	9 (1.2)
Other	93 (12.4)	0 (0.0)	98 (12.5)
Unknown	1 (0.1)	0 (0.0)	1 (0.1)
Missing (n)	n = 24	n = 0	n = 24
Laterality of amputation			
Unilateral Right	370 (47.7)	0 (0.0)	370 (45.8)
Unilateral left	406 (52.3)	0 (0.0)	406 (50.3)
Bilateral	0 (0.0)	32 (100.)	32 (4.0)
Missing (n)	n = 0	n = 0	n = 0
Primary Prosthesis Type			
Body powered	326 (43.1)	22 (68.8)	348 (44.2)
Myoelectric	102 (13.5)	5 (15.6)	(13.6)
Cosmetic	22 (2.9)	2 (6.3)	24 (3.1)
None	306 (40.5)	3 (9.4)	309 (39.2)
Missing (n)	n = 20	n = 0	n = 20
Amputation Level			
Forequarter	23 (3.0)	1 (3.1)	0 (0.0)
At the shoulder joint	71 (9.2)	1 (3.1)	1 (3.1)
Above the elbow	236 (30.4)	5 (15.6)	4 (12.5)
At the elbow	40 (5.2)	14 (43.8)	1 (3.1)
Below the elbow	280 (36.1)	10 (31.3)	20 (62.5)
At the wrist joint	126 (16.2)	0 (0.0)	6 (18.8)
Through the hand	0 (0.0)	1 (3.1)	0 (0.0)
Missing (n)	n = 0	n = 0	
Etiology of amputation			
Combat injury	275 (35.5)	9 (28.1)	9 (28.1)
Accident	481 (62.1)	20 (62.5)	20 (62.5)
Burn	81 (10.5)	13 (40.6)	13 (40.6)
Cancer	30 (3.9)	0 (0.0)	0 (0.0)
Diabetes	11 (1.4)	0 (0.0)	1 (3.1)
Infection	86 (11.1)	9 (28.1)	8 (25.0)
Other	417 (54.0)	21 (65.6)	23 (71.9)
Missing (n)	n = 0 to 3	n = 0	n = 0

relevant variable. Age, MCS, and infection etiology were independently associated with willingness to consider surgery to restore a sense of touch. Specifically, persons 65–75 years old and over 75 years old had 0.42 (p= 0.0009) and 0.19 (p< 0.0001) the odds of considering surgery. Those in the highest MCS group had 0.47 (p= 0.0005) the odds as those in the

Table 2. Proportion of participants willing to undergo surgery for touch or control.

		Willing to consider surgery to restore.					
		Sense of touch			More control		
	N	Yes (N = 326)	No (N = 360)	Not Sure (N = 95)	Yes (N = 386)	No (N = 331)	Not Sure (N = 64)
Laterality							
Unilateral	776	313 (41.8)	342 (45.7)	94 (12.6)	370 (49.3)	318 (42.4)	62 (8.3)
Bilateral	32	13 (40.6)	18 (55.3)	1 (3.1)	16 (49.2)	13 (43.9)	2 (3.1)
Amputation Level*							
Unilateral Sh	94	38 (41.8)	40 (44.0)	13 (14.3)	42 (46.2)	39 (42.9)	10 (11.0)
Unilateral TH	276	112 (42.3)	121 (45.7)	32 (12.1)	139 (52.3)	104 (39.1)	23 (8.7)
Unilateral TR	406	163 (41.5)	181 (46.1)	49 (12.5)	189 (48.1)	175 (44.5)	29 (7.4)
Bilateral amputation	32	13 (40.6)	18 (56.3)	1 (3.1)	16 (51.6)	13 (41.9)	2 (6.5)
Ever used prosthesis							
Yes	749	308 (42.3)	336 (46.1)	85 (11.7)	362 (49.7)	308 (42.3)	59 (8.1)
No	52	17 (34.0)	24 (48.0)	9 (18.0)	22 (44.0)	23 (46.0)	5 (10.0)
Prosthesis Type							
Body powered	348	127 (37.7)	169 (50.2)	41 (43.6)	148 (43.8)	160 (47.3)	30 (8.9)
Myoelectric	107	57 (54.8)	35 (33.7)	12 (11.5)	73 (70.2)	24 (23.1)	7 (6.7)
Cosmetic	24	7 (30.4)	12 (52.2)	4 (17.4)	9 (39.1)	12 (52.2)	2 (8.7)
None	309	130 (42.9)	139 (45.9)	34 (11.2)	147 (48.7)	130 (43.1)	25 (8.3)
Gender							
Male	764	315 (41.4)	352 (46.3)	94 (12.4)	377 (49.5)	322 (42.3)	62 (8.2)
Female	20	11 (55.0)	8 (40.0)	1 (5.0)	9 (45.0)	9 (45.0)	2 (10.0)
Age							
18≤ age <45	104	61 (58.7)	33 (31.7)	10 (9.6)	78 (75.0)	22 (21.2)	4 (3.9)
46≤ age <65	216	114 (52.8)	71 (32.9)	31 (14.4)	133 (61.6)	61 (28.2)	22 (10.2)
66≤ age <75	353	128 (36.5)	180 (51.3)	43 (12.3)	148 (42.2)	172 (49.0)	31 (8.8)
75+	111	23 (20.9)	76 (69.1)	11 (10.0)	27 (24.6)	76 (69.1)	7 (6.4)
PCS							
Low	234	94 (40.5)	102 (44.0)	36 (15.5)	110 (47.6)	102 (44.2)	19 (8.2)
Medium	511	215 (42.2)	237 (46.6)	57 (11.2)	259 (50.8)	209 (41.0)	42 (8.2)
High	13	6 (46.2)	5 (38.5)	2 (15.4)	6 (46.2)	6 (46.2)	1 (7.7)
MCS							
Low	188	98 (52.1)	66 (35.1)	24 (12.8)	110 (58.5)	64 (34.0)	14 (7.5)
Medium	344	137 (40.2)	153 (44.9)	51 (15.0)	166 (48.7)	144 (42.2)	31 (9.1)
High	226	80 (35.6)	125 (55.6)	20 (8.9)	99 (44.0)	109 (48.4)	17 (7.6)
Etiology of amputation							
Combat injury							
Yes	284	100 (36.4)	150 (54.6)	25 (9.1)	124 (45.1)	133 (48.4)	18 (6.6)
No	523	226 (44.9)	210 (41.5)	70 (13.8)	262 (51.8)	198 (39.1)	46 (9.1)
Accident							
Yes	501	210 (43.1)	204 (41.9)	73 (15.0)	253 (52.0)	189 (38.8)	45 (9.2)
No	305	116 (39.5)	156 (53.1)	22 (7.5)	133 (45.2)	142 (48.3)	19 (6.5)
Burn							
Yes	94	29 (32.6)	43 (48.3)	17 (19.1)	41 (46.6)	37 (42.1)	10 (11.4)
No	711	297 (42.9)	317 (45.8)	78 (11.3)	345 (49.8)	294 (42.4)	54 (7.8)
Cancer							
Yes	30	8 (28.6)	15 (53.6)	5 (17.9)	10 (35.7)	15 (53.6)	3 (10.7)
No	776	318 (42.2)	345 (45.8)	90 (12.0)	376 (49.9)	316 (42.0)	61 (8.1)
Diabetes							
Yes	12	6 (50.0)	4 (33.3)	2 (16.7)	9 (75.0)	3 (25.0)	0 (0.0)
No	792	320 (41.6)	356 (46.3)	93 (12.1)	377 (49.0)	328 (42.7)	64 (8.3)
Infection							
Yes	95	42 (42.7)	33 (35.9)	17 (18.5)	46 (50.6)	32 (35.2)	13 (14.3)
No	709	284 (41.2)	327 (47.5)	78 (11.3)	340 (49.3)	299 (43.4)	51 (7.4)
Other							
Yes	440	181 (42.2)	189 (44.1)	59 (13.8)	211 (49.2)	178 (41.5)	40 (9.3)
No	365	145 (41.2)	171 (48.6)	36 (10.2)	175 (49.7)	153 (43.5)	24 (6.8)

lowest MCS group of considering surgery. Persons who had lost their limb secondary to infection had 1.70 (p= 0.03) the odds of considering this surgery as compared to persons without an etiology of infection.

In the multivariate model of willingness to consider surgery for movement control, persons who were 65–75 and over 75 years old had 0.28 and 0.12 times the odds of considering surgery as compared to those 18–45 years old (p's<0.0001). Myoelectric users had 2.16 times the odds of considering surgery as compared to body-powered device users (p= 0.006). Those in the highest MCS category had 0.61 times the odds of considering surgery as compared to the lowest MCS category (p= 0.03).

3.6. Willingness to accept surgical risks

Table 5 shows the proportion of respondents willing to accept each specific risk among those who indicated that they were or might be willing to consider each type of surgery. Overall, long-term risks, such as chronic pain, loss of some nerve

Table 3. Bivariate analyses comparing characteristics of participants by their willingness to undergo surgery.

		Willing to consider surgery to restore.					
		Sense of touch			More control		
	N	Yes/Not Sure (N = 421)	No (N = 360)	chisq p	Yes/Not Sure (N = 450)	No (N = 331)	chisq p
Amputation Level				0.6786			0.5875
Unilateral Sh	94	51 (56.0)	40 (44.0)		52 (57.1)	39 (42.9)	
Unilateral TH	276	144 (54.3)	121 (45.7)		162 (60.9)	104 (39.1)	
Unilateral TR	406	212 (53.9)	181 (46.1)		218 (55.5)	175 (44.5)	
Bilateral amputation	32	14 (43.8)	18 (56.3)		18 (58.1)	13 (41.9)	
Laterality				0.2393			0.9591
Unilateral	776	407 (54.3)	342 (45.7)		432 (57.6)	318 (42.4)	
Bilateral	32	14 (43.8)	18 (55.3)		18 (58.1)	13 (43.9)	
Ever used prosthesis				0.7933			0.6038
Yes	749	393 (53.9)	336 (46.1)		421 (57.8)	308 (42.3)	
No	52	26 (52.0)	24 (48.0)		27 (54.0)	23 (46.0)	
Prosthesis Type				**0.0288**			**0.0002**
Body powered	348	168 (49.9)	169 (50.2)		178 (52.7)	160 (47.3)	
Myoelectric	107	69 (66.4)	35 (33.7)		80 (76.9)	24 (23.1)	
Cosmetic	24	11 (47.8)	12 (52.2)		11 (47.8)	12 (52.2)	
None	**309**	164 (54.1)	139 (45.9)		172 (57.0)	120 (43.1)	
Gender				0.5796			0.8103
Male	764	409 (53.8)	352 (46.3)		439 (57.7)	322 (42.3)	
Female	20	12 (60.0)	8 (40.0)		11 (55.5)	9 (45.0)	
Age				**<0.0001**			**<0.0001**
18≤ age <45	104	71 (68.3)	33 (31.7)		82 (78.9)	22 (21.2)	
46≤ age <65	216	145 (67.1)	71 (32.9)		155 (71.8)	61 (28.2)	
66≤ age <75	353	171 (48.7)	180 (51.3)		179 (51.0)	172 (49.0)	
75+	111	34 (30.9)	76 (69.1)		34 (30.9)	76 (69.1)	
PCS				0.7024			0.6874
Low	234	130 (56.0)	102 (44.0)		129 (55.8)	102 (44.2)	
Medium	511	272 (53.4)	237 (46.6)		301 (59.0)	209 (41.0)	
High	13	8 (61.5)	5 (38.5)		7 (53.9)	6 (46.2)	
MCS				**0.0002**			**0.0127**
Low	188	122 (64.9)	66 (35.1)		124 (66.0)	64 (34.0)	
Medium	344	188 (55.1)	153 (44.9)		197 (57.8)	144 (42.2)	
High	226	100 (44.4)	125 (55.6)		116 (51.6)	109 (48.4)	
Etiology of amputation							
Combat injury				**0.0005**			**0.0126**
Yes	284	125 (45.5)	150 (54.6)		142 (51.6)	133 (48.4)	
No	523	296 (58.5)	210 (41.5)		308 (60.9)	198 (39.1)	
Accident				**0.0024**			**0.0093**
Yes	501	283 (58.1)	204 (41.9)		298 (61.2)	189 (38.8)	
No	305	138 (46.9)	156 (53.1)		152 (51.7)	142 (48.3)	
Burn				0.6554			0.9460
Yes	94	46 (51.7)	43 (48.3)		51 (58.0)	37 (42.1)	
No	711	375 (54.2)	316 (45.7)		399 (57.6)	293 (42.3)	
Cancer				0.4189			0.2224
Yes	30	13 (46.4)	15 (53.6)		13 (46.4)	15 (53.6)	
No	776	408 (54.2)	345 (45.8)		437 (58.0)	316 (42.0)	
Diabetes				0.3715			0.2195
Yes	12	8 (66.7)	4 (33.3)		9 (75.0)	3 (25.0)	
No	792	413 (53.7)	355 (46.2)		441 (57.4)	327 (42.6)	
Infection				**0.0362**			0.1383
Yes	95	59 (64.1)	33 (35.9)		59 (64.8)	32 (35.2)	
No	709	362 (52.5)	327 (47.5)		391 (56.7)	299 (43.4)	
Other				0.2070			0.5786
Yes	440	240 (55.9)	189 (44.1)		251 (58.5)	178 (41.5)	
No	365	181 (51.4)	171 (48.6)		199 (56.5)	153 (43.5)	

function, or device failure requiring removal, were unacceptable to the greatest proportion of respondents for surgery to restore a sense of touch (27.1% each) and to gain movement control (27.0%). Overnight hospital stays were unacceptable to the smallest proportion of respondents (2.1% who were willing to consider surgery to restore a sense of touch and 3.1% for those who were willing to consider surgery to gain movement control) followed by short-term restrictions on movement and exercise, pain or weakness for about a month, and infections requiring antibiotics (all <10%).

3.7. Acceptable risk and benefit importance

The pattern of importance ratings of benefit factors for both surgeries were very similar across risk types. All potential benefits were considered 'very important' or 'somewhat important' for each risk condition by most respondents. Having a durable/reliable device, the ability to do more activities, and having a comfortable device were consistently rated as 'very important' or 'somewhat important' by the highest proportion of respondents (97.5% or more) for every risk con-

Table 4. Multivariable logistic regressions predicting willingness to undergo surgery for the sense of touch and control.

	Sense of touch N-754		More control N-754	
	OR (95% CI)	p	OR (95% CI)	p
Amputation Level				
Unilateral SH	1.02 (0.60–1.73)	0.9418	1.06 (0.62–1.81)	0.8461
Unilateral TH	1.03 (0.71–1.48)	0.8812	1.31 (0.90–1.90)	0.1540
Unilateral TR	(ref)		(ref)	
Bilateral amputation	0.56 (0.25–1.23)	0.1468	1.07 (0.46–2.46)	0.8773
Age				
18≤ age <45	(ref)			
46≤ age <65	0.70 (0.39–1.24)	0.2162	0.57 (0.30–1.06)	0.0752
66≤ age <75	0.42 (0.25–0.70)	**0.0009**	0.28 (0.16–0.49)	**<0.0001**
75+	0.19 (0.10–0.36)	**<0.0001**	0.12 (0.06–0.24)	**<0.0001**
Prosthesis Type				
Body powered	(ref)		(ref)	
Myoelectric	1.56 (0.94–2.59)	0.0823	2.16 (1.25–3.74)	**0.0055**
Cosmetic	0.80 (0.32–1.97)	0.6210	0.72 (0.29–1.78)	0.4759
None	0.90 (0.62–1.31)	0.5780	0.89 (0.61–1.30)	0.5493
VR-Mental Component				
Low	(ref)		(ref)	
Medium	0.73 (0.50–1.08)	0.1183	0.80 (0.53–1.19)	0.2617
High	0.47 (0.31–0.72)	**0.0005**	0.61 (0.39–0.94)	**0.0250**
Etiology of amputation				
Combat injury				
Yes	0.65 (0.41–1.03)	0.0684	0.77 (0.48–1.25)	0.2959
No	(ref)		(ref)	
Accident				
Yes	1.34 (0.86–2.09)	0.1920	1.40 (0.89–2.21)	0.1459
No	(ref)		(ref)	
Infection				
Yes	1.70 (1.04–2.80)	**0.0349**	1.47 (0.89–2.42)	0.1362
No	(ref)		(ref)	

dition of each surgery. In contrast, naturalness of touch, water-resistance, and lifting 20 pounds were the benefits rated 'not at all important' by the greatest proportion of respondents for a surgery to gain a sense of touch (5.3–6.9%, 4.1–5.6%, and 3.9–5.6%, respectively). For surgery to gain movement control, water-resistance and lifting 20 pounds were rated 'not at all important' by the most respondents (4.1–4.8% and 3.5–4.2%, respectively). As an example, Figure 3(a,b) shows the importance ratings of each potential benefit, given the risk of incurring an infection requiring antibiotics from surgeries to gain a sense of touch or movement control, respectively. Importance rating for all other risks are shown in Appendix B.

3.8. Amputation levels and importance ratings

For surgery that would restore a sense of touch, Kruskal–Wallis comparisons of importance ratings for each potential benefit-risk combination by amputation level showed statistically significant differences for several benefit-risk combinations. There were significant differences ($p< 0.05$) by amputation level in the importance ratings of durability/reliability, water/dirt resistance, lightweight devices, and ability to lift 20 pounds for those willing to risk an overnight stay, infection requiring antibiotics, or infection requiring device removal. There were also significant differences ($p< 0.05$) between amputation level groups in the importance ratings of lightweight devices and ability to lift 20 pounds for those willing to risk pain or weakness during recovery or short-term movement restrictions. Trends by amputation level were generally consistent across those willing to accept each specific risk (Appendix B). As an example, Figure 4(a) shows the importance of potential benefits for those willing to risk infection requiring antibiotics. All respondents with bilateral amputation rated durability ($p= 0.006$), water resistance ($p= 0.02$), and lifting ability ($p= 0.05$) as 'very important,' while persons with SH amputation rated these potential benefits as 'very 'important' the least often. Persons with bilateral amputation rated the benefit of lightweight devices ($p= 0.01$) as 'very important' the least often, while those with TR and TH level amputation rated it 'very important' the most often.

For surgery to regain greater movement control, Kruskal–Wallis comparisons of importance ratings for each potential benefit-risk combination by amputation level showed statistically significant differences for several benefit-risk combinations. Importance ratings for lifting 20 pounds were significantly different ($p< 0.05$) by amputation level in all risk condition sub-groups except among those willing to risk skin irritation or breakdown ($p= 0.07$). For all risk conditions, direct control was rated as 'very important' by the smallest proportion of persons with SH amputation (57.5–62.1%, $p's<0.05$). Figure 4(b) shows data for those willing to risk infection requiring antibiotics; 57.8% of SH group valued direct control as 'very important' ($p = 0.004$). Ability to lift 20 pounds ($p= 0.01$) was rated 'very important' by the smallest proportion of persons with SH amputation (54.6%) and the greatest proportion of persons with bilateral amputation (92.3%).

3.9. Prosthesis use and importance ratings

For surgery for restoration of touch, Wilcoxon rank-sum tests comparing importance ratings for each benefit-risk combination by current prosthetic use found statistically significant

Table 5. Willingness to accept each surgical risk condition among those definitely or not sure willing to undergo surgery for a sense of touch or control.

	Sense of touch N = 421			Movement control N = 450		
	Yes	Not sure	No	Yes	Not sure	No
Risk condition	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Surgery would require an overnight stay	310 (73.8)	101 (24.1)	9 (2.1)	352 (78.2)	84 (18.7)	14 (3.1)
Risk of infection that would require antibiotics	295 (70.2)	88 (21.0)	37 (8.8)	328 (73.1)	85 (18.9)	36 (8.0)
Risk of serious infection that would require removing the device	253 (60.8)	91 (21.9)	72 (17.3)	278 (62.1)	99 (22.1)	71 (15.9)
Long-term risks	200 (48.0)	104 (24.9)	113 (27.1)	225 (50.1)	103 (22.9)	121 (27.0)
Pain or weakness during the recovery from surgery of about 1 month	301 (71.7)	85 (20.2)	34 (8.1)	339 (75.5)	77 (15.2)	33 (7.4)
Short-term restrictions on movement and exercise for up to 1 month	324 (77.1)	73 (17.4)	23 (5.5)	345 (76.7)	79 (17.6)	26 (5.8)
Skin irritation or breakdown from the socket or components socket				258 (57.6)	120 (26.8)	70 (15.6)

differences in the importance of two potential benefits (Appendix B). The importance of durable/reliable devices was rated significantly higher for prosthetic users as compared to nonusers among all risk groups ($p< 0.05$), except for those willing to risk pain or weakness during recovery ($p= 0.06$). The importance of water/dirt resistant devices was rated significantly higher for prosthetic users than nonusers among all risk groups ($p< 0.05$), except those willing to risk an overnight stay ($p= 0.06$) or risking pain or weakness during recovery ($p= 0.07$).

For surgery to improve movement control, Wilcoxon rank-sum comparing importance ratings for each benefit-risk combination by current prosthetic use found that among those willing to risk infection requiring device removal, water/dirt resistant devices ($p= 0.04$) and ability to lift 20 pounds ($p= 0.04$) were both significantly more important to current prosthesis users than nonusers (Appendix B).

4. Discussion

We conducted a national study of Veterans that assessed upper limb amputees' willingness to consider surgeries to restore a sense of touch and gain greater control over prosthesis movement. Our survey also evaluated the importance of receiving specific benefits and examined whether these importance rankings varied by amputation level, for unilateral versus bilateral amputees, and for prosthesis users versus non-users.

Our study offers a unique contribution to the literature and our understanding of Veterans' perspectives due to its size and representativeness. Prior studies on patient perspectives for new technologies were smaller and not nationally representative of Veterans. Our findings are important for research teams developing new technologies that find it challenging to identify individuals who are willing to participate in their studies. The population of upper limb amputees is geographically dispersed, and there is no central registry of persons with upper limb amputation. Our findings provide an understanding of the types of Veterans most interested in surgery and their perspectives on benefits and risks.

Overall, more than half of the respondents were willing to consider or might be willing to consider both types of surgeries. Older age was associated with decreased likelihood of interest in these types of surgeries. Factors associated with increased likelihood of interest included myoelectric device use, poorer mental health function, and amputation secondary to infection.

Our findings regarding older age are not surprising, in that older age may be associated with greater co-morbidity, greater surgical risks, and more complicated surgical recovery. Younger persons may be less likely to have adapted to their limb loss and accepted their limitations as compared to older persons, and thus are more open to technological solutions. In addition, older persons are, in general, less risk-tolerant than younger persons [35] and may be less interested in increasing their activities. These findings are consistent with results reported by Engdahl et al., who surveyed upper limb amputees about their interest in novel prosthetic interfaces. They found that younger participants were more likely to be interested in the three invasive interfaces that they studied [26].

We also found that myoelectric prosthesis users were twice as likely to be willing to consider surgery to improve prosthesis control. This finding makes sense, given the limitations of surface EMG control and the challenges of controlling newer prostheses that may have multiple degrees of freedom. There have been major advances in surgical techniques, such as targeted muscle reinnervation (TMR), which can be used in conjunction with newer control strategies, such as EMG pattern recognition control [36,37]. A prior study found that myoelectric device users were more likely to be interested in myoelectric controls than were body-powered users [26]. Our findings are consistent with this interest in advanced technology and suggest that a greater proportion of myoelectric device users are aware of these advances.

The association between poorer mental health and increased willingness to consider surgery was somewhat surprising. Our measure of mental health functioning (VR-12 MCS) was a generic, norm-based measure which captured psychological distress. It is possible lower scores of the VR-12 MCS are, in part, the result of psychological distress caused by dissatisfaction with the prosthesis and with functional abilities. This hypothesis could be explored in future research.

We categorized etiology of amputation using multiple categories to be consistent with the prior work done by Reiber and found that amputation secondary to infection was associated with an increased interest in restoration of sense of touch, but not in surgery to improve prosthesis control [38]. It is challenging to explain these findings. One hypothesis is that there was a greater

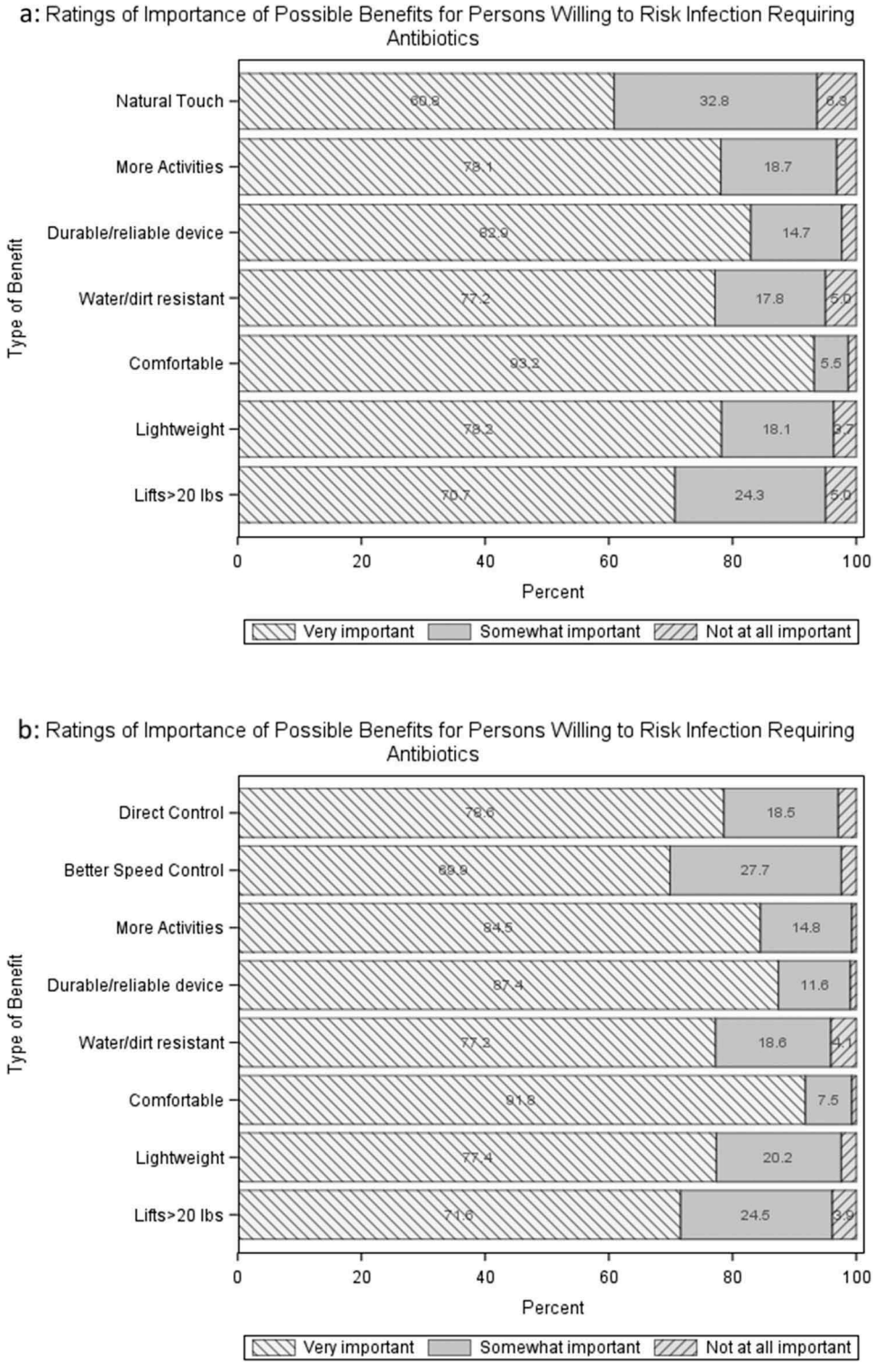

Figure 3. Sub-group comparisons of importance of factors for those who were willing to undertake specific risks (yes/maybe) in order to obtain a prosthesis that could restore a sense of touch by amputation level.

*significant at $p < 0.05$

proportion of respondents with infection as an etiology of limb loss who had also lost sensation in their contralateral upper limb. It is not uncommon for persons who lose upper limbs due to infection to lose more than one limb, and/or sustain damage to their remaining limbs. Further research is needed to confirm or refute this hypothesis.

For those who indicated that they were or might be willing to consider each type of surgery, we examined whether ratings of benefit importance varied by specific risk conditions. The ability to do more activities, have durable/reliable devices, and comfort were the benefits rated most important by the most respondents. The benefits that were generally rated the

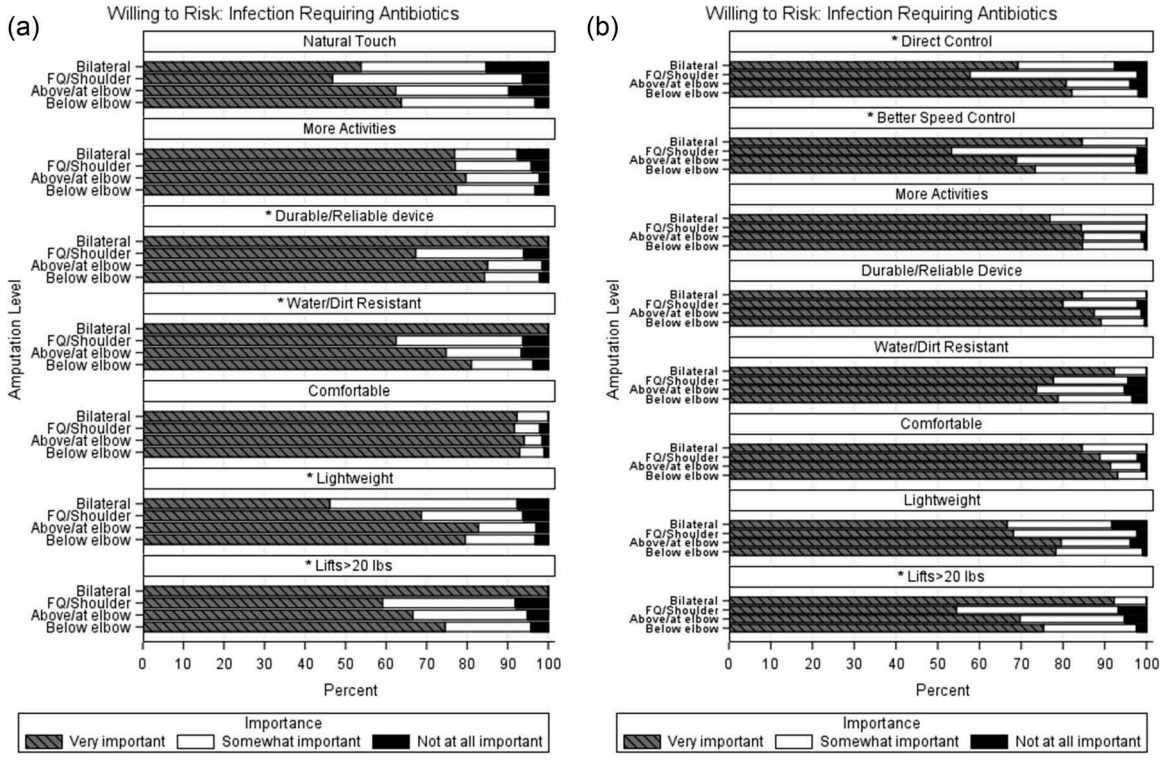

Figure 4. Sub-group comparisons of importance of factors for those who were willing to undertake specific risks (yes/maybe) in order to obtain a prosthesis that could restore better movement control by amputation level.

*significant at $p < 0.05$

least important across risks included restoration of a natural sense of touch (presented for the restoration of sense of touch surgery survey section only), water/dirt resistance, and ability to lift more than 20 pounds. There was consistency in the ratings of benefits that were important across risk sub-groups, with all potential benefits considered somewhat or very important by at least 90% of participants. This finding suggests that the formative research utilized to identify the potential benefits important to persons with upper limb amputees successfully identified a list of important potential benefits of prosthetic devices.

Nearly half of Veterans reported a potential willingness to consider (willing to consider or not sure if they would consider) surgery to restore a sense of touch. No prior study has surveyed upper limb amputees to ascertain their interest in surgery to restore a sense of touch. Engdahl's survey asked respondents to indicate their interest in successive levels of performance (defined by complexity and features) for four prosthesis control options, one non-invasive (EMG control) and the others requiring surgical intervention (targeted muscle reinnervation, peripheral nerve interfaces, cortical interfaces) [25]. Sensation was added as a functional feature of the highest performance level of these control options. Although Engdahl concluded that few participants were interested in sensation as a feature of prosthetic control options, that study never asked about interest in restoration of touch alone, and thus our findings are not comparable.

Our study also quantified the acceptability of incurring a variety of post-surgical risks among those who indicated that they had a willingness or might have a willingness to consider each type of surgery. All risks were acceptable or possibly acceptable to the majority of respondents (72.9–97.9%) who were willing or might be willing to consider surgery. This demonstrates that persons who are open to considering surgery are willing to risk some adversity. Our results help sort these post-surgical risks by their perceived severity, where short-term risks (overnight stays and movement restriction) were the most acceptable while serious infection requiring device removal and long-term risks (including chronic pain, loss of some nerve function, or device failure requiring it to be removed) were the least acceptable. We found that the risk of a serious infection that would require antibiotics was not a deterrent to most participants, with over 90% of respondents indicating that they were willing or may be willing to accept this risk.

We found that ratings of benefit importance were consistent across all risk categories. However, persons with bilateral amputation weighed the importance of potential benefits directly related to function differently than did unilateral amputees. For surgeries to restore a sense of touch, virtually all persons with bilateral amputation indicated that durability, water resistance, and lifting 20 pounds were very important to them. In contrast, they rated having a lightweight prosthesis as least important, in contrast to unilateral amputees. For surgeries restoring movement control, persons with bilateral amputation prioritized lifting 20 pounds and better speed control. However, respondents with shoulder level amputation (who are often more functionally impaired than those at other amputation levels) rated better speed control and direct control as least important, perhaps because they have accepted

that limited prosthetic options are available for persons with their level of amputation.

5. Limitations

Our study had several limitations. First, it is likely that participants may not have fully understood what the surgery to obtain each of these benefits would involve. We did not assess whether or not participants were familiar with these types of surgery and made no attempt to describe the variety of emerging surgical approaches to obtain these benefits [6,12,37,39]. Thus, participants indicated their willingness to consider surgical approaches without having full information that would be provided before they would be consented for actual procedures. It is possible that upper limb amputees might weigh the benefits and risks differently in specific scenarios depending on the potential capabilities offered by the technological advance. It is also likely that respondents did not fully understand what 'naturalness of touch' would mean for a prosthesis, given that they had never experienced prostheses with any type of sensory capabilities.

Second, our sample included only Veterans who had received care at VA Medical Centers between 2010 and 2015. It is possible that these participants differ from the larger population of Veterans or of US upper limb amputees in general; however, there are no data available on the characteristics of Veterans with upper limb amputations who do not receive care at the VA. We sampled 100% of Veterans who met our eligibility criteria and had a good response rate (48%), and thus our findings are likely generalizable to Veterans with upper limb amputation receiving healthcare at the VA.

Third, our comparisons of importance ratings should be considered exploratory. Importance ratings for each risk were analyzed separated. While each analytic subsample was different, there was significant overlap between the individuals within each of the subsamples who were willing to incur a specific risk. We believe that this largely explains the consistency of importance rankings across risk sub-groups given that similar individuals rated the importance of benefits in the same pattern, regardless of risk.

Another limitation is that our survey did not differentiate between levels of risk or ask respondents to trade between benefits and risks, approaches that have been used in other benefit-risk surveys. In our cognitive testing, we tested a version of the survey that used a rating scale approach with a direct elicitation method that aimed to assess respondents' willingness to trade between benefits associated with novel prosthetic technologies and potential risks. In that version, respondents were asked to identify a likelihood value (using a scale of 0–100%) that they would require for receiving each one of the major benefits, given 1%, 5% and 20% chance of incurring risks. Separate items were asked about each of the risks. It was immediately clear that this format was too complex and confusing. We then tested a revised version that asked respondents if they were willing to accept each of the specific risks, given specific probabilities (25%, 50%, 75%, 90%) of receiving one of the major benefits. Separate questions were asked for risks of 1%, 5%, and 20%. Cognitive interviews conducted with additional participants revealed that the items were still too difficult to understand. Thus, we chose to simplify the survey to its current form.

Lastly, although we conducted statistical comparisons of importance for specific risk conditions, our analyses were limited due to small sample sizes for shoulder level and bilateral amputees, which may have resulted in insufficient power to detect small differences. Further research with larger samples and non-Veterans is needed to confirm or refute our findings.

6. Conclusions

We conducted a national survey of Veterans with major upper limb loss to assess their willingness to consider surgery to restore a sense of touch or more control over the movements of their prostheses and to understand their perspectives on the potential benefits and risks associated with these novel surgeries. Forty-two percent of respondents were willing to consider surgery to regain a sense of touch, and 49% were willing to consider surgery to gain movement control. Our multivariate models showed that persons who were older and who had better mental health functioning were less willing to consider either surgery, while those who had lost their limb due to infection were more likely (as compared to persons who had not lost their limbs due to infection) to be willing to consider surgery to restore a sense of touch. Respondents who were willing to consider surgery indicated that the most important potential benefits were having a durable/reliable device, the ability to do more activities, and having a comfortable device. Most were willing to accept one or more risks of surgery. However, long-term risks including chronic pain, loss of nerve function, and device failure were considered the most unacceptable.

7. Expert opinion

Patient perspectives on benefits and risks of surgeries to advance prosthesis ability are vital to patient-centric development and evaluation of medical devices.

Author contributions

Linda Resnik: design, acquisition of funding, analysis, interpretation of data, drafting and revising manuscript, final approval of publication

Matt Borgia: design, data analysis and interpretation, drafting and revising manuscript, final approval of publication

Melissa Clark: design, data collection, data analysis and interpretation, drafting and revising manuscript, final approval of publication

Heather Benz: design, data analysis and interpretation, drafting and revising manuscript, final approval of publication

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Declaration of interest

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

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Appendix A

Benefit-Risk Questions

1 Would you consider undergoing surgery to have a prosthesis that would **restore a sense of touch**?
1 YES
2 NO
3 NOT SURE
99 REFUSED [DO NOT READ]

[ASK IF 1 = 1 (YES) OR 3 (NOT SURE)]

2. How important are the following benefits in your decision to consider undergoing surgery for a device that **restores a sense of touch?**

	Very important	Somewhat important	Not at all important	DON'T KNOW/NOT SURE [DO NOT READ]	REFUSED [DO NOT READ]
a. A sense of touch that feels natural [Would you say Very Important, Somewhat Important, or Not at All Important?]	1	2	3	98	99
b. The ability to do more activities with the prosthesis	1	2	3	98	99
c. Getting a durable and reliable prosthesis that seldom needs repair	1	2	3	98	99
d. A prosthesis that can get wet or dirty	1	2	3	98	99
e. A comfortable prosthesis	1	2	3	98	99
f. A lightweight prosthesis	1	2	3	98	99
g. A prosthesis that can be used to lift more than 20 pounds	1	2	3	98	99

[ASK IF U1 = 1 (YES) OR 3 (NOT SURE)]

3. Would you be willing to accept the following risks and inconveniences to undergo a surgery that would let you use a prosthesis that **restores a sense of touch?**

	Yes	No	Maybe	DON'T KNOW/NOT SURE [DO NOT READ]	REFUSED [DO NOT READ]
a. Surgery would require an overnight stay [Would you say yes, no, or maybe?	1	2	3	98	99
b. Risk of infection that would require antibiotics	1	2	3	98	99
c. Risk of serious infection that would require removing the device	1	2	3	98	99
d. Long-term risks, such as chronic pain, loss of some nerve function, or device failure requiring it to be removed	1	2	3	98	99
e. Pain or weakness during the recovery from surgery of about 1 month	1	2	3	98	99
f. Short-term restrictions on movement and exercise for up to 1 month	1	2	3	98	99

4. Would you consider undergoing surgery to have a prosthesis that would give you **more control over finger movements, grasps, or wrist motions**?

[INTERVIEWER NOTE: DO NOT READ UNLESS NECESSARY**]**

1 YES
2 NO
3 NOT SURE
99 REFUSED [DO NOT READ]

[ASK IF 4 = 1 (YES) OR 3 (NOT SURE)]

5. . How important are the following benefits in your decision to consider undergoing surgery to have a device that gives you **more control over finger movements, grasps, or wrist motions**?

	Very important	Somewhat important	Not at all important	DON'T KNOW/NOT SURE [DO NOT READ]	REFUSED [DO NOT READ]
a. The ability to directly control the prosthesis finger movements, grasps, or wrist motions [Would you say Very Important, Somewhat Important, or Not at All Important?]	1	2	3	98	99
b. A device that allows for better control over the speed of the prosthesis movement	1	2	3	98	99
c. The ability to do more activities with the prosthesis	1	2	3	98	99
d. Getting a durable and reliable prosthesis that seldom needs repair	1	2	3	98	99
e. A prosthesis that can get wet or dirty	1	2	3	98	99
f. A comfortable prosthesis	1	2	3	98	99
g. A lightweight prosthesis	1	2	3	98	99
h. A prosthesis that can be used to lift more than 20 pounds	1	2	3	98	99

ASK IF 4 = 1 (YES) OR 3 (NOT SURE)]

6. Would you be willing to accept the following risks and inconveniences to undergo a surgery that would let you use a prosthesis to gain **more control over finger movements, grasps, or wrist motions**?

	Yes	No	Maybe	DON'T KNOW/NOT SURE [DO NOT READ]	REFUSED [DO NOT READ]
a. Surgery would require an overnight stay [Would you say Yes, No, or Maybe?]	1	2	3	98	99
b. Risk of infection that would require antibiotics	1	2	3	98	99
c. Risk of serious infection that would require removing the device	1	2	3	98	99
d. Long-term risks, such as chronic pain, loss of some nerve function, or device failure requiring it to be removed	1	2	3	98	99
e. Pain or weakness during the recovery from surgery of about 1 month	1	2	3	98	99
f. Short-term restrictions on movement and exercise for up to 1 month	1	2	3	98	99
g. Skin irritation or breakdown from the socket or components socket	1	2	3	98	99

Appendix B

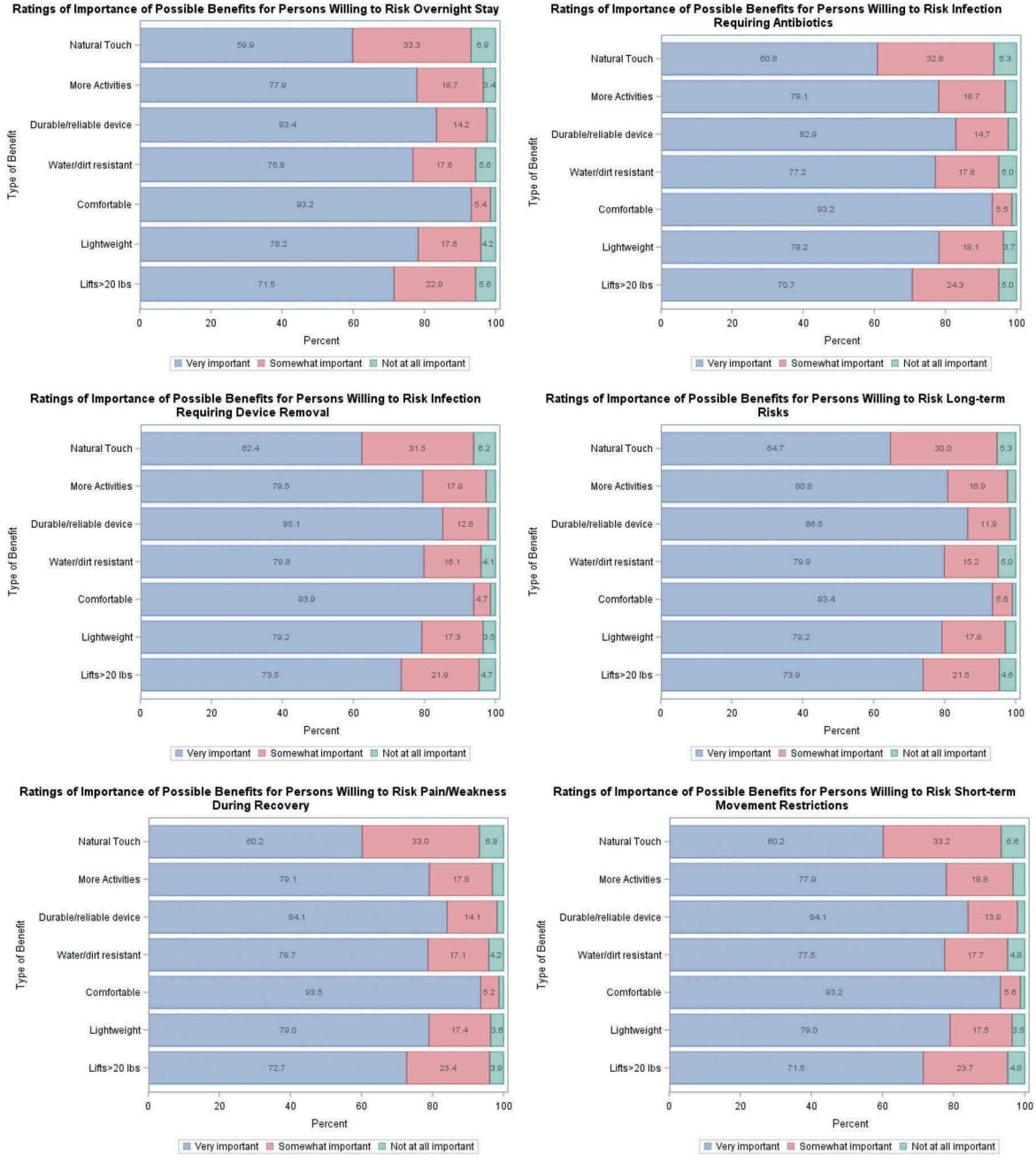

Figure 1A. Benefit factor ratings for those who would consider surgery to have a prosthesis that could restore a sense of touch (yes/maybe): unilateral and bilateral amputees.

*significant at $p < 0.05$

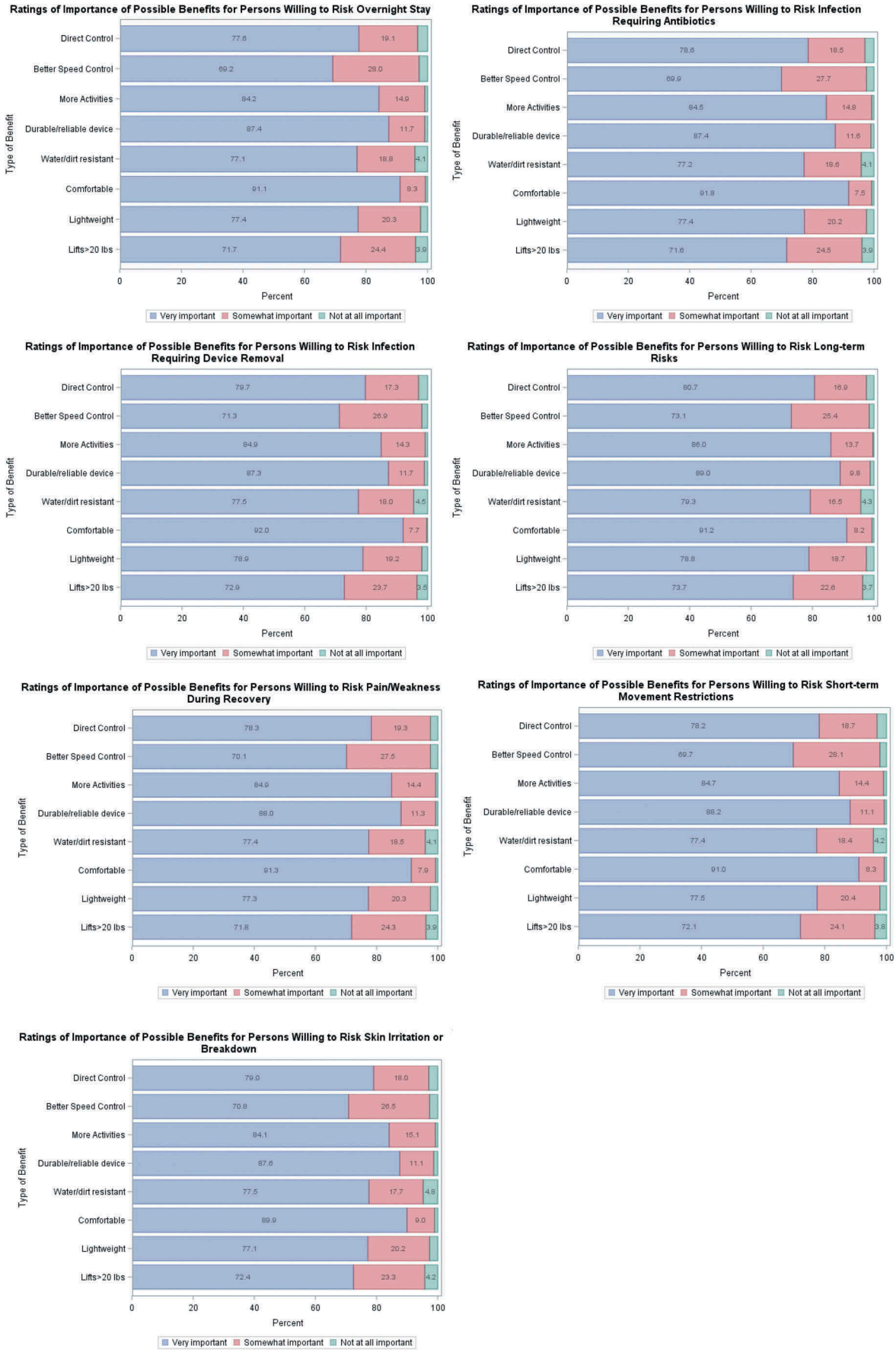

Figure 2A. Benefit factor ratings for those who would consider surgery to have a prosthesis that gives more control over finger movements, grasps or wrist motions (yes/maybe): unilateral and bilateral amputee.

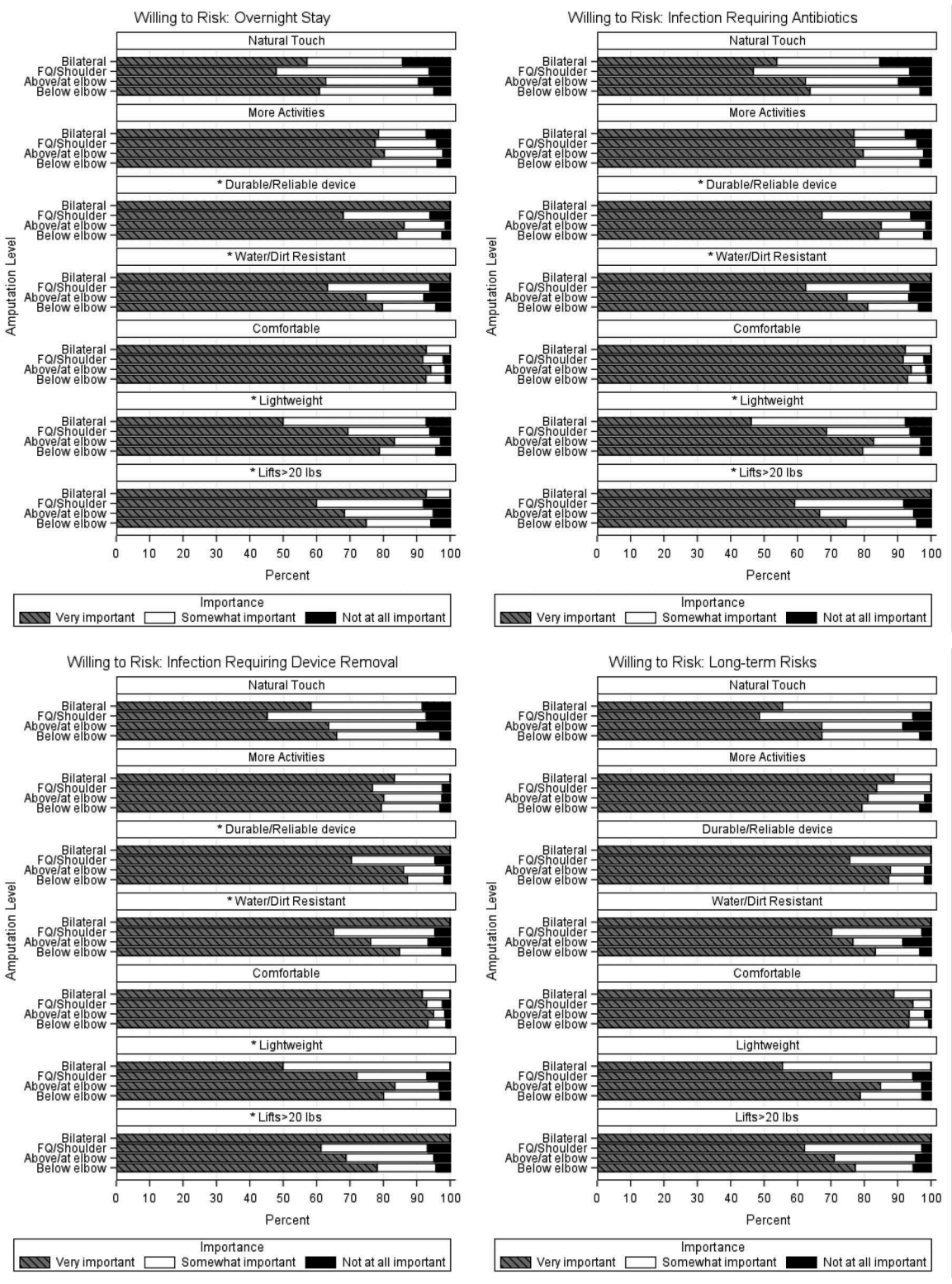

Figure 3A. Sub-group comparisons of importance of factors for those who were willing to undertake specific risks (yes/maybe) in order to obtain a prosthesis that could restore a sense of touch by amputation level.

*significant at $p < 0.05$

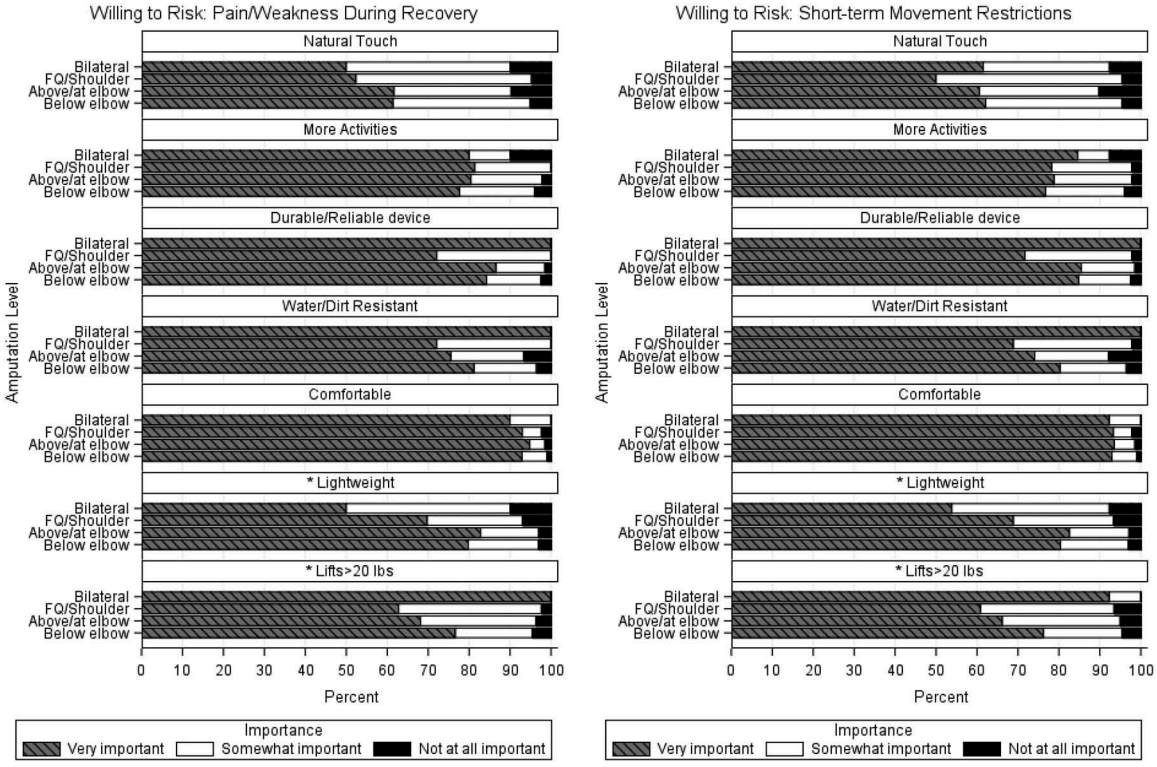

Figure 3A. (Continued).

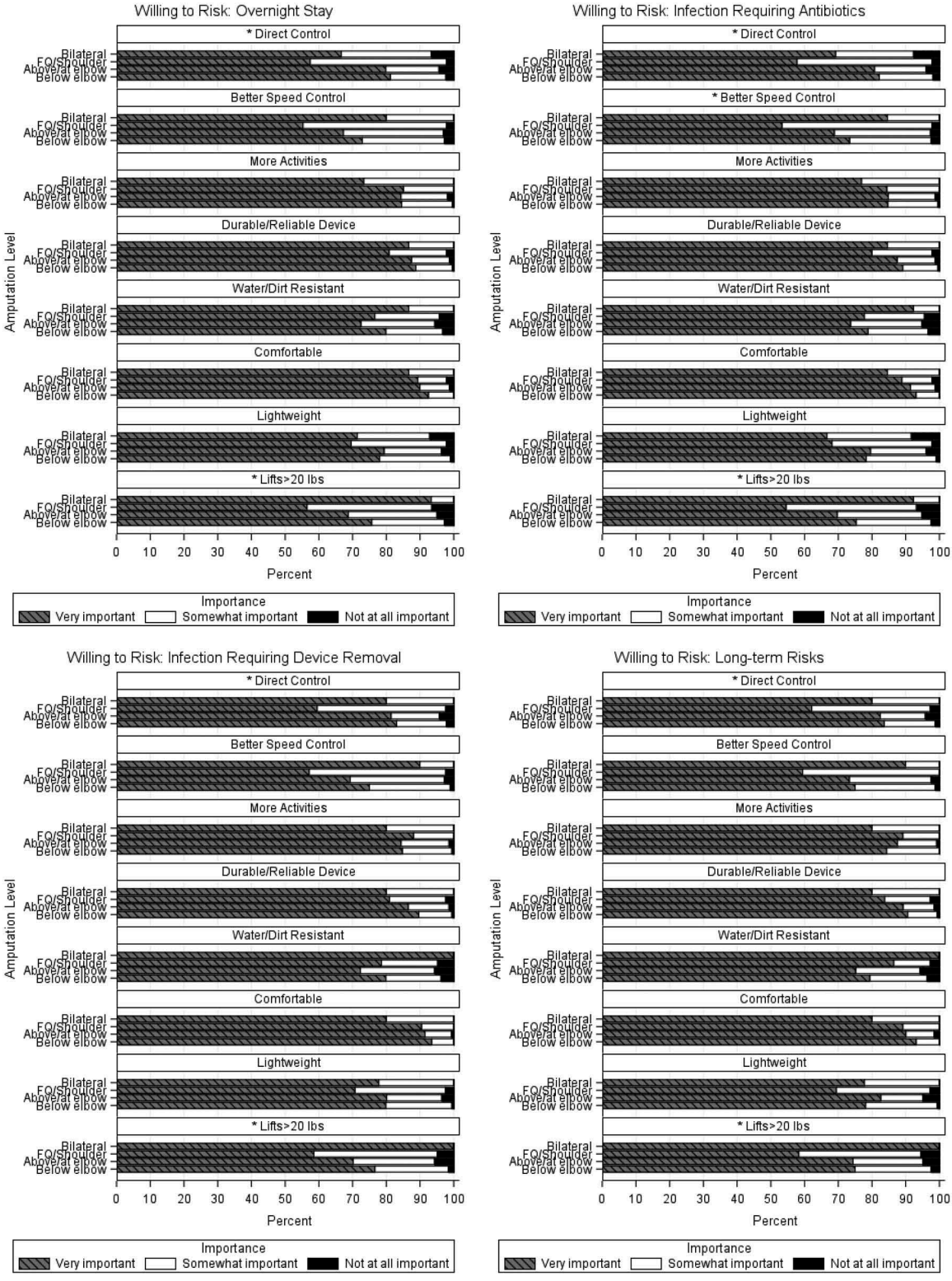

Figure 4A. Sub-group comparisons of importance of factors for those who were willing to undertake specific risks (yes/maybe) in order to obtain a prosthesis that could restore better movement control by amputation level.

*significant at $p < 0.05$

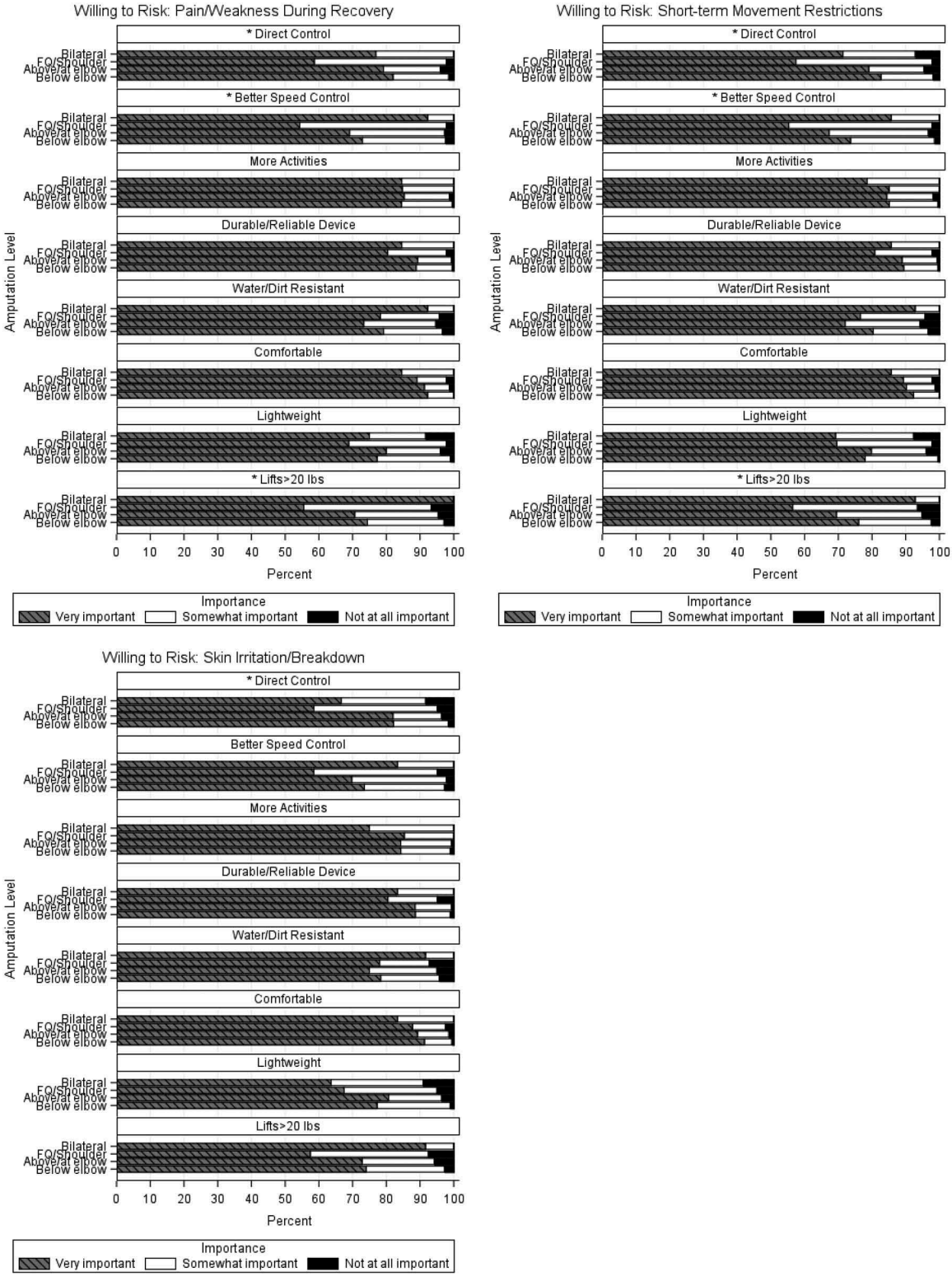

Figure 4A. (Continued).

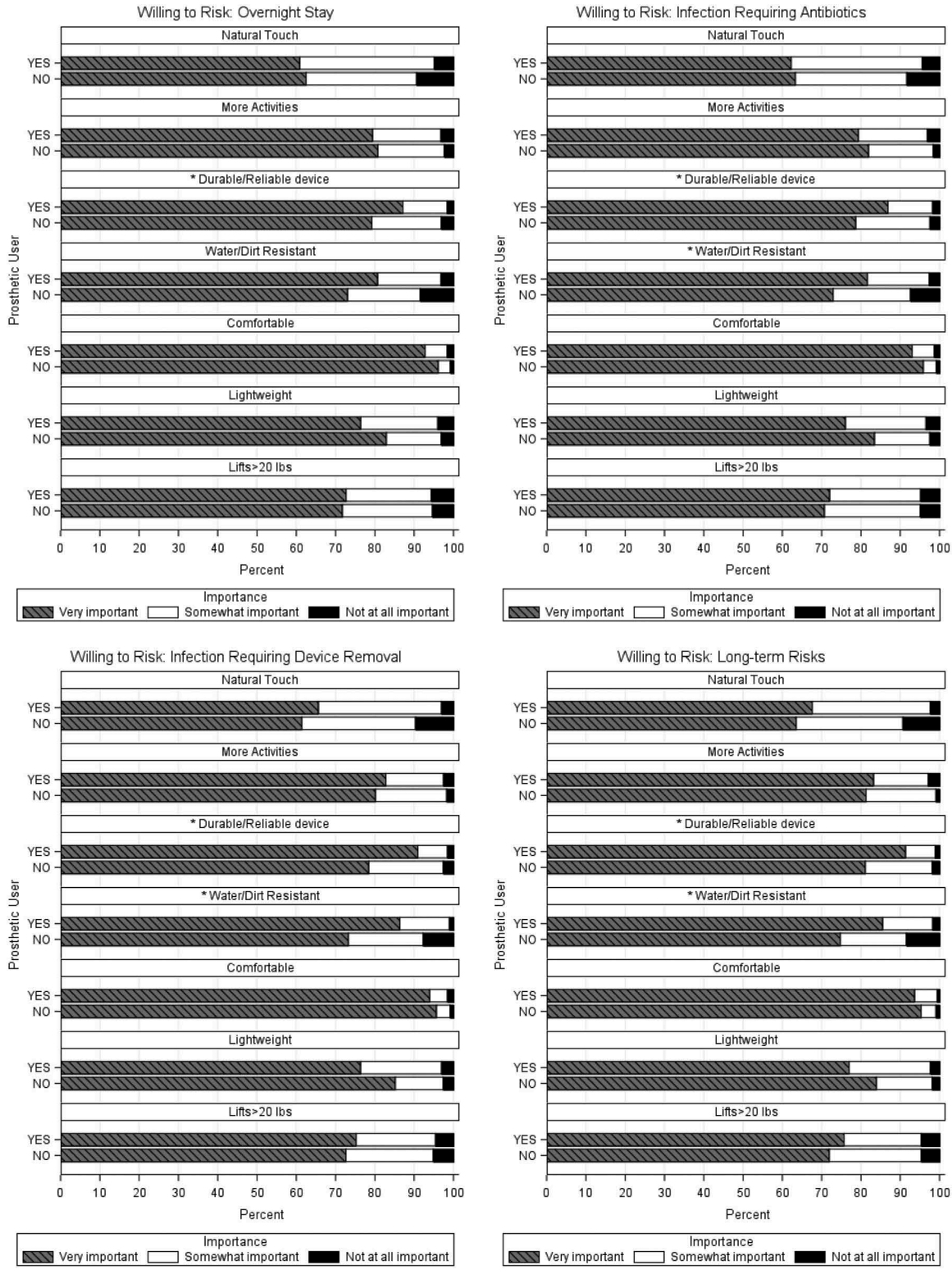

Figure 5A. Sub-group comparisons of importance of factors for those who were willing to undertake specific risks a (yes/maybe) in order to obtain a prosthesis that could restore a sense of touch by amputation level.

*significant at $p < 0.05$

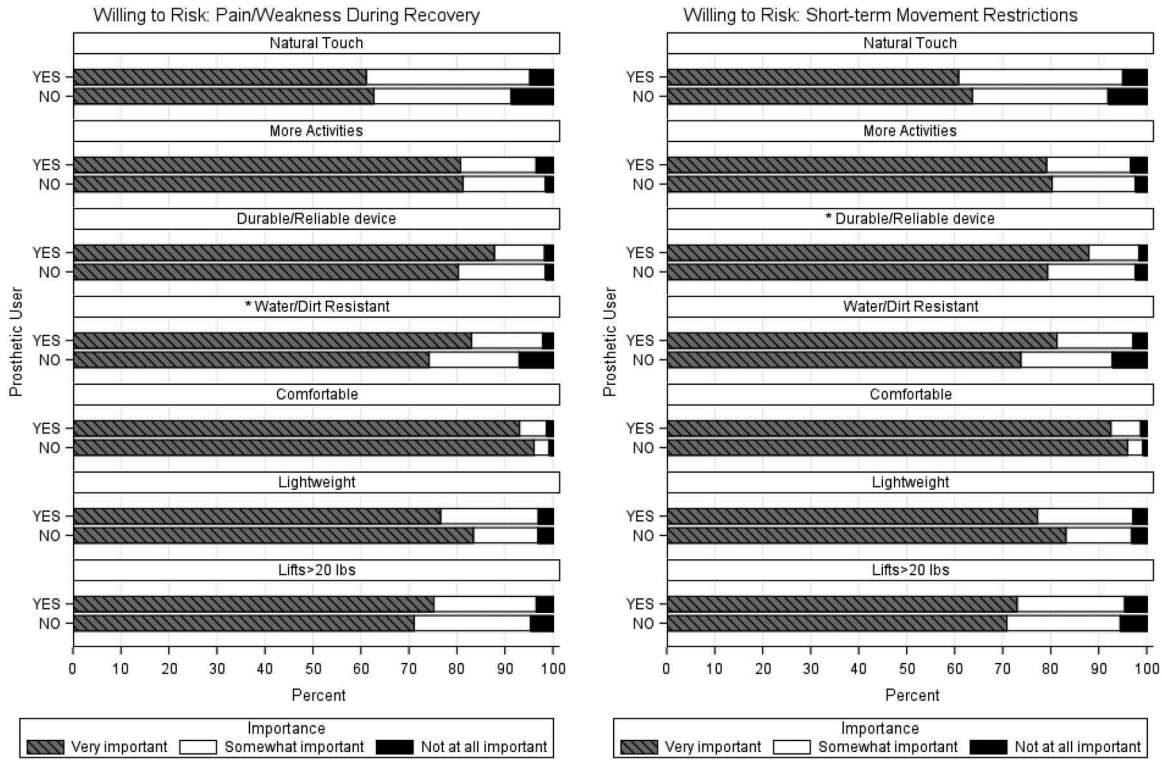

Figure 5A. (Continued).

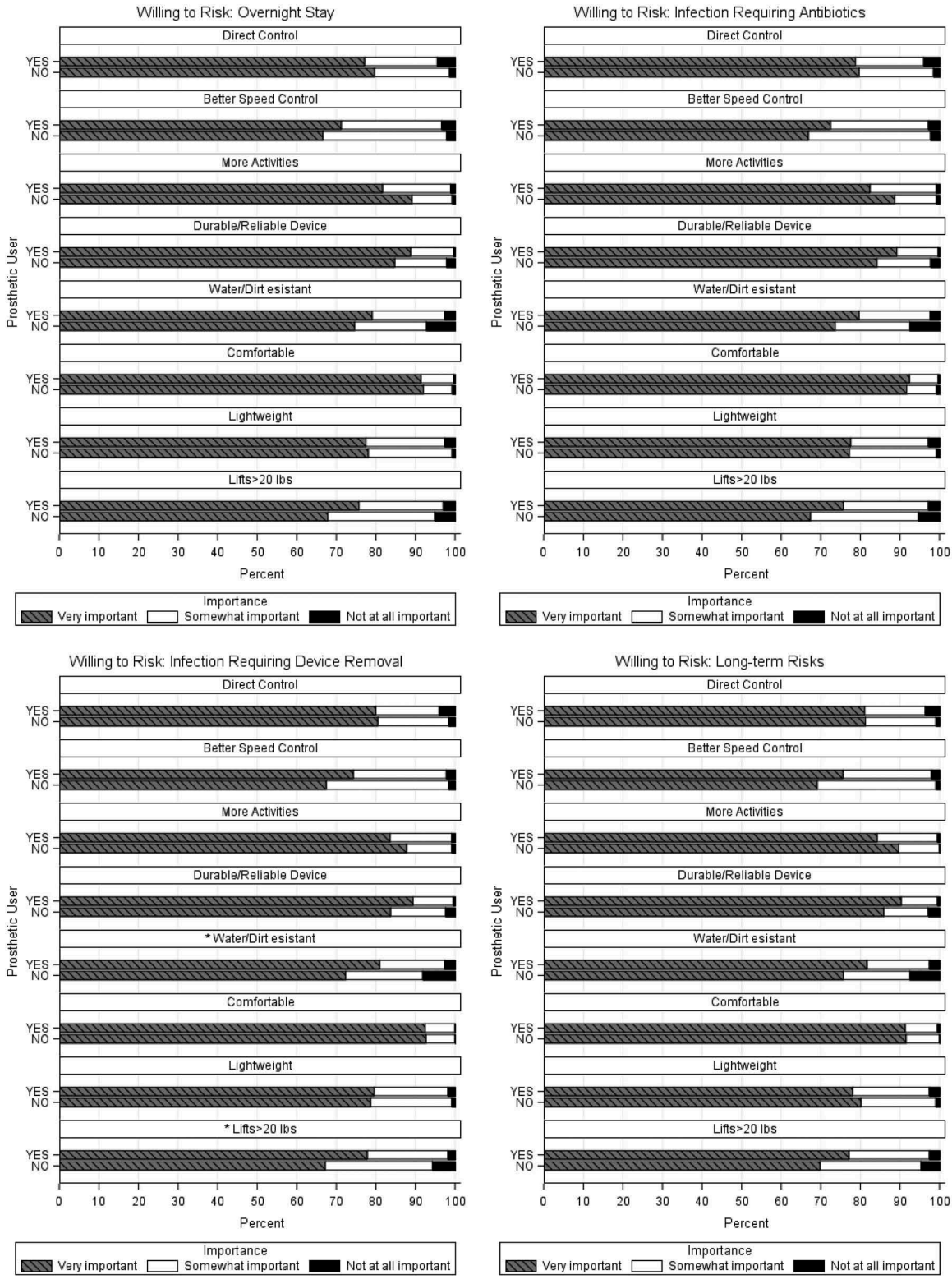

Figure 6A. Sub-group comparisons of importance of factors for those who were willing to undertake specific risks a (yes/maybe) in order to obtain a prosthesis that could restore better movement control by amputation level.

*significant at $p < 0.05$

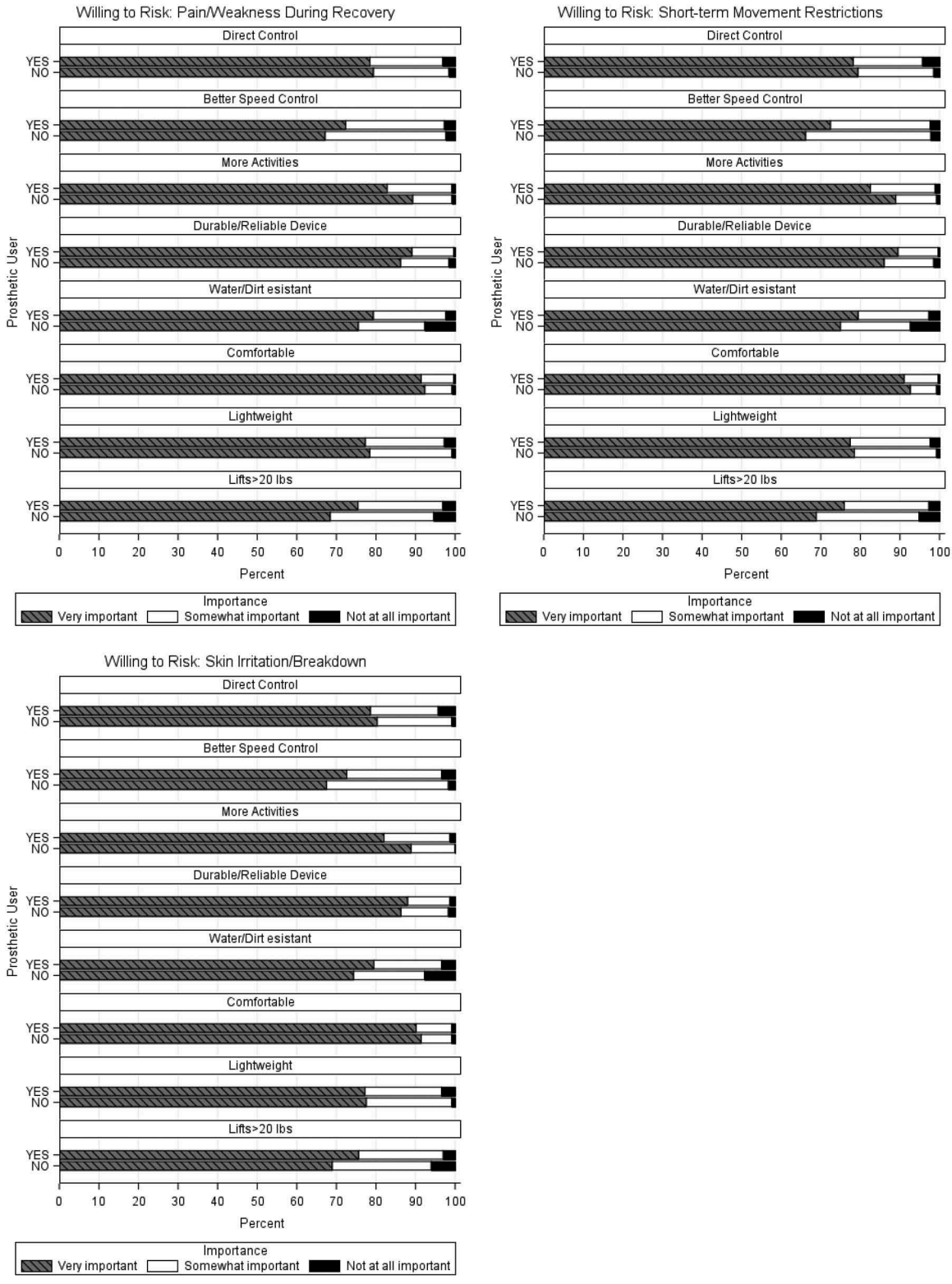

Figure 6A. (Continued).

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Original Research

Patient Perspectives on Osseointegration: A National Survey of Veterans with Upper Limb Amputation

Linda Resnik, PhD, Heather Benz, PhD, Matthew Borgia, AM, Melissa A. Clark, PhD

Abstract

Introduction: Osseointegrated (OI) prostheses have a unique benefit-risk profile among prosthetic alternatives and have been marketed in the United States under a Humanitarian Device Exemption since 2015. Information about upper limb prosthesis user perspectives on benefits and risks, prosthesis-user subpopulations for whom OI is most acceptable, and outcomes that matter most to patients could help inform clinical and regulatory decision-making. Recent 21st Century Cures legislation expanded the role of patient experience data in the decision-making process of the U.S. Food and Drug Administration, recognizing that patient perspectives may be informative to regulators.
Objective: To better understand prosthesis user perspectives about the benefits and risks associated with upper limb OI prostheses.
Design: Patient perspective survey.
Setting: Telephone administration.
Participants: National sample of veterans with upper limb loss.
Interventions: NA
Main Outcome Measures: Benefit-risk survey developed for this study.
Results: Twenty-eight percent of unilateral and 13% of bilateral amputees were willing to consider osseointegration surgery. Multivariate logistic regression models [OR; 95% CI] showed that transhumeral amputation level [OR 1.40; 1.01-1.98] was associated with greater willingness to consider surgery, whereas older age [OR 0.17; 0.09-0.32] and higher VR-12 Mental Component Summary [OR 0.53; 0.35-0.81] were associated with less willingness. Having a durable/reliable device, the ability to do more activities, and having a comfortable device were rated as very important or somewhat important by 98% or more for every risk condition.
Conclusions: Persons who were older, had transradial amputation (compared to transhumeral), and those who had better mental functioning were less willing to consider this surgery. Respondents who were willing to consider surgery indicated that the most important potential benefits were obtaining a durable/reliable device, the ability to do more activities, and having a comfortable device. Most were willing to accept one or more risks of surgery, with long-term risks including chronic pain, loss of nerve function, or device failure considered the most unacceptable.
Level of Evidence: III

Introduction

Osseointegrated (OI) prostheses, which are attached to a residual limb by means of a fixture anchored in the bone, have a unique benefit-risk profile among prosthetic alternatives. They may improve user comfort, function, and sensation but involve significant risks such as aseptic loosening (reported in 13%-23% in upper extremity implants), periprosthetic fracture (reported in 0%-18% of transfemoral implants, but 0% in upper extremity implants), intermedullary device breakage (reported in 27% of transradial implants), and infection (reported in 23%-29%).[1,2] They have been marketed in Europe since the 1990s, in Australia since 2011, and in the United States under a Humanitarian Device Exemption since 2015. Although lower-limb OI surgery is available in the United States through the Humanitarian Device Exemption, upper-limb OI surgery has not yet been approved by the U.S. Food and Drug Administration (FDA) in the United States. However, clinical trials of upper-limb OI surgery are ongoing. OI has been a treatment option for individuals with lower and upper limb loss in Europe for over 20 years.[3]

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Evidence has grown about the potential benefits and risks associated with OI prostheses,[2] and the trade-offs between OI and other prostheses make the choice to pursue an OI prosthesis a shared decision between patients and healthcare professionals. Information about the diversity of upper-limb prosthesis user perspectives on these distinctive benefits and risks, prosthesis-user subpopulations for whom OI is most acceptable, and the outcomes that matter most to patients could help inform clinical and regulatory decision-making.

Recent 21st Century Cures legislation expanded the role of patient experience data in the FDA decision-making process, recognizing that the perspectives patients have about the impact of a condition and therapeutic options on their lives may be informative to regulators.[4] U.S. medical device approvals now include information about patient input considered during the approval process, and the impact of OI prostheses on quality of life is increasingly a part of the conversation about decision-making related to clinical use of these devices.[5–7] To better understand prosthesis user perspectives about the benefits and risks associated with upper-limb OI prostheses, we developed a patient perspective survey and administered it to a national sample of veterans with upper-limb loss.

Methods

Patient Perspective Survey Development and Pilot Testing

All aspects of this study were approved by appropriate institutional review boards and all participants gave informed consent. Development of the patient perspective survey involved three stages: development of an initial item set, prioritization of the survey content, and cognitive and pilot testing. Each stage is shown in Figure 1. Detailed description of survey development is provided in Appendix A. Briefly, in Stage A, semistructured interviews were conducted with 7 participants to understand the desired improvements in prosthetic technology that might motivate persons to incur risks to obtain new devices, and an initial item set was developed. As described in a previous article,[7] this stage resulted in lists of challenges and limitations related to function and quality of life faced by the respondents and desired improvements in prosthetic technology. Preliminary items addressing potential benefits and risks were then drafted by one of the authors (H.B.).

In Stage B, participants with upper-limb difference prioritized the lists of benefits and risks for inclusion in the survey. This stage involved a point allocation exercise to prioritize the potential benefit-risk considerations, followed by a focus group, and a survey reported elsewhere.[8] During the focus group, participants discussed challenges they had experienced with amputation or limb difference, what they liked and disliked about the prostheses they had used, their experiences with pain, and what they would like to see in prostheses. Then they were asked to explain their responses to the prioritization exercise. Findings were used to refine items for inclusion in the benefit-risk survey. In Stage C, we tested potential participants' understanding of the item sets produced in Stage B and iteratively refined the items through cognitive testing and then pilot testing. Stage C resulted in the final version of the survey used in the national study. The final survey contained a yes/no screening question to ascertain participants' willingness to consider undergoing surgery to obtain a prosthesis that could restore sense of touch, provide more control over several types of prosthesis device movement, or eliminate the need for a prosthetic socket and harness, in addition to willingness to undergo specific risks associated with surgery. The benefit-risk items were administered only to those who answered yes to the screening question, indicating that they would consider undergoing surgery to obtain a particular benefit. The final version of the osseointegration survey section is shown in Appendix B. This article reports on the data related to osseointegration. The results of benefit-risk questions about surgery to restore a sense of touch and provide more control over device movement will be reported elsewhere.[9]

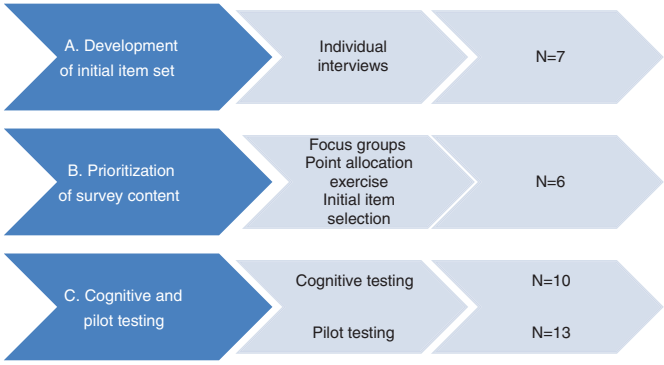

Figure 1. Stages of benefit–risk survey development.

Recruitment

All veterans with major upper-limb amputation who received care in the Department of Veterans Affairs (VA) between 2010-2016 (N = 5639) were identified from Corporate Data Warehouse sources. A total of 2288 persons were excluded (1479 deceased, and 601 missing valid addresses and/or phone numbers). Recruitment materials with opt-out cards were sent to the remaining 3559 persons. Veterans who did not opt out of participation (N = 408) or inform us that they did not meet eligibility criteria (N = 208) were contacted by telephone. Up to 10 phone call attempts were made. Veterans who were reached by phone (N = 1893) were screened for eligibility (Figure 2).

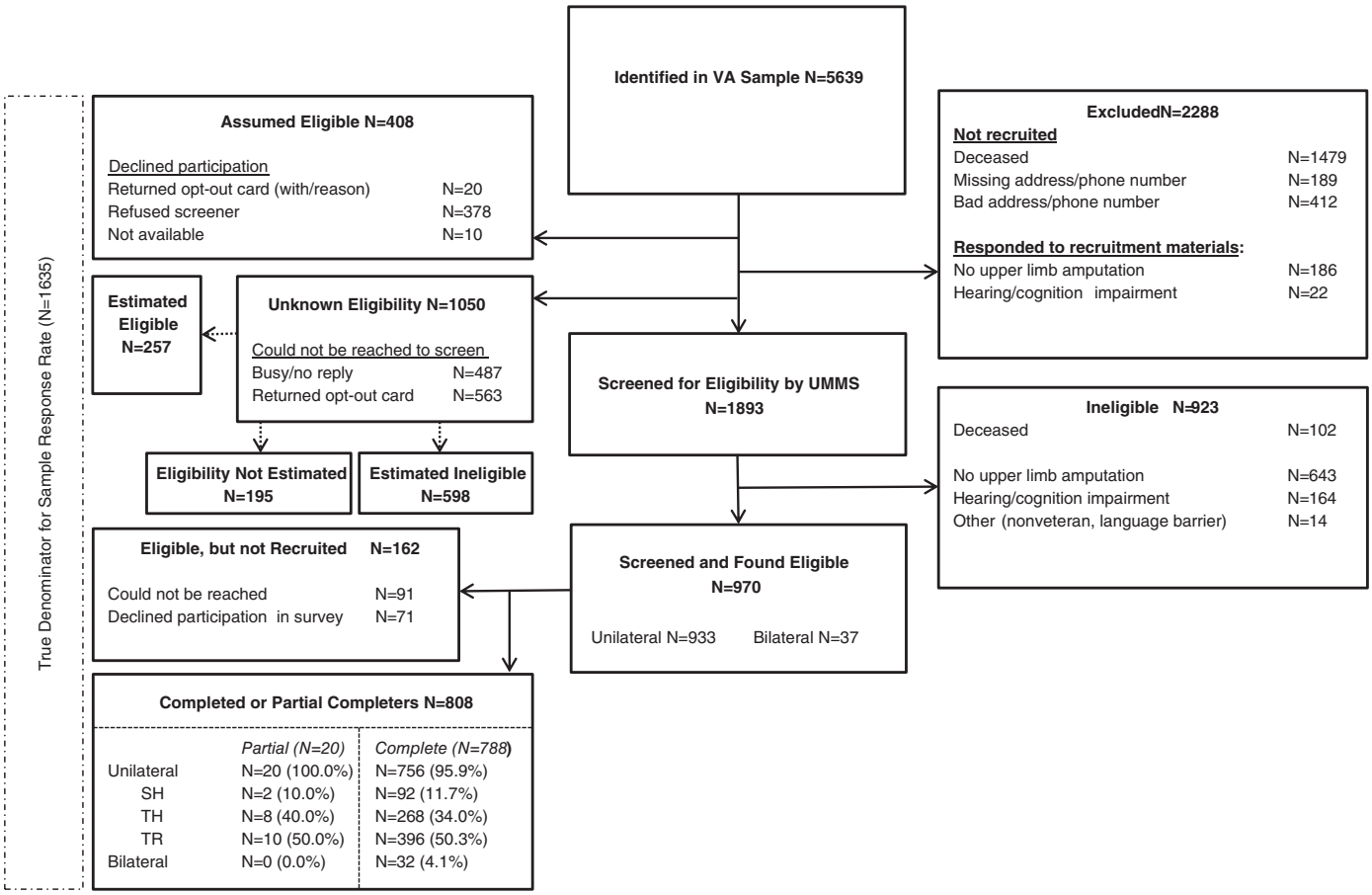

Figure 2. Flow diagram.

Data Collection

A total of 808 persons completed all or part of the larger national interview survey. This survey, described elsewhere,[9] contained questions related to demographics, amputation level, laterality and etiology, and prosthesis use, as well as standardized measures including the VR-12 measure of health-related quality of life (HRQoL). The VR-12 is a veteran version of the SF-12 Health Survey that produces the Physical Component Summary (PCS) (Cronbach alpha in this sample = 0.86) and the Mental Component Summary (MCS) (Cronbach alpha in this sample = 0.88) scores.[10,11]

Data Analyses

We characterized demographics, amputation characteristics and prosthetic use for respondents. Descriptive analyses examined the proportion of respondents who indicated yes, no or not sure of their willingness to consider surgery for osseointegration by laterality of amputation (unilateral vs bilateral), amputation level shoulder ([SH], transhumeral [TH], and transradial [TR], gender, age group, category of HRQoL, and etiology of amputation. We categorized HRQoL by separately grouping VR-12 PCS and MCS scores into three groups (low, medium, and high). The MCS and PCS have a population mean of 50 with a SD of 10 (normative values). We considered those with scores more than 1 SD below the mean on each scale to have low scores on that scale, those within 1 SD of the mean to have medium scores, and those with more than 1 SD above the mean to have high scores.

We collapsed the categories of yes and not sure of willingness to consider surgery for osseointegration and used chi-square tests to examine bivariate relationships between key patient-related variables (age category, unilateral/bilateral amputation, amputation level, gender, laterality of amputation, etiology of amputation) and willingness to consider surgery. To examine differences between subgroups with three or more categories, we performed multiple comparison tests for variables using a Tukey-type method in SAS.[12] We then created a multivariate logistic regression model for willingness to consider surgery for osseointegration, including all variables that were significant in the bivariate analyses at $P < .10$.

For respondents who indicated a willingness (yes/unsure) to consider surgery, we examined ratings of importance of obtaining potential benefits (eg, natural touch, better speed of movement control, ability to do more activities) given specific risks (eg, overnight hospital stay, infection requiring antibiotics, infection requiring device

removal). For respondents who indicated that they were willing to accept specific risks, we calculated the proportion who indicated that each of the specific benefits was important, somewhat important, or not important. We analyzed these data graphically to determine whether patterns of importance ratings varied by willingness to accept each type of risk.

We described the proportion of persons who were willing to accept each of the risks. We then compared ratings of benefit importance for each of the risks for prosthesis users and nonusers, and by amputation level graphically and using Fisher's exact tests.

Results

Sampling Frame and Response Rate

A total of 808 (83%) of those screened to be eligible were successfully recruited into the study. The survey response rate and cooperation rate, calculated using the American Association for Public Opinion Research (AAPOR) methodology,[13] was 47.7% and 63.3%, respectively.

Demographic, Amputation-Related, and Prosthetic Use Characteristics

The sample consisted of 776 unilateral amputees and 32 bilateral amputees (Table 2). Median age of the sample was 67.0 years (range 25-95); 764 (97.4%) were male and 20 (2.6%) were female. Table 1 shows characteristics of the sample. The entire interview was completed by 788 persons, and 20 completed part but not the entire interview. Seventy-five percent of the sample identified as white, and 8.6% identified as Hispanic or Latino. Seventy percent of the sample were retired. Respondents had lost their limbs a median of 33.0 (range: 18.3-72.3) years prior to the interview. Amputation levels of respondents were 36.1% transradial (TR), 30.4% transhumeral (TH), 16.2% wrist joint (WD), 9.2% shoulder disarticulation (SD), 5.2% elbow disarticulation, and 3.0% forequarter amputation (FQ). Accident was the most common cause of amputation (62.1% unilateral, 62.5% bilateral), followed by "other" (54% unilateral, and 71.9% bilateral), and combat injury (35.5% unilateral, 28.1% bilateral). Burns were a prevalent cause of amputation for those with bilateral amputation (40.6%). Most respondents were current prosthesis users (60% unilateral, 84% bilateral respondents).

Willingness to Undergo Surgery

Table 2 shows the proportion of respondents who indicated willingness to consider osseointegration surgery by subgroup characteristics. We found that 28.2% of unilateral and 12.9% of bilateral amputees were willing to consider osseointegration surgery, and 13.4% of unilateral and 12.9% of bilateral amputees were unsure.

By amputation level, persons with TH amputation were the subgroup most likely to consider osseointegration surgery (35.0% yes, 10.9% unsure). A smaller proportion of respondents who had lost their limbs due to combat injury and a greater proportion of those who had lost their limbs due to accident indicated a willingness to undergo osseointegration surgery compared to persons with amputation from other etiologies.

Results of the bivariate analyses comparing participant characteristics associated with willingness to undergo surgery (yes or unsure vs no) for each of the major benefits are shown in Table 3. Younger age, MCS category, and noncombat amputation were statistically associated with willingness to undergo osseointegration surgery. Post hoc analyses revealed that there were statistically significant differences between the high and low and high and medium categories for MCS, with those with the highest category (best mental HrQoL) being less likely to be willing to consider surgery for osseointgration (results not shown). Post hoc analyses by amputation level did not show any statistically significant differences by level (results not shown).

Multivariate logistic regression models that included all variables statistically significant at $P \leq .10$ showed that age, amputation levels, and MCS were independently associated with willingness to consider surgery (Table 4). Specifically, the odds of being willing to consider surgery were 0.17 times lower for those 75 and older compared to those 18-45 years. Relative to those with unilateral transradial level amputation, the odds of being willing to consider surgery were 1.40 higher for persons with unilateral transhumeral-level amputation and 0.50 lower for those with bilateral amputation.

Table 5 shows the proportion of respondents willing to accept each specific risk among those who were definitely or maybe willing to consider osseointegration surgery. Overall, long-term risks, such as chronic pain, loss of some nerve function, or device failure requiring it to be removed, were unacceptable to the greatest proportion of respondents (21.7%). Short-term restrictions on movement as well as pain and weakness for about a month were unacceptable to the smallest proportion (2.5%). Forty-seven percent of respondents were willing and 40% were maybe willing to risk a serious infection that would require antibiotics.

Importance ratings of benefit factors were very similar across risk types. All potential benefits were considered very important or somewhat important for each risk condition by the majority of respondents. Having a durable/reliable device, the ability to do more activities, and having a comfortable device were rated as very important or somewhat important by 98% or more respondents for every risk condition. In contrast, naturalness of touch and water resistance were the benefits rated not at all important by the greatest proportion of respondents (7.3%-8.1% and 4.2%-5.5% respectively). As

Table 1
Characteristics of unilateral and bilateral amputee respondents

	Unilateral Amputees N = 776	Bilateral Amputees N = 32		All N = 808
	Median (range)	Median (range)		Median (range)
Age (yr)	67.0 (25.0, 93.0)	67.0 (33.0, 95.0)		67.0 (25.0, 95.0)
Missing (n)	n = 24	n = 0		n = 24
Years since initial amputation (either side)	33.1 (1.3, 73.6)	31.2 (5.4, 72.3)		33.0 (1.3, 73.6)
Years since amputation (second side)	NA	29.8 (5.4, 72.3)		NA
Missing (n)	n = 21	n = 0		n = 21
	N (%)	N (%)		N (%)
Age category				
18–45	99 (13.2)	5 (15.6)		104 (13.3)
45–65	207 (27.5)	9 (28.1)		216 (27.6)
65–75	340 (45.2)	13 (40.6)		353 (45.0)
75+	106 (14.1)	5 (15.6)		111 (14.2)
Missing (n)	n = 24	n = 0		n = 24
Gender				
Male	755 (97.3)	32 (100.0)		787 (97.4)
Female	21 (2.7)	0 (0.0)		21 (2.6)
Missing (n)	n = 0	n = 0		n = 0
Race				
White	583 (77.5)	22 (68.8)		605 (74.9)
Black	86 (11.4)	3 (9.4)		89 (11.0)
Native American	5 (0.7)	0 (0.0)		5 (0.6)
Other (including mixed race)	30 (4.0)	4 (12.5)		34 (4.2)
Unknown	48 (6.4)	3 (9.4)		75 (9.3)
Missing (n)	n = 24	n = 0		n = 24
Hispanic or Latino				
Yes	62 (8.2)	5 (15.6)		67 (8.6)
No	678 (90.2)	26 (81.3)		704 (89.8)
Unknown	12 (1.6)	1 (3.1)		13 (1.7)
Missing (n)	n = 24	n = 0		n = 24
Employment				
Employed full time	73 (9.7)	1 (3.1)		74 (9.4)
Employed part time	31 (4.1)	13 (40.6)		31 (4.0)
Student	20 (2.7)	0 (0.0)		20 (2.6)
Retired, but employed after amputation	373 (49.6)	13 (40.6)		386 (49.2)
Retired, but not employed after amputation	152 (20.2)	5 (15.6)		165 (21.1)
On medical leave	9 (1.2)	0 (0.0)		9 (1.2)
Other	93 (12.4)	0 (0.0)		98 (12.5)
Unknown	1 (0.1)	0 (0.0)		1 (0.1)
Missing (n)	n = 24	n = 0		n = 24
Laterality of amputation				
Unilateral right	370 (47.7)	0 (0.0)		370 (45.8)
Unilateral left	406 (52.3)	0 (0.0)		406 (50.3)
Bilateral	0 (0.0)	32 (100.)		32 (4.0)
Missing (n)	n = 0	n = 0		n = 0
Amputation Level				
Forequarter	23 (3.0)	1 (3.1)	0 (0.0)	
At the shoulder joint	71 (9.2)	1 (3.1)	1 (3.1)	
Above the elbow	236 (30.4)	5 (15.6)	4 (12.5)	
At the elbow	40 (5.2)	14 (43.8)	1 (3.1)	
Below the elbow	280 (36.1)	10 (31.3)	20 (62.5)	
At the wrist joint	126 (16.2)	0 (0.0)	6 (18.8)	
Through the hand	0 (0.0)	1 (3.1)	0 (0.0)	
Missing (n)	n = 0	n = 0		
Etiology of amputation				
Combat injury	275 (35.5)	9 (28.1)	9 (28.1)	
Accident	481 (62.1)	20 (62.5)	20 (62.5)	
Burn	81 (10.5)	13 (40.6)	13 (40.6)	
Cancer	30 (3.9)	0 (0.0)	0 (0.0)	
Diabetes	11 (1.4)	0 (0.0)	1 (3.1)	
Infection	86 (11.1)	9 (28.1)	8 (25.0)	
Other	417 (54.0)	21 (65.6)	23 (71.9)	
Missing (n)	n = 0 to 3	n = 0	n = 0	

Table 2
Proportion of participants willing to consider osseointegration

		Willing to consider osseointegration?		
	N	Yes (N = 215)	No (N = 461)	Not Sure (N = 104)
Laterality				
Unilateral	776	211 (28.2)	438 (58.5)	100 (13.4)
Bilateral	32	4 (12.9)	23 (74.2)	4 (12.9)
Amputation Level				
Unilateral SH	94	25 (27.5)	521(56.0)	15 (16.5)
Unilateral TH	276	93 (35.0)	144 (54.1)	29 (10.9)
Unilateral TR	406	93 (23.7)	243 (62.0)	56 (14.3)
Ever used prosthesis				
Yes	749	202 (94.0)	431 (93.5)	95 (91.4)
No	52	12 (5.6)	29 (6.3)	9 (8.7)
Unknown	2	1 (0.5)	1 (0.2)	0 (0.0)
Current prosthesis user				
Yes	490	120 (59.4)	290 (67.8)	63 (66.3)
No	254	82 (40.6)	136 (31.8)	32 (33.7)
Unknown	2	0 (0.0)	2 (0.5)	0 (0.0)
Gender				
Male	764	208 (96.7)	450 (97.6)	102 (98.1)
Female	20	7 (35.0)	11 (55.0)	2 (10.0)
Age				
18–45	104	41 (39.4)	45 (43.3)	18 (17.3)
45–65	216	71 (32.9)	108 (50.0)	37 (17.1)
65–75	353	87 (24.8)	220 (62.7)	44 (12.5)
75+	111	16 (14.7)	88 (80.7)	5 (4.6)
PCS				
Low	234	68 (29.4)	131 (56.7)	32 (13.9)
Medium	511	136 (26.7)	304 (59.7)	69 (13.6)
High	13	3 (23.1)	10 (76.9)	0 (0.0)
MCS				
Low	188	60 (31.9)	96 (51.1)	32 (17.0)
Medium	344	100 (29.3)	196 (57.5)	45 (13.2)
High	226	47 (21.0)	153 (68.3)	24 (10.7)
Etiology of amputation				
Combat injury				
Yes	284	61 (22.3)	176 (64.2)	37 (13.5)
No	523	154 (30.4)	285 (56.3)	67 (13.2)
Accident				
Yes	501	137 (28.1)	280 (57.5)	70 (14.4)
No	305	78 (26.6)	181 (61.8)	34 (11.6)
Burn				
Yes	94	17 (19.3)	57 (64.8)	14 (15.9)
No	711	198 (28.6)	404 (58.4)	90 (13.0)
Cancer				
Yes	30	8 (28.6)	18 (64.3)	2 (7.1)
No	776	207 (27.5)	443 (58.9)	102 (13.6)
Diabetes				
Yes	12	6 (50.0)	5 (41.7)	1 (8.3)
No	792	209 (27.2)	456 (59.4)	103 (13.4)
Infection				
Yes	95	29 (31.5)	48 (52.2)	15 (16.3)
No	709	186 (27.0)	413 (60.0)	89 (12.9)
Other				
Yes	440	116 (27.0)	250 (58.3)	63 (14.7)
No	365	99 (28.2)	211 (60.1)	41 (11.7)

SH = shoulder disarticulation or forequarter; TH = transhumeral; TR = transradial; PCS = Physical Component Summary of the VR-12 Health Survey; MCS = Mental Component Summary of the VR-12 Health Survey.

an example, Figure 3 shows the importance ratings of each potential benefit, given the risk of incurring an infection requiring IV antibiotics and hospitalization. Importance rating for all other risks are shown in Appendix C.

Comparison of importance ratings for each potential benefit-risk combination by amputation level showed differences at $P < .05$ for several benefits. We observed several statistically significant differences in importance rankings by amputation level. Although there were small

Table 3
Bivariate comparisons of characteristics of participants by willingness to consider osseointegration

	N	Yes/Maybe (N = 319)	No (N = 461)	Chi-square/Fisher's Exact *P*
Amputation Level				.062
Unilateral SH	94	40 (44.0)	51 (56.5)	
Unilateral TH	276	122 (45.9)	144 (54.1)	
Unilateral TR	406	149 (38.0)	243 (62.0)	
Laterality				.081
Unilateral	776	311 (41.5)	438 (58.5)	
Bilateral	32	8 (25.8)	23 (74.2)	
Ever used prosthesis				.943
Yes	749	297 (93.1)	431 (93.5)	
No	52	21 (6.6)	29 (6.3)	
Missing	2	1 (0.3)	1 (0.2)	
Current prosthesis user				.080
Yes	490	183 (61.6)	200 (67.8)	
No	254	114 (36.4)	136 (31.8)	
Missing	2	0 (0.0)	2 (0.5)	
Gender				.705
Male	764	310 (40.8)	450 (97.6)	
Female	20	9 (45.0)	11 (55.0)	
Age				**<.001**
18–45	104	59 (56.7)	45 (43.3)	
45–65	216	108 (50.0)	108 (50.0)	
65–75	353	131 (37.3)	220 (62.7)	
75+	111	21 (19.3)	88 (80.7)	
PCS				.311
Low	234	100 (43.3)	131 (56.7)	
Medium	511	205 (40.3)	304 (59.7)	
High	13	3 (23.1)	10 (76.9)	
MCS				**.001**
Low	188	92 (48.9)	96 (51.1)	
Medium	344	145 (42.5)	196 (57.5)	
High	226	71 (31.7)	153 (68.3)	
Etiology of amputation				
Combat injury				**.032**
Yes	284	98 (35.8)	176 (64.2)	
No	523	221 (43.7)	285 (56.3)	
Accident				.239
Yes	501	207 (42.5)	280 (57.5)	
No	305	112 (38.2)	181 (61.8)	
Burn				.251
Yes	94	31 (35.2)	57 (64.8)	
No	711	288 (41.6)	403 (58.3)	
Cancer				.570
Yes	30	10 (35.7)	18 (64.3)	
No	776	309 (41.1)	443 (58.9)	
Diabetes				.246
Yes	12	7 (58.3)	5 (41.7)	
No	792	312 (40.6)	455 (59.3)	
Infection				.150
Yes	95	44 (47.8)	48 (52.2)	
No	709	275 (40.0)	413 (60.1)	
Other				.603
Yes	440	179 (41.7)	250 (58.3)	
No	365	140 (39.9)	211 (60.1)	

SH = shoulder disarticulation or forequarter; TH = transhumeral; TR = transradial; PCS = Physical Component Summary of the VR-12 Health Survey; MCS = Mental Component Summary of the VR-12 Health Survey.

differences in statistically significant findings, there was good consistency of findings across benefit-risk combinations by amputation level (Appendix C). As an example, for the risk of willingness to incur infection requiring IV antibiotics and an overnight hospital stay (Figure 4), there were differences in group rankings for the importance of more activities and durability/reliability of the device. The smallest proportion of persons with shoulder-level amputation rated the ability to do more activities as very important. Although not statistically

Table 4
Multivariable logistic regressions predicting willingness to consider osseointegration

	Osseointegration (N = 753)	
	OR (95% CI)	*P*
Amputation Level		
Unilateral SH	1.19 (0.73-1.95)	.488
Unilateral TH	1.40 (1.00-1.97)	.050
Unilateral TR	(ref)	
Bilateral amputation	0.50 (0.21-1.20)	.118
Age		
18-45	(ref)	
45-65	0.57 (0.34-0.96)	**.033**
65-75	0.40 (0.25-0.64)	<.001
75+	0.17 (0.09-0.32)	**<.001**
MCS		
Low	(ref)	
Medium	0.86 (0.59-1.24)	.414
High	0.53 (0.35-0.81)	**.003**
Etiology of amputation		
Combat injury		
Yes	0.68 (0.44-1.07)	.093
No	(ref)	
Accident		
Yes	1.01 (0.67-1.54)	.952
No	(ref)	
Infection		
Yes	1.32 (0.82-2.12)	.256
No	(ref)	

OR = odds ratio; SH = shoulder disarticulation or forequarter; TH = transhumeral; TR = transradial; MCS = Mental Component Summary of the VR-12 Health Survey.

Table 5
Willingness to accept each surgical risk condition among those definitely or maybe willing to undergo osseointegration surgery

	N = 319		
	Yes	Maybe	No
Risk condition	N (%)	N (%)	N (%)
Risk of infection that would require antibiotics	149 (47.2)	126 (39.9)	41 (13.0)
Risk of serious infection that would require removing the device	186 (58.5)	96 (30.2)	36 (11.3)
Risk of bone breaking that would require surgery to remove the device	162 (50.9)	97 (30.5)	59 (18.6)
Long-term risks	163 (51.9)	83 (26.4)	68 (21.7)
Pain or weakness during the recovery from surgery of about 1 mo	250 (78.9)	53 (16.7)	14 (4.4)
Short-term restrictions on movement and exercise for up to 1 mo	258 (81.4)	51 (16.1)	8 (2.5)
Up to 6 mo of physical therapy	261 (82.3)	47 (14.8)	9 (2.8)

significantly different by subgroup in any risk condition, we also found that 100% of bilateral amputees rated water and dirt resistance and ability to lift more than 20 lbs. as very important in willingness to incur risk, and nearly 100% rated durability and reliability as very important. In contrast, the naturalness of touch was the benefit rated not at all important by the greatest proportion of respondents across all amputation levels in most every risk condition.

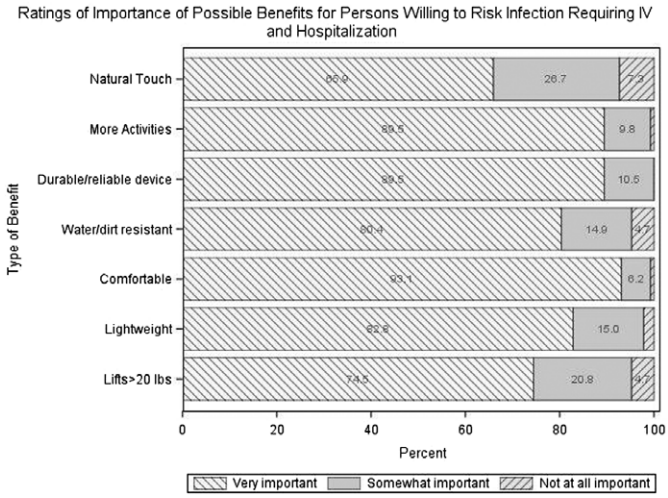

Figure 3. Benefit factor ratings for those who would consider osseointegration surgery (yes/maybe): Example figure using those willing to risk infection requiring IV antibiotics and hospitalization).

Comparisons of importance ratings for each potential benefit-risk combination by current prosthetic use did not show statistical differences except for the benefit of water/dirt resistance among those willing to consider long-term risks of pain or weakness during recovery (Appendix C). In these two comparisons, water/dirt resistance was more important to prosthetic users than to nonusers ($P < .05$).

Discussion

We conducted a national study that assessed upper-limb amputees' willingness to consider osseointegration surgery. Our survey, limited to veterans, also evaluated the importance of receiving specific benefits and examined whether these importance rankings varied by amputation level and for unilateral and bilateral amputees. Our survey demonstrates that among veterans, there are a substantial proportion who would consider OI surgery should it be available. Our specific findings highlight those risks that are considered most and least acceptable, as well as the benefits most desired. This information is informative to researchers recruiting participants to OI trials and to clinicians who discuss the risks and benefits of OI with their patients. We found that 28% of unilateral and 13% of bilateral amputees were willing to consider osseointegration surgery, whereas a substantial proportion (approximately 13%) were unsure. A greater proportion of respondents who were in older age categories, had bilateral amputation, and had better mental health functioning answered that they would not consider surgery. We found that persons with transhumeral amputation, a group with high abandonment rates,[14] who may have difficulties with prosthesis socket fit, and thus are likely to receive the greatest benefit, were most likely to say they would consider this surgery (35%).

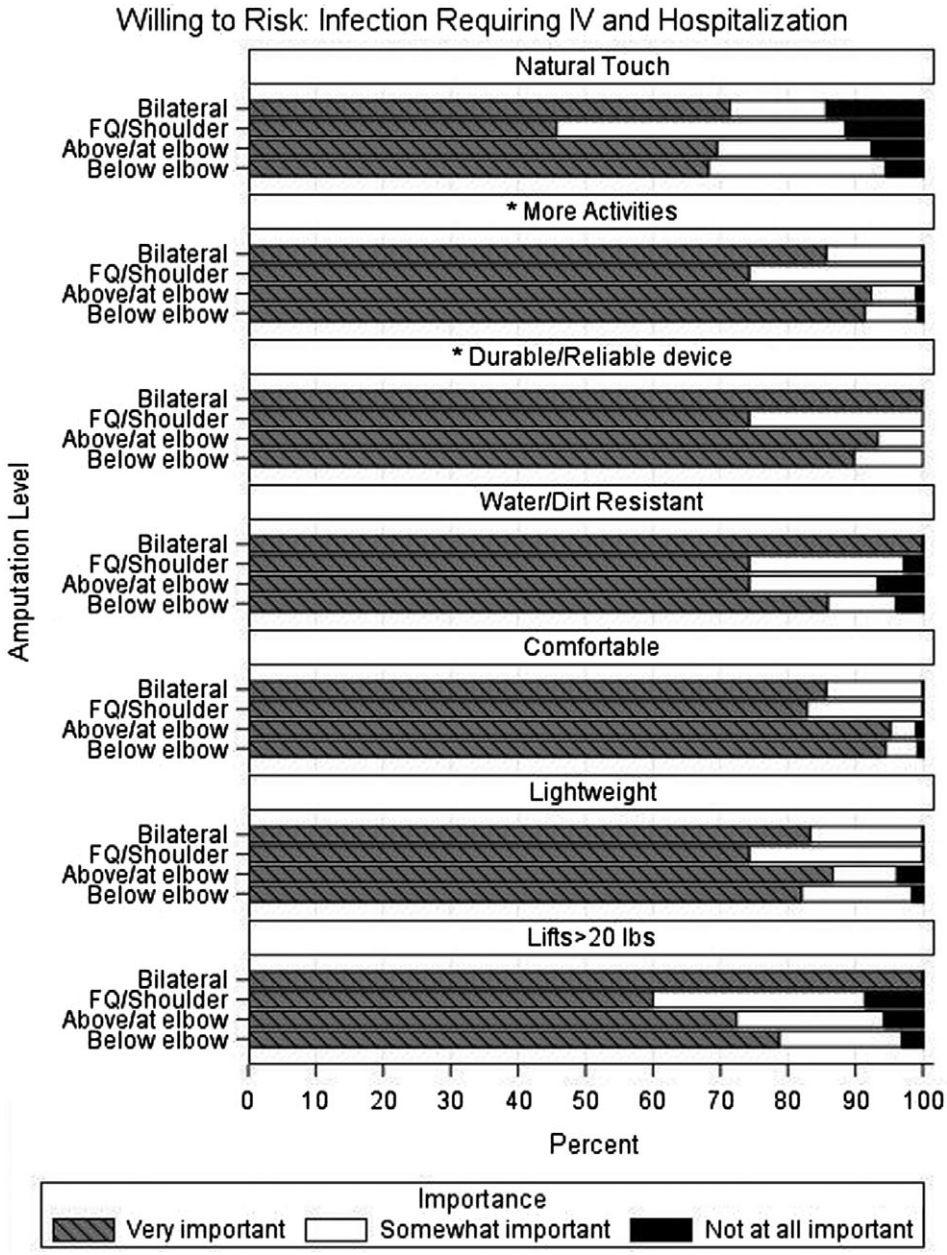

Figure 4. Subgroup comparisons of importance of factors for those who were willing to risks infection requiring antibiotics in order to obtain an osseointegrated prosthesis by amputation level.
*significant at $P < .05$
FQ=Forequarter

Our findings mirror those reported by Engdahl et al, who surveyed upper-limb amputees about their interest in novel prosthetic interfaces but did not explicitly study osseointegration. They found that younger participants and those with unilateral amputation were more likely to be interested in the three invasive interfaces that they studied.[15]

For those who indicated that they were or might be willing to consider osseointegration surgery, we examined whether ratings of benefit importance varied by specific risk conditions. The benefits that were rated least important across risks included natural touch, water/dirt resistant, and ability to lift more than 20 lbs. We found remarkable consistency in the ratings of benefits that were important across risks, with all potential benefits considered very important or somewhat important by most participants. This finding is not surprising because the list of potential benefits in our survey was identified through formative research with persons with amputation and other stakeholders.

Our study also quantified the acceptability of incurring a variety of postsurgical risks among those who indicated

an openness to considering osseointegration surgery. All risks were acceptable or possibly acceptable to the majority of respondents who were willing or might be willing to consider osseointegration surgery. This demonstrates that persons who are open to considering surgery at all are willing to risk some adversity. Our results help sort these postsurgical risks by their perceived severity, with short-term risks and 6 months of physical therapy the most acceptable and risk of bone breaking and long-term risks (including chronic pain, loss of some nerve function, or device failure requiring it to be removed) the most unacceptable. The risk of a serious infection that would require antibiotics was not a deterrent to most participants, with 87% of respondents willing or maybe willing to accept this risk.

We found that ratings of benefit importance were consistent across all risk categories, but that persons with bilateral and shoulder-level amputation, who are arguably more functionally impaired, weighed the importance of potential benefits directly related to function differently. Virtually all persons with bilateral amputation indicated that durability, water resistance, and lifting >20 lbs were very important. In comparison, a greater proportion of persons with above and below elbow-level amputation indicated that more activities and comfortable fit were very important.

We observed that persons categorized as having poor mental health were more likely to be willing to consider surgery for osseointegration. Further study is needed to disentangle the relationship between mental health and willingness or unwillingness to consider osseointegration surgery. We hypothesize that persons with poor prosthesis fit or who are uncomfortable about the appearance of their prosthesis may have poorer mental health and may be more open to considering interventions that can remediate their condition.

Limitations

Our study had several limitations. First, it is possible that some participants did not fully understand what osseointegration surgery was. We did provide a brief explanation of osseointegration surgery, but we did not assess whether participants were familiar with this surgery or not, and we did not assess comprehension after the explanation was provided. Some may not have fully understood what the surgery entailed or appreciated how osseointegration would be used to attach the prosthesis. Although osseointegration has been available in Europe for decades, most U.S. amputees have not been exposed to this technology, and it is unlikely that they have ever met a person who had an OI limb.

Another limitation is that our sample included only veterans who had received care at VA Medical Centers. These participants may not represent the larger population of veterans or of U.S. upper-limb amputees more generally. However, we sampled 100% of Veterans who met our eligibility criteria and had a strong response rate, and thus our findings are likely generalizable to veterans with upper limb amputation receiving healthcare at the VA. We believe that the findings are generalizable to both male and female veterans. Although the veteran sample is predominantly male, the response rate for females was high (62.8% female vs 47.3% male). However, given the small number of females in the sample overall, there are limitations for generalizing from our findings of female veterans to the civilian population..

Lastly, although we conducted statistical comparisons of importance for specific risk conditions, our analyses were limited due to small sample sizes for shoulder-level and bilateral amputees, which may have resulted in insufficient power to detect small differences. Further research with larger samples and nonveterans is needed to confirm or refute our findings.

Conclusions

We conducted a national survey of veterans with major upper-limb loss to assess their willingness to consider osseointegration and to understand their perspectives on osseointegration's potential benefits and risks. Twenty-eight percent of respondents were willing to consider osseointegration surgery. Persons who were older, had transradial amputation (compared to transhumeral), or had better mental functioning were less willing to consider this surgery. Respondents who were willing to consider surgery indicated that the most important potential benefits were having a durable/reliable device, the ability to do more activities, and having a comfortable device. Most were willing to accept one or more risks of surgery, with long-term risks including chronic pain, loss of nerve function, or device failure, considered the most unacceptable.

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Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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Disclosure

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ORIGINAL RESEARCH

Function and Quality of Life of Unilateral Major Upper Limb Amputees: Effect of Prosthesis Use and Type

Check for updates

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Abstract

Objective: To compare patient-reported outcomes of disability, activity difficulty, and health-related quality of life (HRQOL) by prosthetic device use and configuration and to identify factors associated with these outcomes.

Design: Telephone survey.

Setting: General community.

Participants: Population-based sample of veterans (N=755) with unilateral upper limb amputation recruited from a national sample of veterans with upper limb amputation who received care at the Veterans Affairs clinic from 2010-2015.

Interventions: Not applicable.

Main Outcome Measures: Upper limb–related disability was measured using Disabilities of the Arm, Shoulder, and Hand score (QuickDASH). HRQOL was measured using the Veterans RAND 12-item Health Survey Mental and Physical Component scores. Activity difficulty was assessed for 1-handed and 2-handed tasks and by questions about the need for help with activities of daily living (ADLs).

Results: Patients who did not use a prosthesis had more difficulty performing 1-handed tasks using the residual limb as compared with those who used body-powered prostheses. Cosmetic device users had more task difficulty than body-powered or myoelectric users. Linear regression models did not show an association between type of prosthesis used and HRQOL scores, but did show that those who did not use a prosthesis (non-users) had worse QuickDASH scores ($\beta=9.4$; $P=.0004$) compared to body-powered users. In logistic regression modeling, the odds of needing help with ADLs were 1.84 times higher (95% confidence interval, 1.16-2.92) for non-users compared with body-powered users.

Conclusions: Amputees who did not use a prosthesis or used a cosmetic prosthesis reported more difficulty in activities and greater disability as compared with those who use body-powered and myoelectric devices. Non-users were more likely to need help with ADLs as compared with those who used a body-powered prosthesis. Our findings highlight the clinical importance of encouraging prosthesis use. Further research is needed to compare physical performance by prosthesis configuration.

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A wide variety of upper limb prostheses and components are available to upper limb amputees; however, it is unclear which devices are best, and clinicians have little evidence to guide decision-making around specific prosthetic components and device types. The inconclusive results of recent systematic reviews comparing body-powered prostheses to myoelectric prostheses[1,2] underscore the need for studies that address the comparative effectiveness of upper limb prosthetic devices and components.

In the past decade, multi–degrees of freedom (DOF) prosthetic terminal devices that enable multiple grip patterns have become commercially available. Although surveys of upper limb amputees have identified a desire for terminal devices with additional grip patterns,[3,4] few studies compare single- vs multi-DOF terminal devices.[5] Several small studies that measured dexterity of single- vs multi-DOF terminal devices showed no clear pattern of superiority of one type of device over another.[6-9] Without a body of evidence quantifying the relative benefits of specific devices and components, clinicians have to rely only on expert opinion,

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experience, manufacturers' claims, limited clinical practice guidelines, and small studies when prescribing prostheses.

This study was a first step in addressing this knowledge gap. We conducted a national survey of veterans with upper limb amputation and examined the associations between prosthesis configuration and outcomes. Our purposes were to (1) compare outcomes of disability, activity difficulty, and health-related quality of life (HRQOL) by device configuration and (2) identify other potentially modifiable factors associated with disability, activity difficulty, and HRQOL among upper limb amputees.

Methods

Survey, participants, and recruitment

The study, with a waiver of written informed consent, was approved by the central institutional review board of the Department of Veterans Affairs (VA). The sampling frame consisted of all veterans with a diagnosis of major upper limb amputation who received care in the VA between 2010-2015, identified using VA Corporate Data Warehouse sources, including the inpatient, outpatient, and fee files. We sent recruitment packages to all nondeceased veterans with current addresses and phone numbers. Veterans who did not opt out of participation or inform us that they did not meet study eligibility criteria were contacted by the study interviewers to obtain oral informed consent. Eight hundred and eight veterans were interviewed. After excluding 32 participants with bilateral amputation and 21 with unknown or other prosthesis type, the analytical sample included 755 individuals with unilateral amputation.

Survey development and content

The development and pilot testing of the survey instrument with 10 cognitive interviews and 13 pretest subjects was reported previously.[10] The survey contained existing survey items and standardized metrics, and new or modified items designed for this study. The survey asked questions about demographic, amputation, and prothesis characteristics. The current paper focuses on the sections of the survey pertaining to prosthesis use and type, function, and HRQOL.

Key variables

Outcome variables

disability and quality of life

The survey included the Disabilities of the Arm, Shoulder, and Hand (QuickDASH) score which measures perceived disability by assessing difficulty performing activities, amount of limitation, extent of interference with activities, and extent of arm, shoulder, and hand pain and tingling.[11-13] The Physical Component Summary (PCS) score and the Mental Component Summary (MCS) score of the Veterans RAND 12-item Health Survey (VR-12) measured HRQOL.[14,15] The survey asked about the need for help with daily activities (ADLs) and hours of help needed. New items asked about difficulty in unilateral and bilateral task performance to quantify any additive benefit of using a prosthesis vs using the residual limb only and to compare prosthesis configuration. Respondents who were prosthesis users rated difficulty performing the activities first with and then without the device.

List of abbreviations:

ADL	activity of daily living
DOF	degrees of freedom
HRQOL	health-related quality of life
MCS	Mental Component Summary
PCS	Physical Component Summary
QuickDASH	Disabilities of the Arm
Shoulder	and Hand score
VA	Veterans Affairs
VR-12	Veterans RAND 12-item Health Survey

Primary independent variable

The primary independent variable, prosthesis configuration, was defined as the combination of primary prosthesis and terminal device type used. We categorized terminal device based on the DOF of the device. Cosmetic devices were classified as having no DOF, while hooks, electronic terminal devices, Greifers and sensor speed hands were categorized as 1 DOF, and I-Limb/Michelangelo or Bebionic hand were categorized as multi-DOF. We used information on prosthesis and terminal device type to create the 5-category prosthesis configuration variable: (1) no prosthesis, (2) body-powered, (3) myoelectric single-DOF terminal devices, (4) myoelectric multi-DOF terminal device, and (5) cosmetic. When terminal device type was unknown and the device type was either body-powered or myoelectric, we classified the prosthesis type as myoelectric single DOF given that this is the most common type of device. We also expected that recipients of multi-DOF terminal devices, who are typically very involved in the device selection, would be able to name the brand correctly.

Statistical analyses

We described demographic and amputation characteristics by prosthesis configuration; missing data were presented in descriptives of categorical variables but treated as missing in subsequent analysis. SAS,[a] version 9.4, was used for statistical analyses. We compared characteristics across prosthesis configuration groups using chi-square and Fisher exact tests. We compared difficulty in task performance by prosthesis configuration for tasks done without a prosthesis, with a prosthesis, and with the residual limb using Kruskal-Wallis tests, and conducted Dunn post-hoc analyses to determine which groups significantly differed. We also compared difficulty in task performance without a prosthesis, with the primary prosthesis, and with the residual limb (unilateral tasks only) using Wilcoxon signed-rank tests. These analyses were conducted separately for each prosthesis configuration.

Spearman correlations were estimated between task difficulty and hours of ADL help. We compared QuickDASH; VR-12 MCS and PCS scores; likelihood of needing any help; and hours of help needed across prosthesis configuration using analysis of variance, chi-square, and Kruskal-Wallis tests as appropriate. We also conducted Tukey, Tukey-style,[16] and Dunn post-hoc analyses, respectively, to identify differences between groups. Bivariate linear regression models examined associations between potential confounders and outcomes. We included variables with associations at $P<.10$ in subsequent multivariate models. Separate multivariable linear regression models examined the association between prosthesis configuration and the VR-12 MCS, PCS, and QuickDASH. A multivariable logistic regression model examined the association between primary prosthesis configuration and

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likelihood of needing any ADL help. Regression models controlled for age, years since amputation, race, marital status, amputation level, ever having used a prosthesis, lower limb amputation, amputation of dominant side, amputation etiology, initial and current prosthesis training, year of prosthesis receipt, and number of prostheses. We conducted sensitivity analyses to determine whether there was detectable bias introduced by excluding the group with unknown terminal device type.

Results

Sample

Eighty-three percent (N = 808) of those screened to be eligible were recruited into the main study (Fig 1). The survey response rate and cooperation rate were 47.7% and 63.3%, respectively, as calculated using the American Association for Public Opinion Research methodology. The analysis reported here included only participants with unilateral amputation. We excluded 21 participants who had incomplete or conflicting data on prosthesis use: 9 of these due to missing information about prosthesis use, 11 due to missing information on type of prosthesis or reports that the primary prosthesis was a sports device, and 1 because of a mismatch between prosthesis and terminal device type. The final analytic sample (N = 755) included 306 (39.4%) patients with no prosthesis, 325 (43.1%) patients with body-powered devices, 62 (8.2%) patients with a myoelectric or hybrid single-DOF terminal device, 40 (5.3%) patients with a myoelectric multi-DOF terminal device, and 22 (2.8%) patients with cosmetic devices.

Demographic characteristics

Table 1 shows the characteristics of respondents. Participants were on average (mean ± SD) aged 63.5±13.9. On average, it had been 31.4±18.3 years since amputation. The sample was 97.2% male and 75.8% white. Most participants were married or cohabitating (62.4%). Overall, 35.8% had below elbow amputation, 30.9% above elbow, 16.4% wrist disarticulation, 9.1% shoulder disarticulation, 4.9% elbow disarticulation, and 2.9% forequarter amputation. The most common amputation etiology of limb loss was classified as "accident" (63.7%) followed by "combat injury" (35.1%). Most respondents received training for their initial and current prostheses (75.7% and 65.5%, respectively) and had only 1 prosthesis (63.3%).

Difficulty in activity performance

There were no meaningful differences in self-reported difficulty of performing two-handed tasks without a prosthesis by prosthesis configuration (table 2). Difficulty of performing 2-handed tasks with a prosthesis differed significantly by prosthesis type ($P<.01$). Cosmetic device users rated tasks as the most difficult, followed by myoelectric multi-DOF and single-DOF users. Post-hoc

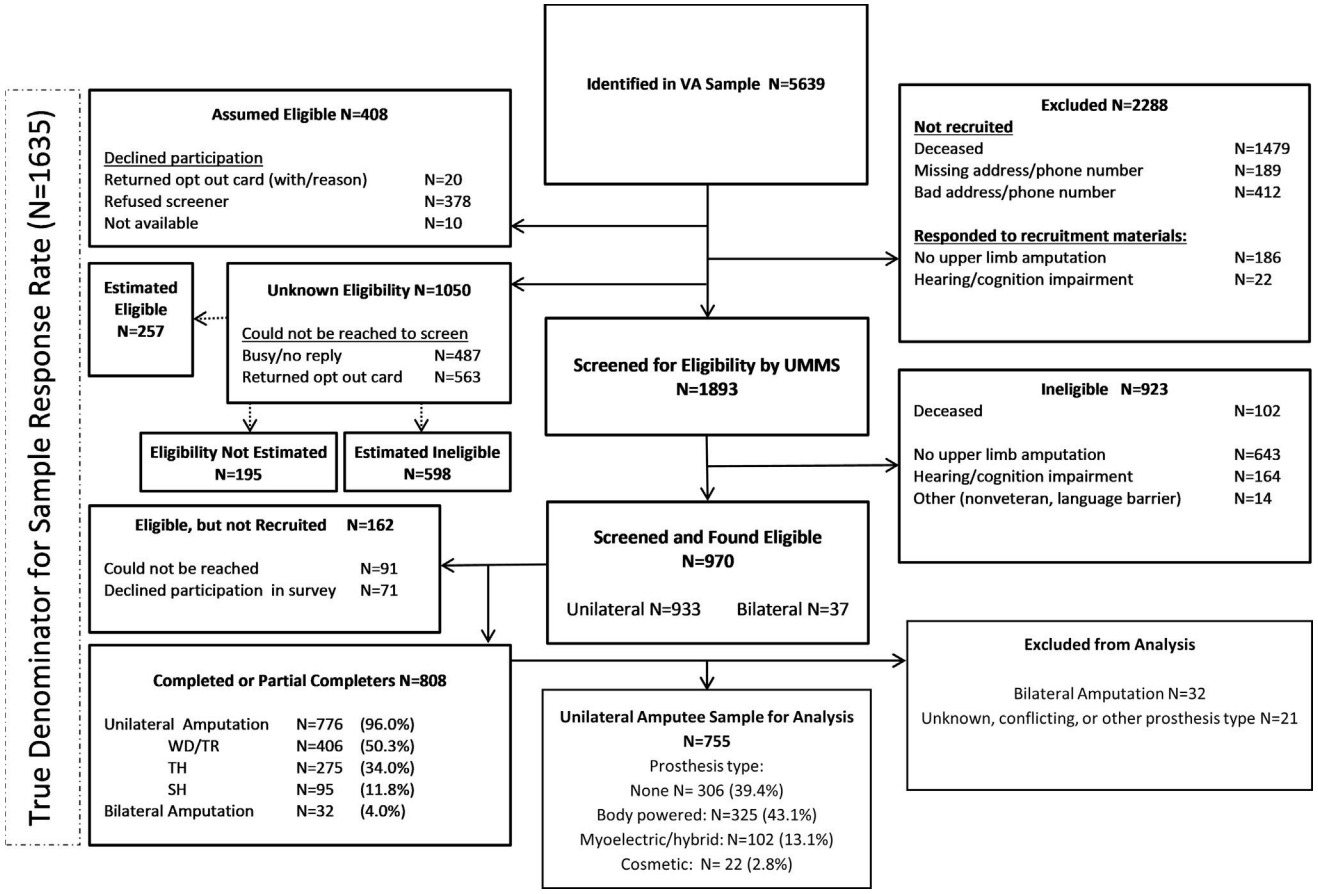

Fig 1 Flow diagram.

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Table 1 Demographics and amputation related characteristics by primary device type

	Prosthesis Configuration					
Variables	Body-Powered n = 325 Mean ± SD	Myoelectric Single/Unknown DOF n = 62 Mean ± SD	Myoelectric Multi-DOF n = 40 Mean ± SD	Cosmetic n = 22 Mean ± SD	Non-Users n = 306 Mean ± SD	All N = 755 Mean ± SD
Age, y	65.8±12.4	58.7±15.9	63.9±10.4	63.9±10.4	63.6±14.1	63.5±13.9
Missing, n	10	2	1	1	4	18
Time since initial amputation, y	36.6±17.4	25.7±18.4	32.8±17.8	32.8±17.8	28.3±18.0	31.4±18.3
Missing, n	6	2	1	1	8	18
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Age, y						
18-45	26 (8.3)	15 (25.0)	14 (35.9)	1 (4.8)	37 (12.3)	93 (12.6)
45-65	72 (22.9)	18 (30.0)	14 (35.9)	7 (33.3)	92 (30.5)	203 (27.5)
65-75	170 (54.0)	18 (30.0)	11 (28.2)	12 (57.1)	124 (41.1)	335 (45.5)
75+	47 (14.9)	9 (15.0)	0 (0.0)	1 (4.8)	49 (16.2)	105 (14.4)
Time since initial amputation, y						
0-20	77 (24.1)	31 (51.7)	23 (59.0)	6 (28.6)	119 (39.9)	256 (34.7)
20-50	181 (56.7)	24 (40.0)	15 (38.5)	13 (61.9)	149 (50.0)	382 (51.8)
50+	61 (19.1)	5 (8.3)	1 (2.6)	2 (9.5)	30 (10.1)	99 (13.4)
Sex						
Male	322 (99.1)	62 (100.0)	38 (95.0)	19 (86.4)	293 (95.8)	734 (97.2)
Female	3 (0.9)	0 (0.0)	2 (5.0)	3 (13.6)	13 (4.3)	21 (2.8)
Race						
White	254 (78.2)	51 (82.3)	23 (57.5)	10 (45.5)	234 (76.5)	572 (75.8)
Black	30 (9.2)	5 (8.1)	7 (17.5)	8 (36.4)	36 (11.8)	86 (11.4)
Other (including mixed race)	16 (4.9)	2 (3.2)	1 (2.5)	2 (9.1)	13 (4.3)	34 (4.5)
Missing	25 (7.7)	4 (6.5)	9 (22.5)	2 (9.1)	23 (7.5)	63 (8.3)
Hispanic or Latino ethnicity						
Yes	22 (6.8)	6 (9.7)	7 (17.5)	1 (4.6)	23 (7.5)	59 (7.8)
No	288 (88.6)	54 (87.1)	31 (77.5)	20 (90.9)	273 (89.2)	666 (88.2)
Missing	15 (4.6)	2 (3.2)	2 (5.0)	1 (4.6)	10 (3.3)	30 (4.0)
Employment						
Employed full-time	32 (9.9)	9 (14.5)	8 (20.0)	2 (9.1)	20 (6.5)	71 (9.4)
Employed part-time	15 (4.6)	2 (3.2)	1 (2.5)	1 (4.6)	11 (3.6)	30 (4.0)
Student	2 (0.6)	2 (3.2)	2 (5.0)	1 (4.6)	10 (3.3)	17 (2.3)
Retired, but employed after amputation	187 (57.5)	31 (50.0)	11 (27.35	9 (40.9)	139 (42.5)	368 (48.7)
Retired, but not employed after amputation	49 (15.1)	13 (21.0)	8 (20.0)	6 (27.3)	74 (24.2)	150 (19.9)
On medical leave	3 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	6 (2.0)	9 (1.2)
Other	26 (8.0)	3 (4.8)	9 (22.5)	2 (9.1)	51 (16.7)	91 (12.1)
Missing	11 (3.4)	2 (3.2)	1 (2.5)	1 (4.6)	4 (1.3)	19 (2.5)
Marital status						
Married or living together	219 (67.4)	40 (64.5)	27 (67.5)	12 (54.6)	173 (56.5)	471 (62.4)
Divorced or separated	61 (18.8)	14 (22.6)	11 (27.5)	2 (9.1)	78 (25.5)	166 (22.0)

(*continued on next page*)

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Table 1 (*continued*)

Widowed	19 (5.9)	3 (4.8)	0 (0.0)	2 (9.1)	20 (6.5)	44 (5.8)
Never married	16 (4.9)	3 (4.8)	1 (2.5)	5 (22.7)	30 (9.8)	55 (7.3)
Missing	10 (3.1)	2 (3.2)	1 (2.5)	1 (4.6)	5 (1.6)	19 (2.5)
Amputation level						
Forequarter	5 (1.5)	2 (3.2)	1 (2.5)	3 (13.6)	11 (3.6)	22 (2.9)
At the shoulder joint	9 (2.8)	2 (3.2)	4 (10.0)	1 (4.5)	53 (17.3)	69 (9.1)
Above the elbow	79 (24.3)	8 (12.9)	8 (20.0)	4 (18.2)	134 (43.8)	233 (30.9)
At the elbow	16 (4.9)	2 (3.2)	1 (2.5)	0 (0.0)	18 (5.9)	37 (4.9)
Below the elbow	148 (45.5)	32 (51.6)	17 (42.5)	11 (50.0)	62 (20.3)	270 (35.8)
At the wrist joint	68 (20.9)	16 (25.8)	9 (22.5)	3 (13.6)	28 (9.2)	124 (16.4)
Amputation of lower limb						
Yes	38 (11.7)	10 (16.1)	3 (7.5)	6 (27.3)	34 (11.1)	91 (12.1)
No	287 (88.3)	52 (83.9)	37 (92.5)	16 (72.7)	272 (88.9)	664 (88.0)
Amputation of dominant side						
Yes	174 (53.5)	28 (45.2)	25 (62.5)	9 (40.9)	152 (49.7)	388 (51.4)
No	149 (45.9)	34 (54.8)	15 (37.5)	13 (59.1)	154 (50.3)	365 (48.3)
Missing	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.3)
Etiology of amputation (may be more than one)						
Combat injury	145 (44.6)	26 (41.9)	19 (47.5)	8 (36.4)	67 (21.9)	265 (35.1)
Accident	202 (62.2)	41 (66.1)	25 (62.5)	13 (59.1)	200 (65.4)	481 (63.7)
Burn	35 (10.8)	6 (9.7)	4 (10.0)	2 (9.1)	30 (9.8)	77 (10.2)
Cancer	4 (1.2)	1 (1.6)	2 (5.0)	2 (9.1)	21 (6.9)	30 (4.0)
Diabetes	3 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	7 (2.3)	10 (1.3)
Infection	34 (10.5)	6 (9.7)	1 (2.5)	2 (9.1)	44 (114.4)	87 (11.5)
Ever used prothesis						
Yes	235 (100.0)	62 (100.0)	40 (100.0)	22 (100.0)	254 (83.0)	703 (93.1)
No	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	52 (17.0)	52 (6.9)
Prothesis users (ever) only	n=325	n=62	n=40	n=22	n=254	n=703
Initial prosthesis training						
Yes	245 (75.4)	53 (85.5)	31 (77.5)	11 (50.0)	192 (75.6)	532 (75.7)
No	77 (23.7)	9 (14.5)	9 (22.5)	10 (45.5)	59 (23.2)	164 (23.3)
Missing	3 (0.9)	0 (0.0)	0 (0.0)	1 (4.6)	3 (1.2)	7 (1.0)
Prothesis users (current) only	n=325	n=62	n=40	n=22	n=0	n=449
Current prosthesis training						
Yes	208 (64.0)	46 (74.2)	33 (82.5)	7 (31.8)		294 (65.5)
No	112 (34.5)	15 (24.2)	7 (31.8)	15 (68.2)		149 (33.2)
Missing	5 (1.5)	1 (1.6)	0 (0.0)	0 (0.0)		6 (1.3)
Most recent prothesis received						
<1 year ago	76 (23.4)	19 (30.7)	9 (22.5)	3 (13.5)		107 (23.8)
1 to < 4 years ago	128 (39.4)	29 (46.8)	27 (67.5)	9 (40.9)		193 (43.0)
4 years ago +	120 (36.9)	14 (22.6)	3 (7.5)	10 (45.5)		147 (32.7)
Missing	1 (0.3)	0 (0.0)	1 (2.5)	0 (0.0)		2 (0.5)
Number of prostheses						
1	227 (69.9)	24 (38.7)	19 (47.5)	14 (63.6)		284 (63.3)
2 +	98 (30.2)	38 (61.3)	21 (52.5)	8 (36.4)		165 (36.8)

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Table 2 Difficulty of activity performance under 4 conditions between primary device configuration (n = 741)

Conditions	Body-Powered n = 325 Mean ± SD	Myoelectric Single/Missing DOF n = 62 Mean ± SD	Myoelectric Multi-DOF n = 40 Mean ± SD	Cosmetic n = 22 Mean ± SD	Non-Users n = 306 Mean ± SD	Kruskal-Wallis *P* Value
Without a prosthesis: two-handed tasks						
Lift and carry bulky objects like grocery bags or crates that weigh more than 15 lb?	2.7±1.1	2.8±1.0	2.7±1.1	3.0±1.2	2.9±1.1	.2471
Spread peanut butter on fresh bread?	3.0±1.0	3.2±1.1	3.3±1.2	3.1±1.2	3.1±1.1	.3524
Do housework such as carrying a laundry basket?	2.6±1.0	2.7±1.0	2.8±1.2	3.1±1.6	2.9±1.2	.1552
With primary prosthesis: two-handed tasks						
Lift and carry bulky objects like grocery bags or crates that weigh more than 15 lb?	2.4±1.1	2.5±1.1	2.8±1.3	3.6±1.4	NA	.0006
Spread peanut butter on fresh bread?	2.9±1.3	2.9±1.2	3.1±1.4	3.9±1.3	NA	.0056
Do housework such as carrying a laundry basket?	2.3±1.0	2.4±1.0	2.5±1.1	3.5±1.5	NA	.0003
With primary prosthesis: one-handed tasks						
Pick up small objects such as coins and paper clips using your amputated side?	3.2±1.2	3.4±1.2	3.5±1.1	4.2±1.2	NA	.0028
Grasp rounded objects, such as cans, using your amputated side?	2.7±1.2	2.5±1.0	2.6±1.2	4.1±1.2	NA	<.0001
Residual limb without prosthesis: one-handed tasks						
Pick up small objects such as coins and paper clips using your amputated side?	4.4±1.0	4.4±1.1	4.5±1.1	4.6±0.9	4.6±0.9	.0899
Grasp rounded objects, such as cans, using your amputated side?	4.0±1.3	4.0±1.3	4.1±1.2	4.5±0.9	4.4±1.1	.0002

NOTE. Response categories: 1 = very easy; 2 = easy; 3 = difficult; 4 = very difficult; 5 = cannot do at all.
Abbreviation: NA, not available.

comparisons showed that cosmetic device users had significantly ($\alpha = .05$) more difficulty in all three 2-handed tasks with a prosthesis as compared with body-powered users and more difficulty than myoelectric single-DOF users with lifting bulky objects and spreading peanut butter. Difficulty with 1-handed task performance using a prosthesis was also significantly different by prosthesis type ($P < .005$). Post-hoc analyses showed that cosmetic users had significantly more difficulty ($\alpha = .05$) than body-powered users in picking up small items, and more difficulty than all other groups in grasping rounded objects. The 1-handed task of grasping rounded objects with the residual limb was significantly different by prosthesis type ($P = .0002$); in the post-hoc analysis, non-users had significantly more difficulty than body-powered users.

Table 3 shows task difficulty with and without a prosthesis, stratified by device type. Lifting bulky objects and doing housework was rated as easier when done with a prosthesis only by body-powered users ($P < .0001$). Spreading peanut butter on fresh bread was rated as easier without using a prosthesis by cosmetic users. Picking up small objects and grasping rounded objects were rated as easier when done with a prosthesis as compared to without (with residual limb) by all but the cosmetic users ($P < .001$).

There were statistically significant weak to moderate correlations (r: 0.12-0.33; $P < .05$) between the hours of help needed per day and self-rated difficulty in performing 1- and 2-handed tasks with and without the prosthesis (supplemental table S1, available online only at http://www.archives-pmr.org/).

Performance and satisfaction outcomes

Bivariate linear regression results are shown in supplemental table S2 (available online only at http://www.archives-pmr.org/). After controlling for potential confounders in multivariable models, there were no meaningful differences in MCS or PCS scores by prosthesis configuration (table 4). MCS scores were better for respondents with longer amputation histories and those who received training with their initial prosthesis but lower for those who were black or unknown race as compared to white. PCS scores were better for those who were younger, had longer amputation histories, those who received training to use their current prosthesis, and those who had 2 or more prostheses. PCS

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Table 3 Difficulty of activity performance under 3 conditions by primary device type

Task Type	Without a Prosthesis	Primary Prosthesis	Residual Limb Without Prosthesis	Wilcoxon Signed-Ranks
	Mean ± SD	Mean ± SD	Mean ± SD	*P* Value
Two-handed tasks	**Body-powered (n=312)**			
Lift and carry bulky objects like grocery bags or crates that weigh more than 15 lb?	2.7±1.1	2.4±1.1	NA	<.0001
Spread peanut butter on fresh bread?	3.2±1.0	2.9±1.3	NA	.1516
Do housework such as carrying a laundry basket?	2.6±1.0	2.3±1.0	NA	<.0001
One-handed tasks				
Pick up small objects such as coins and paper clips using your amputated side?	NA	3.2±1.2	4.4±1.0	<.0001
Grasp rounded objects, such as cans, using your amputated side?	NA	2.6±1.2	4.0±1.3	<.0001
Two-handed tasks	Myoelectric/Hybrid: Single/Unknown DOF (n=59)			
Lift and carry bulky objects like grocery bags or crates that weigh more than 15 lb?	2.8±1.0	2.5±1.1	NA	.1064
Spread peanut butter on fresh bread?	3.2±1.2	2.9±1.2	NA	.2211
Do housework such as carrying a laundry basket?	2.7±1.0	2.4±1.0	NA	.1119
One-handed tasks				
Pick up small objects such as coins and paper clips using your amputated side?	NA	3.4±1.2	4.4±1.1	<.0001
Grasp rounded objects, such as cans, using your amputated side?	NA	2.5±1.0	4.0±1.3	<.0001
Two-handed tasks	Myoelectric/Hybrid: Multi-DOF (n=40)			
Lift and carry bulky objects like grocery bags or crates that weigh more than 15 lb?	2.7±1.1	2.8±1.3	NA	.6749
Spread peanut butter on fresh bread?	3.3±1.3	3.1±1.4	NA	.5978
Do housework such as carrying a laundry basket?	2.8±1.2	2.5±1.1	NA	.1155
One-handed tasks				
Pick up small objects such as coins and paper clips using your amputated side?	NA	3.5±1.1	4.5±1.1	.0008
Grasp rounded objects, such as cans, using your amputated side?	NA	2.6±1.2	4.1±1.2	<.0001
Two-handed tasks	Cosmetic (n=21)			
Lift and carry bulky objects like grocery bags or crates that weigh more than 15 lb?	3.0±1.2	3.6±1.4	NA	.1172
Spread peanut butter on fresh bread?	3.2±1.2	3.9±1.3	NA	.0215
Do housework such as carrying a laundry basket?	3.1±1.5	3.5±1.5	NA	.2334
One-handed tasks				
Pick up small objects such as coins and paper clips using your amputated side?	NA	4.2±1.2	4.6±0.9	.1250
Grasp rounded objects, such as cans, using your amputated side?	NA	4.1±1.2	4.5±0.9	.2500

NOTE. Response categories: 1=very easy; 2=easy; 3=difficult; 4=very difficult; 5=cannot do at all.
Abbreviation: NA, not available.

scores were worse for participants who had never used a prosthesis compared with those who had ever used a prosthesis.

In multivariate analyses, respondents who did not use a prosthesis had significantly higher (worse) QuickDASH scores (β=8.18; *P*=.002) as compared with body-powered users. QuickDASH scores were also higher for participants who had shorter amputation histories and were black, other race, or unknown race, as compared to white.

Chi-squared analysis found that need for ADL help differed (*P*=.01) by prothesis configuration (not shown). Post-hoc analyses showed that the only statistically significant difference in needing help was between non-users and body-powered users. Bivariate linear regression results are shown in supplemental table S3 (available online only at http://www.archives-pmr.org/). Multivariate logistic regression models showed that the odds of needing ADL help were 1.84 times higher for respondents who did not use a prosthesis, as compared to body-powered users (table 5). Amputation level was not associated with need for ADL help. Black participants had 3.44 times the odds of white participants of needing ADL help. Participants had lower odds of needing ADL help if they were divorced or separated (β=0.51) or never married (β=0.26) compared to those married or living as married.

Discussion

This study compared disability, HRQOL, and ADL assistance for persons with major upper limb amputation who did not use a prosthesis, and those who used body-powered, myoelectric single-

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Table 4 Multivariate linear regression modeling outcomes: results of separate models

	HRQOL				Disability	
	VR-12 MCS		VR-12 PCS		QuickDASH	
Variables	Beta (95% CI)	*P* Value	Beta (95% CI)	*P* Value	Beta (95% CI)	*P* Value
Age, y	0.00 (−0.11 to 0.10)	.9363	−0.12 (−0.19 to −0.06)	.0004	0.08 (−0.09 to 0.25)	.3451
Years since amputation	0.11 (0.03-0.20)	.0088	0.06 (0.01-0.12)	.0213	−0.17 (−0.30 to −0.05)	.0078
Race						
White (ref)						
Black	−5.16 (−8.27 to −2.06)	.0012	−1.85 (−3.83 to 0.13)	.0677	11.66 (6.82-16.50)	<.0001
Other	−1.20 (−5.93 to 3.54)	.6202	0.73 (−2.30 to 3.75)	.6363	8.17 (0.85-15.48)	.0287
Missing	−5.91 (−10.10 to −1.72)	.0057	-0.20 (−2.87 to 2.48)	.8847	9.27 (2.80-15.74)	.0050
Marital status						
Married or living together (ref)						
Divorced or separated	−1.96 (−4.40 to 0.49)	.1161	−0.92 (−2.48 to 0.64)	.2493	−0.17 (−3.93 to 3.60)	.9297
Widowed	2.90 (−1.35 to 7.14)	.1808	−0.36 (−3.07 to 2.35)	.7947	−3.03 (−9.58 to 3.51)	.3631
Never married	−1.55 (−5.54 to 2.43)	.4452	0.08 (−2.47 to 2.63)	.9511	3.73 (−2.17 to 9.63)	.2152
Amputation level						
SH/FQ	1.39 (−1.89 to 4.68)	.4056	0.61 (−1.49 to 2.71)	.5664	2.74 (−2.27 to 7.75)	.2838
TH/ED	0.59 (−1.70 to 2.89)	.6111	0.96 (−0.50 to 2.43)	.1980	0.20 (−3.32 to −3.73)	.9100
TR/wrist (ref)						
Etiology						
Combat injury	−0.03 (−3.21 to 3.15)	.9874	1.26 (−0.77 to 3.29)	.2246	−1.18 (−6.12 to 3.77)	.6409
Accident	−1.15 (−4.03 to 1.74)	.4359	1.08 (−0.76 to 2.92)	.2503	−1.20 (−5.66 to 3.26)	.5984
Infection	1.27 (−1.94 to 4.47)	.4383	−1.10 (−3.15 to 0.94)	.2898	−0.27 (−5.17 to 4.63)	.9136
Ever used prothesis						
Yes (ref)						
No	2.87 (−1.95 to 7.70)	.2428	−3.33 (−6.41 to −0.23)	.0344	−4.54 (−11.77 to 2.69)	.2176
Prosthesis configuration						
Body (ref)						
Myoelectric/hybrid Single/missing DOF	2.07 (−1.73 to 5.87)	.2855	0.17 (−2.26 to 2.59)	.8921	−1.72 (−7.58 to 4.14)	.5640
Myoelectric/hybrid multi-DOF	2.59 (−2.14 to 7.32)	.2825	−0.97 (−3.99 to 2.05)	.5295	1.24 (−5.88 to 8.36)	.7326
Cosmetic	−3.65 (−10.04 to 2.75)	.2634	1.40 (−2.69 to 5.48)	.5022	4.60 (−5.03 to 14.22)	.3488
Non-users	−2.23 (−5.49 to 1.03)	.1796	−0.41 (−2.49 to 1.67)	.6977	8.18 (3.16-13.20)	.0015
Initial prosthesis training						
Yes	3.32 (0.46-6.17)	.0229	−1.47 (−3.30 to 0.35)	.1130	−1.40 (−5.79 to 3.00)	.5323
No (ref)						
Current prosthesis training						
Yes	0.08 (−3.04 to 3.21)	.9577	2.66 (0.67-4.66)	.0090	−2.43 (−7.22 to 2.36)	.3192
No (ref)						
Number of prostheses						
1 (ref)						
2+	−2.75 (−5.55 to 0.05)	.0543	2.38 (0.59-4.17)	.0092	0.69 (−3.62 to 4.99)	.7546
Model n, R^2	688, 0.10		668, 0.12		698, 0.14	

Abbreviations: CI, confidence interval; ED, elbow disarticulation; FQ, forequarter amputation; ref, reference; SH, amputation at the forequarter or shoulder disarticulation level; TH, transhumeral amputation; TR, transradial amputation.

DOF, myoelectric multi-DOF, and cosmetic devices. We found that amputees who do not use a prosthesis report more difficulty in activities, greater overall disability, and lower physical function compared with amputees who use any type of active prosthesis. Furthermore, those who do not use a prosthesis are more likely to need help with ADLs compared with those who use a body-powered prosthesis. These findings demonstrate the value of active prostheses in improving HRQOL and highlight the clinical imperative to encourage prosthesis use by addressing factors such as early prosthetic training to improve satisfaction with devices and reduce abandonment.[17,18]

Our analyses of task difficulty ratings with and without a prosthesis demonstrate the value of active prostheses in unilateral tasks involving fine motor activities, and to a lesser extent in bilateral activities. While cosmetic devices, a preference of many female amputees,[19] may enhance body image and psychosocial adjustment,[20,21] they are not suitable for specific activities (ie, spreading peanut butter, grasping rounded objects). Users of

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Table 5 Multivariate logistic model of ADL help needed

	ADL Help Needed	
Variables	OR (95% CI)	*P* Value
Age, y		
18-45	1.18 (0.64-2.17)	.5947
45-65 (ref)		
65-75	0.92 (0.57-1.47)	.7190
75+	0.49 (0.23-1.03)	.0593
Years since initial amputation		
0-20 (ref)		
20-50	0.57 (0.36-0.91)	.0185
50+	0.93 (0.46-1.87)	.8364
Race		
White (ref)		
Black	3.44 (2.05-5.79)	<.0001
Other	0.97 (0.39-2.42)	.9475
Missing	1.79 (0.89-3.62)	.1037
Marital Status		
Married or living together (ref)		
Divorced or separated	0.51 (0.32-0.81)	.0042
Widowed	0.90 (0.39-2.09)	.8142
Never married	0.26 (0.11-0.62)	.0025
Amputation Level		
SH/FQ	0.89 (0.50-1.61)	.7095
TH/ED	1.00 (0.66-1.52)	.9927
TR/wrist (ref)		
Prosthesis Configuration		
Body (ref)		
Myoelectric/hybrid single/missing DOF	0.55 (0.24-1.23)	.1435
Myoelectric/hybrid multi-DOF	1.75 (0.81-3.79)	.1557
Cosmetic	0.44 (0.11-1.72)	.2395
Non-users	1.84 (1.16-2.92)	.0094
Protheses used, n		
1 (ref)		
2+	1.31 (0.78-2.21)	.3133

Abbreviations: CI, confidence interval; ED, elbow disarticulation; FQ, forequarter amputation; OR, odds ratio, ref, reference; SH, amputation at the forequarter or shoulder disarticulation level; TH, transhumeral amputation; TR, transradial amputation.

cosmetic prostheses also report the most difficulty in general task performance such as housework. These findings are not surprising given that cosmetic devices have no ability for active grasp and can only be used as stabilizers.[22]

Despite the promise of multi-DOF terminal devices, in our sample, myoelectric multi-DOF users generally had greater disability (QuickDASH) as compared with body-powered and single-DOF myoelectric device users. However, we did not observe any differences in those tasks that require grasp of small and rounded objects. It is possible that our measure of task difficulty was not sufficiently sensitive to detect differences in device type, or that these data were confounded by other factors. For example, multi-DOF terminal devices may be more likely to be prescribed to persons with greater disability in the hopes of improving their function. Further study is needed to compare fine motor and activity performance of users of single- vs multi-DOF terminal devices.

Our multivariable models, which controlled for factors potentially associated with disability and quality of life outcomes, did not detect any differences in these outcomes by device configuration. However, we did identify other factors associated with these outcomes. Interestingly, persons who reported that they used 2 or more types of prostheses had better PCS scores, suggesting that having multiple devices provides greater functionality; perhaps this is because the amputee can select the device that best matches his or her needs for activity on any given day. Other research highlights the value of having multiple prostheses, and indicates that amputees may utilize their devices selectively, best matching the device for particular functions or activities.[23,24]

We found that PCS scores were better for those who had training to use their current prosthesis, an important finding that supports the best practice recommendations of clinical experts.[25-28] Receipt of initial prosthetic training was associated with better MCS scores, which may suggest that early quality of amputation care has long-lasting effects on mental health.

Years since amputation was independently associated with better physical function and lower disability, and less likelihood of needing any ADL help. These findings clearly demonstrate that amputees adapt and gain skills and function as they accommodate to their amputation regardless of whether they utilize a prosthesis or not.

We found significant differences in outcomes for black veterans, who reported lower mental function, greater disability, and higher likelihood of needing help with ADLs as compared to white veterans. This finding is consistent with the literature on racial and ethnic disparities in rehabilitation outcomes for persons with stroke,[29] where racial or ethnic minorities have been reported to be less likely to achieve equivalent health outcomes as compared with non-minorities.[29] It is possible that differences in outcomes are explained by a greater prevalence of adverse psychosocial factors such as depression, self-efficacy, and health literacy in combination with lower socioeconomic status among black veterans. Additionally, some studies show that patients who are black have greater pain intensity and pain-related disability as compared to white patients.[30] Further study is needed to understand the sources of racial disparities among veterans with upper limb amputation that we observed.

Study limitations

Results of our comparisons between prosthesis configurations should be interpreted cautiously given the limitations of our study design. Our study was cross-sectional and observational. There are limits to generalizability of results beyond the veteran and male population, and those not served by VA care. Participants were not randomly assigned to prosthesis configurations, and prosthesis users had varying amounts of training and experience, 2 factors that may affect skillfulness of prosthesis use. It is possible that differences between multi- and single-DOF terminal devices were not detected because of confounding by indication. This may have occurred if amputees with greater disability and need are more likely to be prescribed multi-DOF devices. Given the cross-sectional nature of our study, we have no way to examine outcomes before and after prescription of a multi-DOF device. Prospective, longitudinal studies would be helpful in assessing whether there are differences associated with prosthesis configuration.

Another limitation is that this study relied on self-reported survey data which may not fully reflect physical performance. Additional studies that utilize performance metrics to compare outcomes by prosthesis configuration are needed. While our study

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was very large for a study of upper limb amputees, it may have been underpowered to detect differences by certain prosthesis configuration subgroups due to their relatively small size. It is also possible that our study was affected by missing or incomplete data on terminal device type and by our decision to categorize unknown terminal device type as single DOF. In sensitivity analyses for unknown terminal device type classification, we found that 2-handed tasks were significantly harder without a prosthesis for those in the myoelectric single-DOF group, only when those with unknown DOF were excluded. There were no changes in any findings on the association of prosthesis type with disability, HRQOL, or help with ADLs.

Conclusions

This large survey of veterans with upper limb amputation found that those who did not use a prosthesis reported more difficulty in activities, greater disability, and lower HRQOL as compared with those who used any type of active prosthesis. Those who do not use a prosthesis are more likely to need help with ADLs as compared with those who use a body-powered prosthesis. Users of cosmetic prostheses report greater difficulty in task performance compared with users of active prostheses. However, no differences were observed between body-powered, myoelectric single-DOF, and myoelectric multi-DOF devices in perceived activity difficulty, likelihood of needing assistance with ADLs, self-reported disability, or HRQOL. Further study is needed to compare fine motor and activity performance of users of different types of prostheses to assess if and how specific device configurations contribute to performance.

Supplier

a. SAS version 9.4; SAS Institute.

Keywords

Amputation; Quality of life; Rehabilitation; Survey; Upper limb; Veterans

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ORIGINAL RESEARCH

Function and Quality of Life of Unilateral Major Upper Limb Amputees: Effect of Prosthesis Use and Type

Check for updates

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Abstract

Objective: To compare patient-reported outcomes of disability, activity difficulty, and health-related quality of life (HRQOL) by prosthetic device use and configuration and to identify factors associated with these outcomes.

Design: Telephone survey.

Setting: General community.

Participants: Population-based sample of veterans (N=755) with unilateral upper limb amputation recruited from a national sample of veterans with upper limb amputation who received care at the Veterans Affairs clinic from 2010-2015.

Interventions: Not applicable.

Main Outcome Measures: Upper limb–related disability was measured using Disabilities of the Arm, Shoulder, and Hand score (QuickDASH). HRQOL was measured using the Veterans RAND 12-item Health Survey Mental and Physical Component scores. Activity difficulty was assessed for 1-handed and 2-handed tasks and by questions about the need for help with activities of daily living (ADLs).

Results: Patients who did not use a prosthesis had more difficulty performing 1-handed tasks using the residual limb as compared with those who used body-powered prostheses. Cosmetic device users had more task difficulty than body-powered or myoelectric users. Linear regression models did not show an association between type of prosthesis used and HRQOL scores, but did show that those who did not use a prosthesis (non-users) had worse QuickDASH scores ($\beta=9.4$; $P=.0004$) compared to body-powered users. In logistic regression modeling, the odds of needing help with ADLs were 1.84 times higher (95% confidence interval, 1.16-2.92) for non-users compared with body-powered users.

Conclusions: Amputees who did not use a prosthesis or used a cosmetic prosthesis reported more difficulty in activities and greater disability as compared with those who use body-powered and myoelectric devices. Non-users were more likely to need help with ADLs as compared with those who used a body-powered prosthesis. Our findings highlight the clinical importance of encouraging prosthesis use. Further research is needed to compare physical performance by prosthesis configuration.

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A wide variety of upper limb prostheses and components are available to upper limb amputees; however, it is unclear which devices are best, and clinicians have little evidence to guide decision-making around specific prosthetic components and device types. The inconclusive results of recent systematic reviews comparing body-powered prostheses to myoelectric prostheses[1,2] underscore the need for studies that address the comparative effectiveness of upper limb prosthetic devices and components.

In the past decade, multi–degrees of freedom (DOF) prosthetic terminal devices that enable multiple grip patterns have become commercially available. Although surveys of upper limb amputees have identified a desire for terminal devices with additional grip patterns,[3,4] few studies compare single- vs multi-DOF terminal devices.[5] Several small studies that measured dexterity of single- vs multi-DOF terminal devices showed no clear pattern of superiority of one type of device over another.[6-9] Without a body of evidence quantifying the relative benefits of specific devices and components, clinicians have to rely only on expert opinion,

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experience, manufacturers' claims, limited clinical practice guidelines, and small studies when prescribing prostheses.

This study was a first step in addressing this knowledge gap. We conducted a national survey of veterans with upper limb amputation and examined the associations between prosthesis configuration and outcomes. Our purposes were to (1) compare outcomes of disability, activity difficulty, and health-related quality of life (HRQOL) by device configuration and (2) identify other potentially modifiable factors associated with disability, activity difficulty, and HRQOL among upper limb amputees.

Methods

Survey, participants, and recruitment

The study, with a waiver of written informed consent, was approved by the central institutional review board of the Department of Veterans Affairs (VA). The sampling frame consisted of all veterans with a diagnosis of major upper limb amputation who received care in the VA between 2010-2015, identified using VA Corporate Data Warehouse sources, including the inpatient, outpatient, and fee files. We sent recruitment packages to all nondeceased veterans with current addresses and phone numbers. Veterans who did not opt out of participation or inform us that they did not meet study eligibility criteria were contacted by the study interviewers to obtain oral informed consent. Eight hundred and eight veterans were interviewed. After excluding 32 participants with bilateral amputation and 21 with unknown or other prosthesis type, the analytical sample included 755 individuals with unilateral amputation.

Survey development and content

The development and pilot testing of the survey instrument with 10 cognitive interviews and 13 pretest subjects was reported previously.[10] The survey contained existing survey items and standardized metrics, and new or modified items designed for this study. The survey asked questions about demographic, amputation, and prothesis characteristics. The current paper focuses on the sections of the survey pertaining to prosthesis use and type, function, and HRQOL.

Key variables

Outcome variables

disability and quality of life

The survey included the Disabilities of the Arm, Shoulder, and Hand (QuickDASH) score which measures perceived disability by assessing difficulty performing activities, amount of limitation, extent of interference with activities, and extent of arm, shoulder, and hand pain and tingling.[11-13] The Physical Component Summary (PCS) score and the Mental Component Summary (MCS) score of the Veterans RAND 12-item Health Survey (VR-12) measured HRQOL.[14,15] The survey asked about the need for help with daily activities (ADLs) and hours of help needed. New items asked about difficulty in unilateral and bilateral task performance to quantify any additive benefit of using a prosthesis vs using the residual limb only and to compare prosthesis configuration. Respondents who were prosthesis users rated difficulty performing the activities first with and then without the device.

List of abbreviations:

ADL	activity of daily living
DOF	degrees of freedom
HRQOL	health-related quality of life
MCS	Mental Component Summary
PCS	Physical Component Summary
QuickDASH	Disabilities of the Arm
Shoulder	and Hand score
VA	Veterans Affairs
VR-12	Veterans RAND 12-item Health Survey

Primary independent variable

The primary independent variable, prosthesis configuration, was defined as the combination of primary prosthesis and terminal device type used. We categorized terminal device based on the DOF of the device. Cosmetic devices were classified as having no DOF, while hooks, electronic terminal devices, Greifers and sensor speed hands were categorized as 1 DOF, and I-Limb/Michelangelo or Bebionic hand were categorized as multi-DOF. We used information on prosthesis and terminal device type to create the 5-category prosthesis configuration variable: (1) no prosthesis, (2) body-powered, (3) myoelectric single-DOF terminal devices, (4) myoelectric multi-DOF terminal device, and (5) cosmetic. When terminal device type was unknown and the device type was either body-powered or myoelectric, we classified the prosthesis type as myoelectric single DOF given that this is the most common type of device. We also expected that recipients of multi-DOF terminal devices, who are typically very involved in the device selection, would be able to name the brand correctly.

Statistical analyses

We described demographic and amputation characteristics by prosthesis configuration; missing data were presented in descriptives of categorical variables but treated as missing in subsequent analysis. SAS,[a] version 9.4, was used for statistical analyses. We compared characteristics across prosthesis configuration groups using chi-square and Fisher exact tests. We compared difficulty in task performance by prosthesis configuration for tasks done without a prosthesis, with a prosthesis, and with the residual limb using Kruskal-Wallis tests, and conducted Dunn post-hoc analyses to determine which groups significantly differed. We also compared difficulty in task performance without a prosthesis, with the primary prosthesis, and with the residual limb (unilateral tasks only) using Wilcoxon signed-rank tests. These analyses were conducted separately for each prosthesis configuration.

Spearman correlations were estimated between task difficulty and hours of ADL help. We compared QuickDASH; VR-12 MCS and PCS scores; likelihood of needing any help; and hours of help needed across prosthesis configuration using analysis of variance, chi-square, and Kruskal-Wallis tests as appropriate. We also conducted Tukey, Tukey-style,[16] and Dunn post-hoc analyses, respectively, to identify differences between groups. Bivariate linear regression models examined associations between potential confounders and outcomes. We included variables with associations at $P<.10$ in subsequent multivariate models. Separate multivariable linear regression models examined the association between prosthesis configuration and the VR-12 MCS, PCS, and QuickDASH. A multivariable logistic regression model examined the association between primary prosthesis configuration and

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likelihood of needing any ADL help. Regression models controlled for age, years since amputation, race, marital status, amputation level, ever having used a prosthesis, lower limb amputation, amputation of dominant side, amputation etiology, initial and current prosthesis training, year of prosthesis receipt, and number of prostheses. We conducted sensitivity analyses to determine whether there was detectable bias introduced by excluding the group with unknown terminal device type.

Results

Sample

Eighty-three percent (N = 808) of those screened to be eligible were recruited into the main study (Fig 1). The survey response rate and cooperation rate were 47.7% and 63.3%, respectively, as calculated using the American Association for Public Opinion Research methodology. The analysis reported here included only participants with unilateral amputation. We excluded 21 participants who had incomplete or conflicting data on prosthesis use: 9 of these due to missing information about prosthesis use, 11 due to missing information on type of prosthesis or reports that the primary prosthesis was a sports device, and 1 because of a mismatch between prosthesis and terminal device type. The final analytic sample (N = 755) included 306 (39.4%) patients with no prosthesis, 325 (43.1%) patients with body-powered devices, 62 (8.2%) patients with a myoelectric or hybrid single-DOF terminal device, 40 (5.3%) patients with a myoelectric multi-DOF terminal device, and 22 (2.8%) patients with cosmetic devices.

Demographic characteristics

Table 1 shows the characteristics of respondents. Participants were on average (mean ± SD) aged 63.5±13.9. On average, it had been 31.4±18.3 years since amputation. The sample was 97.2% male and 75.8% white. Most participants were married or cohabitating (62.4%). Overall, 35.8% had below elbow amputation, 30.9% above elbow, 16.4% wrist disarticulation, 9.1% shoulder disarticulation, 4.9% elbow disarticulation, and 2.9% forequarter amputation. The most common amputation etiology of limb loss was classified as "accident" (63.7%) followed by "combat injury" (35.1%). Most respondents received training for their initial and current prostheses (75.7% and 65.5%, respectively) and had only 1 prosthesis (63.3%).

Difficulty in activity performance

There were no meaningful differences in self-reported difficulty of performing two-handed tasks without a prosthesis by prosthesis configuration (table 2). Difficulty of performing 2-handed tasks with a prosthesis differed significantly by prosthesis type ($P<.01$). Cosmetic device users rated tasks as the most difficult, followed by myoelectric multi-DOF and single-DOF users. Post-hoc

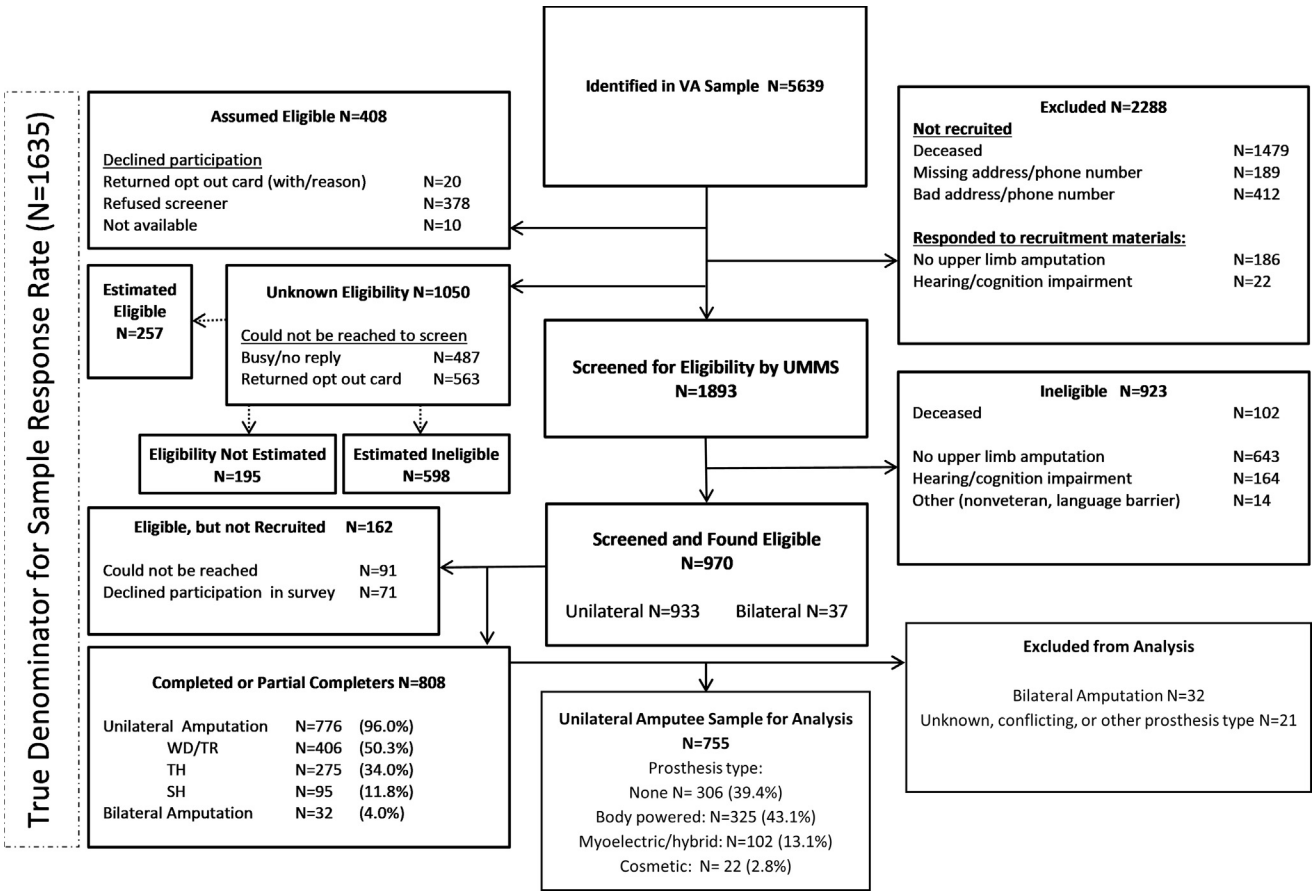

Fig 1 Flow diagram.

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Table 1 Demographics and amputation related characteristics by primary device type

	Prosthesis Configuration					
	Body-Powered n=325	Myoelectric Single/Unknown DOF n=62	Myoelectric Multi-DOF n=40	Cosmetic n=22	Non-Users n=306	All N=755
Variables	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
Age, y	65.8±12.4	58.7±15.9	63.9±10.4	63.9±10.4	63.6±14.1	63.5±13.9
Missing, n	10	2	1	1	4	18
Time since initial amputation, y	36.6±17.4	25.7±18.4	32.8±17.8	32.8±17.8	28.3±18.0	31.4±18.3
Missing, n	6	2	1	1	8	18
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Age, y						
18-45	26 (8.3)	15 (25.0)	14 (35.9)	1 (4.8)	37 (12.3)	93 (12.6)
45-65	72 (22.9)	18 (30.0)	14 (35.9)	7 (33.3)	92 (30.5)	203 (27.5)
65-75	170 (54.0)	18 (30.0)	11 (28.2)	12 (57.1)	124 (41.1)	335 (45.5)
75+	47 (14.9)	9 (15.0)	0 (0.0)	1 (4.8)	49 (16.2)	105 (14.4)
Time since initial amputation, y						
0-20	77 (24.1)	31 (51.7)	23 (59.0)	6 (28.6)	119 (39.9)	256 (34.7)
20-50	181 (56.7)	24 (40.0)	15 (38.5)	13 (61.9)	149 (50.0)	382 (51.8)
50+	61 (19.1)	5 (8.3)	1 (2.6)	2 (9.5)	30 (10.1)	99 (13.4)
Sex						
Male	322 (99.1)	62 (100.0)	38 (95.0)	19 (86.4)	293 (95.8)	734 (97.2)
Female	3 (0.9)	0 (0.0)	2 (5.0)	3 (13.6)	13 (4.3)	21 (2.8)
Race						
White	254 (78.2)	51 (82.3)	23 (57.5)	10 (45.5)	234 (76.5)	572 (75.8)
Black	30 (9.2)	5 (8.1)	7 (17.5)	8 (36.4)	36 (11.8)	86 (11.4)
Other (including mixed race)	16 (4.9)	2 (3.2)	1 (2.5)	2 (9.1)	13 (4.3)	34 (4.5)
Missing	25 (7.7)	4 (6.5)	9 (22.5)	2 (9.1)	23 (7.5)	63 (8.3)
Hispanic or Latino ethnicity						
Yes	22 (6.8)	6 (9.7)	7 (17.5)	1 (4.6)	23 (7.5)	59 (7.8)
No	288 (88.6)	54 (87.1)	31 (77.5)	20 (90.9)	273 (89.2)	666 (88.2)
Missing	15 (4.6)	2 (3.2)	2 (5.0)	1 (4.6)	10 (3.3)	30 (4.0)
Employment						
Employed full-time	32 (9.9)	9 (14.5)	8 (20.0)	2 (9.1)	20 (6.5)	71 (9.4)
Employed part-time	15 (4.6)	2 (3.2)	1 (2.5)	1 (4.6)	11 (3.6)	30 (4.0)
Student	2 (0.6)	2 (3.2)	2 (5.0)	1 (4.6)	10 (3.3)	17 (2.3)
Retired, but employed after amputation	187 (57.5)	31 (50.0)	11 (27.35	9 (40.9)	139 (42.5)	368 (48.7)
Retired, but not employed after amputation	49 (15.1)	13 (21.0)	8 (20.0)	6 (27.3)	74 (24.2)	150 (19.9)
On medical leave	3 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	6 (2.0)	9 (1.2)
Other	26 (8.0)	3 (4.8)	9 (22.5)	2 (9.1)	51 (16.7)	91 (12.1)
Missing	11 (3.4)	2 (3.2)	1 (2.5)	1 (4.6)	4 (1.3)	19 (2.5)
Marital status						
Married or living together	219 (67.4)	40 (64.5)	27 (67.5)	12 (54.6)	173 (56.5)	471 (62.4)
Divorced or separated	61 (18.8)	14 (22.6)	11 (27.5)	2 (9.1)	78 (25.5)	166 (22.0)

(*continued on next page*)

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Table 1 (*continued*)

Widowed	19 (5.9)	3 (4.8)	0 (0.0)	2 (9.1)	20 (6.5)	44 (5.8)
Never married	16 (4.9)	3 (4.8)	1 (2.5)	5 (22.7)	30 (9.8)	55 (7.3)
Missing	10 (3.1)	2 (3.2)	1 (2.5)	1 (4.6)	5 (1.6)	19 (2.5)
Amputation level						
Forequarter	5 (1.5)	2 (3.2)	1 (2.5)	3 (13.6)	11 (3.6)	22 (2.9)
At the shoulder joint	9 (2.8)	2 (3.2)	4 (10.0)	1 (4.5)	53 (17.3)	69 (9.1)
Above the elbow	79 (24.3)	8 (12.9)	8 (20.0)	4 (18.2)	134 (43.8)	233 (30.9)
At the elbow	16 (4.9)	2 (3.2)	1 (2.5)	0 (0.0)	18 (5.9)	37 (4.9)
Below the elbow	148 (45.5)	32 (51.6)	17 (42.5)	11 (50.0)	62 (20.3)	270 (35.8)
At the wrist joint	68 (20.9)	16 (25.8)	9 (22.5)	3 (13.6)	28 (9.2)	124 (16.4)
Amputation of lower limb						
Yes	38 (11.7)	10 (16.1)	3 (7.5)	6 (27.3)	34 (11.1)	91 (12.1)
No	287 (88.3)	52 (83.9)	37 (92.5)	16 (72.7)	272 (88.9)	664 (88.0)
Amputation of dominant side						
Yes	174 (53.5)	28 (45.2)	25 (62.5)	9 (40.9)	152 (49.7)	388 (51.4)
No	149 (45.9)	34 (54.8)	15 (37.5)	13 (59.1)	154 (50.3)	365 (48.3)
Missing	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.3)
Etiology of amputation (may be more than one)						
Combat injury	145 (44.6)	26 (41.9)	19 (47.5)	8 (36.4)	67 (21.9)	265 (35.1)
Accident	202 (62.2)	41 (66.1)	25 (62.5)	13 (59.1)	200 (65.4)	481 (63.7)
Burn	35 (10.8)	6 (9.7)	4 (10.0)	2 (9.1)	30 (9.8)	77 (10.2)
Cancer	4 (1.2)	1 (1.6)	2 (5.0)	2 (9.1)	21 (6.9)	30 (4.0)
Diabetes	3 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	7 (2.3)	10 (1.3)
Infection	34 (10.5)	6 (9.7)	1 (2.5)	2 (9.1)	44 (114.4)	87 (11.5)
Ever used prothesis						
Yes	235 (100.0)	62 (100.0)	40 (100.0)	22 (100.0)	254 (83.0)	703 (93.1)
No	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	52 (17.0)	52 (6.9)
Prothesis users (ever) only	n=325	n=62	n=40	n=22	n=254	n=703
Initial prosthesis training						
Yes	245 (75.4)	53 (85.5)	31 (77.5)	11 (50.0)	192 (75.6)	532 (75.7)
No	77 (23.7)	9 (14.5)	9 (22.5)	10 (45.5)	59 (23.2)	164 (23.3)
Missing	3 (0.9)	0 (0.0)	0 (0.0)	1 (4.6)	3 (1.2)	7 (1.0)
Prothesis users (current) only	n=325	n=62	n=40	n=22	n=0	n=449
Current prosthesis training						
Yes	208 (64.0)	46 (74.2)	33 (82.5)	7 (31.8)		294 (65.5)
No	112 (34.5)	15 (24.2)	7 (31.8)	15 (68.2)		149 (33.2)
Missing	5 (1.5)	1 (1.6)	0 (0.0)	0 (0.0)		6 (1.3)
Most recent prothesis received						
<1 year ago	76 (23.4)	19 (30.7)	9 (22.5)	3 (13.5)		107 (23.8)
1 to < 4 years ago	128 (39.4)	29 (46.8)	27 (67.5)	9 (40.9)		193 (43.0)
4 years ago +	120 (36.9)	14 (22.6)	3 (7.5)	10 (45.5)		147 (32.7)
Missing	1 (0.3)	0 (0.0)	1 (2.5)	0 (0.0)		2 (0.5)
Number of prostheses						
1	227 (69.9)	24 (38.7)	19 (47.5)	14 (63.6)		284 (63.3)
2 +	98 (30.2)	38 (61.3)	21 (52.5)	8 (36.4)		165 (36.8)

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Table 2 Difficulty of activity performance under 4 conditions between primary device configuration (n=741)

Conditions	Body-Powered n=325 Mean ± SD	Myoelectric Single/Missing DOF n=62 Mean ± SD	Myoelectric Multi-DOF n=40 Mean ± SD	Cosmetic n=22 Mean ± SD	Non-Users n=306 Mean ± SD	Kruskal-Wallis *P* Value
Without a prosthesis: two-handed tasks						
Lift and carry bulky objects like grocery bags or crates that weigh more than 15 lb?	2.7±1.1	2.8±1.0	2.7±1.1	3.0±1.2	2.9±1.1	.2471
Spread peanut butter on fresh bread?	3.0±1.0	3.2±1.1	3.3±1.2	3.1±1.2	3.1±1.1	.3524
Do housework such as carrying a laundry basket?	2.6±1.0	2.7±1.0	2.8±1.2	3.1±1.6	2.9±1.2	.1552
With primary prosthesis: two-handed tasks						
Lift and carry bulky objects like grocery bags or crates that weigh more than 15 lb?	2.4±1.1	2.5±1.1	2.8±1.3	3.6±1.4	NA	.0006
Spread peanut butter on fresh bread?	2.9±1.3	2.9±1.2	3.1±1.4	3.9±1.3	NA	.0056
Do housework such as carrying a laundry basket?	2.3±1.0	2.4±1.0	2.5±1.1	3.5±1.5	NA	.0003
With primary prosthesis: one-handed tasks						
Pick up small objects such as coins and paper clips using your amputated side?	3.2±1.2	3.4±1.2	3.5±1.1	4.2±1.2	NA	.0028
Grasp rounded objects, such as cans, using your amputated side?	2.7±1.2	2.5±1.0	2.6±1.2	4.1±1.2	NA	<.0001
Residual limb without prosthesis: one-handed tasks						
Pick up small objects such as coins and paper clips using your amputated side?	4.4±1.0	4.4±1.1	4.5±1.1	4.6±0.9	4.6±0.9	.0899
Grasp rounded objects, such as cans, using your amputated side?	4.0±1.3	4.0±1.3	4.1±1.2	4.5±0.9	4.4±1.1	.0002

NOTE. Response categories: 1=very easy; 2=easy; 3=difficult; 4=very difficult; 5=cannot do at all.
Abbreviation: NA, not available.

comparisons showed that cosmetic device users had significantly (α=.05) more difficulty in all three 2-handed tasks with a prosthesis as compared with body-powered users and more difficulty than myoelectric single-DOF users with lifting bulky objects and spreading peanut butter. Difficulty with 1-handed task performance using a prosthesis was also significantly different by prosthesis type (P<.005). Post-hoc analyses showed that cosmetic users had significantly more difficulty (α=.05) than body-powered users in picking up small items, and more difficulty than all other groups in grasping rounded objects. The 1-handed task of grasping rounded objects with the residual limb was significantly different by prosthesis type (P=.0002); in the post-hoc analysis, non-users had significantly more difficulty than body-powered users.

Table 3 shows task difficulty with and without a prosthesis, stratified by device type. Lifting bulky objects and doing housework was rated as easier when done with a prosthesis only by body-powered users (P<.0001). Spreading peanut butter on fresh bread was rated as easier without using a prosthesis by cosmetic users. Picking up small objects and grasping rounded objects were rated as easier when done with a prosthesis as compared to without (with residual limb) by all but the cosmetic users (P<.001).

There were statistically significant weak to moderate correlations (r: 0.12-0.33; P<.05) between the hours of help needed per day and self-rated difficulty in performing 1- and 2-handed tasks with and without the prosthesis (supplemental table S1, available online only at http://www.archives-pmr.org/).

Performance and satisfaction outcomes

Bivariate linear regression results are shown in supplemental table S2 (available online only at http://www.archives-pmr.org/). After controlling for potential confounders in multivariable models, there were no meaningful differences in MCS or PCS scores by prosthesis configuration (table 4). MCS scores were better for respondents with longer amputation histories and those who received training with their initial prosthesis but lower for those who were black or unknown race as compared to white. PCS scores were better for those who were younger, had longer amputation histories, those who received training to use their current prosthesis, and those who had 2 or more prostheses. PCS

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Table 3 Difficulty of activity performance under 3 conditions by primary device type

Task Type	Without a Prosthesis Mean ± SD	Primary Prosthesis Mean ± SD	Residual Limb Without Prosthesis Mean ± SD	Wilcoxon Signed-Ranks *P* Value
Two-handed tasks	**Body-powered (n=312)**			
Lift and carry bulky objects like grocery bags or crates that weigh more than 15 lb?	2.7±1.1	2.4±1.1	NA	<.0001
Spread peanut butter on fresh bread?	3.2±1.0	2.9±1.3	NA	.1516
Do housework such as carrying a laundry basket?	2.6±1.0	2.3±1.0	NA	<.0001
One-handed tasks				
Pick up small objects such as coins and paper clips using your amputated side?	NA	3.2±1.2	4.4±1.0	<.0001
Grasp rounded objects, such as cans, using your amputated side?	NA	2.6±1.2	4.0±1.3	<.0001
Two-handed tasks	Myoelectric/Hybrid: Single/Unknown DOF (n=59)			
Lift and carry bulky objects like grocery bags or crates that weigh more than 15 lb?	2.8±1.0	2.5±1.1	NA	.1064
Spread peanut butter on fresh bread?	3.2±1.2	2.9±1.2	NA	.2211
Do housework such as carrying a laundry basket?	2.7±1.0	2.4±1.0	NA	.1119
One-handed tasks				
Pick up small objects such as coins and paper clips using your amputated side?	NA	3.4±1.2	4.4±1.1	<.0001
Grasp rounded objects, such as cans, using your amputated side?	NA	2.5±1.0	4.0±1.3	<.0001
Two-handed tasks	Myoelectric/Hybrid: Multi-DOF (n=40)			
Lift and carry bulky objects like grocery bags or crates that weigh more than 15 lb?	2.7±1.1	2.8±1.3	NA	.6749
Spread peanut butter on fresh bread?	3.3±1.3	3.1±1.4	NA	.5978
Do housework such as carrying a laundry basket?	2.8±1.2	2.5±1.1	NA	.1155
One-handed tasks				
Pick up small objects such as coins and paper clips using your amputated side?	NA	3.5±1.1	4.5±1.1	.0008
Grasp rounded objects, such as cans, using your amputated side?	NA	2.6±1.2	4.1±1.2	<.0001
Two-handed tasks	Cosmetic (n=21)			
Lift and carry bulky objects like grocery bags or crates that weigh more than 15 lb?	3.0±1.2	3.6±1.4	NA	.1172
Spread peanut butter on fresh bread?	3.2±1.2	3.9±1.3	NA	.0215
Do housework such as carrying a laundry basket?	3.1±1.5	3.5±1.5	NA	.2334
One-handed tasks				
Pick up small objects such as coins and paper clips using your amputated side?	NA	4.2±1.2	4.6±0.9	.1250
Grasp rounded objects, such as cans, using your amputated side?	NA	4.1±1.2	4.5±0.9	.2500

NOTE. Response categories: 1=very easy; 2=easy; 3=difficult; 4=very difficult; 5=cannot do at all.
Abbreviation: NA, not available.

scores were worse for participants who had never used a prosthesis compared with those who had ever used a prosthesis.

In multivariate analyses, respondents who did not use a prosthesis had significantly higher (worse) QuickDASH scores (β=8.18; *P*=.002) as compared with body-powered users. QuickDASH scores were also higher for participants who had shorter amputation histories and were black, other race, or unknown race, as compared to white.

Chi-squared analysis found that need for ADL help differed (*P*=.01) by prothesis configuration (not shown). Post-hoc analyses showed that the only statistically significant difference in needing help was between non-users and body-powered users. Bivariate linear regression results are shown in supplemental table S3 (available online only at http://www.archives-pmr.org/). Multivariate logistic regression models showed that the odds of needing ADL help were 1.84 times higher for respondents who did not use a prosthesis, as compared to body-powered users (table 5). Amputation level was not associated with need for ADL help. Black participants had 3.44 times the odds of white participants of needing ADL help. Participants had lower odds of needing ADL help if they were divorced or separated (β=0.51) or never married (β=0.26) compared to those married or living as married.

Discussion

This study compared disability, HRQOL, and ADL assistance for persons with major upper limb amputation who did not use a prosthesis, and those who used body-powered, myoelectric single-

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Table 4 Multivariate linear regression modeling outcomes: results of separate models

	HRQOL				Disability	
	VR-12 MCS		VR-12 PCS		QuickDASH	
Variables	Beta (95% CI)	*P* Value	Beta (95% CI)	*P* Value	Beta (95% CI)	*P* Value
Age, y	0.00 (−0.11 to 0.10)	.9363	−0.12 (−0.19 to −0.06)	.0004	0.08 (−0.09 to 0.25)	.3451
Years since amputation	0.11 (0.03-0.20)	.0088	0.06 (0.01-0.12)	.0213	−0.17 (−0.30 to −0.05)	.0078
Race						
White (ref)						
Black	−5.16 (−8.27 to −2.06)	.0012	−1.85 (−3.83 to 0.13)	.0677	11.66 (6.82-16.50)	<.0001
Other	−1.20 (−5.93 to 3.54)	.6202	0.73 (−2.30 to 3.75)	.6363	8.17 (0.85-15.48)	.0287
Missing	−5.91 (−10.10 to −1.72)	.0057	-0.20 (−2.87 to 2.48)	.8847	9.27 (2.80-15.74)	.0050
Marital status						
Married or living together (ref)						
Divorced or separated	−1.96 (−4.40 to 0.49)	.1161	−0.92 (−2.48 to 0.64)	.2493	−0.17 (−3.93 to 3.60)	.9297
Widowed	2.90 (−1.35 to 7.14)	.1808	−0.36 (−3.07 to 2.35)	.7947	−3.03 (−9.58 to 3.51)	.3631
Never married	−1.55 (−5.54 to 2.43)	.4452	0.08 (−2.47 to 2.63)	.9511	3.73 (−2.17 to 9.63)	.2152
Amputation level						
SH/FQ	1.39 (−1.89 to 4.68)	.4056	0.61 (−1.49 to 2.71)	.5664	2.74 (−2.27 to 7.75)	.2838
TH/ED	0.59 (−1.70 to 2.89)	.6111	0.96 (−0.50 to 2.43)	.1980	0.20 (−3.32 to −3.73)	.9100
TR/wrist (ref)						
Etiology						
Combat injury	−0.03 (−3.21 to 3.15)	.9874	1.26 (−0.77 to 3.29)	.2246	−1.18 (−6.12 to 3.77)	.6409
Accident	−1.15 (−4.03 to 1.74)	.4359	1.08 (−0.76 to 2.92)	.2503	−1.20 (−5.66 to 3.26)	.5984
Infection	1.27 (−1.94 to 4.47)	.4383	−1.10 (−3.15 to 0.94)	.2898	−0.27 (−5.17 to 4.63)	.9136
Ever used prothesis						
Yes (ref)						
No	2.87 (−1.95 to 7.70)	.2428	−3.33 (−6.41 to −0.23)	.0344	−4.54 (−11.77 to 2.69)	.2176
Prosthesis configuration						
Body (ref)						
Myoelectric/hybrid Single/missing DOF	2.07 (−1.73 to 5.87)	.2855	0.17 (−2.26 to 2.59)	.8921	−1.72 (−7.58 to 4.14)	.5640
Myoelectric/hybrid multi-DOF	2.59 (−2.14 to 7.32)	.2825	−0.97 (−3.99 to 2.05)	.5295	1.24 (−5.88 to 8.36)	.7326
Cosmetic	−3.65 (−10.04 to 2.75)	.2634	1.40 (−2.69 to 5.48)	.5022	4.60 (−5.03 to 14.22)	.3488
Non-users	−2.23 (−5.49 to 1.03)	.1796	−0.41 (−2.49 to 1.67)	.6977	8.18 (3.16-13.20)	.0015
Initial prosthesis training						
Yes	3.32 (0.46-6.17)	.0229	−1.47 (−3.30 to 0.35)	.1130	−1.40 (−5.79 to 3.00)	.5323
No (ref)						
Current prosthesis training						
Yes	0.08 (−3.04 to 3.21)	.9577	2.66 (0.67-4.66)	.0090	−2.43 (−7.22 to 2.36)	.3192
No (ref)						
Number of prostheses						
1 (ref)						
2+	−2.75 (−5.55 to 0.05)	.0543	2.38 (0.59-4.17)	.0092	0.69 (−3.62 to 4.99)	.7546
Model n, R^2	688, 0.10		668, 0.12		698, 0.14	

Abbreviations: CI, confidence interval; ED, elbow disarticulation; FQ, forequarter amputation; ref, reference; SH, amputation at the forequarter or shoulder disarticulation level; TH, transhumeral amputation; TR, transradial amputation.

DOF, myoelectric multi-DOF, and cosmetic devices. We found that amputees who do not use a prosthesis report more difficulty in activities, greater overall disability, and lower physical function compared with amputees who use any type of active prosthesis. Furthermore, those who do not use a prosthesis are more likely to need help with ADLs compared with those who use a body-powered prosthesis. These findings demonstrate the value of active prostheses in improving HRQOL and highlight the clinical imperative to encourage prosthesis use by addressing factors such as early prosthetic training to improve satisfaction with devices and reduce abandonment.[17,18]

Our analyses of task difficulty ratings with and without a prosthesis demonstrate the value of active prostheses in unilateral tasks involving fine motor activities, and to a lesser extent in bilateral activities. While cosmetic devices, a preference of many female amputees,[19] may enhance body image and psychosocial adjustment,[20,21] they are not suitable for specific activities (ie, spreading peanut butter, grasping rounded objects). Users of

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Table 5 Multivariate logistic model of ADL help needed

	ADL Help Needed	
Variables	OR (95% CI)	*P* Value
Age, y		
18-45	1.18 (0.64-2.17)	.5947
45-65 (ref)		
65-75	0.92 (0.57-1.47)	.7190
75+	0.49 (0.23-1.03)	.0593
Years since initial amputation		
0-20 (ref)		
20-50	0.57 (0.36-0.91)	.0185
50+	0.93 (0.46-1.87)	.8364
Race		
White (ref)		
Black	3.44 (2.05-5.79)	<.0001
Other	0.97 (0.39-2.42)	.9475
Missing	1.79 (0.89-3.62)	.1037
Marital Status		
Married or living together (ref)		
Divorced or separated	0.51 (0.32-0.81)	.0042
Widowed	0.90 (0.39-2.09)	.8142
Never married	0.26 (0.11-0.62)	.0025
Amputation Level		
SH/FQ	0.89 (0.50-1.61)	.7095
TH/ED	1.00 (0.66-1.52)	.9927
TR/wrist (ref)		
Prosthesis Configuration		
Body (ref)		
Myoelectric/hybrid single/missing DOF	0.55 (0.24-1.23)	.1435
Myoelectric/hybrid multi-DOF	1.75 (0.81-3.79)	.1557
Cosmetic	0.44 (0.11-1.72)	.2395
Non-users	1.84 (1.16-2.92)	.0094
Protheses used, n		
1 (ref)		
2+	1.31 (0.78-2.21)	.3133

Abbreviations: CI, confidence interval; ED, elbow disarticulation; FQ, forequarter amputation; OR, odds ratio, ref, reference; SH, amputation at the forequarter or shoulder disarticulation level; TH, transhumeral amputation; TR, transradial amputation.

cosmetic prostheses also report the most difficulty in general task performance such as housework. These findings are not surprising given that cosmetic devices have no ability for active grasp and can only be used as stabilizers.[22]

Despite the promise of multi-DOF terminal devices, in our sample, myoelectric multi-DOF users generally had greater disability (QuickDASH) as compared with body-powered and single-DOF myoelectric device users. However, we did not observe any differences in those tasks that require grasp of small and rounded objects. It is possible that our measure of task difficulty was not sufficiently sensitive to detect differences in device type, or that these data were confounded by other factors. For example, multi-DOF terminal devices may be more likely to be prescribed to persons with greater disability in the hopes of improving their function. Further study is needed to compare fine motor and activity performance of users of single- vs multi-DOF terminal devices.

Our multivariable models, which controlled for factors potentially associated with disability and quality of life outcomes, did not detect any differences in these outcomes by device configuration. However, we did identify other factors associated with these outcomes. Interestingly, persons who reported that they used 2 or more types of prostheses had better PCS scores, suggesting that having multiple devices provides greater functionality; perhaps this is because the amputee can select the device that best matches his or her needs for activity on any given day. Other research highlights the value of having multiple prostheses, and indicates that amputees may utilize their devices selectively, best matching the device for particular functions or activities.[23,24]

We found that PCS scores were better for those who had training to use their current prosthesis, an important finding that supports the best practice recommendations of clinical experts.[25-28] Receipt of initial prosthetic training was associated with better MCS scores, which may suggest that early quality of amputation care has long-lasting effects on mental health.

Years since amputation was independently associated with better physical function and lower disability, and less likelihood of needing any ADL help. These findings clearly demonstrate that amputees adapt and gain skills and function as they accommodate to their amputation regardless of whether they utilize a prosthesis or not.

We found significant differences in outcomes for black veterans, who reported lower mental function, greater disability, and higher likelihood of needing help with ADLs as compared to white veterans. This finding is consistent with the literature on racial and ethnic disparities in rehabilitation outcomes for persons with stroke,[29] where racial or ethnic minorities have been reported to be less likely to achieve equivalent health outcomes as compared with non-minorities.[29] It is possible that differences in outcomes are explained by a greater prevalence of adverse psychosocial factors such as depression, self-efficacy, and health literacy in combination with lower socioeconomic status among black veterans. Additionally, some studies show that patients who are black have greater pain intensity and pain-related disability as compared to white patients.[30] Further study is needed to understand the sources of racial disparities among veterans with upper limb amputation that we observed.

Study limitations

Results of our comparisons between prosthesis configurations should be interpreted cautiously given the limitations of our study design. Our study was cross-sectional and observational. There are limits to generalizability of results beyond the veteran and male population, and those not served by VA care. Participants were not randomly assigned to prosthesis configurations, and prosthesis users had varying amounts of training and experience, 2 factors that may affect skillfulness of prosthesis use. It is possible that differences between multi- and single-DOF terminal devices were not detected because of confounding by indication. This may have occurred if amputees with greater disability and need are more likely to be prescribed multi-DOF devices. Given the cross-sectional nature of our study, we have no way to examine outcomes before and after prescription of a multi-DOF device. Prospective, longitudinal studies would be helpful in assessing whether there are differences associated with prosthesis configuration.

Another limitation is that this study relied on self-reported survey data which may not fully reflect physical performance. Additional studies that utilize performance metrics to compare outcomes by prosthesis configuration are needed. While our study

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was very large for a study of upper limb amputees, it may have been underpowered to detect differences by certain prosthesis configuration subgroups due to their relatively small size. It is also possible that our study was affected by missing or incomplete data on terminal device type and by our decision to categorize unknown terminal device type as single DOF. In sensitivity analyses for unknown terminal device type classification, we found that 2-handed tasks were significantly harder without a prosthesis for those in the myoelectric single-DOF group, only when those with unknown DOF were excluded. There were no changes in any findings on the association of prosthesis type with disability, HRQOL, or help with ADLs.

Conclusions

This large survey of veterans with upper limb amputation found that those who did not use a prosthesis reported more difficulty in activities, greater disability, and lower HRQOL as compared with those who used any type of active prosthesis. Those who do not use a prosthesis are more likely to need help with ADLs as compared with those who use a body-powered prosthesis. Users of cosmetic prostheses report greater difficulty in task performance compared with users of active prostheses. However, no differences were observed between body-powered, myoelectric single-DOF, and myoelectric multi-DOF devices in perceived activity difficulty, likelihood of needing assistance with ADLs, self-reported disability, or HRQOL. Further study is needed to compare fine motor and activity performance of users of different types of prostheses to assess if and how specific device configurations contribute to performance.

Supplier

a. SAS version 9.4; SAS Institute.

Keywords

Amputation; Quality of life; Rehabilitation; Survey; Upper limb; Veterans

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Prosthesis satisfaction in a national sample of Veterans with upper limb amputation

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Abstract

Background: Many persons with upper limb amputation reject prostheses, and many are not satisfied with their devices. Research is needed to understand modifiable factors related to device satisfaction. Myoelectric devices with multiple degrees of freedom are now available; however, no studies have examined whether they lead to greater device satisfaction. Prosthetic training contributes to more skillful prosthesis use and greater likelihood of long-term use; however, the relationship between training and device satisfaction is unclear.

Objectives: (1) To describe and compare satisfaction by prosthesis and terminal device type and (2) to identify factors associated with satisfaction.

Study design: Cross-sectional study.

Methods: Participants were 449 persons with unilateral upper limb amputation who used a prosthesis. Participants described their prostheses, prosthetic training, device repairs, visits to a prosthetist, and rated device satisfaction using two standardized measures (Trinity Amputation and Prosthesis Experience Scales Satisfaction scale and Orthotics and Prosthetics Users' Survey - Client Satisfaction with Devices scale). Multivariate generalized linear regression models examined the relationship between prosthesis and terminal device type and satisfaction, controlling for covariates that were meaningful in bivariate analyses.

Results: There were no differences in satisfaction by prosthesis type or terminal device degrees of freedom. Satisfaction was associated with receipt of training to use the initial prosthesis, amputation level, age, and race.

Conclusion: No differences in satisfaction by device or terminal device type were observed. Worse satisfaction was associated with more proximal amputation level, younger age, and black race. The association between receipt of initial prosthetic training and device satisfaction points to the critical role of occupational or physical therapy in the early stages of prosthetic care.

Clinical relevance

Prosthetic satisfaction did not vary by device or terminal device degrees of freedom. Proximal amputation level, younger age, and black race were associated with lower prosthetic satisfaction. Receipt of initial prosthetic training was associated with greater device satisfaction, pointing to the critical role and lasting impact of early training.

Keywords

upper limb, amputation, survey, satisfaction, Veterans

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Background

Many persons with upper limb amputation abandon or reject their prostheses, and a substantial proportion of prosthesis users are not satisfied with their devices.[1–5] Surveys have identified factors associated with dissatisfaction such as problems with function, comfort, fit, and device weight.[1,5–7] Many wish their prostheses had features such as powered wrist movement and multiple grip patterns.[8,9] Limited powered wrist movement is available through some myoelectric/hybrid devices, and myoelectric devices with multiple degrees of freedom (DOF) have become commercially available. However,

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no studies have examined whether greater functionality offered by new technologies is associated with greater device satisfaction.

Some data suggest that individuals using prostheses with advanced technologies are not more satisfied with their prostheses than individuals using older technologies. For example, Veterans who lost their limbs in combat in Operation Enduring Freedom and Operation Iraqi Freedom, a group with greater access to prostheses with more advanced technologies, are not more satisfied with their prostheses than Vietnam era combat Veterans with amputations.[10] Additional research is needed to understand influences on device satisfaction, particularly factors that might be modified to improve patient experience and enhance device adoption. Prosthetic training is an essential aspect of rehabilitative care[11] and contributes to more skillful prosthesis use[12] and greater likelihood of long-term use.[13,14] However, the relationship between training and device satisfaction has not been studied.

A recent study of Veterans with upper limb amputation collected detailed data on prosthesis satisfaction. Results about satisfaction with prostheses, comparing satisfaction ratings of persons with unilateral and bilateral amputation,[15] and device satisfaction by gender[16] have been reported. However, these studies have not compared satisfaction by prosthesis configuration or examined the relationship between initial prosthesis training and device satisfaction. Thus, the objectives of this study were to (1) describe and compare device satisfaction by device type in a national sample of Veterans with upper limb amputation and (2) identify factors that are associated with device satisfaction. We hypothesized that prosthesis satisfaction would be associated with primary device type, terminal device DOF, and receipt of training to use the device.

Methods

Study design

The study, approved by the Department of Veterans Affairs (VA) Central Institutional Review Board (IRB) and the University of Massachusetts Medical School IRB, was a telephone administered survey, described in detail elsewhere.[15] Participants, identified from the VA's Corporate Data Warehouse (CDW) sources, were Veterans with major upper limb amputation who received any type of medical or clinical care in the VA between 2010 and 2015.[15] Eligible participants were alive, with valid telephone numbers and addresses with no significant cognitive or hearing deficits preventing participation by telephone. Participants gave verbal informed consent before participating in the survey. Results reported here are for the subset of respondents with unilateral amputation using a body-powered, myoelectric, hybrid, or cosmetic prosthesis.

Measures

Dependent variables

We used two measures of prosthesis satisfaction: the Trinity Amputation and Prosthesis Experience Scales Satisfaction scale (TAPES-SAT)[17] and the Orthotics and Prosthetics Users' Survey (OPUS) Client Satisfaction with Devices scale (OPUS-CSD).[18] The 10-item TAPES-SAT addresses color, shape, noise, appearance, weight, usefulness, reliability, fit, comfort, and overall satisfaction.[17] Respondents rate items on a 5-point scale (1 = very dissatisfied, 5 = very satisfied). The TAPES-SAT content and scoring were developed for persons with lower limb amputations; however, its structural validity was examined and scoring modified for persons with upper limb amputation.[17] The TAPES-SAT summary score is the average of item ratings.

A variety of studies have evaluated the measurement properties of non-English (translated) versions of the 11-item OPUS-CSD,[19–25] with some recommending removal of several items.[22] Additional research on the structural validity of the OPUS-CSD is needed. We administered the original OPUS-CSD in the survey, but decided to use a modified version after conducting Rasch analysis (using Winsteps version 4.4.2) of the original version. We removed two items (affordability of purchase and repair costs) due to dimensionality issues. We also dropped an item addressing wear and tear on clothing because of item misfit (Mms outfit > 2.0). The eight items in the modified scale address satisfaction with: fit, weight, comfort, donning ease, appearance, durability, skin irritation, and pain. Respondents use a 4-point scale (1 = strongly agree, 4 = strongly disagree) with higher OPUS-CSD scores indicating less satisfaction. The 8-item OPUS-CSD Rasch measure had a person separation of 0.82 and 10.7% of unexplained variance in the first residual factor from a principal component analysis (PCA). The Rasch score can be calculated from the total score using the complete score-to-measure table shown in the Supplemental Appendix Table 1. We evaluated the three items dropped from the 8-item summary scale separately.

We also administered seven new items, which we believed were important elements of prosthesis satisfaction not addressed in the TAPES-SAT or OPUS-CSD. These items addressed satisfaction with terminal device size, prosthesis size, self-consciousness wearing the prosthesis, desire to change to another prosthesis type, inability to wear the prosthesis because of fit, satisfaction with device movement, and unintended movement. Respondents used a 4-point scale (1 = strongly agree, 4 = strongly disagree).

Independent variables: prosthesis type, characteristics, and training

Primary prosthesis type was categorized as body-powered, myoelectric/hybrid, or cosmetic based on responses to items about primary prosthesis and terminal device type.

Respondents also answered questions about number of devices and terminal devices used, when the most recent device was received, and whether they received training with the initial and/or current device (yes/no).

Frequency of prosthesis use was classified as daily, weekly, monthly, every few months, and 1–2 times/year. Intensity of prosthesis use was categorized as <2 h, 2 to <4 h, 4 to <8 h, 8 to <12 h, and >12 h. The most recent date a prosthesis was received was categorized as <2 years, ⩾2 years, and unknown. Number of prostheses and terminal devices used was categorized as 1, 2 or more, or unknown.

Respondents indicated whether their primary terminal device was a body-powered hook, Greifer, powered hook, sensor speed hand, I-Limb/Michaelangelo or Bebionic hand, Cosmetic hand, or unknown. Because of small sample sizes, we collapsed terminal device categories based on device DOF. Cosmetic devices were classified as 0 DOF, while hooks, electronic terminal devices (ETDs), Greifers and sensor speed hands, and unknown myoelectric terminal devices types were categorized as 1 DOF, and I-Limb/Michaelangelo or Bebionic hand were categorized as Multi-DOF. Secondary type of prosthesis was classified as body-powered, myoelectric, hybrid, cosmetic, sports/recreation, or unknown.

Receipt of training for initial and for current prosthesis were classified as yes, no, or unknown. The number of times the prosthesis was repaired and number of visits to a prosthetist for socket adjustment in the prior 12 months were classified as 0, 1, 2–3, ⩾4, and unknown.

Participant characteristics

Participant age was evaluated as a continuous variable and categorized as: 18 to <45, 45 to <65, 65 to <75, and ⩾75 years. Gender was self-reported as male or female. Race was classified as white, black, other (which included >1 race), and unknown. Hispanic ethnicity was classified as yes, no, and unknown. Employment was self-reported as: employed full-time, employed part-time, student, retired but employed after amputation, retired but not employed after amputation, on medical leave, other, or unknown. Marital status was self-reported as married/living together, divorced/separated, widowed, never married, or unknown.

Amputation level was collapsed into a three-category variable for analysis: (1) shoulder (forequarter or shoulder disarticulation), (2) TH (transhumeral or elbow disarticulation), and (3) TR (transradial and wrist disarticulation). Participants indicated the etiology of their amputation using seven yes/no variables: combat injury, accident, burn, cancer, diabetes, infection, and other. The majority (94%) of 244 respondents who indicated "other" etiology provided a description of the etiology. We examined these descriptions among respondents who did not endorse any of the seven provided etiologies and were able to classify etiology in all but two cases. Therefore, we dropped "other" etiology from comparative analyses. Amputation of one or both lower limbs was categorized as yes or no. Participants reported time since initial amputation in years.

Statistical analyses

We described the participant characteristics and prosthesis use characteristics for the overall analytic sample and by type of primary prosthesis used. Descriptive analyses examined the proportion of missing/unknown responses; however, these responses were excluded from subsequent analyses, with the exception of race (which had a high proportion of missing values) and terminal device DOF (classification described above).

Number of repairs and visits to a prosthetist for socket adjustment by primary device type were compared using Kruskal–Wallis tests. TAPES-SAT and OPUS-CSD scores were compared across prosthesis types using one-way analyses of variance (ANOVAs), and Kruskal–Wallis tests were used to compare ordinal ratings of individual items. Tukey's method was used as a post hoc comparison of any differences in summary scores. Simple general linear regression models (GLM) for TAPES-SAT and the OPUS-CSD were used to examine bivariate relationships with the following participant and prosthesis characteristics: age, gender, race, marital status, amputation etiology, amputation of lower limb, amputation of dominant side, recency of prosthesis receipt, number of prostheses and terminal devices, DOF of primary device, training with initial and current prosthesis, number of prosthesis repairs and adjustment visits in prior year, and frequency and intensity of prosthesis use.

We then constructed multivariate GLM models of (1) TAPES-SAT and (2) the OPUS-CSD score including prosthesis type, and simultaneously controlling for all variables with bivariate association at $p < 0.20$ with either satisfaction score. We did not include frequency and intensity of prosthesis use because we believed that they were strong consequences of prosthesis satisfaction. Persons who used cosmetic prostheses were excluded from the multivariate analysis due to the small subgroup size ($N = 22$). We examined assumptions of GLM. Residual plots supported homoscedasticity, specification tests did not reject the assumption of identical and independent error terms, and Durbin–Watson's statistics also supported the independence assumption. Examination of Q-Q plots supported normality of residuals. Pearson correlations between independent variables were all below 0.4 and the variance inflation factors were below 5.

Results

Sample

Eighty-three percent ($N = 808$) of those screened eligible were recruited into the main study (Figure 1). The survey

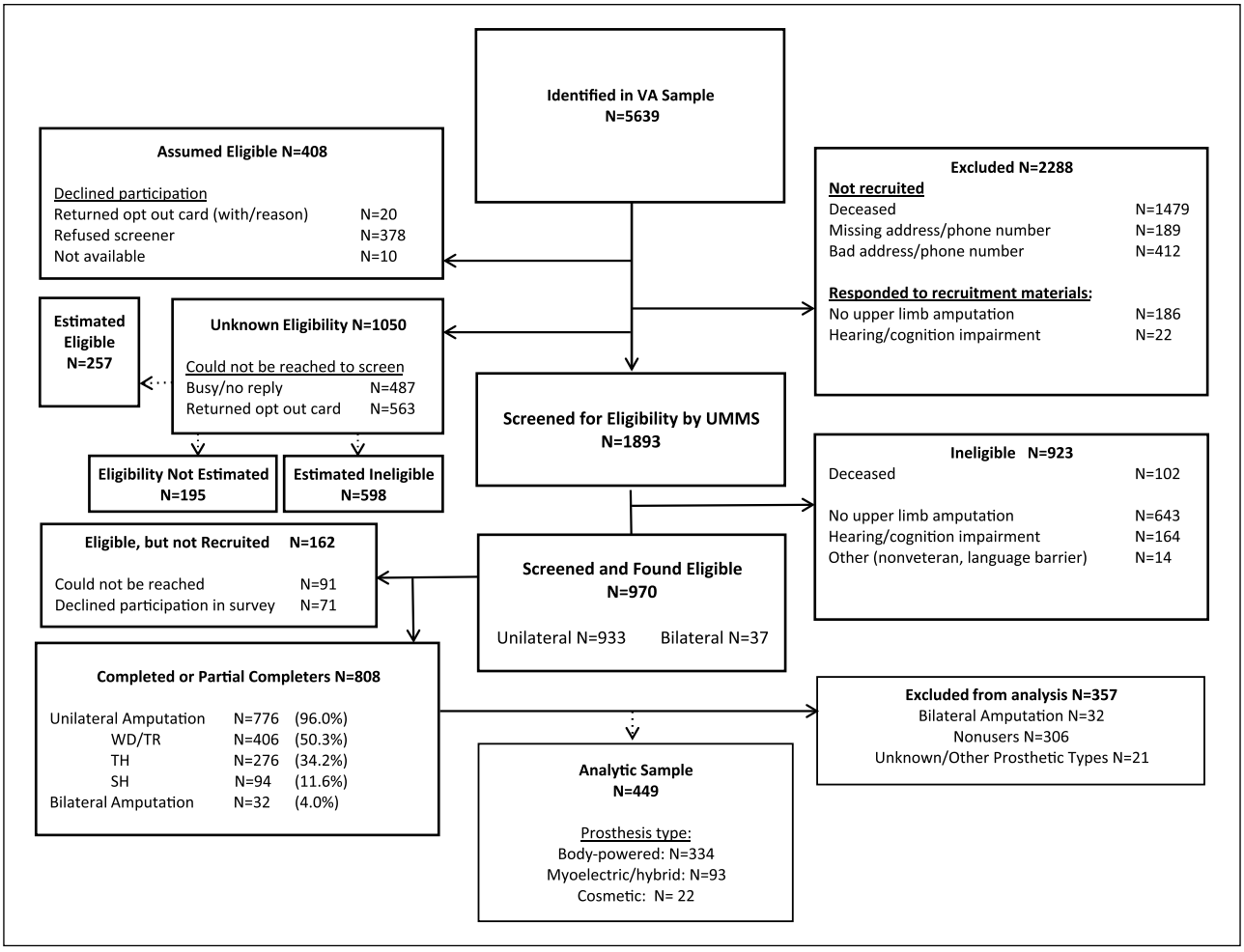

Figure 1. Flow diagram.

response rate and cooperation rate were 47.7% and 63.3%, respectively, as calculated using the American Association for Public Opinion Research methodology.[26] The analytic sample for this report was 449 persons. We excluded 20 participants for whom we had incomplete information on prosthesis use or type of prosthesis, and one participant with conflicting data on type of device used. Nine participants who self-identified as myoelectric or hybrid prosthesis users but specified that they used a body-powered hook as their terminal device were reclassified as users of a body-powered prosthesis type.

The final analytic sample of 429 included 334 (74.4%) body-powered, 88 myoelectric (19.6%), 5 (1.1%) hybrid, and 22 (5%) cosmetic users.

Demographic characteristics

Participants were on average 63.4 years (standard deviation (SD), 13.8) of age, with myoelectric users being the youngest group (mean = 55.6, SD = 15.7) (Table 1). Participants reported an average of 33.5 (SD = 18.2) years since amputation, with myoelectric users having more recent amputations (mean = 23.7 years, SD = 17.5). The sample was 98% male. A greater proportion of females were in the cosmetic prosthesis group (13.6%), compared to 1%–2% of females in other groups. The sample was 75% white. A greater proportion of black participants were in the cosmetic group (36.4%) compared to 10% in other groups. Almost 17% of respondents in the myoelectric group were employed full-time versus 10.2% and 9.1% for body-powered and cosmetic users, respectively. Most participants were married or cohabitating (66.4%).

Amputation level of respondents was 46.3% transradial, 22.1% transhumeral, 21.4% wrist joint, 4.2% elbow disarticulation, 3.6% shoulder, and 3.5% forequarter amputation. A greater proportion with amputation at the forequarter or shoulder level were cosmetic users. The most common amputation etiology was "accident" (62.6%) followed by "combat injury" (44.1%).

Forty percent of body-powered users, 57.0% of myoelectric users, and 27.3% of cosmetic users received their device within the prior 2 years (Table 2). A greater portion of myoelectric users reported use of two or more prostheses (55.9%) or terminal devices (64.5%). Among

Table 1. Demographics and amputation–related characteristics by primary device type.

	Prosthesis type			
	Body-powered *N* = 334	**Myoelectric/hybrid *N* = 93**	**Cosmetic *N* = 22**	**All *N* = 449**
	Mean (SD)	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**
Age (years)	65.5 (12.7)	55. 7 (15.4)	63.9 (10.4)	63.4 (13.8)
Missing (*n*)	10	3	1	14
Years since initial amputation	36.3 (17.6)	23.5 (17.1)	32.8 (17.8)	33.5 (18.2)
Missing (*n*)	6	3	1	10
	***N* (%)**	***N* (%)**	***N* (%)**	***N* (%)**
Gender				
Male	331 (99.1)	91 (97.9)	19 (86.4)	441 (98.2)
Female	3 (0.9)	2 (2.2)	3 (13.6)	8 (1.8)
Age				
18–45	30 (9.3)	25 (27.8)	1 (4.8)	56 (12.9)
45–65	73 (22.5)	31 (34.4)	7 (33.3)	111 (25.5)
65–75	172 (53.1)	27 (30.0)	12 (57.1)	211 (48.5)
75+	49 (15.1)	7 (7.8)	1 (4.8)	57 (13.1)
Race				
White	260 (77.8)	68 (73.1)	10 (45.5)	338 (75.3)
Black	33 (9.9)	9 (9.7)	8 (36.4)	50 (11.1)
Other (including mixed race)	16 (4.8)	3 (3.2)	2 (9.1)	21 (4.7)
Unknown	25 (7.5)	13 (14.0)	2 (9.1)	40 (8.9)
Hispanic or Latino				
Yes	23 (6.9)	12 (12.9)	1 (4.6)	36 (8.0)
No	296 (88.6)	77 (82.9)	20 (90.9)	393 (87.5)
Unknown	15 (4.5)	4 (4.3)	1 (4.6)	20 (4.5)
Employment				
Employed full-time	34 (10.2)	15 (16.1)	2 (9.1)	51 (11.4)
Employed part-time	15 (4.5)	3 (3.2)	1 (4.6)	19 (4.2)
Student	2 (0.6)	4 (4.3)	1 (4.6)	7 (1.6)
Retired, but employed after amputation	191 (57.1)	38 (40.9)	9 (40.9)	238 (53.0)
Retired, but not employed after amputation	54 (15.3)	19 (20.4)	6 (27.3)	76 (16.9)
On medical leave	3 (0.9)	0 (0.0)	0 (0.0)	3 (0.7)
Other	27 (8.1)	11 (11.8)	2 (9.1)	40 (8.9)
Unknown	11 (3.3)	3 (3.2)	1 (4.6)	15 (3.3)
Marital status				
Married or living together	2124 (67.0)	62 (66.7)	12 (54.6)	298 (66.4)
Divorced or separated	64 (19.2)	22 (23.7)	2 (9.1)	88 (19.6)
Widowed	20 (6.0)	2 (2.2)	2 (9.1)	24 (5.4)
Never married	16 (4.8)	4 (4.3)	5 (22.7)	25 (5.6)
Unknown	10 (3.0)	3 (3.2)	1 (4.6)	14 (3.1)
Amputation level				
Forequarter	5 (1.5)	3 (3.2)	3 (13.6)	11 (3.5)
At the shoulder joint	9 (2.7)	6 (6.5)	1 (4.5)	16 (3.6)
Above the elbow	79 (23.7)	16 (17.2)	4 (18.2)	99 (22.1)
At the elbow	17 (5.1)	2 (2.2)	0 (0.0)	19 (4.2)
Below the elbow	153 (45.8)	44 (47.3)	11 (50.0)	208 (46.3)
At the wrist joint	71 (21.3)	22 (23.7)	3 (13.6)	96 (21.4)
Etiology of amputation (may be more than one)				
Combat injury	149 (44.6)	41 (44.1)	8 (36.4)	198 (44.1)
Accident	208 (62.3)	60 (64.5)	13 (59.1)	281 (62.6)

(Continued)

Table 1. (Continued)

	N (%)	*N* (%)	*N* (%)	*N* (%)
Burn	35 (10.5)	10 (10.8)	2 (9.1)	47 (10.5)
Cancer	4 (1.2)	3 (3.2)	2 (9.1)	9 (2.0)
Diabetes	3 (0.9)	0 (0.0)	0 (0.0)	3 (1.0)
Infection	35 (10.5)	6 (6.5)	2 (9.1)	43 (9.6)
Amputation of lower limb				
Yes	39 (11.7)	12 (12.9)	6 (27.3)	57 (12.7)
No	295 (88.3)	81 (87.1)	16 (72.7)	392 (87.3)
Amputation of dominant side				
Yes	179 (53.6)	48 (51.6)	9 (40.9)	346 (52.6)
No	153 (45.8)	45 (48.4)	13 (59.1)	211 (47.0)
Unknown	2 (0.6)	0 (0.0)	0 (0.0)	2 (0.5)

SD: standard deviation.

Table 2. Prosthesis use characteristics.

	Body-powered ***N*** **= 334**	**Myoelectric/hybrid** ***N*** **= 93**	**Cosmetic** ***N*** **= 22**
Frequency of prosthesis use			
Daily	257 (78.1)	72 (78.3)	14 (63.6)
Weekly	43 (13.1)	8 (8.7)	5 (22.7)
Monthly	14 (4.3)	5 (5.4)	0 (0.0)
Every few months	11 (3.3)	2 (2.2)	1 (4.6)
1 to 2 times per year	4 (1.2)	5 (5.4)	2 (9.1)
Intensity of prosthesis use (h)			
<2	68 (20.6)	12 (13.0)	4 (18.2)
2 to <4	29 (8.8)	11 (12.0)	2 (9.1)
4 to <8	58 (17.6)	20 (21.7)	5 (22.7)
8 to <12	64 (19.4)	18 (19.6)	3 (13.6)
$\geqslant 12$	111 (33.6)	31 (33.7)	8 (36.4)
Most recent prosthesis received			
<2 years ago	135 (40.4)	53 (57.0)	6 (27.3)
2+ years ago	198 (59.3)	39 (41.9)	16 (72.7)
Unknown	1 (0.3)	1 (1.1)	0 (0.0)
Number of prostheses used			
One	229 (68.6)	41 (41.1)	14 (63.6)
Two or more	105 (31.4)	52 (55.9)	8 (36.4)
Number of terminal devices used			
One	209 (62.6)	30 (32.3)	17 (77.3)
Two or more	123 (36.8)	60 (64.5)	4 (18.2)
Unknown	2 (0.6)	3 (2.9)	1 (4.7)
Primary type of terminal device used			
Body-powered hook	334 (100.0)	0 (0.0)	0 (0.0)
Greifer	0 (0.0)	6 (6.5)	0 (0.0)
Power hook (ETD)	0 (0.0)	15 (16.1)	0 (0.0)
Sensor speed hand	0 (0.0)	9 (9.7	0 (0.0)
I-Limb/Michaelangelo hand/Bebionic hand	0 (0.0)	40 (43.0)	0 (0.0)
Cosmetic	0 (0.0)	0 (0.0)	22 (100.0)
Unknown	0 (0.0)	23 (24.7)	0 (0.0)
DOF of primary terminal device			
No DOF (cosmetic)	0 (0.0)	0 (0.0)	22 (100.0)
Single DOF	334 (100.0)	30 (32.3)	0 (0.0)

(Continued)

Table 2. (Continued)

	Body-powered N = 334	Myoelectric/hybrid N = 93	Cosmetic N = 22
Multi-DOF	0 (0.0)	40 (43.0)	0 (0.0)
Unknown	0 (0.0)	23 (24.7)	0 (0.0)
Received training to use initial prosthesis			
Yes	254 (76.1)	75 (80.7)	11 (50.0)
No	77 (23.1)	18 (19.4)	10 (45.5)
Unknown	3 (0.9)	0 (0.0)	1 (4.9)
Received training to use current prosthesis			
Yes	216 (64.7)	75 (76.3)	7 (31.8)
No	113 (33.8)	21 (22.6)	15 (68.2)
Unknown	5 (1.5)	1 (1.1)	0 (0.0)
How many times was your prosthesis repaired in the past 12 months?			
0	138 (42.6)	37 (40.2)	12 (57.1)
1	85 (26.2)	14 (15.2)	6 (28.6)
2–3	68 (21.0)	22 (23.9)	3 (14.3)
⩾4	33 (10.2)	19 (20.7)	0 (0.0)
How many times did you visit a prosthetist for adjustment to your socket in the past 12 months?			
0	217 (66.4)	49 (53.3)	12 (60.0)
1	42 (12.8)	16 (17.4)	4 (20.0)
2–3	46 (14.1)	19 (20.7)	1 (5.0)
⩾4	22 (6.7)	8 (8.7)	3 (15.0)
Prosthetic users with two or more prostheses	**Body-powered N = 98**	**Myoelectric/hybrid N = 59**	**Cosmetic N = 8**
Secondary type of prosthesis used			
Body-powered	43 (41.0)	28 (53.9)	1 (12.5)
Myoelectric/hybrid	50 (47.6)	12 (23.1)	3 (37.5)
Cosmetic	1 (1.0)	1 (1.9)	3 (37.5)
Sports/recreation	8 (7.6)	9 (17.3)	1 (12.5)
Unknown	3 (2.9)	2 (3.9)	0 (0.0)
Frequency of secondary prosthesis use			
Daily	23 (21.9)	16 (30.8)	4 (50.0)
Weekly	45 (42.9)	22 (42.3)	1 (12.5)
Monthly	11 (10.5)	5 (9.6)	1 (12.5)
Every few months	12 (11.4)	3 (5.8)	0 (0.0)
1 to 2 times per year	14 (13.3)	4 (7.7)	2 (25.0)
Unknown	0 (0.0)	2 (3.9)	0 (0.0)

ETD: electronic terminal devices; DOF: degrees of freedom.

myoelectric users, 32.3% reported a single DOF terminal device, 43.0% a multi-DOF terminal device, and for 24.7% the terminal DOF was unknown.

Eighty-one percent of myoelectric users reported receiving initial prosthetic training and 76.3% received current device training. In contrast, 76.1% of body-powered users received initial training and 64.7% current training, while among cosmetic users 50.0% received initial training and 31.8% current training.

Myoelectric users were more likely to report two or more repairs in the past 12 months as compared to other device type users, and cosmetic users reported the fewest. There was no meaningful association between prosthesis type and visits for socket adjustments. Among respondents using two or more prostheses ($N = 165$), the most common secondary devices for body-powered users were myoelectric prostheses (48%), while the most common secondary devices for myoelectric users were body-powered prostheses (54%). Secondary devices of cosmetic users were distributed between myoelectric and additional cosmetic prostheses (37.5% each). There was no significant difference in prosthesis use intensity or frequency by primary prosthesis type, with 63.6%–78.3% reporting daily device use (Supplemental Appendix Table A.2).

Satisfaction outcomes

Results of bivariate analyses show that TAPES-SAT summary scores (Supplemental Appendix Table A.3) varied by prosthesis type (DF = 2, $F = 3.42$, $p = 0.03$) though post hoc analysis revealed no significant group differences. Ratings of color, noise, appearance, weight, reliability, and overall satisfaction items also varied by prosthesis type; body-powered users reported the highest satisfaction. Ratings were lowest among myoelectric users for items assessing weight, reliability, and overall satisfaction. Satisfaction ratings for color and noise were lowest among cosmetic users.

The OPUS-CSD summary scores did not differ by prosthesis type in bivariate analyses; however, there were differences in two items. Cosmetic users disagreed more with "my prosthesis looks good," while users of body-powered devices agreed most with "my prosthesis is durable." Body-powered users disagreed most with the original OPUS-CSD item, "my clothes are free of wear and tear." Cosmetic users disagreed most with "I am self-conscious about wearing my prosthesis," and with "I am satisfied with the way my primary prosthesis and terminal device moves." Myoelectric users agreed most with, "my primary prosthesis sometimes moves in a way that I do not intend it to."

Bivariate analyses identified the following variables as associated ($p < 0.20$) with either the TAPES-SAT or OPUS-CSD scores: amputation level, type of prosthesis, age, race, marital status, etiology of amputation (burn, cancer, and diabetes), amputation of lower limb, training with initial prosthesis, number of prosthesis repairs, number of visits to a prosthetist for socket adjustment, frequency of prosthesis use, and intensity of prosthetic use. Terminal device DOF was not associated with either the TAPES-SAT or OPUS-CSD scores in the full sample (Supplemental Appendix Table A.4) or in the subsample of myoelectric device users.

Multivariate GLMs of outcome measures (Table 3) show that, after controlling for other covariates, there were no differences in summary satisfaction scores for body-powered versus myoelectric device users. TAPES-SAT scores were lower (worse) for those with SH and TH level amputation compared to those with TR. TAPES-SAT scores were higher for older respondents and those who received training with their initial prosthesis. OPUS-CSD scores were higher (worse) for those with SH level amputation compared to those with TR level amputation, and for those who identified as black compared to white, and lower (better) for older versus younger respondents.

Discussion

We analyzed data from 449 unilateral upper limb prosthesis users to assess satisfaction by prosthesis type and identify factors associated with satisfaction. Our study used two primary measures of satisfaction, the TAPES-SAT and an adapted version of the OPUS-CSD. Results contribute new knowledge on prosthesis satisfaction as well as a new version of a prosthesis satisfaction measure for use with persons with upper limb amputation.

When controlling for multiple covariates in regression models, prosthesis type was not associated with device satisfaction as measured by TAPES-SAT or OPUS-CSD. Bivariate comparisons of individual satisfaction items across prosthesis types largely mirrored results of systematic reviews comparing body-powered and myoelectric devices.[27,28] Body-powered users were more satisfied with reliability, durability, and lower weight, but not with wear and tear on clothes. Myoelectric users were less satisfied with weight and unintended movement. Cosmetic users were least satisfied with device color and noise, but reported lower levels of self-consciousness.

We had expected to see greater satisfaction for persons using multi-DOF terminal device, a newer technology that promises greater functionality and which is more anthropomorphic. Over 43% of the 93 myoelectric users reported using a multi-DOF terminal device, a prevalence that is likely higher in the VA than in the civilian sector, given the high costs for these devices and the limitations on prosthetic coverage outside of the VA. Bivariate analyses found no differences in device satisfaction for myoelectric device users of multi-DOF versus single-DOF terminal devices, and thus we did not add terminal device DOF to the multivariate models. Further research is needed on consumer satisfaction with multi-DOF terminal devices.

We found that receipt of training to use the initial prosthesis, amputation level, age, and race were independently associated with device satisfaction. Current device training was not added to the multivariate models because it was not associated with device satisfaction in bivariate analyses. These findings point to the importance of providing initial training and its role in promoting device use, consistent with earlier reports on the association between device abandonment and prosthesis training.[13,14]

Differences observed in prosthesis satisfaction by amputation level are consistent with the literature reporting greater dissatisfaction and abandonment in persons with proximal amputations.[7,13,29] Persons with TR amputation had the lowest rate of rejection (6%), followed by TH (57%) and SD (60%).[2] These findings highlight the need for continued research to improve prosthetic options and care for persons with proximal amputations.

We also found that older persons were more satisfied with their prostheses, perhaps because, on average, they had been prosthesis users for the longest period of time and perhaps had come to value their devices. Finally, our models found that black respondents were less satisfied with their devices than were white respondents, a finding which needs further exploration to understand the root causes.

Table 3. Multivariate linear regression models predicting device satisfaction (*N* = 379).

	TAPES-SAT		OPUS-CSD[b]	
	N = 408		*N* = 384	
	Beta[a]	*p*	Beta[a]	*p*
Amputation level				
SH/FQ	–0.35	**0.0141**	8.63	**0.0265**
TH/ED	–0.25	**0.0006**	4.34	**0.0366**
TR/Wrist (ref)				
Type of prosthesis				
Body-powered (ref)				
Myoelectric/hybrid	–0.08	0.3368	1.19	0.5893
Age (years)	0.01	**0.0007**	–0.20	**0.0043**
Race				
White (ref)				
Black	–0.19	0.0730	5.84	**0.0434**
Other	–0.05	0.7267	–1.74	0.6762
Unknown	–0.09	0.4900	6.04	0.1262
Marital status				
Married or living together (ref)				
Divorced or separated	0.03	0.7057	1.80	0.4072
Widowed	0.04	0.7900	–4.30	0.3002
Never married	–0.17	0.2498	2.36	0.5507
Etiology				
Burn	0.10	0.3642	1.47	0.6127
Cancer	0.38	0.1164	–9.85	0.1331
Diabetes	0.58	0.1996	–3.81	0.7532
Amputation of lower limb				
Yes	0.13	0.1717	–5.02	0.0625
No (ref)				
Received training to use initial prosthesis				
Yes	0.27	**0.0005**	–3.03	0.1524
No (ref)				
How many times was your prosthesis repaired in the past 12 months?				
0 (ref)				
1	0.08	0.3220	–0.84	0.7221
2–3	0.10	0.2661	–2.17	0.3988
4 or more	–0.05	0.6884	–1.53	0.6401
How many times did you visit a prosthetist for adjustment to your socket in the past 12 months?				
0 (ref)				
1	0.00	0.9870	2.83	0.3096
2–3	0.01	0.9132	0.13	0.9636
4 or more	–0.16	0.2466	6.41	0.0863
Model R^2	0.15		0.12	

TAPES-SAT: Trinity Amputation and Prosthesis Experience Scales Satisfaction scale; OPUS-CSD: Orthotics and Prosthetics Users' Survey - Client Satisfaction with Devices scale.
[a]Unstandardized regression coefficient.
[b]Rasch scores of 8-item OPUS-CSD.
P-values below 0.05 are in bold font.

Limitations

The sample included Veterans who had received care at the VA between 2010 and 2015; nearly 62% was 65 years or older, with a minority under age 45 years, reflecting the age distribution of the US Veteran population. Thus, findings may not be generalizable to the larger Veteran population, to non-Veterans with upper limb amputations who have limited access to prosthetic care, or to younger persons with upper limb amputations. Although the study had a high response rate, there were few women and cosmetic devices users, limiting our ability to compare these prosthesis users. That said, this sample is one of the largest

reporting device satisfaction and provides strong evidence about device satisfaction in older individuals with good access to prosthetic care.

The sample included current prosthesis users, so it is likely that persons who were most dissatisfied with prostheses were excluded. Thus, conclusions are limited to prostheses users only.

Although we used two measures of prosthesis satisfaction, we acknowledge that they address limited facets of prosthesis use. Both measures focus on device attributes and neither addresses satisfaction with prosthesis function. Only one item in the TAPES-SAT addresses usefulness which may be related to function, while no items in the 8-item OPUS-CSD address function. Studies that use other satisfaction measures or that compare satisfaction with device function are needed.

Conclusion

We evaluated satisfaction with upper limb prostheses using data from a national survey of Veterans. Users of body-powered, myoelectric, and cosmetic prostheses were equally satisfied with their devices. We did not observe meaningful differences in overall device satisfaction between users of multi-DOF terminal devices and users of single-DOF terminal devices. Lower device satisfaction was observed among individuals with more proximal amputations (TH and SH), younger age, and black race. Receipt of initial prosthetic training was associated with greater device satisfaction, pointing to the critical role of occupational or physical therapy in the early stages of prosthetic care.

Author contributions

L.R. obtained funding, designed the study, led data analyses, and wrote the manuscript. M.B. assisted in study design, performed data analyses, and wrote portions of the manuscript. A.W.H. assisted in design of analyses of the OPUS-CSD data, participated in reviewing analytical results, and participated in manuscript writing. M.A.C. participated in study design, supervised data collection, and participated in data analyses and manuscript writing.

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Supplemental material

Supplemental material for this article is available online.

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Original Research—CME

A National Survey of Prosthesis Use in Veterans with Major Upper Limb Amputation: Comparisons by Gender

Linda J. Resnik, PT, PhD, FAPTA, Matthew L. Borgia, AM, Melissa A. Clark, PhD

Abstract

Background: A better understanding of women veterans with upper limb amputation is needed.
Objective: To compare prosthetic use and outcomes of female and male veterans with upper limb amputation.
Design: Cross-sectional survey: Amputation characteristics, prosthesis use, and quality of life outcomes were compared by gender. Separate logistic regression models examined association of gender with prosthesis use and receipt of training to use a prosthesis. Separate linear regression models examined the relationship between gender and health-related quality of life (HRQoL) outcomes.
Participants: Participants were veterans with major upper limb amputation who received care at the Department of Veterans Affairs (VA) in 2010-2015, identified from VA data sources. A total of 808 individuals (755 men, 21 women) were surveyed by telephone.
Main Outcome Measures: Disabilities of the Arm, Shoulder and Hand (QuickDASH), VR-12 Physical Component Summary (PCS) and VR-12 Mental Component Summary (MCS), Trinity Amputation and Prosthetic Experience Scale satisfaction scale, Orthotics and Prosthetic User's Survey client satisfaction with devices scale.
Setting: Telephone survey of community dwelling participants.
Interventions: Not applicable.
Results: Survey response rate was 47.3% for men and 62.8% for women. Women were less likely to have ever used a prosthesis (adjusted odds ratio [aOR] = 0.26; confidence interval [CI] 0.08-0.88), have received training for an initial prosthesis (aOR: 0.24; CI 0.08-0.70), be current users (aOR = 0.34; CI 0.12-1.01), and have received training for a current prosthesis (aOR: 0.15; 0.03-0.87). A greater proportion of women used cosmetic and a smaller proportion used body-powered devices compared to men ($P < .05$). Device heaviness or fatigue was the most common reason for abandonment. There were no significant differences in outcome measures by gender.
Conclusions: Women were less likely than men to have ever used and currently use prostheses or to have received prosthetic training, more likely to use cosmetic devices, and less likely to use body-powered devices. Efforts to develop prostheses that are cosmetically acceptable, yet lightweight and functional, are needed.

Introduction

The number of female veterans from the U.S. armed services is currently 9.4%, and it is projected to increase, given that 14.6% (approximately 200 000 persons) of the current active duty force are women.[1] Prior research suggests that female veterans have high rates of comorbid conditions and are more likely to be diagnosed with a mental health disorder as compared to male veterans.[2-4] Studies show that they are also more likely to have chronic pain and to develop chronic musculoskeletal pain, with rates of 19.4% vs 15.7% for men.[5] Increasingly, women in the military are being deployed in combat or in supportive roles in combat environments and thus are being exposed to greater risks, including the risk of traumatic limb loss.

Although the Department of Veterans Affairs (VA) recognizes the concerns of female veterans, including those with limb loss, female veterans with upper limb amputation have not been well studied.[2] Studies that have been conducted with veterans with upper limb amputation have included very small numbers of women .[6] Women were found to receive a greater number of prostheses than men and to reject devices at a higher rate than men.[6] A recent study that included women reported

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that prosthesis rejection or abandonment rates of veterans with upper limb amputation were 24%-30%, with rates even higher for those with transhumeral (TH) amputations or above.[7] Rejection or abandonment of prostheses is a well-documented problem in the civilian population as well, affecting approximately 20% of all upper limb amputees.[8]

Prior studies of civilians have shown mixed results with regard to prosthesis use and rejection by gender. Some studies reported higher abandonment rates among women,[9,10] whereas others reported no differences by gender.[11–13] Pezzin et al found that men were more likely than women to be satisfied with prosthesis fit, comfort, and appearance.[14] A systematic review concluded that gender was associated with prosthesis selection, with women using more anthropomorphic devices.[15]

It is difficult to focus services and interventions to best serve the needs of female veterans with amputation without having a better understanding of this population. Therefore, the overall purpose of this study was to compare prosthetic use and outcomes of female and male veterans with upper limb amputation. Specifically, we aimed to conduct comparisons by gender of (1) demographic and amputation-related characteristics; (2) patterns of prosthesis use, training and abandonment, and hours of prosthesis use; and (3) prosthetic satisfaction, health-related quality of life (HRQoL), and disability.

Methods

Recruitment

We identified individuals with major upper limb amputation who had been treated at the VA between 2010 and 2015 using VA Corporate Data Warehouse (CDW) sources (including Inpatient, Outpatient, Fee domains and Patient domains; the main source for information regarding Veterans Health Administration Benefit compensation and pension benefits paid to veterans and their beneficiaries; and Veteran's Benefits Administration [VBA] disability ratings). We defined major upper limb amputation using diagnosis codes for amputation at the forequarter, shoulder disarticulation, TH, elbow disarticulation, transradial (TR), or wrist disarticulation level. The CDW Patient domain was used to obtain contact information and death data. We included nondeceased veterans with valid addresses and phone numbers. These veterans were sent an initial recruitment package, including a stamped envelope to return in order to opt out. Up to 10 screening phone call attempts were made to contact those who did not opt out of participation or inform us that they did not meet eligibility criteria. Persons were excluded from the survey if they had a hearing or cognition impairment or if had a significant language barrier precluding participation. Data collection was conducted from June 2017 to May 2018.

Data Collection

Participants provided oral informed consent to participate in a comprehensive 45 minute telephone survey.[16] The survey was developed through cognitive (N = 10) and pilot testing (N = 10) to ensure that items were comprehensible and clear. We described the survey development process in a previous publication.[16] This manuscript reports on selected portions of the survey as described subsequently.

The survey's demographics section included items on gender, age, race/ethnicity, and employment. In cases where the gender item was not answered at the time of interview, we utilized the gender variable from VA CDW. The amputation section included items asking about the side and level of amputation; date, etiology, and surgical history related to the amputation; and prior hand dominance. For analysis, we collapsed the original categories of amputation level into the following three categories: SH (forequarter and shoulder disarticulation), TH (transhumeral and elbow disarticulation) and TR (transradial and wrist disarticulation). The prosthesis use section included items on current device use, types of device and terminal device used, suspension methods, frequency and hours of use, receipt of prosthetic training, as well as history of prior prosthesis use and abandonment.

The survey included two standardized measures of prosthetic satisfaction: the Trinity Amputation and Prosthetic Experience Scale (TAPES) satisfaction scale[17] and the Orthotics and Prosthetics User's Survey (OPUS) client satisfaction with devices (CSD) scale. The TAPES satisfaction scale consists of 10 items addressing color, shape, noise, appearance, weight, usefulness, reliability, fit, comfort, and overall satisfaction each rated on a 5-point scale (1 = very dissatisfied, 5 = very satisfied), with scores summed and averaged for a total score. The CSD consists of 11 items rated on a 4-point scale that address prosthesis weight, ease of donning, durability, fit, appearance, comfort, wear and tear from clothes, pain of wearing, skin abrasions, cost of maintenance, and cost of repair. The cost-related items are scored separately, and the other 9 items are used to calculate the final score, which is the sum of item scores (all items without missing values) crosswalked to the norm-based values shown in the OPUS Scoring Guide.[18] The survey also included investigator-generated items asking about desire to change devices, inability to wear the prosthesis because of poor socket fit, satisfaction with the way the prostheses and terminal device moves, and unintended movement of the prosthesis.

The survey included measures of HRQoL and disability. HRQoL was measured using the veteran version of the SF-12 Health Survey (VR-12). The VR-12 produces the Physical Component Summary (PCS) and the Mental Component Summary (MCS) scores.[19,20] Disability was measured using the 11-item Disabilities of the Arm, Shoulder and Hand

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(QuickDASH) score, which has been validated in upper limb amputees.[21] QuickDASH items assess difficulty performing activities, amount of limitation, or the extent of interference with activities as well as extent of arm, shoulder, and hand pain and tingling.[22,23] The survey also asked several investigator-generated items including whether or not respondents needed help from another person to perform daily activities, and if so, the number of hours of help required in a typical day. For additional details about the survey, see Resnik et al.[24]

Statistical Methods

We calculated response and cooperation rates (RR and CR) separately for women and men using the American Association for Public Opinion Research (AAPOR) guidelines.[25] We used AAPOR RR4 and CR4 where partial interviews are considered as completers. We examined statistics by gender to characterize respondents, their patterns of prosthesis use and abandonment, the prostheses and componentry used, and the receipt of prosthetic training. We conducted bivariate analyses to understand differences by gender in select characteristics including prosthesis use, type and number of prostheses/terminal devices used, device abandonment, and reasons for abandonment. We compared prevalence of phantom limb, residual limb, neck and low back pain, and sound-side musculoskeletal conditions including carpal tunnel syndrome, tendonitis of the wrist, tendonitis of the elbow, tendonitis of the finger, tendonitis of the thumb, ganglion cyst, rotator cuff tendinitis, osteoarthritis, nerve damage, or other problem by gender. We also compared hours of prosthetic use by gender. Fisher's exact and Wilcoxon Mann-Whitney tests were used as appropriate. We performed multiple comparison tests using the COMPROP macro, a Tukey-type method[26] in SAS to examine differences between subgroups. We also conducted bivariate comparisons of scores for QuickDASH, VR-12 PCS and MCS scores, prosthetic satisfaction (TAPES, CSD), and investigator-generated satisfaction items by gender using nonparametric Wilcoxon Mann-Whitney tests.

Given that women had more recent amputation and that standards of prosthetic rehabilitation have changed over time,[27,28] we computed separate logistic regression models to assess the relationship between gender and (1) ever having used a prosthesis, (2) receipt of training to use initial prosthesis, (3) current prosthesis use (among those who had ever used a prosthesis), and (4) receipt of training to use the current prosthesis. These models controlled for key confounders hypothesized to be related to

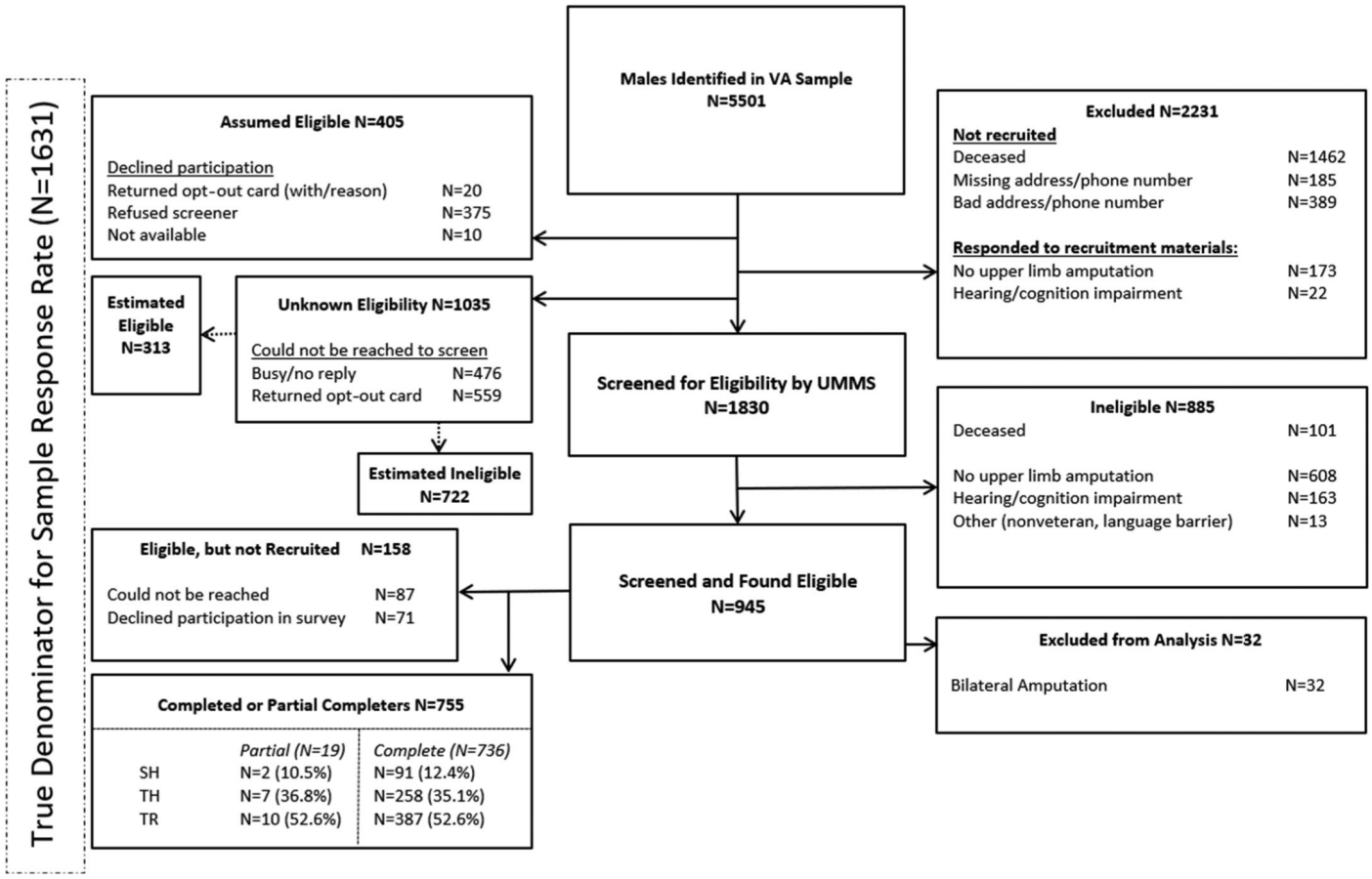

Figure 1. Male flow diagram.

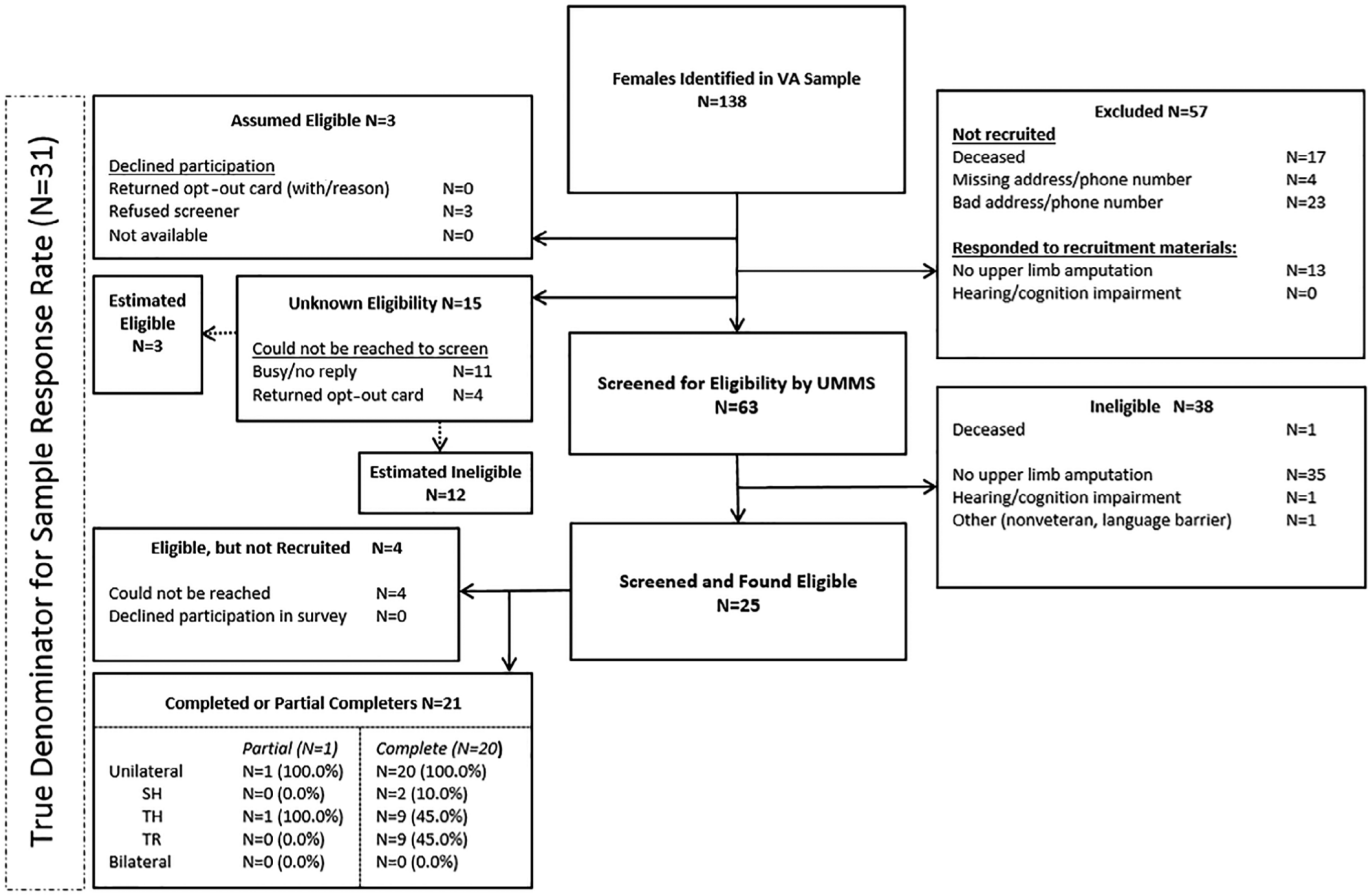

Figure 2. Female flow diagram.

prosthesis use and training, based on prior research including year of amputation (prior to 2000, 2001-2009, 2010-2016), age (in years), amputation level, and prosthesis type. The model for training to use current prosthesis also included a variable indicating whether there had been a change in prosthesis type from the initial prosthesis received to the type currently reported. Using linear regression models, we examined the relationship of gender with QuickDASH, VR-12 PCS and VR-12 MCS scores, while controlling for age, years as amputee, amputation level, and current prosthesis type. Unknown data were treated as missing for prosthesis use, training, and years of amputation in all regression analyses. For linear models, we examined homogeneity, independence, and distribution of the residuals. Residual plots supported homoscedasticity, moment specification tests did not reject the assumption of identical and independent error terms, and Durbin-Watson's statistics were 2.051, 1.991, and 2.006. Examination of Q-Q plots supported normality of residuals.

Results

Sampling Frame and Response Rate

Our initial sampling frame (based on upper limb amputation codes) consisted of 5501 men and 138 women. We excluded 2080 persons (2036 men and 44 women), 1479 (1462 men and 17 women) who were listed as deceased, and 601 (564 men and 27 women) who were missing valid contact information. Recruitment materials with opt-out cards were sent to the remaining 3522 men and 94 women. One hundred ninety-five men and 13 women returned opt-out cards stating that they did not meet study eligibility criteria, and 405 men and three women declined participation. 1035 men and 15 women could not be reached for screening. The 1893 veterans who were reached by phone (63 women and 1830 men) were screened for eligibility. Of these, 923 (885 men and 38 women) were determined to be ineligible.

In total, 945 men and 25 women were found eligible. Seven hundred eighty-seven (83%) of the men eligible after screening were recruited into the study, and 21 (84%) of the women were recruited. Seven hundred eighty-eight individuals completed the survey in its entirety, and 20 completed at least part of the survey. Because there were no female respondents with bilateral amputation, we further excluded men with bilateral amputation from the analytic sample to enhance validity of our comparisons. The final RR and CR for the men were 46.5% and 61.8%, respectively.[25] Among women, the RR was 66.8% and the CR was 87.5%. Figures 1 and 2 show the flow diagrams of participants by gender. The final

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Table 1
Demographics characteristics by gender

	Men N = 755 Mean (SD)	Women N = 21 Mean (SD)	All N = 776 Mean (SD)
Age (Years)	63.5 (14.1)	54.5 (9.6)	63.2 (14.1)
Missing (n)	23	1	24
Years since initial amputation	31.7 (18.4)	18.1 (12.1)	31.3 (18.4)
Missing (n)	21	0	21
	N (%)	**N (%)**	**N (%)**
Year of initial amputation			
1940-1979	344 (45.6)	0 (0.0)	344 (44.3)
1980-2000	155 (20.5)	10 (47.6)	165 (21.3)
2001-2009	131 (17.4)	4 (19.1)	135 (17.4)
2010-2016	104 (13.8)	7 (33.3)	111 (14.3)
Unknown	21 (2.8)	0 (0.0)	21 (2.7)
Race			
White	571 (75.6)	12 (57.1)	583 (75.1)
Black	82 (10.9)	4 (19.1)	86 (11.1)
Other (including mixed race)	34 (4.5)	1 (4.8)	35 (4.5)
Unknown	68 (9.0)	4 (19.1)	72 (9.3)
Hispanic or Latino/Latina			
Yes	61 (8.1)	1 (4.8)	62 (8.0)
No	659 (87.3)	19 (90.5)	678 (87.4)
Unknown	35 (4.6)	1 (4.8)	36 (4.6)
Employment			
Employed full time	69 (9.1)	4 (19.1)	73 (9.4)
Employed part time	31 (4.1)	0 (0.0)	31 (4.0)
Student	20 (2.7)	0 (0.0)	20 (2.6)
Retired, but employed after amputation	369 (49.9)	4 (19.1)	373 (48.1)
Retired, but not employed after amputation	146 (19.3)	6 (28.6)	152 (19.6)
On medical leave	8 (1.1)	1 (4.8)	9 (1.2)
Other	88 (11.7)	5 (23.8)	93 (12.0)
Unknown	24 (3.2)	1 (0.0)	24 (3.2)
Amputation level			
Forequarter	23 (3.1)	0 (0.0)	23 (3.0)
At the shoulder joint	69 (9.1)	2 (9.5)	71 (9.2)
Above the elbow	226 (29.9)	10 (47.6)	236 (30.4)
At the elbow	40 (5.3)	0 (0.0)	40 (5.2)
Below the elbow	272 (36.0)	8 (38.1)	280 (36.1)
At the wrist joint	125 (16.6)	1 (4.8)	126 (16.2)
Etiology of amputation*			
Combat injury	272 (36.1)	3 (14.3)	275 (35.5)
Accident	476 (63.1)	14 (66.7)	490 (63.1)
Burn	79 (10.5)	2 (9.5)	81 (10.5)
Cancer	30 (4.0)	0 (0.0)	30 (3.9)
Diabetes	10 (1.3)	1 (4.8)	11 (1.4)
Infection	85 (11.3)	4 (19.1)	89 (11.5)
Amputation of lower limb			
Yes	93 (12.3)	1 (4.8)	94 (12.1)
No	662 (87.7)	20 (95.2)	682 (87.9)
Those with amputation of lower limb	**N = 93**	**N = 1**	**N = 94**
Amputation of lower limb			
Right side	38 (40.9)	1 (100.0)	39 (41.5)
Left side	23 (24.7)	0 (0.0)	23 (24.5)
Both sides	32 (34.4)	0 (0.0)	32 (34.0)

*May indicate more than one etiology.

disposition codes for the sample are available upon request to the author.

Sample Characteristics

The analytic sample consisted of 776 persons with unilateral amputation. Demographic and detailed amputation characteristics are shown in Table 1. Briefly, 57.1% of women identified as white and 4.8% as Hispanic or Latina. Seventy-six percent of men were white, and 8.1% Hispanic or Latino. Average age was 54.5 years ([standard deviation] SD 9.6) for women and 63.5 years (SD 14.1) for men. Women had been amputees for an average of 18.1 (SD 12.1) years, and men an average of 31.7 (SD 18.4) years.

Table 2
Type of prostheses, suspension methods, terminal devices, and prosthetic training: comparison of female and male unilateral upper limb amputees

	Men N = 755 N (%)	Women N = 21 N (%)
Ever used a prosthesis		
Yes	700 (92.7)	17 (81.0)
No	48 (6.4)	4 (19.1)
Unknown	7 (0.9)	0 (0.0)
Prothesis users (ever)	Men N = 700	Women N = 17
Initial type of prosthesis used		
Body powered	554 (79.1)	11 (64.7)
Myoelectric/Hybrid	102 (14.6)	5 (29.4)
Cosmetic	19 (2.7)	1 (5.9)
Sports/Recreation/Unknown	25 (3.6)	0 (00)
Received training to use first prosthesis		
Yes	535 (76.4)	10 (58.8)
No	158 (22.6)	7 (41.1)
Unknown	7 (1.0)	0 (0.0)
Currently use a prosthesis		
Yes	453 (64.7)	8 (47.1)
No	245 (35.0)	9 (52.9)
Unknown	2 (0.3)	0 (0.0)
Current prosthesis users	Men N = 453	Women N = 8
Received training to use current prosthesis		
Yes	298 (65.8)	3 (37.5)
No	148 (32.7)	5 (62.5)
Unknown	7 (1.6)	0 (0.0)
Prosthesis users: most recent prosthesis received		
<2 y ago	193 (42.6)	6 (75.0)
2 + y ago	259 (57.2)	1 (12.5)
Unknown	1 (0.2)	1 (12.5)
Number of prostheses used		
One	290 (64.0)	1 (12.5)
Two or more	163 (36.0)	7 (87.5)
Number of terminal devices used		
One	256 (56.5)	3 (37.5)
Two or more	190 (42.9)	5 (62.5)
Unknown	7 (1.6)	0 (0.0)
Primary type of prosthesis used		
Body powered	323 (71.3)	3 (37.5)
Myoelectric/Hybrid	100 (22.1)	2 (25.0)
Cosmetic	19 (4.2)	3 (37.5)
Sports/Recreation/Unknown	11 (2.4)	0 (0.0)
Initial to current prosthesis type		
Same	339 (74.8)	3 (37.5)
Changed	105 (23.2)	5 (62.5)
Unknown	9 (2.0)	0 (0.0)
Suspension type for primary prosthesis		
Suction	152 (33.6)	4 (50.0)
Gel or silicone liner with pin	85 (18.8)	6 (75.0)
Vacuum	50 (11.0)	1 (12.5)
Self-suspending because of the socket shape	168 (37.1)	4 (50.0)
Harnessing	341 (75.3)	4 (50.0)
External suspension	61 (13.5)	1 (12.5)
Unsure	3 (0.4)	0 (0.0)
Primary type of terminal device used		
Voluntary opening/closing hook	276 (60.9)	5 (62.5)
Greiffer	6 (1.3)	0 (0.0)
Power hook (Electric Terminal Device)	17 (3.8)	0 (0.0)
Sensor speed hand	11 (2.4)	0 (0.0)
I-Limb/Michelangelo hand/Bebionic hand	46 (10.2)	3 (37.5)
Unknown	97 (21.4)	0 (0.0)

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Table 2.
Continued

	Men N = 755 N (%)	Women N = 21 N (%)
Prosthetic users with two or more prostheses	Men N = 163	Women N = 7
Secondary type of prosthesis used		
Body powered	72 (44.2)	2 (28.6)
Myoelectric/Hybrid	64 (39.5)	2 (28.6)
Cosmetic	5 (3.1)	0 (0.0)
Sports/Recreation/Unknown	21 (10.5)	3 (42.9)

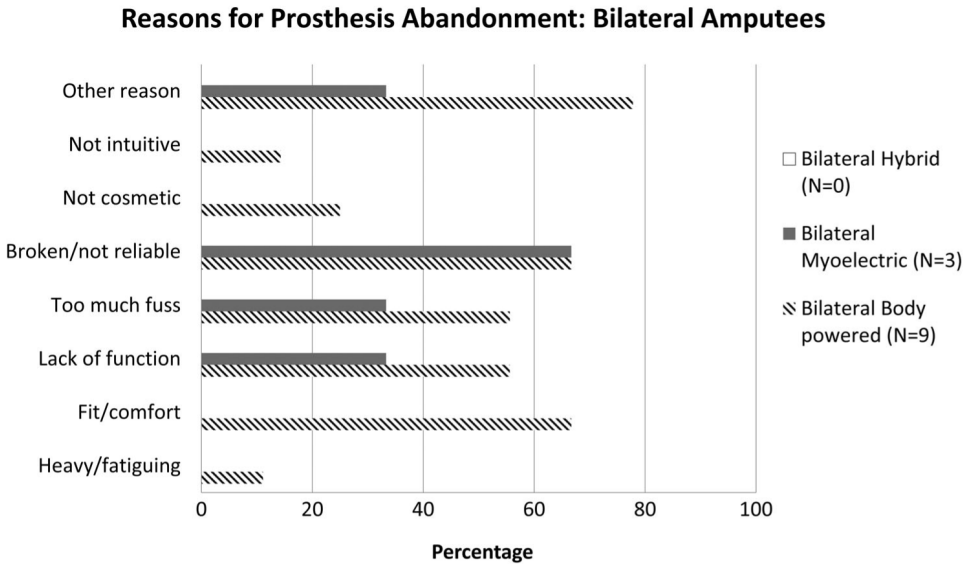

Figure 3. Reasons for abandonment over all device types.

Nineteen percent of women and 13% of men were working full or part time, and 48% and 69% (respectively) were retired. Amputation level for women and men, respectively, was 9.5% and 12.2% shoulder/forequarter, 47.6% and 35.2% transhumeral/at the elbow, and 42.9% and 52% transradial/at the wrist joint. The two most common etiologies of amputation (respondents indicated all etiologies that applied) were accident (66.7% of women, 63.1% of men) and infection for women (19.1%) and combat injury for men (36.1%).

Prosthesis Use, Abandonment, and Training

There was a greater proportion of women (19.1%) compared to men (6.4%) who had never used a prosthesis ($P = .08$) (Table 2). Current prosthesis use was reported in 47.1% and 64.7% of female and male respondents, respectively. A larger proportion of women used two or more prostheses as compared to men; 87.5% versus 36.0%, ($P = .005$). Among those who used a prosthesis, 75% of women and 42.6% of men received their most recent prosthesis within the prior 2 years ($P = .002$).

Myoelectric/hybrid devices were used by about the same proportion of women and men. However, compared to men, women were less likely to use body-powered devices (37.5% vs 71.3%) and more likely to use cosmetic devices (37.5% vs 4.2%). Comparison of all primary prosthesis types by gender was significant at $P = .006$. Post-hoc comparisons found significant differences between only body-powered and cosmetic device use. Descriptively, differences were also noted in prosthetic suspension types used. The most common suspension for women was gel or silicone liner (75.0%), whereas harnessing was the most commonly used type of suspension for men (75.3%). The most commonly used terminal device was a hook (women 62.5%, men 60.9%). However, a greater proportion of women used a multifunctional terminal device than men (37.5% vs 10.2%).

A smaller proportion of women had received training to utilize their first prosthesis (58.8% vs 76.4%) although this difference was not statistically significant in bivariate analyses. Similarly, 37.5% of women and 65.8% of men had received training to use their current prosthesis.

Table 3 shows that a greater proportion of women had abandoned a prosthesis (76.5% women vs 52.3% men;

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Table 3
Prosthesis abandonment by gender

	Men N = 700	Women N = 17
Have you ever stopped using a prosthesis?		
Yes	366 (52.3)	13 (76.5)
No	324 (46.3)	3 (17.7)
Unknown	10 (1.4)	1 (5.9)
Those who stopped using a prosthesis	Men N = 366	Women N = 13
Were any of the prostheses that you stopped using?		
Body powered	268 (73.2)	8 (61.5)
Myoelectric	129 (35.3)	6 (46.2)
Hybrid	26 (7.1)	0 (0.0)
Other	20 (5.5)	1 (7.7)
If ever stopped using body-powered device:	Men N = 268	Women N = 8
Major reasons for stopping device use were		
It was too heavy or fatiguing to wear	141 (52.6)	4 (50.0)
It did not fit or was uncomfortable	197 (73.5)	7 (87.5)
It was not functional enough	172 (64.2)	5 (62.5)
It was too much fuss	154 (57.5)	6 (75.0)
It broke or was unreliable	81 (30.2)	2 (25.0)
It was not cosmetic	54 (20.2)	1 (12.5)
It was not intuitive to use	111 (41.4)	3 (37.5)
Some other reason	161 (60.1)	8 (100.0)
If ever stopped using myoelectric device	Men N = 129	Women N = 6
Major reasons for stopping device use were		
It was too heavy or fatiguing to wear	79 (61.2)	5 (83.3)
It did not fit or was uncomfortable	90 (69.8)	4 (66.7)
It was not functional enough	89 (69.0)	5 (83.3)
It was too much fuss	86 (66.7)	4 (66.7)
It broke or was unreliable	64 (49.6)	3 (50.0)
It was not cosmetic	23 (17.8)	1 (16.7)
It was not intuitive to use	46 (35.7)	2 (33.3)
Some other reason	77 (59.7)	3 (50.0)
If ever stopped using hybrid device	Men N = 26	Women N = 0
Major reasons for stopping device use were:		
It was too heavy or fatiguing to wear	18 (69.2)	0 (0.0)
It did not fit or was uncomfortable	19 (73.1)	0 (0.0)
It was not functional enough	20 (76.9)	0 (0.0)
It was too much fuss	19 (73.1)	0 (0.0)
It broke or was unreliable	10 (38.5)	0 (0.0)
It was not cosmetic	4 (15.4)	0 (0.0)
It was not intuitive to use	12 (46.2)	0 (0.0)
Some other reason	14 (53.9)	0 (0.0)

P = .02), and the majority of devices abandoned were body powered. The most common reason for abandonment of body-powered devices was that it did not fit or was uncomfortable (87.5% women, 73.5% men); the most common reason for abandoning a myoelectric device was heaviness or fatigue (83.3%) for women and poor fit/comfort (69.8%) for men.

The reasons reported for abandoning any type of device are shown in Figure 3. The most common overall reason was uncomfortable fit for men; uncomfortable fit and "other" reasons were most common among women. For both men and women, the least common reason was that the device was not cosmetic.

In the logistic regression models, adjusting for potential confounders (Table 4), women had lower odds of ever having used a prosthesis (adjusted odds ratio [aOR]: 0.26; 95% confidence interval [CI]: 0.08-0.88), to have received training for an initial prosthesis (aOR: 0.24; 95% CI: 0.08-0.70), to be current prosthesis users (aOR: 0.34; 95% CI: 0.12-1.01), and to have received training for their current prosthesis (aOR: 0.15; 95% CI: 0.03-0.87). In crude models (unadjusted for confounders), odds ratios (ORs) and 95% CIs for these outcomes were 0.29 (0.09-0.88), 0.41 (0.15-1.09), 0.48 (0.18-1.26), and 0.29 (0.07-1.24), respectively.

Older amputees (OR: 0.98; 95% CI: 0.95-1.00), more recent amputees, and those with TH (OR: 0.18; 95% CI: 0.08-0.41) and SH (OR: 0.13; 95% CI: 0.05-0.32) amputation had lower odds of ever having used a prosthesis (Table 4, column 2). The odds of ever using a prosthesis were also lower for those with amputations in 2001-2009 (OR: 0.35; 95% CI: 0.16-0.77) and 2010-2016 (OR: 0.27; 95% CI: 0.12-0.61) compared to those with amputations before 2000. Older age (OR: 0.97; 95% CI:0.95-0.99) and initial prosthesis use with cosmetic (rather than body-powered) devices (OR: 0.31; 95% CI: 0.11-0.86) were significantly associated with lower odds of training with the initial prosthesis among those who had ever used a prosthesis (Table 4, column 3). Compared to persons with TR amputation, persons with TH and SH amputation had 0.22 (95% CI: 0.16-0.32) and 0.14 (95% CI: 0.08-0.24) times the odds of currently using a prosthesis, respectively (Table 4, column 4). Among those currently using a prosthesis, cosmetic users (OR: 0.20; 95% CI: 0.07-0.60) had lower odds of having received training on that device than body-powered users did. Older age (OR = 0.97; 95% CI: 0.95-1.00) was also associated with lower odds of training on the current device (Table 4, column 5).

Bivariate outcome comparisons by gender are shown in Table 5. There were no statistically significant differences in disability (QuickDASH) or physical HRQoL (PCS) scores by gender. However, women had lower MCS scores (mean 43.9, SD 13.6) compared to men (mean 49.7, SD 13.4). There were no differences in the percent of participants with any pain, or with musculoskeletal conditions by gender. TAPES and CSD item or summary scores also did not differ by gender (item scores not shown) among prosthesis users. Women rated satisfaction with prosthesis/terminal device movement more favorably compared to men (*P* = .01). There were no differences in hours of prosthesis use by gender.

Linear regression models of QuickDASH (R^2 = 0.07), VR-12 PCS (R^2 = 0.05), and VR-12 MCS (R^2 = 0.06) scores

Table 4
Results of separate logistic regressions estimating the impact of year of amputation and gender on prosthesis use and training

	Ever used a prosthesis (N = 732)		Training to use initial prosthesis (N = 676)		Currently use a prosthesis (N = 681)		Training to use current prosthesis (N = 434)	
	OR	95% CI	OR	95% CI	OR	95% CI	OR	95% CI
Gender								
Male (ref)								
Female	**0.26**	**0.08-0.88**	**0.24**	**0.08-0.70**	0.34	0.12-1.01	**0.15**	**0.03-0.87**
Age (Years)	**0.98**	**0.95-1.00**	**0.97**	**0.95-0.99**	0.99	0.97-1.00	**0.97**	**0.95-1.00**
Year of amputation								
1940-2000 (ref)								
2001-2009	**0.35**	**0.16-0.77**	0.61	0.33-1.13	0.74	0.43-1.24	0.68	0.33-1.41
2010-2016	**0.27**	**0.12-0.61**	0.75	0.39-1.44	0.72	0.40-1.27	1.07	0.47-2.44
Amputation level								
Transradial (ref)								
Transhumeral	**0.18**	**0.08-0.41**	1.10	0.71-1.70	**0.22**	**0.16-0.32**	1.17	0.72-1.90
Shoulder/forequarter	**0.13**	**0.05-0.32**	0.87	0.47-1.63	**0.14**	**0.08-0.24**	1.09	0.43-2.72
Initial prosthesis								
Body-powered (ref)								
Myo-hybrid			3.05	1.38-6.75				
Cosmetic			**0.31**	**0.11-0.86**				
Other/Unknown			3.22	0.66-15.75				
Primary prosthesis current								
Body-powered (ref)								
Myo-hybrid							1.22	0.60-2.49
Cosmetic							**0.20**	**0.07-0.60**
Other/Unknown							**0.16**	**0.03-0.94**
Initial to current prosthesis type								
Same (ref)								
Changed							1.37	0.67-2.81
Unknown							9.33	0.65-134.7
Model Fit								

Bold font in odds ratio (OR) and confidence interval (CI) indicates statistically significant values at $P < .05$.

(Table 6) showed no significant association with gender. QuickDASH disability scores were on average 0.20 points (95% CI: −0.32, −0.08) lower (better) for each additional year of being an amputee, 9.5 points (95% CI: 0.20, 18.71) higher for users of cosmetic prostheses and 8.8 points higher for nonusers (95% CI: 5.09, 12.51) compared to users of body-powered prostheses (Table 6, column 2). VR-12 PCS scores were 0.13 points (95% CI: −0.19, −0.06) lower (worse) on average for each additional year of age, 0.06 points (95% CI: 0.01, 0.11) higher with each additional year as an amputee, and 2.8 points (95% CI: −4.40, −1.32) lower (worse) for nonusers compared to users of body-powered prostheses (Table 6, column 3). VR-12 MCS scores were also 0.14 points (95% CI: 0.06, 0.09) higher (better) for those for each additional year as an amputee; amputation level was not significantly associated with any of the outcome measures.

Discussion

We conducted the first of its kind, national study of veterans with upper limb amputation and compared prosthesis use and abandonment, receipt of training, and important outcomes by gender. We found that women were less likely to have ever used a prosthesis compared to men. These findings are consistent with earlier reports that women with upper limb amputation were more likely to reject devices outright and never use them.[10,29] Women in prior studies have expressed preferences for, and challenges in obtaining, appropriately gendered prostheses that are smaller sized and look more feminine.[30–32]

We also found that time since amputation was independently associated with ever having used a prosthesis, with the likelihood of ever having used a prosthesis increasing with time. This suggests that with greater opportunities for exposure through more years as an amputee, veterans are more likely to try a prosthesis.

Multivariable models did not show a statistically significant association between gender and current prosthesis use after controlling for age, year of amputation, and amputation level. Although men reported prosthesis use at a higher rate (65%) compared to women (47%), these differences were explained by covariates. It is possible that further studies with larger samples could establish whether a small, but significant difference in prosthesis use by gender does exist.

We found that male and female veterans who used prostheses were similarly satisfied with them according to TAPES and OPUS CSD scores. However, women used

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Table 5
Prosthesis satisfaction, disability, and quality of life: comparison of female and male upper limb amputees

	Men N = 755		Women N = 21		
Full sample	N	Mn (SD)	N	Mn (SD)	WMW *P*
QuickDASH	724	36.8 (27.1)	19	40.2 (19.1)	.24
VR-12 PCS	708	45.1 (8.6)	19	43.8 (10.5)	.44
VR-12 MCS	708	49.7 (13.4)	19	43.9 (13.6)	**.05**
	N	**N (%)**	**N**	**N (%)**	**Fisher's Exact *P***
Phantom limb pain (yes/no)	740	534 (72.2)	20	17 (85.0)	.31
Residual limb pain (yes/no)	740	441 (59.6)	20	16 (80.0)	.10
Neck pain (yes/no)	740	538 (73.1)	20	17 (85.0)	.31
Low back pain (yes/no)	740	418 (64.8)	20	14 (77.8)	.32
Musculoskeletal conditions of sound side	**N**	**N (%)**	**N**	**N (%)**	**Fisher's Exact *P***
Carpal tunnel	746	173 (23.2)	21	5 (23.8)	>.99
Tendonitis wrist	746	122 (16.4)	21	1 (4.8)	.23
Tendonitis elbow	746	144 (19.3)	21	2 (9.5)	.40
Tendonitis finger	742	88 (11.9)	21	0 (0.0)	.16
Tendonitis thumb	741	78 (10.5)	21	0 (0.0)	.15
Ganglion cyst	731	39 (5.3)	21	1 (4.8)	>.99
Rotator cuff tendinitis	743	199 (26.8)	21	3 (14.3)	.31
Osteoarthritis	741	163 (22.0)	21	5 (25.0)	.78
Nerve damage	747	170 (22.8)	21	5 (23.8)	>.99
Other problem	747	182 (24.4)	21	5 (23.8)	>.99
Prosthetic Users	**Men N = 453**		**Women N = 8**		
	N	**Mn (SD)**	**N**	**Mn (SD)**	**WMW *P***
TAPES	446	4.0 (0.9)	7	4.3 (0.5)	.35
OPUS CSD	342	25.0 (5.1)	5	26.0 (7.6)	.98
Additional satisfaction-related items					
My terminal device is appropriately sized for me	311	1.8 (0.6)	7	1.7 (1.0)	.62
Overall, my prosthetic device is appropriately sized	311	1.8 (0.6)	7	1.7 (1.1)	.34
I am self-conscious about wearing my prosthesis	440	2.9 (0.9)	7	2.4 (1.0)	.15
Desire to change devices	422	2.7 (0.9)	7	2.3 (1.0)	.29
Inability to wear the prosthesis due to fit	433	3.1 (0.8)	7	3.1 (0.9)	.92
Satisfaction with prosthesis/terminal device movement	436	1.8 (0.8)	7	2.4 (0.8)	**.01**
Unintended movement	434	2.5 (0.9)	6	2.2 (0.4)	.27
Prosthetic Users	**Men N = 453**		**Women N = 8**		
	N (%)		**N (%)**		**Fisher's Exact *P***
Hours of prosthesis use/d					.69
Less than 2 h	86 (19.0)		2 (25.0)		
2 to less than 4 h	41 (9.1)		1 (12.5)		
4 to less than 8 h	83 (18.3)		2 (25.0)		
8 to less than 12 h	86 (19.0)		2 (25.0)		
12 h or more a day	151 (33.3)		1 (12.5)		
Unknown	6 (1.3)		0 (0.0)		
Hours of prosthesis use/d					.48
Less than 8 h	210 (47.0)		5 (62.5)		
8 or more a day	237 (53.0)		3 (37.6)		

CSD = client satisfaction with devices; MCS = Mental Component Summary; Mn = Mean; PCS = Physical Component; SD = standard deviation Summary; QuickDASH = Disabilities of the Arm, Shoulder and Hand; WMW = Wilcoxon Mann-Whitney test.

more and different types of devices as compared to men. Among prosthesis users, 88% of women used two or more protheses whereas 36% of men used two or more. Women used cosmetic devices as their primary prosthesis more often than did men and used body powered prostheses less often. Further more, a higher proportion of women used multifunctional terminal devices; in fact, all women who were using myoelectric devices also had multifunctional terminal devices. These findings suggest that women may be more sensitive to prosthesis appearance, preferring more natural-looking and anthropomorphic devices, findings that have been widely reported by prior researchers.[29,30] Our findings suggest that women may prefer the option of switching between several types of devices, depending upon need and lifestyle, a finding supported by our earlier work.[32] The higher prevalence of use of anthropomorphic terminal devices among women suggests a desire to have a less conspicuous, more natural-looking device.[33]

The most common reasons for prosthesis abandonment for women were poor fit/discomfort, other reasons, and heaviness or fatigue. We examined the text descriptions of "other reasons" for abandonment but found no clear patterns. A greater proportion of women as compared to

Table 6
Linear regression of outcome measures

	QuickDASH (N = 669)		VR-12 PCS (N = 662)		VR-12 MCS (N = 662)	
	β (95% CI)	*P*	β (95% CI)	*P*	β (95%CI)	*P*
Gender						
Male (ref)						
Female	3.69 (−6.55, 13.93)	.479	0.02 (−4.35, 4.39)	.993	−6.08 (−12.92, 0.76)	.081
Age (Years)	0.09 (−0.06, 0.25)	.238	−0.13 (−0.19, −0.06)	**<.001**	−0.02 (−0.12, 0.09)	.755
Years as amputee	−0.20 (−0.32, −0.08)	**.001**	0.06 (0.01, 0.11)	**.018**	0.14 (0.06, 0.09)	**<.001**
Amputation level						
Transradial (ref)						
Transhumeral	2.25 (−1.29, 5.80)	.213	0.57 (−0.90, 2.04)	.445	0.02 (−2.28, 2.33)	.984
Shoulder/forequarter	5.19 (−0.10, 10.48)	.054	−0.56 (−2.77, 1.65)	.619	1.11 (−2.34, 4.57)	.527
Current prosthesis type						
Body-powered (ref)						
Myo-hybrid	−0.17 (−5.00, 4.67)	.946	0.66 (−1.36, 2.68)	.522	1.31 (−1.86, 4.47)	.417
Cosmetic	9.45 (0.20, 18.71)	**.045**	1.08 (−2.85, 5.01)	.591	−4.41 (−10.55, 1.74)	.160
Other/Unknown	9.09 (−3.93, 22.11)	.171	3.55 (−1.84, 8.93)	.196	0.73 (−7.70, 9.15)	.866
Nonuser	8.80 (5.09, 12.51)	**<.001**	−2.86 (−4.40, −1.32)	**.003**	−1.29 (−3.70, 1.12)	.293

MCS = Mental Component Summary; PCS = Physical Component Summary; QuickDASH = Disabilities of the Arm, Shoulder and Hand.

men had abandoned a body-powered device, which is consistent with prior reports.[9,10]

Although the role of prosthesis training in abandonment is not clear, it is generally believed that training will lead to better functional outcomes.[11] Although there are no specific guidelines regarding training with a cosmetic prosthesis, the VA/Department of Defense guidelines on upper limb amputation rehabilitation state the importance of early prosthetic training.[28] Many aspects of training, including care of prosthesis, acclimating to wear time, and inspection of the residual limb are certainly applicable regardless of type of device used. We found that women had lower odds than men of having received training for their initial and current prostheses, even after controlling for device type. Taken together, our findings suggest differences in access to prosthesis training or in attitudes toward training either by women or their healthcare providers. Further research is needed to understand why women with upper limb amputation are less likely to receive prosthetic training than men.

Our finding in bivariate analyses that women had lower mental quality of life (MCS) scores as compared to men is consistent with the literature that reports that female veterans are more likely than male veterans to be diagnosed with a mental health condition.[2] However, the relationship between gender and MCS scores was not statistically significant after controlling for age, years as an amputee, amputation level, and prosthesis type/use. Given the consistent association between gender and MCS scores seen in both the bivariate and linear regression analyses, we expect that this relationship would be significant if examined in a larger sample. Behavioral health interventions are an important aspect of amputee rehabilitation.[28]

Our findings are generalizable to male and female veterans with upper limb amputation who receive care at the VA, but there are limits to generalizability outside of this sample. We compared the respondents to eligible individuals who did not respond to the survey and found that on average, respondents were 1.8 y younger, more often female, and had a more recent year of service utilization at the VA.[16] We do not know whether male and female veterans are equally likely to come to the VA for care. If women are less likely to come to the VA for care, then our findings may underrepresent female veterans with upper limb amputation. Furthermore, given that only about 40% of female veterans are currently using services in the Department of Veterans Affairs (VHA),[34] the findings from this study are useful for care providers both within and outside of the VHA. Our survey asked respondents about prosthetic training received and we cannot make any inferences about whether prosthetic training was recommended. Our findings should be interpreted cautiously due to wide confidence intervals around point estimates.

Conclusion

This national study of veterans with upper limb amputation found that women were less likely than men to use or have ever used prostheses or to have received prosthetic training. Women were more likely than men to use cosmetic devices and multifunctional terminal devices and less likely to use body-powered devices. Device heaviness or fatigue was the most common reason for women to have abandoned a prosthesis. Efforts to develop prostheses that are cosmetically acceptable, yet lightweight and functional are needed.

Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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Disclosure

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CME Question

In this article, women veterans with upper limb amputation were more likely to use

a. Gel liner for suspension
b. Harness for suspension
c. Terminal hook
d. Terminal hand

Answer online at https://onlinelearning.aapmr.org/

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The Prevalence and Impact of Back and Neck Pain in Veterans With Upper Limb Amputation

Linda Resnik, PT, PhD, Matthew Borgia, MA, and Melissa A. Clark, PhD

Objective: The aims of the study were (1) to describe frequency of back pain only, neck pain only, and co-occurring pain in veterans with upper limb amputation, (2) to examine changes in pain over 1 yr, and (3) to quantify the association of pain and health-related quality of life and disability.
Design: This is an observational cohort study with a survey of a sample of 792 veterans with upper limb amputation, with 1-yr reassessment of 585 (85.3%) of 777 eligible participants. Pain prevalence and intensity were examined. Logistic and linear regressions identified variables associated with pain and examined associations between intensity and veterans RAND-12 mental component score and physical component score and QuickDASH.
Results: At baseline, 52.3% had co-occurring pain, 20.0% had back pain, and 8.3% had neck pain. Persistent back and neck pain is present in 60.8% and 48.1% respondents, respectively. Pain intensity was unchanged for 59.1% with back pain and 61.3% with neck pain. Mental component score and QuickDASH were significantly worse with severe and moderate back and neck pain, compared with no pain. Severe/moderate back pain intensity was associated with lower physical component score.
Conclusions: Back and neck pain is highly prevalent and persistent in veterans with upper limb amputation. Pain intensity is negatively associated with health-related quality of life and disability. Pain prevention and intervention are needed in this population.

Key Words: Amputation, Upper Limb, Epidemiology, Back Pain, Neck Pain, Veterans

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What Is Known

- Back pain and neck pain are prevalent in persons with upper limb amputation (ULA) and common in veterans with ULA.
- The US veterans are more at risk for low back pain or joint pain than the general population.

What Is New

- Co-occurring back and neck pain in veterans with ULA is common.
- Back pain and neck pain are chronic for many veterans with ULA.
- Pain intensity is associated with worse quality of life and greater disability.
- These findings point to a need for pain prevention and intervention for veterans with ULA.

Loss or absence of one or more upper limbs alters performance of everyday activities resulting in compensatory and adaptive movements,[1] overreliance on the sound side (in persons with unilateral limb loss), or use of the chin, teeth, lower limbs, or other body parts (in persons with bilateral limb loss).[2] These alterations in body mechanics may contribute to the development of musculoskeletal conditions, such as back and neck pain. Indeed, back and neck pain, which is prevalent, costly, and disabling conditions in the general population, seems to disproportionately affect persons with major upper limb amputation (ULA).[3–5] Veterans with ULA are a unique population; many have lost their limbs in combat and simultaneously may have sustained injuries to other body parts and systems. Veterans as a group, and combat veterans in particular, report high rates of severe and chronic pain.[6–8]

In a nationally representative study, veterans with ULA reported back pain and neck pain at rates of 72% and 61%, respectively.[3] These rates far exceed US population–based estimates, which are 9%–30% for back pain[9–13] and 4%–16% for neck pain.[9,11,12] Rates of back pain are also higher than the 64% rate reported in US adults with ULA,[4] and the 27% rate reported among Dutch adults with ULA.[5] Back pain is more prevalent in female individuals as compared with male individuals,[9–11,13] and younger persons have higher rates of pain compared with older persons. Therefore, rates of back and neck pain reported in the veteran ULA population as compared with the general and ULA population are particularly alarming, given that the veteran ULA population is almost exclusively male and older than the US population.

The US veterans are more at risk for low back pain or joint pain, and those who have pain are more likely to report pain as severe, as compared with the general population.[6] An estimated 40% of veterans returning from combat duty reported chronic pain (defined as pain lasting 3 mos or longer).[7]

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Some small, nonrepresentative US studies and studies from outside of the US suggest that chronic back and neck pain is common in ULAs. A study of ULA from the Washington state region of the US reported rates of 52% and 43% for chronic back and neck pain, respectively.[14] An estimated 45%–51% of Norwegian adults with ULA have chronic back pain and 57%–78% have chronic neck pain.[15,16] Only one study to date has reported prevalence rates of chronic back pain in veterans with ULA, and none have reported on rates of chronic neck pain or described the intensity of back or neck pain. Chronic back pain in veterans with ULA was reported by 30% of Vietnam veterans (mean age = 60.7 yrs) and 42% of Operation Iraqi Freedom/Operation Enduring Freedom (OIF/OEF) veterans (mean age = 29.3 yrs).[17,18] This study was limited to Vietnam and OIF/OEF veterans. Further research is needed to quantify the extent of chronic back and neck pain as well as factors associated with high rates of back and neck pain in veterans with ULA. Given efforts to improve the quality of amputation care in the Department of Veterans Health Affairs (VA), data on the prevalence of chronic back and neck pain and co-occurring pain would provide a benchmark for longitudinal analyses. If modifiable factors are identified, efforts can be made to address these factors, potentially reducing the prevalence of pain.

Although back and neck pain is often co-occurring, few studies have estimated the prevalence of comorbid back and neck pain in the general or ULA population, and none have examined comorbid pain in veterans with ULA. A single population-based study of US adults reported that 9% had co-occurring back and neck pain, whereas 17% had only back pain and 4% had only neck pain.[9] The authors' previous study of veterans with ULA, which used the baseline data from the analysis reported in this article, did not distinguish between those with only back pain, only neck pain, or co-occurring pain.[3] Lack of these data makes it impossible to compare prevalence rates with national studies that examine back and neck pain alone and in combination.

Upper limb amputation is associated with reduced physical functioning and quality of life.[19,20] In previous studies using the Veterans RAND 12-item health survey (VR-12), veterans with ULA had physical functioning scores (VR-12 PCS) that were approximately 0.5 SD below population means (for nondisabled), indicating moderately impaired physical functioning; mental health functioning (VR-12 MCS) was at the population mean, indicating unimpaired mental/emotional functioning.[21] However, the impact of back and/or neck pain in combination with ULA on health-related quality of life (HRQoL) has not been specifically examined. These data are needed to appreciate the significance of back and/or neck pain in this population, and findings could be used to motivate targeted interventions and research studies to prevent and reduce pain.

A recently completed follow-up survey of veterans with ULA provides a unique opportunity to examine pain prevalence and intensity over time. This study expands upon analyses of previously collected baseline data and uses additional longitudinal data to (1) describe the frequency and severity of back pain only, neck pain only, and co-occurring back and neck pain in veterans with ULA, (2) examine changes in back pain and changes in neck pain over 1 yr, and (3) quantify the association of back pain and neck pain with HRQoL and disability.

METHODS

Design

A survey of veterans with ULA[3] was conducted, and a follow-up survey was administered 1 yr later. The population included all nondeceased veterans with major ULA who received care in the VA from 2010 to 2015 and had valid telephone numbers and mailing addresses. The sampling frame, identified from VA corporate data warehouse sources, was described in a previous publication.[3] All participants provided oral informed consent to participate in telephone interviews, conducted by trained interviewers from an academic survey center. This study and the oral informed consent procedure were approved by the VA Central Institutional Review Board. Those who indicated that they were willing to participate in future activities were contacted 1 yr after baseline for a follow-up interview. Participants who did not respond to any back or neck pain questions in the survey were excluded from the analytic sample. This study conforms to all Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines and reports the required information accordingly (see Supplemental Checklist, Supplemental Digital Content 1, http://links.lww.com/PHM/B207).

Survey

Baseline and follow-up surveys contained questions asking about the presence of pain "in the past 4 wks." At each time point, respondents were asked about a variety of pain locations: back pain, neck pain, contralateral limb, residual limb, and phantom limb pain.

Survey questions asked respondents to rate how often they experienced each type of pain ("never," "only once or twice," "about once per week," "2–3 times per week," "4–6 times per week," "several times a day," "all the time or almost all the time"). Those who indicated that they had any pain were asked to rate the intensity of pain on a scale from 0 (no pain) to 10 (worst possible pain).

The surveys included the VR-12, a generic measure of HRQoL. The surveys also included the QuickDASH, which measures perceived disability of the arm, shoulder, and hand.[22–24] Higher QuickDASH scores indicate greater disability.

Variable Parameterization

Descriptive analyses identified the numbers and percentages of missing/unknown data in categorical variables. Data were categorized as missing if respondents refused to answer or did not know the answer to an item. Missing categorical data were not included in subsequent analyses, except for the variable for race, which had a high proportion of missing. A separate category for unknown race was created and used in multivariable analyses.

Given that the central focus of this analysis was back and neck pain, we described prevalence of back and neck pain two ways. First, pain was dichotomized as a yes/no variable, and the proportion of respondents who had any back pain and any neck pain was calculated. To understand the magnitude of co-occurring back and neck pain, participants were also categorized as having no back or neck pain, only back pain, only neck pain, or a combination of back and neck pain.

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Pain frequency was examined two ways: (*a*) as a dichotomous variable (never or any frequency reported) and (*b*) as a four-category pain frequency variable ("never," "weekly or less frequent," "2–6 times per week," and "daily/always"). Pain intensity, which was assessed on a 0–10 scale, was also examined in two ways: (*a*) as a continuous variable and (*b*) as a categorical variable with 4 levels ("never had pain," 0–3 = "none to mild," 4–7 = "moderate," 8–10 = "severe").

The VR-12 items were used to calculate the physical component score (PCS) and the mental component score (MCS).[25,26] Higher PCS and MCS indicate better functioning.

Analyses With Baseline Data

Response and cooperation rates at baseline were calculated using the American Association of Public Opinion Research guidelines (response rate 4 and cooperation rate 4).[27]

Characteristics and prosthesis use patterns of respondents in the baseline sample were described. The prevalence of back and neck pain, frequency and intensity of pain, PCS, MCS, and QuickDASH scores were also described.

Two separate multivariable logistic regression models were developed: one to identify variables associated with having any back pain and one to identify variables associated with having any neck pain at baseline. Two separate multivariable linear regression models were also developed: one to identify factors associated with back pain intensity and one to identify factors associated with neck pain intensity at baseline. These four models included amputation level, and the following covariates, which the research team believed, might be potentially related to pain prevalence: age, sex, race, ethnicity, amputation level, amputation of the dominant side, time since amputation, etiology of amputation, back pain (for neck analysis), neck pain (for back analysis), contralateral limb pain, phantom limb pain, residual limb pain, current prosthesis use, primary type of prosthesis used, frequency of prosthesis use, and intensity of daily prosthesis use. Given the number of variables associated with pain outcomes, the extent of multicollinearity was evaluated to determine whether any covariates should be removed. Variable inflation factors were all below 10, and tolerance parameter estimates were all above 0.1; thus, no covariates were removed.

To examine the impact of pain intensity on HRQoL and disability, three separate multivariable linear regression models for PCS, MCS, and QuickDASH were computed. In these models, the key independent variables were categorical intensity of back pain and neck pain. Covariates in the model were based on those identified in previous research on HRQoL and ULA[21] and included the following: age, years since amputation, race, marital status, amputation level, ever having used a prosthesis, lower limb amputation, amputation of dominant side, amputation etiology, initial and current prosthesis training, year of prosthesis receipt, and number of prostheses used. Because we expected other painful conditions to contribute to, and potentially confound, the outcomes, covariates for presence of any contralateral limb, phantom limb, and residual limb pain were also added to the models. Linear regression model fit was evaluated using R^2, root mean square error, and overall F tests. Logistic regression model fit was evaluated using Cox-Snell R^2 and Hosmer-Lemeshow tests. SAS 9.4 was used for statistical analyses.

Longitudinal Analyses

Similar to baseline, response and cooperation rates at follow-up were calculated using the American Association of Public Opinion Research guidelines (response rate 4 and cooperation rate 4).[27] Characteristics and prosthesis use patterns of respondents in the baseline and follow-up survey were described. To assess response bias in loss to follow-up, sociodemographic characteristics and prosthesis use patterns for those who completed follow-up were compared with those lost to follow-up using t tests, χ^2 tests, and Wilcoxon Mann-Whitney tests for continuous, categorical, and ordinal data, respectively.

The prevalence of back and neck pain, frequency and intensity of pain, PCS, MCS, and QuickDASH scores at both baseline and at follow-up were described. Change in pain between baseline and follow-up was classified into three groups: "pain-free," no pain at both time points; "incident," no pain at baseline, but pain at follow-up; "resolved," pain at baseline but none at follow-up; or "persistent," pain at both baseline and follow-up. For those categorized as having persistent pain, we examined change in pain intensity, defined as "improved," "worsened," or "unchanged." Respondents who had a decrease of 2 or more points in pain intensity at follow-up as compared with baseline were categorized as "improved," respondents with an increase of 2 or more in pain intensity at follow-up as "worsened," and those with follow-up scores less than 2 points of baseline scores as "unchanged."

RESULTS

Analytic Sample

The analytic sample included 792 persons and the follow-up survey included 585 participants. Figures 1 and 2 show the recruitment flow diagrams for baseline and follow-up participants. The baseline response rate and cooperation rate were 47.7% (808 of 1693 estimated to be eligible) and 63.3% (808 of 1277), respectively. Fifteen participants were ineligible for the follow-up survey because of hearing/cognitive impairments or death. The follow-up response rate and cooperation rate for completers of the baseline survey were 75.3% (585 completed of 777 eligible) and 82.2% (585 completed of 687 eligible and reached), respectively.

Baseline Sample

Characteristics and prosthesis use patterns are shown in Table 1, with key characteristics presented here. Participants had a mean age of 63.3 yrs (SD = 14.1 yrs) at baseline, and on average, it had been 31.3 yrs (SD = 18.4 yrs) since amputation. The baseline sample was 97.5% male (n = 772) and 76.4% White (n = 605). Overall, 274 (34.6%) had below elbow amputation, 232 (29.3%) above elbow, 124 (15.7%) wrist disarticulation, 71 (9.0%) shoulder disarticulation, 37 (4.7%) elbow disarticulation, and 22 (2.8%) had forequarter amputation. Accidents (n = 502, 63.4%) and combat injury (n = 278, 35.1%) were the most common amputation etiology. The most common prosthesis type reported was body powered (n = 349, 44.1%), followed by none (nonusers; n = 309, 39.0%), myoelectric/hybrid (n = 97, 12.3%), and cosmetic (n = 23, 2.9%).

At baseline, 414 (52.3%) reported both back and neck pain, 158 (20%) reported only back pain, and 66 (8.3%) only

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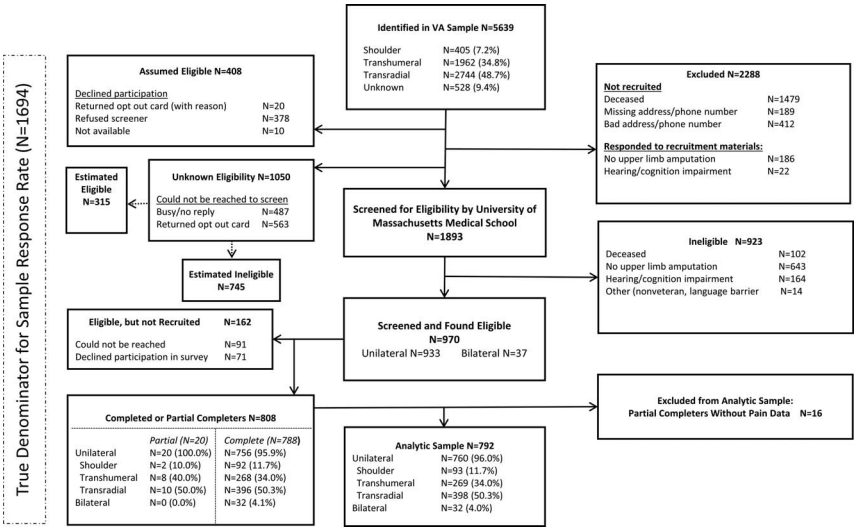

FIGURE 1. Flow diagram of baseline study recruitment.

neck pain (Table 2). Only 154 (19.4%) reported having neither back nor neck pain. Daily (or more frequent) back pain was reported by 311 participants (39.3%), whereas 220 (27.8%) never had back pain; 202 (25.5%) reported daily neck pain, whereas 312 (39.4%) reported never having neck pain. At baseline, back pain intensity was rated as none to mild by 126 participants (15.9%), moderate by 325 (41.1%), and severe by 120 (15.2%), whereas neck pain intensity was rated as none to mild by 121 participants (15.3%), moderate by 267 (33.8%), and severe by 91 (11.5%). The average PCS and MCS were 39.8 and 50.6, respectively, and the average QuickDASH score was 36.1.

Results of multivariable logistic and linear regressions for back pain are shown in Table 3. Those with any neck pain had 4.9 times the odds of reporting any back pain compared with those with no neck pain. The odds of back pain were lower for those 75 yrs or older (compared with those aged 45–64 yrs) and for prosthesis users (compared with nonusers), but higher for those with any contralateral limb pain or any phantom limb pain. No other covariate was significantly independently associated with reporting any back pain. Greater back pain intensity was associated with Black race, missing race as compared with White race, and any neck pain. No variable was independently associated with lower-intensity back pain.

Results of logistic and multivariable linear regressions for neck pain are shown in Table 3. Those with bilateral amputation had 4 times the odds of having any neck pain compared with those with unilateral, transradial amputation. The odds of having any neck pain were higher for those who identified as Hispanic, those with any back pain, those with any contralateral limb pain, and those with any residual limb pain. Those with cancer etiology and those 75 yrs or older (compared with ages 45–64 yrs) had lower odds of having any neck pain. Model fit statistics were acceptable and are shown in Table 3. Factors associated with greater neck pain intensity included the following: Black race (compared with White race), any back pain, and any residual limb pain. The only etiology of amputation associated with lower neck pain intensity was combat etiology.

Results of multivariable linear regressions of HRQoL and disability are shown in Table 4. On average, mental health (MCS) scores were 5.6 points lower for those with severe back pain and 4.7 points lower for those with severe neck pain, compared with those with no to mild pain. The MCSs were 3.1 and 3.4 points lower for those with any phantom limb pain and any residual limb pain, respectively, 5.9 points lower for those with unknown race compared with White race, and 2.7 points lower for those with two or more prostheses (compared with one). Factors associated with higher MCSs were more years since

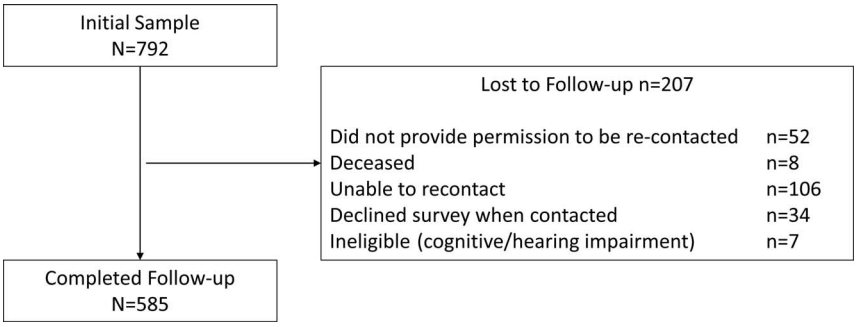

FIGURE 2. Flow diagram of loss to follow-up.

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TABLE 1. Characteristics of respondents to the baseline and longitudinal surveys

	Baseline Sample (n = 792)	Longitudinal Sample (n = 585)
	Mean (SD)	Mean (SD)
Age, yr	63.3 (14.1)	63.7 (13.6)
Missing, *n*	8	0
Years since initial amputation	31.3 (18.4)	31.7 (18.0)
Missing, *n*	19	14
	n (%)	*n* (%)
Sex		
Male	772 (97.5)	575 (98.3)
Female	20 (2.5)	10 (1.7)
Race		
White	605 (76.4)	459 (78.5)
Black	89 (11.2)	60 (10.3)
Unknown	59 (7.5)	34 (5.8)
Other (including mixed race)	39 (4.9)	32 (5.5)
Hispanic or Latino		
Yes	67 (8.5)	46 (7.9)
No	704 (88.9)	532 (90.9)
Unknown	21 (2.7)	7 (1.2)
Employment		
Employed/student	125 (15.9)	94 (16.1)
Retired	551 (70.3)	417 (71.3)
Medical leave/other	107 (13.7)	73 (12.5)
Unknown	1 (0.1)	1 (0.2)
Marital status		
Married or living together	503 (63.5)	368 (66.3)
Divorced or separated	174 (22.0)	121 (20.7)
Widowed	46 (5.8)	34 (5.8)
Never married	60 (7.6)	42 (7.2)
Unknown	9 (1.1)	0 (0.0)
Laterality of amputation		
Unilateral right	363 (45.8)	273 (46.7)
Unilateral left	397 (50.1)	289 (49.4)
Bilateral	32 (4.0)	23 (3.9)
Amputation of lower limb		
Yes	101 (12.8)	73 (12.5)
No	691 (87.3)	512 (87.5)
Side of lower limb amputation		
Right side	40 (39.6)	31 (42.5)
Left side	24 (23.8)	16 (21.9)
Both sides	37 (36.6)	26 (35.6)
Amputation level		
Forequarter	22 (2.8)	18 (3.1)
At the shoulder joint	71 (9.0)	45 (7.7)
Above the elbow	232 (29.3)	175 (29.9)
At the elbow	37 (4.7)	31 (5.3)
Below the elbow	274 (34.6)	198 (33.9)
At the wrist joint	124 (15.7)	95 (16.2)
Bilateral	32 (4.0)	23 (3.9)
Etiology of amputation (may be >1)		
Combat injury	278 (35.1)	200 (34.2)
Accident	502 (63.4)	380 (65.0)
Burn	91 (11.5)	69 (11.8)
Cancer	30 (3.8)	20 (3.4)
Diabetes	12 (1.5)	4 (0.7)
Infection	96 (12.1)	70 (12.0)
Primary prosthesis type		
Body powered	349 (44.1)	269 (46.0)
Myoelectric/hybrid	97 (12.3)	68 (11.6)
Cosmetic	23 (2.9)	14 (2.4)
Nonusers	309 (39.0)	224 (38.3)
Unknown	14 (2.9)	10 (1.7)
Ever used prosthesis		
Yes	738 (93.2)	551 (94.2)
No	52 (6.6)	33 (5.6)
Unknown	2 (0.3)	1 (0.2)
Initial prosthesis training		
Yes	556 (75.3)	410 (74.4)
No	175 (23.7)	136 (24.7)
Unknown	7 (1.0)	5 (0.9)
Current prosthesis use		
Yes	479 (60.5)	358 (61.2)
No	309 (39.0)	224 (38.3)
Unknown	4 (0.5)	3 (0.5)
Current prosthesis users (at baseline)	*n* = 479	*n* = 358
Current prosthesis training		
Yes	315 (65.8)	233 (65.1)
No	162 (33.8)	124 (34.6)
Unknown	2 (0.4)	1 (0.3)
No. prostheses used		
1	307 (64.1)	221 (64.5)
2≥	172 (35.9)	127 (35.5)
Frequency of prosthesis use		
Daily	375 (78.3)	283 (79.1)
Weekly	57 (11.9)	41 (11.5)
Monthly or less	43 (9.0)	30 (8.4)
Unknown	4 (0.8)	4 (1.1)
Intensity of daily prosthesis use		
<2 hrs	88 (18.4)	65 (18.2)
2 to <4 hrs	44 (9.2)	27 (7.5)
4 to <8 hrs	89 (18.6)	65 (18.2)
8 to <12 hrs	91 (19.0)	73 (20.4)
≥12 hrs	162 (33.8)	124 (34.6)
Unknown	5 (1.0)	4 (1.2)

amputation having received training to use the initial prosthesis and having one prosthesis (compared with two or more).

On average, physical health (PCS) scores were 3.4 and 7.1 points lower for those with moderate and severe back limb pain, respectively, as compared with those with no back pain. However, neck pain intensity was not significantly associated with the physical health score. The PCSs were 2.2 points lower for those with any contralateral limb pain and for those with any phantom limb pain. The PCS was also lower with older age and burn etiology. Factors associated with higher PCSs

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TABLE 2. Frequency and intensity of back and neck pain: Baseline and longitudinal cohorts

	Full Sample (N = 792)	Longitudinal Sample (n = 585)	
	Baseline	Baseline	Follow-up
	n (%)	*n* (%)	*n* (%)
Any back pain (yes)	572 (72.2)	420 (71.8)	419 (72.1)
	0	0	4
Any neck pain (yes)	480 (60.6)	353 (60.3)	358 (61.5)
	0	0	3
Other painful conditions			
Contralateral limb pain (yes)	538 (71.1)	407 (72.7)	400 (71.6)
Missing, *n*	3	2	3
Phantom limb pain (yes)	577 (73.2)	427 (73.2)	419 (72.5)
Missing, *n*	4	2	7
Residual limb pain (yes)	454 (65.3)	334 (64.4)	333 (64.5)
Missing, *n*	4	3	6
Back and neck pain co-occurrence			
No back or neck pain	154 (19.4)	112 (19.2)	110 (18.9)
Back pain only	158 (20.0)	120 (20.5)	114 (19.6)
Neck pain only	66 (8.3)	53 (9.1)	52 (9.0)
Co-occurring back and neck pain	414 (52.3)	300 (51.3)	305 (52.5)
Missing, *n*	0	0	4
Back pain frequency			
Never	220 (27.8)	165 (28.2)	162 (27.9)
Weekly or less frequent	135 (17.1)	103 (17.6)	113 (19.5)
2–6 times per week	126 (15.9)	98 (16.8)	108 (18.6)
Daily/always	311 (39.3)	219 (37.4)	198 (34.1)
Missing, *n*	0	0	4
Neck pain frequency			
Never	312 (39.4)	232 (39.7)	224 (38.5)
Weekly or less frequent	160 (20.2)	128 (21.9)	112 (19.2)
2–6 times per week	118 (14.9)	79 (13.5)	111 (19.1)
Daily/always	202 (25.5)	146 (25.0)	135 (23.2)
Missing, *n*	0	0	3
Back pain intensity			
Never had pain	220 (27.8)	165 (28.3)	162 (27.9)
None to mild (0–3)	126 (15.9)	104 (17.8)	104 (17.9)
Moderate (4–7)	325 (41.1)	232 (39.7)	241 (41.6)
Severe (8–10)	120 (15.2)	83 (14.2)	73 (12.6)
Missing, *n*	1	1	5
Neck pain intensity			
Never had pain	312 (39.4)	232 (39.7)	224 (38.5)
None to mild (0–3)	121 (15.3)	99 (17.0)	105 (18.0)
Moderate (4–7)	267 (33.8)	191 (32.7)	194 (33.3)
Severe (8–10)	91 (11.5)	62 (10.6)	59 (10.1)
Missing, *n*	1	1	3
	Mean (SD)	Mean (SD)	Mean (SD)
Pain intensity (for those with any pain)			
Back pain intensity	5.4 (2.3)	5.3 (2.3)	5.2 (2.2)
Missing, *n*	0	0	0
Neck pain intensity	5.2 (2.3)	5.1 (2.3)	5.0 (2.2)
Missing, *n*	0	0	0
Quality of life and disability			
VR-12 PCS	39.8 (11.2)	40.1 (11.4)	40.3 (10.9)
Missing, *n*	34	16	40
VR-12 MCS	50.6 (13.1)	51.1 (13.0)	51.2 (13.1)
Missing, *n*	34	16	40
QuickDASH	36.1 (21.3)	35.6 (21.1)	34.6 (21.3)
Missing, *n*	17	8	28

included more years since amputation and having two or more prostheses.

Disability (QuickDASH) scores were 7.9 points higher (worse) on average for those with severe back pain, and scores were 4.4 and 12.3 points higher for those with moderate and severe neck pain, respectively, compared with those with no pain. The QuickDASH scores were significantly higher for those with any contralateral limb pain (7.1 points), phantom limb pain (7.2 points), and residual limb pain (3.5 points). Other factors associated with higher (worse) QuickDASH scores included shoulder or bilateral amputation, older age, Black or unknown race, never being married, and not using a prosthesis. The factors independently associated with lower (better) QuickDASH scores were cancer etiology, current prosthesis use, and more years since amputation. Model fit statistics were acceptable (Table 4).

Longitudinal Sample

Comparisons between longitudinal completers and those lost to follow-up (Appendix Table 1, Supplemental Digital Content 2, http://links.lww.com/PHM/B208) found significant differences only in sex (higher proportion of female individuals lost to follow-up), race (higher proportion of Black and unknown race lost to follow-up), and diabetes etiology (higher proportion lost to follow-up).

Among the longitudinal sample, daily back pain was reported by 219 participants (37.4%) at baseline and 198 (34.1%) at follow-up; daily neck pain was reported by 146 (25.0%) at baseline and 135 (23.2%) at follow-up (Table 2). Among those with any back pain at both baseline and follow-up, most reported that back pain intensity was moderate. Among those with neck pain at both baseline and follow-up, most reported moderate neck pain intensity. Among those with any pain, average back pain was 5.3 (SD = 2.3) at baseline and 5.2 (SD = 2.2) at follow-up, whereas average neck pain was 5.1 (SD = 2.3) at baseline and 5.0 (SD = 2.2) at follow-up. Average PCSs at baseline and follow-up were 40.1 and 40.3, respectively, average MCSs were 51.1 and 51.2, and average QuickDASH scores were 35.6 and 34.6.

Examination of the change in pain prevalence over 1 yr (Appendix Table 2, Supplemental Digital Content 2, http://links.lww.com/PHM/B208) shows that persistent back and neck pain was present in 60.8% (n = 353) and 48.1% (n = 280) of the sample, respectively. On the other hand, 98

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TABLE 3. Independent factors associated with having any back pain, back pain intensity, any neck pain, and neck pain intensity at baseline: Results of separate multivariable logistic and linear regression

	Logistic Regression: Any Back Pain (Yes/No, *n* = 738)			Linear Regression: Back Pain Intensity (0–10, *n* = 533)			Logistic Regression: Any Neck Pain (Yes/No, *n* = 738)			Linear Regression: Neck Pain Intensity (0–10, *n* = 448)		
Characteristic	**OR**	**95% CI**	***P***	**β**	**95% CI**	***P***	**OR**	**95% CI**	***P***	**β**	**95% CI**	***P***
Amputation level												
Shoulder/forequarter	1.16	0.56 to 2.37	0.6949	−0.15	−0.92 to 0.61	0.6939	1.52	0.76 to 3.03	0.2329	0.51	−0.34 to 1.37	0.2398
Transhumeral/elbow disarticulation	0.68	0.43 to 1.08	0.1037	0.05	−0.41 to 0.52	0.8227	1.16	0.74 to 1.82	0.5188	0.32	−0.16 to 0.81	0.1907
Transradial/wrist disarticulation (ref)												
Bilateral	0.74	0.28 to 1.95	0.5436	0.65	−0.49 to 1.79	0.2613	4.44	1.65 to 11.97	**0.0032**	0.15	−0.99 to 1.28	0.7998
Sex												
Male (ref)												
Female	1.44	0.35 to 5.94	0.6133	−0.39	−1.50 to 0.72	0.4922	2.04	0.56 to 7.35	0.2773	−0.88	−2.00 to 0.25	0.1262
Race												
White (ref)												
Black	1.00	0.52 to 1.90	0.9898	0.94	0.32 to 1.56	**0.0031**	1.85	1.00 to 3.44	0.0501	0.83	0.20 to 1.47	**0.0101**
Unknown	0.82	0.32 to 2.09	0.6773	1.09	0.16 to 2.02	**0.0212**	0.45	0.18 to 1.13	0.0880	0.69	−0.32 to 1.71	0.1807
Other/mixed	1.48	0.52 to 4.18	0.4586	0.12	−0.73 to 0.98	0.7757	1.51	0.59 to 3.86	0.3935	0.34	−0.53 to 1.22	0.4432
Hispanic												
Yes	1.21	0.49 to 2.99	0.6799	0.27	−1.22 to 1.75	0.7261	2.94	1.19 to 7.28	**0.0193**	−1.39	−2.93 to 0.14	0.0755
No (ref)												
Do not Know/unsure	0.99	0.22 to 4.56	0.9897	−0.39	−1.17 to 0.39	0.3229	1.52	0.35 to 6.63	0.5742	−0.53	−1.33 to 0.28	0.1982
Amputation of dominant side												
Yes	0.92	0.62 to 1.37	0.6925	−0.18	−0.58 to 0.22	0.3763	0.72	0.50 to 1.06	0.0948	0.22	−0.20 to 0.65	0.3019
No (ref)												
Age at time of study, yr												
18–44	1.42	0.64 to 3.19	0.3912	−0.42	−1.15 to 0.30	0.2495	0.69	0.34 to 1.42	0.3182	−0.52	−1.32 to 0.28	0.1982
45–64 (ref)												
65–75	0.56	0.34 to 0.94	0.0282	0.14	−0.36 to 0.64	0.5837	0.74	0.45 to 1.21	0.2311	−0.10	−0.64 to 0.44	0.7119
75+	0.41	0.21 to 0.82	**0.0119**	−0.13	−0.90 to 0.63	0.7345	0.47	0.23 to 0.94	**0.0333**	−0.27	−1.16 to 0.61	0.5414
Time since amputation												
0–19 (ref)												
20–49	1.25	0.74 to 2.11	0.4000	0.07	−0.45 to 0.60	0.7880	1.27	0.76 to 2.13	0.3647	0.19	−0.38 to 0.75	0.5196
50+	1.55	0.71 to 3.40	0.2750	0.21	−0.63 to 1.05	0.6255	2.16	0.97 to 4.82	0.0609	0.06	−0.85 to 0.97	0.8968
Amputation etiology												
Combat injury												
Yes	1.25	0.67 to 2.33	0.4857	−0.16	−0.77 to 0.46	0.6215	0.86	0.47 to 1.59	0.6340	−0.77	−1.44 to −0.10	**0.0246**
No (ref)												
Accident												
Yes	1.02	0.56 to 1.86	0.9384	0.15	−0.43 to 0.74	0.6050	0.81	0.46 to 1.44	0.4748	−0.51	−1.13 to 0.11	0.1077
No (ref)												

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Burn												
Yes	1.05	0.57 to 1.93	0.8865	0.03	−0.59 to 0.66	0.9145	1.04	0.57 to 1.89	0.9033	−0.09	−0.75 to 0.57	0.7856
No (ref)												
Cancer												
Yes	1.18	0.41 to 3.39	0.7593	−0.42	−1.58 to 0.73	0.4705	0.35	0.13 to 0.97	**0.0429**	−1.22	−2.72 to 0.27	0.1089
No (ref)												
Diabetes												
Yes	0.73	0.15 to 3.65	0.7018	1.12	−0.88 to 3.12	0.2697	0.52	0.11 to 2.54	0.4187	−1.02	−3.22 to 1.18	0.3635
No (ref)												
Infection												
Yes	0.68	0.38 to 1.23	0.1995	0.61	−0.01 to 1.22	0.0529	1.61	0.87 to 2.97	0.1292	0.39	−0.22 to 1.00	0.2133
No (ref)												
Any back pain												
Yes							4.98	3.30 to 7.50	**<0.0001**	0.79	0.17 to 1.42	**0.0132**
No (ref)												
Any neck pain												
Yes	4.92	3.27 to 7.40	**<0.0001**	0.62	0.15 to 1.09	**0.0104**						
No (ref)												
Any contralateral limb pain												
Yes	1.54	1.01 to 2.35	**0.0471**	0.50	0.01 to 1.00	**0.0466**	4.14	2.74 to 6.27	**<0.0001**	0.38	−0.22 to 0.98	0.2126
No (ref)												
Any phantom limb pain												
Yes	1.56	1.01 to 2.42	**0.0441**	0.39	−0.12 to 0.90	0.1324	1.16	0.74 to 1.79	0.5212	0.45	−0.12 to 1.02	0.1183
No (ref)												
Any residual limb pain												
Yes	1.31	0.83 to 2.07	0.2447	0.31	−0.21 to 0.83	0.2417	2.46	1.59 to 3.82	**<0.0001**	0.73	0.15 to 1.30	**0.0136**
No (ref)												
Current prosthesis use												
Yes	0.54	0.30 to 0.96	**0.0370**	−0.50	−1.13 to 0.12	0.1116	0.81	0.45 to 1.44	0.4651	0.21	−0.44 to 0.86	0.5296
No (ref)												
Primary prosthesis type												
Body powered (ref)												
Myoelectric/hybrid	0.81	0.44 to 1.50	0.5001	−0.25	−0.89 to 0.39	0.4414	1.07	0.59 to 1.96	0.8192	−0.05	−0.73 to 0.63	0.8880
Cosmetic	0.41	0.14 to 1.16	0.0911	0.25	−1.03 to 1.54	0.6995	1.29	0.43 to 3.86	0.6491	0.09	−1.11 to 1.29	0.8828
Frequency of prosthesis use												
Daily (ref)												
Weekly	0.83	0.34 to 1.98	0.6666	0.66	−0.16 to 1.48	0.1129	1.53	0.65 to 3.60	0.3270	−0.17	−1.02 to 0.68	0.7010
Monthly or less	0.96	0.33 to 2.77	0.9386	0.70	−0.34 to 1.74	0.1878	1.06	0.38 to 2.98	0.9153	−0.96	−2.07 to 0.15	0.0914
Intensity of daily prosthesis use												
<2 hrs	1.59	0.65 to 3.89	0.3142	0.02	−0.88 to 0.92	0.9618	1.65	0.68 to 3.96	0.2663	−0.18	−1.14 to 0.77	0.7046
2 to <4 hrs	2.06	0.80 to 5.30	0.1345	−0.09	−1.02 to 0.83	0.8472	1.02	0.41 to 2.55	0.9587	−0.11	−1.11 to 0.88	0.8231
4 to <8 hrs	1.74	0.86 to 3.53	0.1230	0.51	−0.22 to 1.25	0.1719	1.04	0.53 to 2.06	0.9008	0.48	−0.29 to 1.25	0.2218

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TABLE 3. *(Continued)*

Characteristic	Logistic Regression: Any Back Pain (Yes/No, $n = 738$)			Linear Regression: Back Pain Intensity (0–10, $n = 533$)			Logistic Regression: Any Neck Pain (Yes/No, $n = 738$)			Linear Regression: Neck Pain Intensity (0–10, $n = 448$)		
	OR	95% CI	*P*	β	95% CI	*P*	OR	95% CI	*P*	β	95% CI	*P*
8 to <12 hrs	1.15	0.60 to 2.18	0.6767	0.59	−0.17 to 1.35	0.1283	1.14	0.59 to 2.21	0.7038	0.40	−0.40 to 1.20	0.3310
≥12 hrs (ref)												
Adj R^2					0.14						0.16	
F; *P*					2.38, <0.0001						2.27, <0.0001	
RMSE					0.14						2.14	
Cox-Snell R^2		0.20						0.29				
Hosmer-Lemeshow *P*		0.8259						0.0820				

Bold text indicates significance at $P < 0.05$.

CI, confidence interval; OR, odds ratio; RMSE, root mean square error.

participants (16.9%) in the longitudinal sample reported no back pain at both baseline and follow-up and 152 (26.1%) reported no neck pain at either survey. Incident back pain was reported by 66 (11.4%) and resolved back pain by 64 (11.0%). Similarly, incident neck pain was reported by 78 (13.4%) and resolved neck pain by 72 (12.4%).

Most respondents were categorized as having no change in back pain intensity ($n = 208$, 59.1%) and neck pain intensity ($n = 171$, 61.3%). Back pain intensity was categorized as improved for 76 participants (21.6%) and worsened for 68 (19.3%). Neck pain intensity was categorized as improved for 52 participants (18.6%) and worsened for 56 (20.1%).

DISCUSSION

This study was a first of its kind, nationally representative, longitudinal study of veterans with ULA that described the change in prevalence and intensity of back and neck pain over 1 yr. Given the high prevalence rates of back and neck pain previously identified,[3] the prevalence of co-occurring back and neck pain was also examined. In addition, the factors associated with the likelihood of reporting any pain and with having higher intensity pain were identified. Lastly, the associations between pain severity and HRQOL and disability were examined.

Rates of co-occurring back and neck pain were more than 5 times the general US population, and rates of neck pain are more than double the general population rates.[9] However, rates of back pain alone were only slightly higher.[9] Furthermore, mean back and neck pain intensity was moderate, with less than 20% reporting neck or back pain as mild, and at least 12% reporting severe back pain, and 10% reporting severe neck pain. These findings point to the need for clinical interventions to prevent and treat back and neck pain ULAs.

The longitudinal study design enabled quantification of change in pain prevalence and intensity over time. Although the survey asked about the experience of pain over the previous month, the data from baseline and follow-up were used to estimate the proportion of veteran ULAs with chronic pain. Pain was persistent from baseline to follow-up for 61% with any back pain and 48% with any neck pain. The severity of pain was stable for the majority, with approximately one fifth reporting worsening pain and another fifth reporting improvement in pain. These findings suggest that treatment of back and neck pain in ULAs should, in many cases, be informed by evidence-based clinical practice guidelines for chronic pain.

A variety factors that might be associated with likelihood of having pain and intensity of pain were explored. Other painful conditions, including contralateral, phantom, or residual limb pain, were associated with increased likelihood of having back or neck pain, suggesting that there may be some shared pain etiology, and pointing to the need for pain management interventions in veterans with ULA. Some current theories on etiology of multisite pain point to hyperexcitability of the nervous system and sensitization.[28,29] Some researchers report a relationship between sleep quantity and quality and presence and severity of multisite pain.[30–32] This study did not include items about sleep. This is an area that should be explored in future research.

An effect of Black or missing race was also identified, where those persons identifying as Black or not indicating their

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TABLE 4. Results of separate multivariable linear regression models: Impact of pain on HRQoL and disability

	HRQoL						Disability		
	Mental Health (VR-12 MCS, *n* = 734)			Physical Health (VR 12 PCS, *n* = 735)			QuickDASH (*n* = 723)		
	β	95% CI	*P*	β	95% CI	*P*	β	95% CI	*P*
Amputation level									
Shoulder disarticulation/forequarter	−0.99	−4.39 to 2.40	0.5663	−1.17	−4.08 to 1.74	0.4307	6.13	1.13 to 11.13	**0.0164**
Transhumeral/elbow disarticulation	1.95	−0.17 to 4.07	0.0712	1.25	−0.57 to 3.06	0.1774	−1.73	−4.86 to 1.39	0.2763
Transradial/wrist (ref)									
Bilateral	1.29	−3.62 to 6.19	0.6074	−2.30	−6.51 to 1.90	0.2825	17.37	10.17 to 24.57	**<0.0001**
Back pain intensity									
Never had pain	−0.17	−3.02 to 2.68	0.9086	1.13	−1.32 to 3.57	0.3657	−1.69	−5.87 to 2.48	0.4262
None to mild (0–3, ref)									
Moderate (4–7)	−1.34	−4.07 to 1.40	0.3373	−3.38	−5.73 to −1.04	**0.0048**	2.50	−1.51 to 6.52	0.2210
Severe (8–10)	−5.55	−9.10 to −2.01	**0.0022**	−7.16	−10.19 to −4.12	**<0.0001**	7.91	2.66 to 13.16	**0.0032**
Neck pain intensity									
Never had pain	−0.19	−2.99 to 2.62	0.8971	2.10	−0.31 to 4.50	0.0878	−1.13	−5.25 to 3.00	0.5914
None to mild (0–3, ref)									
Moderate (4–7)	−0.73	−3.67 to 2.21	0.6256	−0.73	−3.25 to 1.78	0.5670	4.40	0.09 to 8.71	**0.0456**
Severe (8–10)	−4.73	−8.59 to −0.87	**0.0164**	−1.81	−5.12 to 1.49	0.2812	12.28	6.62 to 17.93	**<0.0001**
Any contralateral limb pain									
Yes	−1.01	−3.17 to 1.14	0.3573	−2.16	−4.01 to −0.31	**0.0220**	7.10	3.90 to 10.30	**<0.0001**
No (ref)									
Any phantom limb pain									
Yes	−3.02	−5.24 to −0.80	**0.0077**	−2.17	−4.07 to −0.27	**0.0251**	7.19	3.93 to 10.46	**<0.0001**
No (ref)									
Any residual limb pain									
Yes	−3.43	−5.71 to −1.15	**0.0032**	−1.06	−3.01 to 0.89	0.2861	3.46	0.09 to 6.82	**0.0439**
No (ref)									
Age, yr	0.00	−0.10 to 0.10	0.9787	−0.19	−0.27 to −0.10	**<0.0001**	0.18	0.03 to 0.32	**0.0156**
Years since amputation	0.10	0.02 to 0.17	**0.0135**	0.09	0.02 to 0.15	**0.0079**	−0.19	−0.31 to −0.08	**0.0008**
Race									
White (ref)									
Black	−2.74	−5.61 to 0.14	0.0624	−0.65	−3.12 to 1.81	0.6047	6.89	2.64 to 11.15	**0.0015**
Unknown	−5.94	−9.64 to −2.24	**0.0017**	−0.35	−3.48 to 2.79	0.8275	8.79	3.40 to 14.19	**0.0014**
Other/mixed	−0.43	−4.57 to 3.71	0.8378	0.26	−3.29 to 3.80	0.8870	5.13	−0.93 to 11.19	0.0970
Marital status									
Married or living together (ref)									
Divorced or separated	−1.05	−3.24 to 1.13	0.3445	−0.73	−2.60 to 1.14	0.4449	−1.55	−4.80 to 1.70	0.3483
Widowed	2.42	−1.50 to 6.33	0.2259	−0.23	−3.58 to 3.13	0.8948	−1.02	−6.76 to 4.72	0.7267
Never married	−1.38	−4.81 to 2.05	0.4300	−2.37	−5.31 to 0.57	0.1142	5.97	0.94 to 10.99	**0.0201**
Lower limb amputation									
Yes	2.10	−0.68 to 4.89	0.1380	−1.44	−3.82 to 0.95	0.2375	−0.81	−4.90 to 3.29	0.6993
No (ref)									
Etiology									
Combat injury	−0.44	−3.38 to 2.51	0.7719	0.76	−1.77 to 3.28	0.5556	−0.32	−4.71 to 4.08	0.8877
Accident	0.05	−2.74 to 2.85	0.9698	1.07	−1.32 to 3.46	0.3806	−3.18	−7.33 to 0.97	0.1333
Burn	1.76	−1.06 to 4.59	0.2208	−2.78	−5.20 to −0.36	**0.0242**	0.45	−3.70 to 4.61	0.8300
Cancer	4.68	−0.57 to 9.93	0.0807	2.80	−1.70 to 7.30	0.2221	−7.97	−15.77 to −0.17	**0.0452**
Diabetes	1.27	−7.29 to 9.82	0.7714	−5.69	−13.02 to 1.64	0.1281	0.92	−13.40 to 15.25	0.8995
Infection	1.93	−0.91 to 4.77	0.1834	−0.32	−2.74 to 2.10	0.7943	−3.11	−7.28 to 1.05	0.1430
Ever used prosthesis									
Yes (ref)									
No	2.91	−1.34 to 7.15	0.1795	−1.72	−5.36 to 1.91	0.3524	−5.84	−12.12 to 0.45	0.0686

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TABLE 4. *(Continued)*

	HRQoL						Disability		
	Mental Health (VR-12 MCS, *n* = 734)			Physical Health (VR 12 PCS, *n* = 735)			QuickDASH (*n* = 723)		
	β	95% CI	*P*	β	95% CI	*P*	β	95% CI	*P*
Current prosthesis use									
Yes	2.30	−0.66 to 5.26	0.1272	1.31	−1.22 to 3.84	0.3094	−8.75	−13.12 to 4.39	**<0.0001**
No (ref)									
Primary prosthesis type									
Body (ref)									
Myoelectric/hybrid	1.98	−0.96 to 4.93	0.1865	−1.36	−3.88 to 1.15	0.2883	2.43	−1.88 to 6.75	0.2688
Cosmetic	−2.47	−7.94 to 2.99	0.3742	1.54	−3.14 to 6.22	0.5177	3.06	−4.94 to 11.05	0.4533
Nonusers									
Initial prosthesis training									
Yes	3.38	0.84 to 5.91	**0.0091**	−0.33	−2.50 to 1.84	0.7648	−2.19	−5.95 to 1.56	0.2515
No (ref)									
Current prosthesis training									
Yes	−0.15	−2.92 to 2.63	0.9163	2.00	−0.37 to 4.38	0.0980	−1.77	−5.86 to 2.32	0.3952
No (ref)									
No. prostheses									
1 (ref)									
≥2	−2.65	−5.17 to −0.14	**0.0383**	3.47	1.32 to 5.62	**0.0016**	−0.67	−4.38 to 3.03	0.7208
Amputation of dominant side									
Yes	0.04	−1.77 to 1.86	0.9640	−0.90	−2.46 to 0.65	0.2560	1.74	−0.95 to 4.42	0.2042
No (ref)									
n, Adj R^2		734, 0.16			735, 0.22			723, 0.33	
F, *P*		5.11, <0.0001			7.02, <0.0001			11.25, <0.0001	
RMSE		11.84			10.15			117.33	

Bold text indicates significance at $P < 0.05$.

CI, confidence interval; RMSE, root mean square error.

race were more likely to report greater pain intensity. Others have reported an association between Black race and increased pain sensitization,[33] noted disparities in chronic pain management,[34] and found that a few veterans were less likely to be screened for pain.[35] It is unclear how to interpret the finding related to persons who did not provide information on racial group in this study. Data on socioeconomic status or education were not collected, which precludes determining whether there was potential confounding with race. That said, clinical care providers should routinely assess trunk pain in all ULA patients using standardized assessment tools, as recommended by clinical practice guidelines.[36]

Those with bilateral ULA had 4 times the likelihood of having neck pain than those with unilateral amputation, suggesting that compensatory strategies used by this group were major contributors to neck pain, and pointing to the need for prosthetic training that addresses body mechanics and compensation.

Many potentially modifiable factors of pain including frequency and intensity of prosthesis use were examined. Those who used a prosthesis had half the odds of reporting any back pain. However, prosthesis use was not associated with likelihood of reporting neck pain. This finding is somewhat surprising but might be related to increased symmetry of postural muscle use and decreased likelihood of developing scoliosis for those who wear a prosthesis. Further research is needed to investigate this possibility.

Veterans with ULA had physical quality-of-life (PCS) scores below that reported in subgroups of adults with back and/or neck pain, but better mental quality-of-life (MCS) scores. Baseline PCS and MCS in our longitudinal sample were 40.1 and 51.1. General population estimates for PCS and MCS, respectively, for US adults with chronic back pain are 44.9 and 44.5.[37] Estimates of PCS and MCS in a population-based sample of North Carolina adults with chronic neck pain were 38.6 and 50.6, respectively.[38] The HRQoL findings in this study were somewhat better than those in a small study of persons with ULA from the Washington state area, which reported a mean PCS of 38.3 and MCS of 44.0 for those with back pain, and a mean PCS of 37.0 and MCS of 44.8 for those with neck pain.[14]

This study also quantified the independent associations of neck and back pain intensity on HRQoL and disability. In this sample of veterans with ULA, only severe back pain and severe neck pain, but not mild and moderate pain, were independently associated with having worse mental health (MCS) scores, whereas moderate to severe back pain (but not mild) was associated with worse physical health (PCS) scores. Severe back pain and moderate to severe neck pain (but not mild pain) were also associated with greater disability (QuickDASH). These findings suggest a clinical imperative to engage multidisciplinary team members including physical therapists in the care of persons with ULA and to develop programs and interventions to prevent and treat back and neck pain in this population.

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Limitations

This longitudinal study used a large and nationally representative US veteran population. Findings are limited to veterans who had received care at the VA and therefore may not be generalizable outside of the veteran population and the VA system of care. The survey used a narrow definition of pain, asking about pain reported in the previous 4 wks, and identified persistent pain as pain reported at baseline and follow-up. Although persistent pain is most likely chronic pain, it is uncertain whether pain at follow-up was an indicator of chronic pain or an episode of recurrent pain. The survey was administered by telephone, and all data were self-reported by respondents; medical records were not used to establish whether veterans had diagnoses of spinal conditions or pain. This type of self-reported data is subject to recall bias. Future studies would benefit from quantitative measures of back and neck pain that are collected on a routine basis in the home and clinical environments.

The full survey was multidimensional, and questions about pain were a minor component. We have no reason to believe that pain was a major factor in an individual's willingness to participate in the survey or that this would have biased the results in a particular direction. It is possible that some with pain were less likely to participate (because of response burden). However, others may have also been more likely to participate because they wanted to report their experiences.

CONCLUSIONS

Together, these findings demonstrate the magnitude, severity, and impact of back and neck pain in the veteran ULA population. Back pain and neck pain are pervasive and persistent among veterans with amputation and seem to be negatively associated with quality of life and disability. These findings highlight an unmet need for prevention and intervention of co-occurring and painful back and neck pain in this population.

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Amputation Care Quality and Satisfaction With Prosthetic Limb Services: A Longitudinal Study of Veterans With Upper Limb Amputation

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Purpose: This study sought to measure and identify factors associated with satisfaction with care among veterans. The metrics were colelcted for those receiving prosthetic limb care at the US Department of Veterans Affairs (VA) and US Department of Defense (DoD) care settings and at community-based care providers.

Methods: A longitudinal cohort of veterans with major upper limb amputation receiving any VA care from 2010 to 2015 were interviewed by phone twice, 1 year apart. Care satisfaction was measured by the Orthotics and Prosthetics User's Survey (OPUS) client satisfaction survey (CSS), and prosthesis satisfaction was measured by the OPUS client satisfaction with device (CSD), and the Trinity Amputation and Prosthetic Experience Scale satisfaction scales. The Quality of Care index, developed for this study, assessed care quality. Bivariate analyses and multivariable linear regressions identified factors associated with CSS. Wilcoxon Mann-Whitney rank tests and Fisher exact tests compared CSS and Quality of Care items at follow-up for those with care within and outside of the VA and DoD.

Results: The study included 808 baseline participants and 585 follow-up participants. Device satisfaction and receipt of amputation care in the prior year were associated with greater satisfaction with care quality. Persons with bilateral amputation were significantly less satisfied with wait times. Veterans who received amputation care in the VA or DoD had better, but not statistically different, mean (SD) CSS scores: 31.6 (22.6) vs 39.4 (16.9), when compared with those who received care outside the VA or DoD. Those with care inside the VA or DoD were also more likely to have a functional assessment in the prior year (33.7% vs 7.1%, $P = .06$), be contacted by providers (42.7% vs 18.8%, $P = .07$), and receive amputation care information (41.6% vs 0%, $P = .002$). No statistically significant differences in CSS, Quality of Care scores, or pain measures were observed between baseline and follow-up. In regression models, those with higher CSD scores and with prior year amputation care had higher satisfaction when compared to those who had not received care.

Conclusions: Satisfaction with prosthetic limb care is associated with device satisfaction and receipt of care within the prior year. Veterans receiving amputation care within the VA or DoD received better care quality scores than those receiving prosthetic care outside of the VA or DoD. Satisfaction with care and quality of care were stable over the 12 months of this study. Findings from this study can serve as benchmarks for future work on care satisfaction and quality of amputation rehabilitative care.

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Veterans with upper limb amputation (ULA) are a small, but important population, who have received more attention in the past decade due to the increased growth of the population of veterans with conflict-related amputation from recent military engagements. Among the 808 veterans with ULA receiving any care in the US Department of Veterans Affairs (VA) from 2010 to 2015 who participated in our national study, an estimated 28 to 35% had a conflict-related amputation.[1] The care of these individuals with ULA is highly specialized, and there is a recognized shortage of experienced professionals in this area.[2,3] The provision of high-quality prosthetic care is increasingly complex with advances in technology, such as externally powered devices with multiple functions.

The VA is a comprehensive, integrated health care system that serves more than 8.9 million veterans each year. Interdisciplinary amputation care is provided within the VA through a traditional clinic setting or by using one of several currently available virtual care modalities.[4,5] In consultation with the veteran, VA health care providers (HCPs) prescribe prostheses and services based on the clinical needs and furnish authorized items and services to eligible veterans. Prescribed items and/or services are furnished either by internal VA resources or through a community-based prosthetist who is an authorized vendor or contractor. Although several studies have reported that the majority of veterans with ULA utilize VA services for at least some aspects of their health care, little is known about: (1) prosthetic limb care satisfaction or the quality of care that veterans receive; or (2) how care within the VA or Department of Defense (DoD) compares with care provided in the civilian sector.[6-8]

Earlier studies that examined the amputation rehabilitation services received by veterans with ULA pointed to quality gaps in care

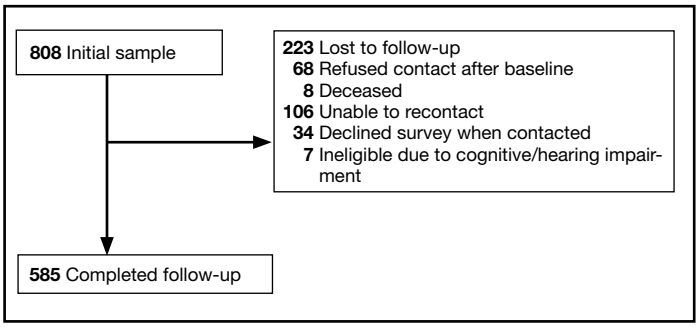
and differences in satisfaction in the VA and DoD when compared with the civilian sector but were limited in their scope and methodology.[7,8] A 2008 study of veterans of the Vietnam War, Operation Iraqi Freedom (OIF), and Operation Enduring Freedom (OEF) compared satisfaction by location of care receipt (DoD only, VA only, private only, and multiple sources). That study dichotomized response categories for items related to satisfaction with care (satisfied/not), but did not estimate degree of satisfaction, calculate summary scores of the items, or utilize validated care satisfaction metrics. That study found that a greater proportion of Vietnam War veterans (compared with OIF/OEF veterans receiving care in the private sector) agreed that they "had a role in choosing prosthesis" and disagreed that they wanted to change their current prosthesis to another type.[7] The assumption made by the authors is that much of this private sector care was actually VA-sponsored care prescribed and procured by the VA but delivered in the community. However, no data were collected to confirm or refute this assumption, and it is possible that some care was both VA sponsored and delivered, some was VA sponsored but commercially delivered, and in some cases, care was sponsored by other sources and delivered in still other facilities.

A 2012 VA Office of the Inspector General study of OIF, OEF, and Operation New Dawn (OND) veterans reported lower prosthetic satisfaction for veterans with upper limb when compared with lower limb amputation and described respondents concerns about lack of VA prosthetic expertise, difficulty with accessing VA services, and dissatisfaction with the sometimes lengthy approval process for obtaining fee-basis or VA contract care.[8] Although this report suggested that there were quality gaps and areas for improvement, it did not employ validated metrics of prosthesis or care satisfaction and instead relied on qualitative data collected through telephone interviews.

Given the VA effort to enhance the quality and consistency of its amputation care services through the formal establishment of the Amputation System of Care, which began in 2008, further evaluation of care satisfaction and quality of care is warranted. In 2014 the VA and DoD released the first evidence-based clinical practice guidelines (CPGs) for the rehabilitation of persons with ULA.[2] The CPG describes care paths to improve outcomes and basic tenets of amputation rehabilitation care and can be used to identify process activities that are essential aspects of quality care. However, the extent to which the CPG has impacted the quality and timeliness of care for veterans with ULA are presently unclear.

Thus, the purposes of this study were to: (1) measure veteran satisfaction with prosthetic limb care and identify factors associated with service satisfaction; (2) assess quality indicators that potentially reflect CPG) adoption; (3) compare care satisfaction and quality for those who received care in or outside of the VA or DoD; and (4) evaluate change in satisfaction over time.

FIGURE Flow Diagram of Analytic Sample



METHODS

The study was approved by the VA Central Institutional Review Board (IRB) (Study #16-20) and Human Research Protection Office, U.S. Army Medical Research and Development Command. The sampling frame consisted of veterans with major ULA who received care in the VA between 2010 and 2015 identified in VA Corporate Data Warehouse. We sent recruitment packages to nondeceased veterans who had current addresses and phone numbers. Those who did not opt out or inform us that they did not meet eligibility criteria were contacted by study interviewers. A waiver of documentation of written informed consent was obtained from the VA Central IRB. When reached by the study interviewer, Veterans provided oral informed consent. At baseline, 808 veterans were interviewed for a response rate of 47.7% as calculated by the American Association for

Public Opinion Research (AAPOR) methodology.[9] Follow-up interviews approximately 1 year later (mean [SD] 367 [16.8] days), were conducted with 585 respondents for a 72.4% response rate (Figure).

Survey Content

Development and pilot testing of the survey instrument previously was reported.[1] The content of the survey drew from existing survey items and metrics, and included new items specifically designed to address patterns of amputation care, based on care goals within the CPG. All new and modified items were tested and refined through cognitive interviews with 10 participants, and tested with an additional 13 participants.

The survey collected data on demographics, amputation characteristics (year of amputation, level, laterality, and etiology), current prosthesis use, and type of prosthesis. This article focused on the sections of the survey pertaining to satisfaction with prosthetic care and indicators of quality of care. A description of the content of the full survey and a synopsis of overall findings are reported in a prior publication.[1] The key independent, dependent, and other variables utilized in the analyses reported in this manuscript are described below.

Primary Independent Variables

In the follow-up survey, we asked respondents whether they had any amputation care in the prior 12 months, and if so to indicate where they had gone for care. We categorized respondents as having received VA/DoD care if they reported any care at the VA or DoD, and as having received non-VA/DoD care if they did not report care at the VA or DoD but indicated that they had received amputation care between baseline and follow-up.

Two primary outcomes were utilized; the Orthotics and Prosthetics User's Survey (OPUS), client satisfaction with services scale (CSS), and a measure of care quality specifically developed for this study. The CSS is a measure developed specifically for orthotic and prosthesis users.[10] This 11-item scale measures satisfaction with prosthetic limb services and contains items evaluating facets of care such as courtesy received from prosthetists and clinical staff, care coordination, appointment wait time, willingness of the prosthetist to listen to participant concerns, and satisfaction with prosthesis training. Items are rated on a 4-point scale (strongly agree [1] to strongly disagree [4]), thus higher CSS scores indicate worse satisfaction with services. The CSS was administered only to prosthesis users.

The Quality of Care assessment developed for this study contained items pertaining to amputation related care receipt and care quality. These items were generated by the study team in consultation with representatives from the VA/DoD Extremity Amputation Center of Excellence after review of the ULA rehabilitation CPG. Survey questions asked respondents about the clinicians visited for amputation related care in the past 12 months, whether they had an annual amputation-related checkup, whether any clinician had assessed their function, worked with them to identify goals, and/or to develop an amputation-related care plan. Respondents were also asked whether there had been family/caregiver involvement in their care and care coordination, whether a peer visitor was involved in their initial care, whether they had received information about amputation management in the prior year, and whether they had amputation-related pain. Those that indicated that they had amputation-related pain were subsequently asked whether their pain was well managed, whether they used medication for pain management, and whether they used any nonpharmaceutical strategies.

Quality of Care Index

We initially developed 15 indicator items of quality of care. We selected 7 of the items to create a summary index. We omitted 3 items about pain management, since these items were completed only by participants who indicated that they had experienced pain; however, we examined the 3 pain items individually given the importance of this topic. We omitted an additional 2 items from the summary index because they would not be sensitive to change because they pertained to the care in the year after initial amputation. One of these items asked whether caregivers were involved in initial amputation management and the other asked whether a peer visit occurred after amputation. Another 3 items

TABLE 1 Demographics of Respondents at Baseline and Follow-up

Characteristics	Baseline (N = 808)	Follow-up (n = 585)
Age, mean (SD), y	63.3 (14.1)	64.7 (13.6)
Time since amputation, mean (SD), y	31.4 (18.3)	32.6 (18.0)
Era of amputation, No. (%)		
Before Vietnam	51 (6.3)	32 (5.5)
Vietnam War	259 (32.1)	197 (33.7)
After Vietnam through Gulf War	157 (19.4)	111 (19.0)
After Gulf War to September 10, 2001	79 (9.8)	68 (11.6)
September 11, 2001 to present	241 (29.8)	163 (27.9)
Unknown	21 (2.6)	14 (2.4)
Male gender, No. (%)	787 (97.4)	575 (98.3)
Race, No. (%)		
White	605 (74.9)	459 (78.5)
Black	89 (11.0)	60 (10.3)
Other (including mixed race)	39 (4.8)	32 (5.5)
Unknown	75 (9.3)	34 (5.8)
Hispanic or Latino, No. (%)		
Yes	67 (8.3)	46 (7.9)
No	704 (87.1)	532 (90.9)
Unknown	37 (4.6)	7 (1.2)
Employment, No. (%)		
Workings/student	124 (15.4)	93 (15.9)
Retired	525 (65.0)	400 (68.4)
Medical leave/other	102 (12.6)	68 (11.6)
Unknown	57 (7.1)	24 (4.1)
Amputation level, No. (%)		
Shoulder	94 (11.6)	63 (10.8)
Transhumeral	276 (34.2)	206 (35.2)
Transradial	406 (50.3)	293 (50.1)
Bilateral	32 (4.0)	23 (3.9)
Primary prothesis type, No. (%)		
Body powered	357 (44.2)	258 (44.1)
Myoelectric/hybrid	98 (12.1)	91 (15.6)
Cosmetic	24 (3.0)	12 (2.1)
Other/unknown	10 (1.2)	7 (1.2)
Nonuser	309 (38.2)	216 (36.9)
Unknown	10 (1.2)	1 (0.2)
Etiology of amputation, No. (%)		
Combat injury	284 (35.2)	200 (34.2)
Accident	510 (63.1)	380 (65.0)
Burn	94 (11.6)	69 (11.8)
Cancer	30 (3.7)	20 (3.4)
Diabetes mellitus	12 (1.5)	4 (0.7)
Infection	98 (12.1)	70 (12.0)
Geographic region, No. (%)		
Northeast	150 (18.6)	108 (18.5)
South	277 (34.3)	201 (34.4)
Upper Midwest	192 (23.8)	146 (24.5)
West	189 (23.4)	130 (22.2)
Amputation care in prior year, No. (%)		
Yes	185 (22.9)	118 (20.2)
No	597 (73.9)	461 (78.8)
Unknown	26 (3.2)	6 (1.0)
Care in prior year to follow-up AND between baseline and follow-up, No. (%)		113 (19.3)
Location of care in period between baseline and follow-up, No. (%)		76 (67.3)
Only VA care		5 (4.4)
Only DoD care		8 (7.1)
VA and DoD care		16 (14.2)
Other care		
Missing		8 (7.1)

Abbreviations: DoD, US Department of Defense; VA, US Department of Veterans Affairs.

were omitted because they only were completed by small subsamples due to intentional skip patterns in the survey. These items addressed whether clinical HCPs discussed amputation care goals in the prior year, worked to develop a care plan in the prior year, or helped to coordinate care after a move. Completion rates for all items considered for the index are shown in eAppendix 1 (Available at doi:10.12788/fp.0096). After item selection, we generated an index score, which was the number of reported "yes" responses to the seven relevant items.

Other Variables

We created a single variable called level/laterality which categorized ULA as unilateral or bilateral. We further categorized respondents with unilateral amputation by their amputation level. We categorized respondents as transradial for wrist joint or below the elbow amputations; transhumeral for at or above the elbow amputations; and shoulder for shoulder joint or forequarter amputations. Participants indicated the amputation etiology using 7 yes/no variables: combat injury, accident, burn, cancer, diabetes mellitus, and infection. Participants could select ≥ 1 etiology.

Primary prosthesis type was categorized as body powered, myoelectric/hybrid, cosmetic, other/unknown, or nonuser. The service era was classified based on amputation date as Before Vietnam, Vietnam War, After Vietnam to Gulf War, After Gulf War to September 10, 2001, and September 11, 2001 to present. For race, individuals with > 1 race were

TABLE 2 Service Satisfaction and Comparisons of Respondents With Unilateral and Bilateral Amputation

Orthotics and Prosthetics User's Survey Client Satisfaction With Services	All, mean (SD) (N = 490)	Unilateral, mean (SD) SH (n = 27)	TH (n = 121)	TR (n = 313)	All (n = 461)	Bilateral, mean (SD) (n = 29)	*P* Value[a]
Prosthetist appointment within reasonable time	1.9 (0.7)	2.1 (0.8)	1.8 (0.7)	1.8 (0.7)	1.9 (0.7)	2.1 (0.6)	.02[b]
Received appropriate courtesy/ respect from staff	1.6 (0.6)	1.6 (0.6)	1.5 (0.6)	1.6 (0.6)	1.6 (0.6)	1.8 (0.6)	.14
Waited reasonable time to be seen	1.8 (0.7)	2.0 (0.9)	1.7 (0.7)	1.8 (0.7)	1.8 (0.7)	2.1 (0.8)	.04[b]
Fully informed about equipment choices by staff	2.0 (0.8)	2.1 (0.9)	1.9 (0.8)	2.0 (0.8)	2.0 (0.8)	2.2 (0.7)	.13
Opportunity to express concerns regarding equipment to prosthetist	1.7 (0.6)	2.0 (0.6)	1.6 (0.6)	1.7 (0.7)	1.7 (0.7)	1.9 (0.5)	.14
Prosthetist responsive to concerns and questions	1.7 (0.6)	1.7 (0.6)	1.6 (0.6)	1.7 (0.6)	1.7 (0.6)	1.8 (0.6)	.11
Satisfied with training in use/ maintenance of prosthesis	1.8 (0.7)	1.9 (0.7)	1.8 (0.7)	1.8 (0.8)	1.8 (0.7)	2.0 (0.6)	.09
Prosthetist discussed possible problems with equipment	2.0 (0.7)	2.1 (0.6)	2.0 (0.8)	1.9 (0.7)	2.0 (0.7)	2.1 (0.6)	.16
Staff coordinated services with therapists/doctors	2.0 (0.7)	2.3 (0.7)	1.9 (0.7)	1.9 (0.7)	2.0 (0.7)	2.0 (0.6)	.39
Decision making was collaborative with staff regarding care/equipment	1.9 (0.7)	2.0 (0.6)	1.8 (0.7)	1.9 (0.7)	1.9 (0.7)	2.0 (0.5)	.18
Total score	36.2 (20.0)	42.2 (17.1)	33.4 (20.8)	36.1 (20.0)	35.8 (20.1)	41.4 (18.3)	.21

Abbreviations: SH, shoulder disarticulation or scapulothoracic amputation; TH, transhumeral or elbow disarticulation, TR, transradial or wrist disarticulation.
[a]Wilcoxon rank-sum test compared scores between all unilateral amputation categories combined with bilateral amputation.
[b]Statistically significant.

classified as other. We classified participants by region, using the station identification of the most recent VA medical center that they had visited between January 1, 2010 and December 30, 2015.

The survey also employed 2 measures of satisfaction with the prosthesis, the Trinity Amputation and Prosthetic Experience Scale (TAPES) satisfaction scale and the OPUS Client Satisfaction with Devices (CSD). TAPES consists of 10 items addressing color, shape, noise, appearance, weight, usefulness, reliability, fit, comfort and overall satisfaction.[11] Items are rated on a 5-point Likert scale from very dissatisfied (1) to very satisfied (5). An 8-item version of the CSD scale was created for this study, after conducting a Rasch analysis (using Winsteps version 4.4.2) of the original 11-item CSD. The 8 items assess satisfaction with prosthesis fit, weight, comfort, donning ease, appearance, durability, skin contact, and pain. Items are rated on a 4-point scale from strongly agree (1) to strongly disagree (4); higher CSD scores indicate less satisfaction with devices. Psychometric analysis of the revised CSD score was reported in a prior publication.[12] We also reported on the CSS using the original 10-item measure.

Data Analyses

We described characteristics of respondents at baseline and follow-up. We used baseline data to calculate CSS scores and described scores for all participants, for subgroups of unilateral and bilateral amputees, and for unilateral amputees stratified by amputation level. Wilcoxon rank sum tests were used to compare the CSS item and total scores of 461 prosthesis users with unilateral amputation and 29 with bilateral amputation. To identify factors that we hypothesized might be associated with CSS scores at baseline, we developed separate bivariate

linear regression models. We added those factors that were associated with CSS scores at $P \leq .1$ in bivariate analyses to a multivariable linear regression model of factors associated with CSS score. The $P \leq .1$ threshold was used to ensure that relevant confounders were controlled for in regression models. We excluded 309 participants with no reported prosthesis use (who were not asked to complete the CSS), 20 participants with other/unknown prosthesis types, and 106 with missing data on amputation care in the prior year or on satisfaction metrics. We used baseline data for this analysis to maximize the sample size.

We compared CSS scores for those who reported receiving care within or outside of the VA or DoD in the prior year, using Wilcoxon Mann-Whitney rank tests. We also compared scores of individual quality of care items for these groups using Fisher exact tests. We chose to examine individual items rather than the full Index because several items specified care receipt within the VA and thus would be inappropriate to utilize in comparisons by site location; however, we described responses to all items. In these analyses, we excluded 2 respondents who had conflicting information regarding location of care. We used follow-up data for this analysis because it allowed us to identify location of care received in the prior year.

We also described the CSS scores, the 7-item Quality of Care Index and responses to other items related to quality of care at baseline and follow-up. To examine whether satisfaction with prosthetic care or aspects of care quality had changed over time, we compared baseline and follow-up CSS and quality of care scores for respondents who had measures at both times using Wilcoxon signed ranks tests. Individual items were compared using McNemar tests.

RESULTS

Respondents were 97.4% male and included 776 unilateral amputees and 32 bilateral amputees with a mean (SD) age of 63.3 (14.1) years (Table 1). Respondents had lost their limbs a mean (SD) 31.4 (14.1) years prior, and half were transradial, 34.2% transhumeral, and 11.6% shoulder amputation. At baseline 185 (22.9%) participants received amputation-related care in the prior year and 118 (20.2%) participants received amputation-related care within 1 year of follow-up. Of respondents, 113 (19.3%) stated that their care was between baseline and follow-up and 89 (78.8%) of these received care at either the VA, the DoD or both; just 16 (14.2%) received care elsewhere.

Mean (SD) CSS scores were highest (lower satisfaction) for those with amputation at the shoulder and lowest for those with transhumeral amputation: 42.2 (20.0) vs 33.4 (20.8). Persons with bilateral amputation were less satisfied in almost every category when compared with those with unilateral amputation, although the total CSS score was not substantially different. Wilcoxon rank sum analyses revealed statistically significant differences in wait time satisfaction: bilateral amputees were less satisfied than unilateral amputees. Factors associated with overall CSS score in bivariate analyses were CSD score, TAPES score, amputation care receipt, prosthesis type, race, and region of care (eAppendix 2, available at doi:10.12788/fp.0096).

TABLE 3 Multivariate Linear Regression Model Predicting Care Satisfaction at Baseline (n = 373)[a]

	OPUS Service Satisfaction	
Variables	**β**	***P* Value**
OPUS CSD	0.7	< .001[b]
TAPES	-2.9	.12
Amputation care in prior years		
No (ref)		
Yes	-5.1	.003[b]
Prothesis type		
Body powered (ref)		
Myoelectric/hybrid	-2.2	.25
Cosmetic	2.9	.46
Race		
White (ref)		
Black	2.4	.35
Other/mixed	1.0	.78
Unknown	1.8	.59
Geographic region		
Northeast	-3.1	.18
South (ref)		
Upper Midwest	-2.7	.22
West	-0.4	.85

Abbreviations: CSD; client satisfaction device; CSS, client satisfaction survey; OPUS, Orthotics and Prosthetics User's Survey; TAPES, Trinity Amputation and Prosthetic Experience Scale.
[a]$R^2 = 0.46$.
[b]Statistically significant.

TABLE 4 Comparison of Care Satisfaction and Quality of Care Items by Care Location at Follow-up

Criteria	Care in VA or DoD (n = 89)	Community Care (n = 14)	*P* Value
OPUS CSS, No. [mean, (SD)][a]	**62 [31.6 (22.6)]**	**7 [38.0 (17.7)]**	**.35[b]**
Quality of care, No. (%)			
VA-care specific items			
Prosthetic/amputation checkup at VA in prior year	61 (68.5)	0 (0.0)	< .001[c,d]
Prosthetic/amputation checkup by phone in prior year	17 (19.1)	0 (0.0)	.12[c]
Other			
Functional assessment in prior year	30 (33.7)	1 (7.1)	.06[c]
Amputation-related care in prior yeare	89 (100.0)	14 (100.0)	.99[c]
Contacted by any care provider outside appointments	38 (42.7)	2 (14.3)	.07[c]
Family or caregiver involved in care in prior year	28 (31.5)	2 (14.3)	.34[c]
Received amputation care education in prior year	37 (41.6)	0 (0.0)	.002[c,d]
Pain management			
Well managed	43 (63.2)	3 (60.0)	.99[c]
With medication	31 (44.9)	1 (20.0)	.38[c]
Other strategy	39 (57.4)	4 (80.0)	.64[c]
Initial amputation care			
Family or caregiver involved in initial amputation management	48 (55.2)	9 (64.3)	.58[c]
Peer visit after amputation	28 (31.8)	4 (28.6)	.99[c]
Low response rate items			
Discussed amputation care goals in prior year	26 (54.2)	0 (0.0)	.05[c]
Worked to develop care plan in prior year	17 (65.4)	NA	NA
Any HCP helped coordinate care with new HCP after move in past year	2 (33.3)	0 (0.0)	.99[c]

Abbreviations: CSS; client satisfaction survey; DoD, US Department of Defense; HCP, health care provider; OPUS, Orthotics and Prosthetics User's Survey; VA, US Department of Veterans Affairs.
[a]Higher numbers are worse satisfaction.
[b]Wilcoxon Mann-Whitney test.
[c]Fisher exact test.
[d]Statistically significant.
[e]All respondents reported amputation care in prior year in an earlier survey.

In the multivariate regression model of baseline CSS scores, only 2 variables were independently associated with CSS scores: CSD score and recent amputation care (Table 3). For each 1-point increase in CSD score there was a 0.7 point increase in CSS score. Those with amputation care in the prior year had higher satisfaction when compared with those who had not received care ($P = .003$).

For participants who indicated that they received amputation care between baseline and follow-up, CSS mean (SD) scores were better, but not statistically different, for those who reported care in the VA or DoD vs private care, 31.6 (22.6) vs 38.0 (17.7) (Table 4). When compared with community-based care, more participants who received care in the VA or DoD in the prior year had a functional assessment in that time period (33.7% vs 7.1%, $P = .06$), were contacted by HCPs outside of appointments (42.7% vs 18.8%, $P = .07$), and received information about amputation care in the prior year (41.6% vs 0%, $P = .002$). There was no difference in the proportion whose family/caregivers were involved in care in the prior year.

No statistically significant differences were observed in paired comparisons of the CSS and Quality of Care Index at baseline or follow-up for all participants with data at both time points (Table 5; eAppendix 3 available at doi:10.12788/fp.0096). Individual pain measures did not differ significantly between timepoints. Quality Index mean (SD) scores were 1.3 (1.5) and 1.2 (1.5) at baseline and follow-up, respectively ($P = .07$). For the 214 prosthesis users with longitudinal data, baseline CSS mean (SD) scores were generally worse at baseline than at follow-up: 34.4 (19.8) vs 32.5 (21.0) ($P = .23$). Family/caregiver involvement in amputation care

TABLE 5 Baseline and Follow-up Care Satisfaction and Quality of Care

Criteria	Total, No.	Baseline, mean (SD)	Follow-up, mean (SD)	*P* Value
Orthotics and Prosthetics User's Survey lient satisfaction survey	214	34.4 (19.8)	32.5 (21.0)	.24[a]
Quality of Care Index (7 items)	563	1.3 (1.5)	1.2 (1.5)	.06[a]
US Department of Veterans Affairs-care specific items		No. (%)	No. (%)	
Prosthetic/amputation checkup at VA in prior year	581	146 (25.1)	136 (23.4)	.37[a]
Prosthetic/amputation checkup by phone in prior year	581	32 (5.5)	43 (7.4)	.20[a]
Other items				
Functional assessment in prior year	573	108 (18.9)	95 (16.6)	.25[b]
Amputation-related care in prior year	579	138 (23.9)	118 (20.5)	.08[b]
Contacted by any care provider outside appointments	579	139 (24.0)	137 (23.7)	.86[b]
Family or caregiver care involvement in prior year	581	142 (24.4)	103 (17.7)	.0007[b]
Received amputation care education in prior year	576	71 (12.3)	74 (12.9)	.75
Pain				
Well managed	289	190 (65.7)	177 (61.3)	.16[b]
Manage using medication	299	163 (54.5)	157 (52.5)	.54[b]
Manage using other strategy	297	138 (46.5)	143 (48.2)	.65[b]
Low response rate				
Discussed amputation care goals in prior year	61	31 (50.8)	32 (52.5)	.99[b]
Developed care plan in prior year	21	16 (76.2)	14 (66.7)	.69[b]
Any care providers helped coordinate care with new care providers after move in past year	11	1 (9.1)	1 (9.1)	.99[b]

[a]Wilcoxon Mann-Whitney test.
[b]McNemar test.
[c]Statistically significant.

was significantly higher in the year before baseline when compared with the year prior to follow-up (24.4% vs 17.7%, $P = .001$). There were no other statistically significant differences in Quality of Care items between baseline and follow-up.

DISCUSSION

Our longitudinal study provides insights into the experiences of veterans with major ULA related to satisfaction with prosthetic limb care services and receipt of amputation-related care. We reported on the development and use of a new summary measure of amputation care quality, which we designed to capture some of the key elements of care quality as provided in the VA/DoD CPG.[2]

We used baseline data to identify factors independently associated with prosthetic limb care satisfaction as measured by a previously validated measure, the OPUS CSS. The CSS addresses satisfaction with prosthetic limb services and does not reflect satisfaction with other amputation care services. We found that persons who received amputation care in the prior year had CSS scores that were a mean 5.1 points better than those who had not received recent care. Although causality cannot be determined with this investigation, this finding highlights an important relationship between frequency of care and satisfaction, which can be leveraged by the VA in future care initiatives. Care satisfaction was also better by 0.7 points for every 1-point decrease (indicating higher satisfaction) in the OPUS CSD prosthetic satisfaction scale. This finding isn't surprising, given that a major purpose of prosthetic limb care services is to procure and fit a satisfactory device. To determine whether these same relationships were observed in the smaller, longitudinal cohort data at follow-up, we repeated these models and found similar relationships between recent care receipt and prosthesis satisfaction and satisfaction with services. We believe that these findings are meaningful and emphasize the importance of both service and device satisfaction to the veteran with an ULA. Lower service satisfaction scores among those with amputations at the shoulder and those with bilateral limb loss suggest that these individuals may benefit from different service delivery approaches.

We did observe a difference in satisfaction scores by geographic region in the follow-up (but not the baseline) data with satisfaction higher in the Western vs the Southern region (data not shown). This finding suggests a need for continued monitoring of care satisfaction over time to determine whether differences by region persist. We grouped respondents into geographic region based on the location where they had received their most recent VA care of any type. Many veterans receive care at multiple VA locations. Thus, it is possible that some veterans received their amputation care at a non-VA facility or a VA facility in a different region.

Our findings related to prosthetic limb care services satisfaction are generalizable to veteran prosthesis users. Findings may not be generalizable to nonusers, because in our study, the CSS only was administered to prosthesis users. Thus, we were unable to identify factors associated with care satisfaction for persons who were not current users of an upper limb prosthesis.

The study findings confirmed that most veterans with ULA receive amputation-related care in the VA or DoD. We compared CSS and Quality of Care item scores for those who reported receiving care at the VA or DoD vs elsewhere. Amputation care within the VA is complex. Some services are provided at VA facilities and some are ordered by VA clinicians but provided by community-based HCPs. However, we found that better (though not statistically significantly different) CSS scores and several Quality of Care items were endorsed by a significantly more of those reporting care in the VA or DoD as compared to elsewhere. Given the dissemination of a rehabilitation of upper limb amputees CPG, we hypothesized that VA and DoD HCPs would be more aware of care guidelines and would provide better care. Overall, our findings supported this hypothesis while also suggesting that areas such as caregiver involvement and peer visitation may benefit from additional attention and program improvement.

We used longitudinal data to describe and compare CSS and Quality of Care Index scores. Our analyses did not detect any statistically significant differences between baseline and follow-up. This finding may reflect that this was a relatively stable population with regard to amputation experiences given the mean time since amputation was 31.4 years. However, we also recognize that our measures may not have captured all aspects of care satisfaction or quality. It is possible that there were other changes that had occurred over the course of the year that were not captured by the CSS or by the Quality of Care Index. It is also possible that some implementation and adoption of the CPG had happened prior to our baseline survey. Finally, it is possible that some elements of the CPG have not yet been fully integrated into clinical care. We believe that the latter is likely, given that nearly 80% of respondents did not report receiving any amputation care within the past year at follow-up, though the CPGs recommend an annual visit.

Aside from recall bias, 2 explanations must be considered relative to the low rate of adherence to the CPG recommendation for an annual follow-up. The first is that the CPG simply may not be widely adopted. The second is that the majority of patients with ULA who use prostheses use a body-powered system. These tend to be low maintenance, long-lasting systems and may ultimately not need annual maintenance and repair. Further, if the veteran's body-powered system is functioning properly and health status has not changed, they may simply be opting out of an annual visit despite the CPG recommendation. Nonetheless, this apparent low rate of annual follow-up emphasizes the need for additional process improvement measures for the VA.

Strengths and Limitations

The VA provides a unique setting for a nationally representative study of amputation rehabilitation because it has centralized data sources that can be used to identify veterans with ULA. Our study had a strong response rate, and its prosthetic limb care satisfaction findings are generalizable to all veterans with major ULA who received VA care from 2010 to 2015. However, there are limits to generalizability outside of this population to civilians or to veterans who do not receive VA care. To examine possible nonresponse bias, which could limit

generalizability, we compared the baseline characteristics of respondents and nonrespondents to the follow-up study (eAppendix 4 available at doi:10.12788/fp.0096). There were no significant differences in satisfaction, quality of care, or receipt of amputation-related care between those lost to follow-up and those with follow-up data. Although, we did find small differences in gender, race, and service era (defined by amputation date). We do not believe that these differences threaten the interpretation of findings at follow-up, but there may be limits to generalizability of these findings to the full baseline sample. The data were from a telephone survey of veterans. It is possible that some veterans did not recall their care receipt or did not understand some of the questions and thus may not have accurately answered questions related to type of care received or the timing of that care.

Our interpretation of findings comparing care received within the VA and DoD or elsewhere is also limited because we cannot say with certainty whether those who indicated no care in the VA or DoD actually had care that was sponsored by the VA or DoD as contract or fee-basis care. Just 8 respondents indicated that they had received care only outside of the VA or DoD in the prior year. There were also some limitations in the collection of data about care location. We asked about receipt of amputation care in the prior year and about location of any amputation care received between baseline and follow-up, and there were differences in responses. Thus, we used a combination of these items to identify location of care received in the prior year.

Despite these limitations, we believe that our study provides novel, important findings about the satisfaction with prosthetic limb care services and quality of amputation rehabilitation care for veterans. Findings from this study can be used to address amputation and prosthetic limb care satisfaction and quality weaknesses highlighted and to benchmark care satisfaction and CPG compliance. Other studies evaluating care guideline compliance have used indicators obtained from clinical records or data repositories.[13-15] Future work could combine self-reported satisfaction and care quality measures with indicators obtained from clinical or repository sources to provide a more complete snapshot of care delivery.

CONCLUSIONS

We reported on a national survey of veterans with major upper limb loss that assessed satisfaction with prosthetic limb care services and quality of amputation care. Satisfaction with prosthetic limb care was independently associated with satisfaction with the prosthesis, and receipt of care within the prior year. Most of the veterans surveyed received care within the VA or DoD and reported receiving higher quality of care, when compared with those who received care outside of the VA or DoD. Satisfaction with care and quality of care were stable over the year of this study. Data presented in this study can serve to direct VA amputation care process improvement initiatives as benchmarks for future work. Future studies are needed to track satisfaction with and quality of care for veterans with ULA.

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Disclaimer

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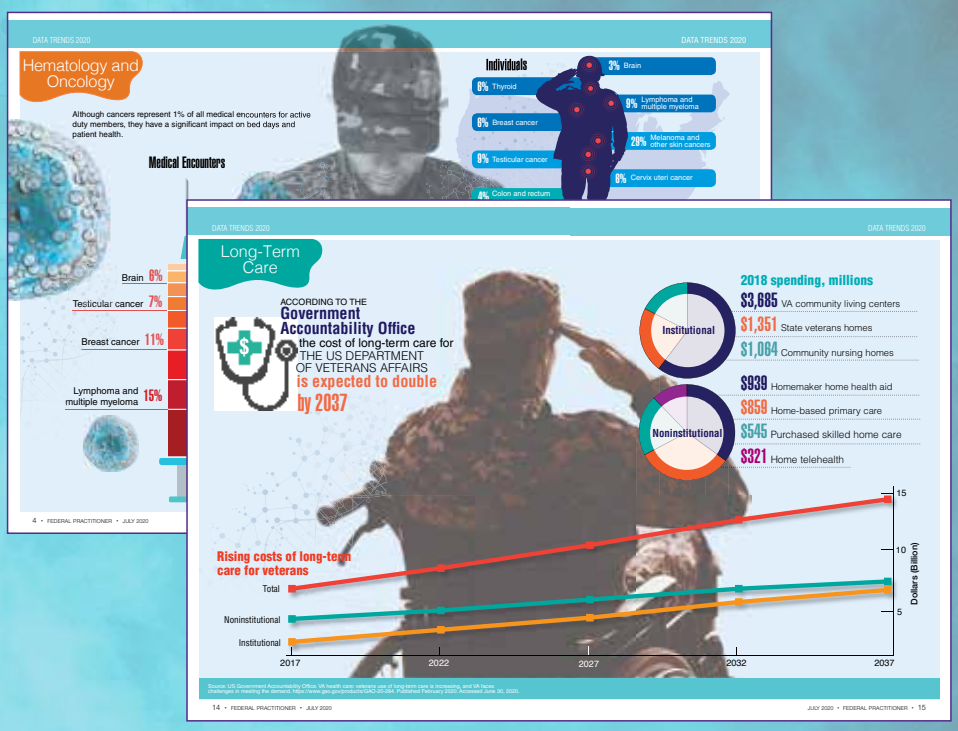

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Contralateral Limb Pain Is Prevalent, Persistent, and Impacts Quality of Life of Veterans with Unilateral Upper-Limb Amputation

Linda Resnik, PT, PhD, FAPTA, Matthew Borgia, MA, Melissa A. Clark, PhD

ABSTRACT

Introduction: Individuals with upper-limb amputation (ULA) have increased risk for contralateral limb pain (CLP), and further study of CLP in ULA is needed. Study objectives were to: (1) describe CLP frequency, intensity, and 1-year change; (2) identify factors associated with CLP; and (3) quantify associations between CLP, health-related quality of life (HRQoL), and disability (QuickDASH).

Methods: A total of 776 veterans with unilateral ULA were surveyed at baseline, and 562 were surveyed again at 1 year. Participants reported CLP frequency and intensity and nonamputated limb conditions. Multivariable models examined factors associated with CLP, as well as associations between CLP intensity and HRQOL (physical component score and mental component score) and disability (QuickDASH).

Results: Contralateral limb pain prevalence was 72.7% (baseline) and 71.6% (follow-up); 59.8% had persistent pain. Contralateral limb conditions and neck and residual limb pain were associated with higher odds of CLP. Black race (vs White), back pain (vs without), and age 45 to 65 years (vs 18–45 years) were associated with greater CLP intensity. Female sex (vs male) and use of cosmetic prostheses (vs body-powered) were associated with lower intensity. The mental component scores were 2.7 and 6.6 points lower for moderate and severe CLP, respectively; the physical component scores were 4.2 and 8.4 points lower for moderate and severe CLP; and QuickDASH scores were 9.4 and 20.7 point higher for moderate and severe CLP, compared with none to mild pain.

Conclusions: Findings suggest that overreliance on the nonamputated limb, leading to CLP, occurs regardless of amputation level or prosthesis use. Further research is needed to understand whether disparities in pain treatment exist by race. Contralateral limb pain is prevalent and persistent in veterans with ULA. Moderate to severe CLP is associated with worse HRQOL and greater disability. Efforts are needed to prevent and treat ULA CLP pain.

Clinical Relevance: Clinicians caring for persons with unilateral ULA should evaluate the contralateral upper limb and refer patients to appropriate therapies to address painful conditions. Persons with ULA should be educated about the risks of development of CLP and be provided with strategies to minimize overuse when possible. (*J Prosthet Orthot.* 2023;35:3–11)

KEY INDEXING TERMS: amputation, arm pain, upper extremity, veteran, quality of life

Individuals with upper-limb amputation (ULA) are at increased risk for contralateral limb pain (CLP) as compared with the general population, in part because of overreliance on the sound limb and increased susceptibility to overuse injuries.[1] Veterans with ULA are at even higher risk.[2] Approximately 80% of adults with ULAs in the United States, the United Kingdom, and Canada use a prosthesis.[3] In comparison, only 60% of the overall population of US veterans with unilateral ULA use a prosthesis.[2]

Those with unilateral amputation depend on their sound limb for daily activities, regardless of whether they use a prosthesis. Upper-limb prosthetic devices can be inefficient and uncomfortable and do not fully restore function, contributing to altered body mechanics and compensatory movements for those who do use them.[4–6]

An estimated 36% to 57% of persons with ULA report CLP.[1,7–10] In a nationally representative study of US adults, prevalence estimates of CLP were the following: 19.9% for the shoulder, 16.8%

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for the hand, 9.8% for the wrist, and 1.2% for the arm.[11] Chronic pain of the upper limb was reported in 4.1% in a US population with ULA.[12] Furthermore, almost one third of persons with ULA in the Washington state area of the United States reported CLP lasting at least 3 months.[13] The rates of CLP in US veterans with ULA exceed rates previously reported, with 71% experiencing CLP.[2] The persistence of CLP in veterans has not been previously examined.

Studies are needed to understand the musculoskeletal conditions experienced by veterans with ULA, the factors associated with CLP, as well as the impact of CLP on disability and quality of life. Research evidence could inform preventative measures or targeted treatment efforts to ameliorate the impact of CLP. Thus, the purposes of this study were to: (1) describe CLP frequency, intensity, and change over 1 year; (2) identify factors associated with CLP; and (3) quantify the associations between CLP, health-related quality of life (HRQoL), and disability.

METHODS

A longitudinal study of veterans with ULA was conducted, with data collected at baseline and 1-year follow-up. This study was approved by the VA Central International Review Board. The sampling frame included veterans with major ULA who received VA care between 2010 and 2015. To maximize generalizability to veterans with ULA, the sampling frame was identified from VA Corporate Data Warehouse sources.[2] All nondeceased veterans with valid addresses and phone numbers were mailed recruitment materials.

All participants provided oral informed consent before participating in baseline telephone interviews. Participants who agreed to participate in future activities were contacted 1 year later for follow-up telephone interviews. Analyses in this article were conducted on those with ULA who participated at baseline (n = 776) and at 1-year follow-up (n = 562; Figure 1).

KEY VARIABLES

Interviews lasted approximately 45 minutes and covered a wide range of topics, described in detail elsewhere,[2] and summarized briefly hereinafter.

INDEPENDENT VARIABLES

The key independent variables used in analyses were presence, frequency and intensity of CLP "in the past 4 weeks," and history of diagnosed musculoskeletal condition of the nonamputated side.

Respondents were asked if they had CLP and if so to rate how often they experienced it ("never," "only once or twice," "about once per week," "2–3 times per week," "4–6 times per week," "several times a day," "all the time or almost all the time"). We examined pain frequency as a dichotomous variable (never or any frequency reported) and as a categorical variable with 4 categories ("never," "weekly or less frequent," "2–6 times per week," and "daily/always"). Those who indicated that they had any pain rated the intensity on a scale from 0 (no pain) to 10 (worst possible pain). We examined pain intensity as a continuous variable and as a categorical variable with 4 levels ("never had pain," 0–3 = "none to mild," 4–7 = "moderate," 8–10 = "severe"). Survey questions asked respondents whether they had ever been diagnosed with any of 9 common conditions in the nonamputated limb (e.g., tendinitis of wrist, elbow, finger, thumb, and rotator cuff, carpal tunnel syndrome, and arthritis). These items were adapted from a previous survey of veterans with amputation.[14]

OUTCOMES

Health-related quality of life was assessed using the VR-12 physical component score (PCS) and mental component score (MCS).[15] Disability was assessed using the QuickDASH, which measures disability of the arm, shoulder, and hand.[16]

OTHER VARIABLES

Respondents reported their age (categorized 18–44, 45–64, 65–74, ≥75 years), sex, race, Hispanic ethnicity, employment status, marital status, time since amputation, side of amputation, amputation level, amputation etiology (combat, accident, burn, cancer, diabetes, and infection), amputation of lower limb, prosthesis use (ever and current), primary prosthesis type (body-powered, myoelectric, hybrid, cosmetic, or other), number of prostheses currently used, frequency of prosthesis use, intensify of prosthesis use, and history of prosthesis training (ever and current), Respondents were also asked about presence, frequency, and intensity of pain in other locations including the back, neck, residual limb, and phantom limb.

ANALYTICAL METHODS

Descriptive analyses were used to identify participant characteristics at baseline and follow-up. Prevalence rates, frequency, and intensity of CLP were quantified at baseline and follow-up, and 1-year changes were examined. Change in pain over the year was categorized as pain free (no pain at both time points),

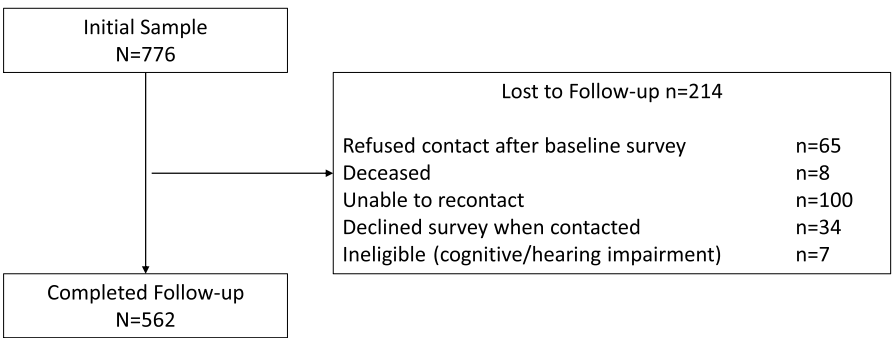

Figure 1. Lost to follow-up flowchart.

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Table 1. Characteristics of the respondents in the baseline and longitudinal samples (individuals with unilateral amputation)

	Baseline Sample (n = 776)	Longitudinal Sample (n = 562)
	Mean (SD)	Mean (SD)
Age, y	63.2 (14.1)	63.7 (13.6)
Missing, n	24	0
Years since initial amputation	31.3 (18.4)	31.6 (18.0)
Missing, n	21	14
	n (%)	n (%)
Sex		
Male	755 (97.3)	552 (98.2)
Female	21 (2.7)	10 (1.8)
Race		
White (ref)	583 (75.1)	441 (78.5)
Black	86 (11.1)	59 (10.5)
Other/mixed	35 (4.5)	30 (5.3)
Unknown	72 (9.3)	32 (5.7)
Hispanic or Latino		
Yes	62 (8.0)	42 (7.5)
No	678 (87.4)	513 (91.3)
Unknown	36 (4.6)	7 (1.3)
Employment		
Employed/student	124 (16.5)	93 (16.6)
Retired	525 (69.8)	400 (71.2)
Medical leave/other	102 (13.6)	68 (12.1)
Unknown	1 (0.1)	1 (0.2)
Employment		
Employed full-time	73 (9.4)	54 (9.6)
Employed part-time	31 (4.0)	24 (4.3)
Student	20 (2.6)	15 (2.7)
Retired, but employed after amputation	373 (48.1)	290 (51.6)
Retired, but not employed after amputation	152 (19.6)	110 (19.6)
On medical leave	9 (1.2)	5 (0.9)
Other	93 (12.0)	63 (11.2)
Unknown	25 (3.2)	1 (0.2)
Marital status		
Married or living together	481 (62.0)	369 (65.7)
Divorced or separated	169 (21.8)	118 (21.0)
Widowed	45 (5.8)	34 (6.1)
Never married	56 (7.2)	41 (7.3)
Unknown	25 (3.2)	0 (0.0)
Side of amputation		
Right	370 (47.7)	273 (48.6)
Left	406 (52.3)	289 (5.14)
Amputation of lower limb		
Yes	94 (12.1)	67 (11.9)
No	682 (87.9)	495 (88.1)
Side of lower-limb amputation		
Right side	39 (41.5)	30 (44.8)
Left side	23 (24.5)	15 (22.4)
Both sides	32 (34.0)	22 (32.8)
Amputation level		
Forequarter	23 (3.0)	18 (3.2)
At the shoulder joint	71 (9.2)	45 (8.0)
Above the elbow	236 (30.4)	175 (31.1)
At the elbow	40 (5.2)	31 (5.5)
Below the elbow	280 (36.1)	198 (35.2)
At the wrist joint	126 (16.2)	95 (16.9)
Etiology of amputation (may be <1)		
Combat injury	275 (35.4)	194 (34.5)
Accident	490 (63.1)	366 (65.1)
Burn	81 (10.4)	60 (10.7)
Cancer	30 (3.9)	20 (3.6)
Diabetes	11 (1.4)	4 (0.7)
Infection	89 (11.5)	63 (11.2)
Primary prosthesis type		
Body-powered	335 (43.2)	252 (44.8)
Myoelectric/hybrid	93 (12.0)	65 (11.6)
Cosmetic	22 (2.8)	12 (2.1)
Nonusers	306 (39.4)	223 (39.7)
Unknown	20 (2.6)	10 (1.8)
Ever used prosthesis		
Yes	717 (92.4)	528 (94.0)
No	52 (6.7)	33 (5.9)
Unknown	7 (0.9)	1 (0.2)
Initial prosthesis training		
Yes	545 (76.0)	397 (75.2)
No	165 (23.0)	126 (23.9)
Unknown	7 (1.0)	5 (1.0)
Current prosthesis use		
Yes	461 (59.4)	336 (59.8)
No	306 (39.4)	223 (39.7)
Unknown	9 (1.2)	3 (0.5)
Current prosthesis users (at baseline)		
Current prosthesis training		
Yes	301 (65.3)	220 (65.5)
No	153 (33.2)	115 (34.2)
Unknown	7 (1.5)	1 (0.3)
No. prostheses used		
1	291 (63.1)	215 (64.0)
≥2	170 (36.9)	121 (36.0)
Frequency of prosthesis use		
Daily	351 (76.1)	261 (77.7)
Weekly	59 (12.8)	41 (12.2)
Monthly or less	44 (9.5)	30 (8.9)
Unknown	7 (1.5)	4 (1.2)
Intensity of daily prosthesis use		
<2 h	68 (19.1)	64 (18.8)
2 to <4 h	42 (9.1)	26 (7.7)
4 to <8 h	85 (18.4)	62 (18.5)
8 to <12 h	88 (19.1)	68 (20.2)
≥12 h	152 (33.0)	113 (33.6)
Unknown	6 (1.3)	4 (1.2)
Musculoskeletal diagnosis on sound-side arm		
Yes	395 (51.2)	296 (52.7)
No	376 (48.8)	266 (47.3)

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incident (no pain at baseline, but pain at follow-up), resolved (pain at baseline, but none at follow-up), or persistent (pain at both baseline and follow-up). We examined change in pain intensity from baseline to follow-up for respondents with persistent pain and categorized respondents as improved, worsened, or unchanged based on change in intensity of at least 2 points. We calculated the prevalence rates of musculoskeletal conditions and grouped responses in the "other" category into clinical categories when possible.

We identified factors associated with any CLP and intensity of CLP at baseline for the full sample (to maximize sample size) using bivariate analyses (t tests/analyses of variance). We used findings from these analyses to construct 2 multivariable models: the first a logistic regression model of any CLP and the second a linear regression model of pain intensity. These models included amputation level and all variables that were statistically significant at $P \leq 0.2$ in bivariate analyses (Supplementary Digital Content Table 1, http://links.lww.com/JPO/A90). We used backwards selection at $P < 0.2$ to determine which variables to retain in the final models. Covariates in the logistic regression model included: age; combat and cancer amputation etiology; presence of musculoskeletal sound-side conditions; as well as presence of any back, neck, residual limb, and phantom limb pain. Covariates in the linear regression model included: age; sex; race; time since amputation; diabetes amputation etiology; presence of any back, neck, residual limb, and phantom limb pain; current prosthesis use; and primary prosthesis type.

We calculated HRQoL (VR-12 MCS and PCS) and disability (QuickDASH) scores at baseline for the full sample and stratified by intensity of CLP to observe crude relationships. We then developed 3 sets of multivariable general linear regression models (GLMs) to examine the association of CLP intensity with HRQoL and disability. The GLMs were constructed in 3 stages. The first stage was development of crude models containing only the primary independent variable of CLP. The second stage was development of adjusted models that contained variables previously identified in bivariate analyses as being associated with HRQoL or disability scores at $P < 0.1$,[17] as well as history of diagnosed musculoskeletal conditions (which had not been previously studied). Covariates in these models included: amputation level, musculoskeletal condition of the sound side (ever), age, years since amputation, race, marital status, amputation etiology (combat accident and infection), prosthesis use (ever), prosthesis type (/current use), initial prosthesis training, current prosthesis training, and number of prostheses. Finally, the third stage was development of fully adjusted models controlling for pain intensity and presence of other types of pain (neck, back, phantom, residual limb). Adjusted R^2 of the models were compared to identify the relative contribution of the other pain locations to the models' explanatory power. SAS 9.4 was used for all analyses.

RESULTS

Response and participation rates were 47.7% and 63.3%, respectively, in the baseline sample, and 72.4% and 85.2%, respectively, in the follow-up sample.

The full sample was 97.3% male and 75.1% White, the mean age of 63.2 years (standard deviation [SD], 14.1 years) with 31.3 years (SD, 18.4 years) since amputation. Thirty-six percent had below elbow amputation, 30.4% above elbow, 16.2% wrist disarticulation, 9.2% shoulder disarticulation, 5.2% elbow disarticulation, and 3.0% forequarter amputation. Accidents (63.1%) and combat injury (35.4%) were the most common amputation etiology. Forty-three percent used a body-powered prosthesis, 39% did not use a prosthesis, 12% used a myoelectric/hybrid, and 3% used a cosmetic prosthesis. Characteristics of baseline and longitudinal samples were similar (Table 1).

The CLP prevalence in the baseline sample was 71.1%. (Table 2). For the longitudinal sample, prevalence was 72.7% at baseline and 71.6% at follow-up. Slightly less than one third of the participants in the baseline and longitudinal samples experienced daily or more frequent pain. For the longitudinal

Table 2. Prevalence, frequency, and intensity of contralateral upper limb pain: baseline and longitudinal samples (unilateral only)

	Full Sample (N = 767)	Longitudinal Sample (n = 585)	
	Baseline	Baseline	Follow-up
	n (%)	n (%)	n (%)
Any contralateral upper limb pain (dichotomized)	538 (71.1)	407 (72.7)	400 (71.6)
Contralateral upper limb pain frequency			
Never (1)	219 (28.9)	153 (27.3)	159 (28.4)
Weekly or less frequent (2–3)	131 (17.3)	112 (20.0)	116 (20.8)
2–6 times per week (4–5)	165 (21.8)	120 (21.4)	103 (18.4)
Daily/always (6–7)	242 (32.0)	175 (31.3)	181 (32.4)
Contralateral upper limb pain intensity			
Never had pain	219 (29.1)	153 (27.4)	159 (28.5)
None to mild (0–3)	167 (22.2)	132 (23.6)	133 (23.8)
Moderate (4–7)	283 (37.5)	211 (37.8)	212 (38.0)
Severe (8–10)	85 (11.3)	63 (11.3)	54 (9.7)
	Mean (SD)	Mean (SD)	Mean (SD)
Contralateral upper limb pain intensity (for those with any pain)	5.0 (2.3)	4.9 (2.3)	4.8 (2.2)

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sample, the average pain intensity at baseline and follow-up was 4.9 (SD, 2.3) and 4.8 (SD, 2.2), respectively. Most participants in the longitudinal sample had persistent pain (59.8%), with 12.8% reporting resolved pain and 11.4% reporting incident pain (Table 3). Among those with persistent pain, most had no change in pain intensity (56.3%), while 24.4% had improved pain and 19.3% worsened pain.

There were 395 participants who reported ever having conditions of the contralateral limb (Table 4). The most prevalent conditions reported were rotator cuff tendonitis (51.1%), osteoarthritis (45.8%), carpal tunnel (45.1%), nerve damage (44.3%), elbow tendonitis (37.0%), and wrist tendonitis (31.1%). Results of bivariate analyses of the relationships between covariates and likelihood and intensity of CLP are shown in Supplementary Digital Content Table 1, http://links.lww.com/JPO/A90.

Results of multivariable logistic and linear regressions models for baseline CLP are shown in Table 5. Those with any diagnosis of a musculoskeletal condition of the contralateral limb had 4.2 (95% confidence interval [CI], 2.9 to 6.2) times the odds of reporting any CLP compared with those without a prior diagnosis. Those with neck pain and residual limb pain had 3.8 (CI, 2.6 to 5.5), and 2.4 (CI, 1.6 to 3.7) times the odds, respectively, of reporting CLP.

Multivariable linear regression identified the following independent correlates of CLP intensity: race, back pain, age, sex, and prosthesis type. The respondents of Black race (compared with White) had, on average, 1.2 points greater CLP intensity and those with back pain (compared with without) had 0.7 points greater CLP intensity. The respondents aged 18 to 45 years (compared with 45–65 years) had 0.9 points lower CLP intensity. The female respondents (compared with male respondents) had 1.4 points lower CLP intensity, and those using cosmetic prosthesis (compared with body-powered) had 1.7 points lower CLP intensity.

Table 6 shows the crude relationship between intensity of CLP, HRQoL, and disability scores. The mean MCS scores ranged from 53.4 for the subgroup with no CLP to 44.7 for the subgroup with severe CLP, whereas the mean PCS ranged from 43.5 to 33.5, and QuickDASH ranged from 26.1 to 52.5. Crude differences between subgroups were diminished after adjusting for potential confounders. Fully adjusted GLMs (Table 7) showed that on average, the VR-12 MCS scores were 2.8 (CI, –5.2 to –0.3) and 6.6 (CI, –10.0 to –3.3) points lower for those reporting moderate and severe CLP, respectively, compared with none to mild CLP. On average, the VR-12 PCS scores were 4.2 (CI, –6.3 to –2.1) and 8.4 (CI, –11.2 to –5.6) points lower for those with moderate and severe CLP, respectively, compared with no to mild CLP. Compared with those with none to mild CLP, those with moderate and severe pain experienced greater disability; QuickDASH scores were 9.3 (CI, 5.8 to 12.8) and 20.5 (CI, 15.8 to 25.2) points higher, respectively. Full results of multivariable linear regressions of HRQoL and disability are provided in Supplementary Digital Content Table 2, http://links.lww.com/JPO/A90.

Table 3. Change in CLP prevalence and intensity

	Longitudinal Sample (n = 585)
Change in pain prevalence	n (%)
Pain free	87 (15.6)
Incident	66 (11.9)
Resolved	71 (12.8)
Persistent	333 (59.8)
Change in pain intensity (those with persistent pain)	(n = 332)
Improved	81 (24.4)
No change	187 (56.3)
Worsened	64 (19.3)

*Improvement/worsening defined as a decrease/increase of 2 points or more in the pain intensity scale at follow-up as compared with baseline.

Table 4. Prevalence of conditions that had ever been diagnosed in the contralateral limb (n = 395)

Condition	n (%)
Rotator cuff tendonitis	202 (51.1)
Osteoarthritis	181 (45.8)
Carpal tunnel	178 (45.1)
Nerve damage	175 (44.3)
Elbow tendonitis	146 (37.0)
Wrist tendonitis	123 (31.1)
Finger tendonitis	88 (22.3)
Thumb tendonitis	78 (19.8)
Ganglion cyst	40 (10.1)
Other	27 (6.8)
Tendon tear	19 (4.8)
Neuropathy	16 (4.1)
Fracture	15 (3.8)
Overuse or other tendonitis	15 (3.8)
Surgery of the shoulder, elbow, or hand	12 (3.0)
Pain	11 (2.8)
Trigger finger	8 (2.0)
Contracture	7 (1.8)
Muscle or nerve injury	7 (1.8)
Weakness	7 (1.8)
Bursitis	5 (1.3)
Stroke or neurological disorder	5 (1.3)
Partial hand amputation	4 (1.0)

DISCUSSION

Our study aimed to examine prevalence and intensity of CLP in veterans with ULA and changes in CLP over a 12-month period. We found that more than 70% of the veterans with unilateral ULA have CLP and more than half had pain that persisted over a 12-month period, with no change in pain intensity. This prevalence rate is far greater than that reported in the general population of US adults and in the civilian ULA population. We identified the most prevalent conditions diagnosed in the contralateral limb as rotator cuff tendonitis, osteoarthritis, carpal tunnel, nerve damage, elbow tendonitis, and wrist tendonitis.

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Table 5. Correlates of contralateral upper limb pain and pain intensity in the baseline sample

	Logistic Regression: Any CLP (Yes/No, N = 746)			Linear Regression: CLP Intensity (0–10, n = 507)		
Characteristic	**OR**	**95% CI**	***P***	**β**	**95% CI**	***P***
Amputation level						
Shoulder/FQ	1.82	0.98 to 3.36	0.0578	0.35	−0.39 to 1.10	0.3517
Transhumeral/ED	1.04	0.69 to 1.57	0.8358	−0.17	−0.61 to 0.28	0.4641
Transradial/WD (ref)						
Sex						
Male (ref)						
Female				−1.39	−2.60 to −0.17	**0.0253**
Race						
White (ref)						
Black				1.17	0.55 to 1.80	**0.0003**
Unknown				0.74	−0.06 to 1.54	0.0693
Other/mixed				0.40	−0.53 to 1.33	0.3931
Age at time of study, y						.
18–44				−0.85	−1.50 to −0.20	**0.0104**
45–64 (ref)						
65–74				0.32	−0.15 to 0.79	0.1824
75+				−0.12	−0.80 to 0.56	0.7229
Amputation etiology						
Combat injury						
Yes	1.31	0.88 to 1.94	0.1830			
No (ref)						
Cancer						
Yes						
No (ref)						
Diabetes						
Yes				−1.81	−0.40 to 4.01	0.1086
No (ref)						
Any musculoskeletal condition of the sound side						
Yes	4.19	2.86 to 6.14	**<0.0001**			
No (ref)						
Any back pain						
Yes				0.65	0.20 to 1.10	**0.0044**
No (ref)						
Any neck pain						
Yes	3.78	2.59 to 5.51	**<0.0001**			
No (ref)						
Any phantom limb pain						
Yes	1.43	0.94 to 2.20	0.0988			
No (ref)						
Any residual limb pain						
Yes	2.41	1.57 to 3.72	**<0.0001**	0.48	−0.01 to 0.98	0.0545
No (ref)						
Current prosthesis use						
Yes				0.36	−0.10 to 0.81	0.1244
No (ref)						
Primary prosthesis type						
Body-powered (ref)						
Myoelectric/hybrid				−0.12	−0.76 to 0.53	0.7231
Cosmetic				−1.65	−0.28 to −0.47	**0.0064**
R^2				0.11		

Boldface text indicates statistical significance at $P < 0.05$.

*Empty shaded boxes indicate variables that were not significant at $P < 0.2$ or those that were dropped in backward selection.

ED, elbow disarticulation; FQ, forequarter; OR, odds ratio; WD, wrist disarticulation.

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Table 6. Health-related quality of life and disability among the baseline sample (N = 776)

		HRQoL		
		MCS	PCS	Disability
	n	Mean (SD)	Mean (SD)	Mean (SD)
No CLP pain	219	53.4 (11.7)	43.5 (10.9)	26.1 (18.3)
Mild CLP pain	167	51.9 (12.2)	42.6 (11.0)	30.8 (19.4)
Moderate CLP pain	283	49.3 (13.6)	37.2 (10.6)	40.8 (19.2)
Severe CLP pain	85	44.7 (14.2)	33.5 (9.8)	52.5 (22.3)

Disability measured with the QuickDASH, quick version of the Disabilities of the Arm Shoulder and Hand Questionnaire.

Our models identified factors associated with likelihood of having pain as well as intensity of CLP pain. We did not observe an association between prosthesis use or amputation level and likelihood of reporting CLP. These findings are consistent with those of Burger and Vidmar[18] who reported that overuse problems did not vary by amputation level or type of prosthesis used. A study of Vietnam and Operation Enduring Freedom and Operation Iraqi Freedom veterans reported that 28% to 36% of those with unilateral ULA used their prosthesis for most daily tasks, 40% to 43% used their prosthesis in a minority of daily tasks, and 24% to 30% did not use a prosthesis.[14] Therefore, our findings may be explained by the fact that the vast majority of persons with unilateral ULA rely on their sound side, regardless of amputation level or prosthesis use.[14]

Independent correlates of having CLP included: contralateral limb conditions, neck pain, and residual limb pain. These findings make sense because residual limb pain may cause persons with ULA to avoid using the amputated limb and rely even more heavily on the nonamputated side, which in turn contributes to overuse injuries. The relationship between CLP and neck pain is also not surprising given that arm pain in many instances can originate from problems in the cervical spine.[19,20]

Mean pain intensity in our sample was approximately 0.8 points higher than previously reported in persons with ULA.[13] We found a relationship between older age and CLP intensity but not prevalence, with persons ages 45 to 64 years reporting more intense pain as compared with those younger than 45. Studies of chronic pain in the US population pain generally report that pain prevalence increases from younger to middle ages and then decreases with older age.[12] We also found that Black race was associated with reporting greater pain intensity. This finding is consistent with prior studies that found an association between Black race and increased pain sensitization[21] and greater pain intensity in Black Americans as compared with White Americans.[22] The literature points to disparities in chronic pain management[22] and pain screening processes

Table 7. Association of CLP with HRQoL (MCS and PCS) and disability (QuickDASH)

	Bivariate Models		Adjusted for Demographics[a]		Fully Adjusted Models[b]	
GLM Regressions	**β (95% CI)**	***P***	**β (95% CI)**	***P***	**β (95% CI)**	***P***
MCS on CL pain intensity						
Never had pain	1.54 (1.04 to 4.13)	0.2402	0.89 (–1.77 to 3.55)	0.5120	–0.80 (–3.50 to 1.90)	0.5621
None to mild (0–3) (ref)						
Moderate (4–7)	–2.70 (–5.16 to –0.24)	**0.0311**	–3.20 (–5.71 to –0.70)	**0.0123**	–2.76 (–5.22 to –0.29)	**0.0284**
Severe (8–10)	–6.63 (–9.99 to –3.27)	**0.0001**	–7.63 (–10.99 to –4.27)	**<0.0001**	–6.64 (–9.95 to –3.32)	**<0.0001**
n, Adj-R^2	749 to 0.04		706 to 0.10		702 to 0.15	
PCS on CL pain intensity						
Never had pain	0.77 (–1.45 to 2.99)	0.4975	1.16 (01.11 to 3.43)	0.3160	–0.67 (–2.93 to 1.60)	0.5647
None to mild (0–3) (ref)						
Moderate (4–7)	–5.13 (–7.23 to –3.02)	**<0.0001**	–4.85 (–6.98 to –2.71)	**<0.0001**	–4.21 (–6.28 to –2.14)	**<0.0001**
Severe (8–10)	–8.86 (–11.7 to –5.97)	**<0.0001**	–9.77 (–12.63 to –6.91)	**<0.0001**	–8.37 (–11.15 to –5.59)	**<0.0001**
n, Adj-R^2	750 to 0.08		707 to 0.17		703 to 0.23	
QuickDASH on CL pain intensity						
Never had pain	–4.68 (–8.62 to –0.75)	**0.0197**	–3.93 (–7.81 to –0.05)	**0.0471**	–0.15 (–4.00 to 3.69)	0.9374
None to Mild (0–3) (ref)						
Moderate (4–7)	10.03 (6.29 to 13.75)	**<0.0001**	10.35 (6.71 to 13.99)	**<0.0001**	9.30 (5.81 to 12.79)	**<0.0001**
Severe (8–10)	21.68 (16.55 to 26.82)	**<0.0001**	22.68 (17.76 to 27.60)	**<0.0001**	20.48 (15.75 to 25.21)	**<0.0001**
n, Adj-R^2	741, 0.16		698, 0.29		694, 0.36	

[a]Covariates include: amputation level, age, years since amputation, race, marital status, amputation etiology (combat accident and infection), prosthesis use (ever), prosthesis type (/current use), Initial prosthesis training, current prosthesis training, and number of prostheses.

[b]Covariates include: amputation level, contralateral pain intensity and indicators of any back, neck, phantom limb, and residual limb pain, age, years since amputation, race, marital status, amputation etiology (combat accident and infection), prosthesis use (ever), prosthesis type (/current use), initial prosthesis training, current prosthesis training, and number of prostheses.

Adj-R^2, adjusted R^2.

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in the VA.[23] Further research is needed to understand whether disparities in pain treatment exist for Black veterans with ULA.

We were initially surprised that cosmetic prosthesis use was associated with lower CLP intensity, given that these passive devices require exclusive use of the nonamputated limb for grasping activities. We do not believe that this is a causal relationship, but rather the result of selection bias, given that persons with bothersome CLP would be more likely to be prescribed or request (and thus use) a functional prosthesis in an attempt to ameliorate overuse and strain on the nonamputated side.

We found that moderate to severe CLP had a negative effect on mental health, physical health, and greater disability. The HRQOL scores in our study for those with severe CLP are comparable with those previously described.[13] Hanley et al[13] reported a PCS of 35.5 (SD, 10.2) and MCS of 44.5 (SD, 11.2) in persons with ULA with persistent, bothersome CLP in the previous 4 weeks to 3 months. Although Hanley et al[13] examined impact of CLP on disability days, we did not find previous studies that examined the impact of CLP in ULAs on QuickDASH scores.

LIMITATIONS

The majority of our analyses used data from the full baseline sample of respondents, which we believe are generalizable to the population of veterans with ULA who receive care at the VA, given the relatively high response rates. Although we observed minor differences in the longitudinal sample, as compared with those lost to follow-up (Supplementary Digital Content Table 3, http://links.lww.com/JPO/A90), we believe that findings about change in pain derived from the longitudinal sample are also largely generalizable to veterans with ULA who receive care within the VA. Participants lost to follow-up were slightly more likely to be female, Black, or other race and to have diabetic etiology. We acknowledge that our results may have more limited generalizability to the civilian population with upper-limb loss. Nevertheless, our study represents one of the largest population-based studies of persons with ULA and provides important insights into factors associated with CLP and the association of CLP with HRQoL and disability. Further studies of the civilian ULA population are needed to confirm or refute our findings.

Although our study provides a snapshot of the prevalence rates of common self-reported conditions of the nonamputated arm, there are limitations to our estimates. First, all conditions were self-reported, and the respondents were asked whether they had ever been diagnosed with a condition of the nonamputated side. No attempt was made to confirm diagnoses. We do believe that there is face validity to our approach, with findings regarding some specific conditions, comparable with those reported in the literature. For example, the proportion of persons in our sample with carpal tunnel syndrome (45.1%) was similar to that reported by Burger and Vidmar[18] (43%), but higher than in those experiencing symptoms suggestive of carpal tunnel syndrome reported by Datta et al[10] (26.1%). Another limitation was that our list of common conditions was limited and based on the list of conditions used in prior research.[14] Almost 50% of the respondents indicated that they had "other" types of conditions and described the condition to the interviewer. Our research team reviewed these responses, recategorized them into existing conditions whenever possible, or created several new categories to represent unique conditions that were reported by at least four people.

CONCLUSIONS

Contralateral limb pain was prevalent and persistent in veterans with ULA. Veterans with histories of musculoskeletal conditions of the contralateral limb, neck, and residual limb pain were more likely to report CLP. Black race and middle age were associated with greater pain intensity, while female sex and use of cosmetic prostheses was associated with lower intensity. Moderate to severe CLP was negatively associated with HRQoL and positively associated with greater perceived disability. Efforts are needed to prevent and treat CLP pain in the veteran ULA population.

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Longitudinal study of prosthesis use in veterans with upper limb amputation

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Abstract

Background: Little is known about the patterns of prosthesis use and satisfaction of those who cease use or begin to use upper limb prostheses.

Objectives: Among a longitudinal sample of Veterans with upper limb amputation, (1) describe changes in prosthesis use over 1 year, (2) examine rates of receipt of new prostheses, and (3) compare prosthesis satisfaction in respondents who received a new prosthesis to those who did not.

Study Design: Longitudinal survey.

Methods: 808 Veterans who had participated in a baseline interview 1 year earlier were invited to participate in structured telephone interviews.

Results: A total of 562 persons with unilateral and 23 with bilateral amputation participated in the interviews (Response rate = 72.4% and 85.2%, respectively). Prosthesis use, frequency and intensity of use, and types of prostheses used were stable over 1 year. About 24% reported using a different primary terminal device type at follow-up than baseline. Prosthesis use was less frequent/intense at baseline among those who discontinued use compared with those who did not ($P < 0.05$), and less frequent/intense for those who started compared with those who continued using a prosthesis ($P < 0.0001$). Rates of prosthetic training were higher among those who received a different prosthesis type compared with those using the same type ($P = 0.06$). Satisfaction scores were higher ($P < 0.01$) for new prosthesis recipients, and lower at baseline for prosthesis abandoners compared with continued users ($P = 0.03$).

Conclusion: Prosthesis abandonment appears to be predicated on dissatisfaction with the device, as well as less frequent/intense prosthesis use. These findings can be used to identify those at risk for prosthesis abandonment and improve their prosthesis experience.

Keywords

Upper limb, amputation, survey, epidemiology, veterans, longitudinal, prosthesis, longitudinal study

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Background

Many cross-sectional studies have examined use and abandonment of upper limb prostheses,[1–6] reporting prevalent dissatisfaction, and abandonment in about 26% of the population.[7] A 2018 survey of Veterans with upper limb amputation found that 60% with unilateral upper limb amputation were using prostheses, a rate of use below that reported in prior systematic reviews and studies of Vietnam and recent combat Veterans.[8] While prevalence rates of rejection for myoelectric and body-powered prostheses have been reported as roughly equivalent,[7] rates of terminal device rejection may vary. Rejection rates for myoelectric hands, body-powered hooks, and passive hands have been reported to be 39%, 50%, and 53%, respectively.[9]

Our survey of Veterans found 50% with unilateral amputation had discontinued using a prosthesis in the past, with 36% of Veterans abandoning body-powered and 18% abandoning myoelectric prostheses.[8] However, to date,

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there have been no data to determine how often Veterans change prosthesis types. Cross-sectional studies provide a snapshot of prosthesis use, but do not provide information about use over time. It is likely that in any given year, some will start using a prosthesis, some will stop using prostheses, some will resume using a device after a period of disuse, and some will switch to a new prosthesis type.

Prior research reported that between 2000 and 2010, Veterans received a new upper limb prosthesis every 3.5 years.[10] However, this research did not evaluate whether new prostheses received were of the same type. The relationship between prosthesis satisfaction and switching to or obtaining a new prosthesis has also not been previously examined. In addition, little is known about the patterns of prosthesis use among those who stop using prostheses or those who begin using new ones. Finally, no studies to date have examined the 1-year incidence rates of prosthesis abandonment or uptake, or the factors associated with these events.

Prevalent dissatisfaction with upper limb prostheses among Veterans has been previously recognized. An Office of the Inspector General (OIG) report called for additional research to evaluate the needs of Veterans with upper limb amputations.[11] To meet this need, we conducted the aforementioned survey of Veterans with upper limb amputation.[8] We followed this cohort over 1 year to examine stability and change in prosthesis use and satisfaction over time. This article presents summary findings from this longitudinal study. The purposes were to (1) describe 1 year changes in prosthesis use; (2) examine the rate of receipt of new prostheses and terminal devices; and (3) compare prosthesis satisfaction among prosthesis users who received a new prosthesis to those who did not.

Methods

The structured baseline interview included a representative sample of Veterans with major upper limb amputation who received care in the Veterans Administration (VA) between 2010 and 2015. The VA is a comprehensive, integrated health care system that serves more than 8.9 million U.S. Veterans annually. VA providers prescribe prostheses and amputation rehabilitation services based upon a Veteran's clinical needs. The VA furnishes authorized items to eligible Veterans through internal VA resources or through an authorized VA vendor or contractor based in the community.

The sampling frame, described in a prior publication, was identified using amputation diagnosis and procedure codes from VA Corporate Data Warehouse (CDW) sources.[8] Those with valid addresses and telephone numbers were contacted by letter and provided an opportunity to opt-out of study participation. Those who did not opt-out were contacted by telephone. Participants provided oral informed consent by telephone prior to participating in the interview. A waiver of documentation of informed consent was obtained from the VA Central IRB. Forty-five-minute structured telephone interviews were conducted at baseline and follow-up by professional interviewers from an academic survey center who were trained by the study PI. Respondents who agreed to participate in future activities were re-contacted 1 year after the baseline interview. Response (RR) and cooperation (CR) rates were calculated using American Association of Public Opinion Research guidelines (AAPOR RR4 and CR4).[12] To assess for potential nonresponse bias, we compared baseline and follow-up respondents to Veterans with upper limb amputation diagnoses identified in the original full sampling frame on data available in CDW (age, sex, and year of most recent encounter at the VA).

Data collection

The content of the interview has been described in detail elsewhere.[8] Items relevant to the analyses presented in this article are described below and provided as supplemental material. The baseline and longitudinal interview contained a demographics section that asked about characteristics including age, sex, marital status, number of children, race/ethnicity, and employment; and a section on amputation that included items on side of limb loss, and amputation level, date, and etiology. For our analyses, we collapsed amputation levels into three groups: (1) TR, which included those with transradial and wrist disarticulation amputation, (2) TH, which included those with transhumeral and elbow disarticulation, and (3) SH, which included those with shoulder disarticulation and forequarter amputation.

The interview also contained questions specific to prosthesis users. Specifically, those who used a prosthesis were asked to identify type of prosthesis and terminal devices that they used, as well as the suspension method. In addition, those who indicated that they used more than one type of prosthesis were asked to identify the primary prosthesis and the prosthesis that they considered their secondary prosthesis. They were then asked how these prostheses were suspended on their body.

Respondents who were current prosthesis users were asked if they had received prosthetic training (yes or no). They were also asked to report frequency of prosthesis use (daily, weekly, monthly, every few months, 1 to 2 times per year), and average hours per day of use. Prosthesis satisfaction was assessed using two measures: the Trinity Amputation and Prosthetic Experience Scale (TAPES) satisfaction scale, and the modified 8-item Orthotics and Prosthetics Users Survey (OPUS) Client Satisfaction with Device (CSD) scale.[13–15]

Statistical analyses

We conducted descriptive analyses to characterize prosthesis use and changes in use between baseline and follow-up and identified respondents who had ceased using,

started using, or continued using a prosthesis. Chi-square analyses were used to compare the proportion of unilateral vs bilateral prothesis users who used two or more prostheses or two or more terminal devices. We examined differences between these groups in terms of days and hours of use with Wilcoxon Mann–Whitney tests. For those who reported using a prosthesis at both baseline and follow-up, we compared days and hours of use at each time point with Wilcoxon signed-ranks tests. For prothesis users with bilateral amputation, prosthesis use of the dominant side was used for analysis. We calculated the proportion of respondents who reported using a different type of primary prosthesis or terminal device in the follow-up and baseline interviews. In these analyses, we utilized the prosthesis and terminal device type of the dominant side for bilateral prosthesis users.

We examined the rates of receipt of a new prosthesis in the year prior to the baseline and follow-up. We also identified respondents who reported a type of prosthesis at follow-up that was not reported at baseline. For those who received a new prosthesis between baseline and follow-up, we used a chi-square test to compare rates of receipt of any prosthetic training between those who received a different prothesis type and those who received a similar prosthesis type. To determine whether there were differences in rates of switching prosthesis types for persons who used body-powered and myoelectric prostheses (the two largest groups), we performed a McNemar's comparison.

We compared CSD and TAPES satisfaction scores at baseline and follow-up for respondents who were using the same primary prosthesis type and for those who received a new device. Because normality tests of the satisfaction measures all rejected the assumption of normality in this sample, Wilcoxon signed-rank tests were used. We used nonparametric Wilcoxon Mann–Whitney tests to determine whether poorer baseline prosthesis satisfaction predicted prosthesis abandonment 1 year later. We also compared baseline satisfaction scores between respondents who had stopped using a prosthesis in the subsequent year to those who continued prosthesis use. A critical alpha of 0.05 was used for all analyses.

Results

Sampling frame and response rate

Eight-hundred eight persons were interviewed at baseline and 585 at follow-up. Figure 1 shows the reasons for loss to follow-up. The response rate and cooperation rate at follow-up among those who completed the baseline survey was 72.4% and 85.2%, respectively. Table 1 shows the characteristics of follow-up respondents, baseline completers, and those identified as eligible or of unknown eligibility in the initial sampling frame.

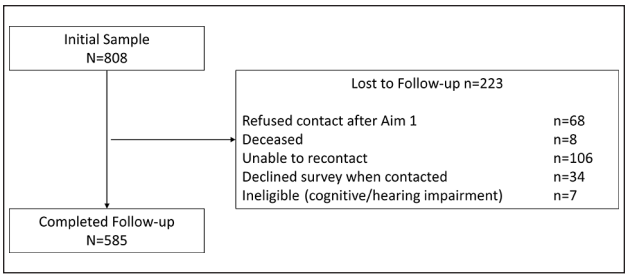

Figure 1. Flow diagram of study participation.

Sample characteristics and prosthesis use

Table 2 compares characteristics of those with unilateral ($n = 562$) and bilateral ($n = 23$) amputation in the longitudinal sample. Fifty-two percent ($n = 293$) of persons with unilateral amputation were classified in the TR group, 37% in the TH group ($n = 206$) and 11% in the SH group ($n = 11$). In the group with bilateral amputation, 65% ($n = 15$) had TR amputation on both sides, 13% ($n = 13$) had TH amputation on both sides, 9% ($n = 2$) had TR on one side and TH on the other side, 9% ($n = 2$) had TR amputation on one side and shoulder level amputation on the other, while 4% ($n = 1$) had shoulder amputation on one side and TH on the other.

There were no changes in amputation level from baseline to follow-up. Prosthesis use was stable over the 1-year period. Among individuals with unilateral amputation, 59.9% and 61.7% used a prosthesis at baseline and follow-up, respectively (Table 3). 95% of individuals with bilateral amputation used a prosthesis (on at least one side) at baseline and at follow-up. 6% of those with unilateral amputation had never used a prosthesis at either baseline or follow-up. Prevalence of prosthesis types at baseline and follow-up are shown in Table 3. Body-powered devices were used by 73% of persons with unilateral amputation and 75% of persons with bilateral amputation (on at least one side) at baseline and 69% of persons with unilateral amputation and 85% of persons with bilateral amputation at follow-up. Figure 2 shows data for persons with bilateral amputation, showing levels of amputation and the prostheses combinations used. 60% of persons with bilateral transradial amputation used a body-powered device on both sides.

The proportion reporting use of multiple prostheses was stable over the 1-year period. 30% of prosthesis users with unilateral amputation used two or more prostheses at follow-up (as compared with 36.0% at baseline), and 22.7% of prosthesis users with bilateral amputation used two or more prostheses on at least one side at follow-up (compared with 27.3% at baseline). Rate of receipt of new prostheses within the past year was stable from baseline to follow-up for those with unilateral (23% and 20%) and bilateral (50% and 50%) amputation. There were no

Table 1. Characteristics of Veterans assumed eligible and those who completed baseline and follow-up interviews.

	Eligible or unknown eligibility ($n = 2428$)	Completed baseline interview ($n = 808$)	Completed 1-year follow-up interview ($n = 585$)
	M (*SD*)	*M* (*SD*)	*M* (*SD*)
Age (years)	64.4 (15.4)	63.2 (14.2)	67.2 (14.9)
	n (%)	*n* (%)	*n* (%)
Sex			
Female	45 (1.9)	21 (2.6)	3 (0.5)
Male	2383 (98.2)	787 (97.4)	581 (99.5)
Race			
White	1663 (68.5)	558 (69.1)	400 (68.5)
Black	284 (11.7)	82 (10.2)	82 (14.0)
Other/mixed	93 (3.8)	30 (3.7)	24 (4.1)
Unknown	388 (16.0)	138 (17.1)	78 (13.4)
Date of last VA encounter[a]			
2010	6 (0.3)	1 (0.1)	1 (0.2)
2011	20 (0.8)	5 (0.6)	6 (1.0)
2012	21 (0.9)	2 (0.3)	7 (1.2)
2013	43 (1.8)	7 (0.9)	10 (1.7)
2014	44 (1.8)	14 (1.7)	7 (1.2)
2015	83 (3.4)	20 (2.5)	27 (4.6)
2016	2211 (91.1)	759 (93.9)	527 (90.1)

[a]Prior to 1 January 2017. M: mean; SD: standard deviation.

Table 2. Longitudinal sample: demographic characteristics.

	Unilateral ($n = 562$)	Bilateral ($n = 23$)	All ($n = 585$)
	M (*SD*)	*M* (*SD*)	*M* (*SD*)
Age (years)	63.2 (14.1)	63.6 (15.3)	63.7 (13.6)
Years since initial amputation	31.3 (18.4)	32.8 (18.1)	31.7 (18.0)
Missing (*n*)	14	0	14
	n (%)	*n* (%)	*n* (%)
Sex			
Male	552 (98.2)	23 (100.0)	575 (98.3)
Female	10 (1.8)	0 (0.0)	10 (1.7)
Race			
White	441 (78.5)	18 (78.3)	459 (78.5)
Black	59 (10.5)	1 (4.4)	60 (10.3)
Native American	5 (0.9)	0 (0.0)	5 (0.9)
Other (including mixed race)	25 (4.5)	2 (8.7)	27 (4.6)
Unknown	32 (5.7)	2 (8.7)	34 (5.8)
Hispanic or Latino			
Yes	42 (7.5)	4 (17.4)	46 (7.9)
No	513 (91.3)	19 (82.6)	532 (90.9)
Unknown	7 (1.3)	0 (0.0)	7 (1.2)
Employment			
Employed full-time	54 (9.6)	1 (4.4)	55 (9.4)
Employed part-time	24 (4.3)	0 (0.0)	24 (4.1)
Student	15 (2.7)	0 (0.0)	15 (2.6)

(Continued)

Table 2. (Continued)

	n (%)	*n* (%)	*n* (%)
Retired, but was employed after amputation	290 (51.6)	10 (43.5)	300 (51.3)
Retired, but was not employed after amputation	110 (19.6)	7 (30.4)	117 (20.0)
On medical leave	5 (0.9)	0 (0.0)	5 (0.9)
Other	63 (11.2)	5 (21.7)	68 (11.6)
Unknown	1 (0.2)	0 (0.0)	1 (0.2)
Laterality of amputation			
Unilateral right	273 (48.6)	0 (0.0)	273 (46.7)
Unilateral eft	289 (51.4)	0 (0.0)	289 (49.4)
Bilateral	0 (0.0)	23 (100.0)	23 (3.9)
Amputation of dominant arm			
Yes	286 (50.9)	23 (100.0)	309 (52.8)
No	274 (48.8)	0 (0.0)	274 (46.8)
Unknown	2 (0.4)	0 (0.0)	2 (0.3)
Amputation of lower limb			
Yes	67 (11.9)	6 (26.1)	73 (12.5)
No	495 (88.1)	17 (73.9)	512 (87.5)
Side of lower limb amputation			
Right side	30 (44.8)	1 (16.7)	31 (42.5)
Left side	15 (22.4)	1 (16.7)	16 (21.9)
Both sides	22 (32.8)	4 (66.7)	26 (35.6)
		Left	Right
Amputation level			
Forequarter	18 (3.2)	1 (4.4)	0 (0.0)
At the shoulder joint	45 (8.0)	1 (4.4)	1 (4.4)
Above the elbow	175 (31.1)	5 (21.7)	4 (17.4)
At the elbow	31 (5.5)	0 (0.0)	0 (0.0)
Below the elbow	198 (35.2)	8 (34.8)	14 (60.9)
At the wrist joint	95 (16.9)	7 (30.4)	4 (17.4)
Through the hand	0 (0.0)	1 (4.4)	0 (0.0)
Etiology of amputation (more than one may apply)			
Combat injury	194 (34.5)	6 (26.1)	6 (26.1)
Accident	366 (65.1)	14 (60.9)	14 (60.9)
Burn	60 (10.7)	9 (39.1)	9 (39.1)
Cancer	20 (3.6)	0 (0.0)	0 (0.0)
Diabetes	4 (0.7)	0 (0.0)	0 (0.0)
Infection	63 (11.2)	7 (30.4)	6 (26.1)

M: mean; SD: standard deviation.

Table 3. Prostheses use and description for persons with unilateral and bilateral amputation at baseline and follow-up.

	Baseline			Follow-up		
	Unilateral (*n* = 562)	Bilateral (*n* = 23)		Unilateral (*n* = 562)	Bilateral (*n* = 23)	
		Left	Right		Left	Right
	n (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)
Currently use a prosthesis						
Yes	336 (59.9)	19 (82.6)	20 (87.0)	347 (61.7)	18 (78.3)	20 (87.0)
No	190 (33.9)	4 (17.4)	3 (13.0)	182 (32.4)	5 (21.7)	3 (13.0)
*Never Used Prosthesis	33 (5.9)	0 (0.0)	0 (0.0)	32 (5.7)	0 (0.0)	0 (0.0)
Unknown	2 (0.4)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
Missing (*n*)	1	0	0	0	0	0

(Continued)

Table 3. (Continued)

Prothesis users only	*n* = 336	*n* = 19	*n* = 20	*n* = 347	*n* = 18	*n* = 20
Type of primary prosthesis						
Body-powered	245 (72.9)	14 (73.7)	15 (75.0)	240 (69.2)	15 (83.3)	17 (85.0)
Myoelectric	68 (20.2)	2 (10.5)	3 (15.0)	83 (23.9)	2 (11.1)	3 (15.0)
Hybrid	4 (1.2)	0 (0.0)	0 (0.0)	5 (1.4)	0 (0.0)	0 (0.0)
Cosmetic	12 (3.6)	3 (15.8)	2 (10.0)	12 (3.5)	1 (5.6)	0 (0.0)
Sport/recreation	4 (1.2)	0 (0.0)	0 (0.0)	7 (2.0)	0 (0.0)	0 (0.0)
Unknown	3 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of protheses used						
One	215 (64.0)	17 (89.5)	14 (70.0)	244 (70.3)	14 (77.8)	15 (75.0)
Two or more	121 (36.0)	2 (10.5)	6 (30.0)	103 (29.7)	4 (22.2)	5 (25.0)
Most recent prosthesis received						
<1 year ago	76 (22.6)	7 (36.8)	8 (40.0)	68 (19.6)	10 (55.6)	10 (50.0)
1 year or more ago	259 (77.1)	12 (63.2)	12 (60.0)	279 (80.4)	8 (44.4)	10 (50.0)
Unknown	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suspension type for primary prosthesis						
Suction	109 (32.4)	4 (21.1)	5 (25.0)	108 (31.1)	1 (5.6)	3 (15.0)
Gel or silicone liner with pin	66 (19.6)	2 (10.5)	2 (10.0)	63 (18.2)	2 (11.1)	3 (15.0)
Vacuum	38 (11.3)	2 (10.5)	3 (15.0)	41 (11.8)	0 (0.0)	1 (5.0)
Self-suspending due to socket shape	131 (39.0)	8 (42.1)	7 (35.0)	111 (32.0)	4 (22.2)	7 (35.0)
Harnessing	253 (75.3)	16 (84.2)	16 (80.0)	256 (73.8)	15 (83.3)	17 (85.0)
External strap	40 (11.9)	3 (15.8)	2 (10.0)	46 (13.3)	2 (11.1)	1 (5.0)
Number of terminal devices used						
One	199 (59.2)	19 (100.0)	17 (85.0)	219 (63.1)	14 (77.8)	14 (70.0)
Two or more	135 (40.2)	0 (0.0)	3 (15.0)	126 (36.3)	4 (22.2)	6 (30.0)
Unknown	2 (0.6)	0 (0.0)	0 (0.0)	2 (0.6)	0 (0.0)	0 (0.0)
Users of one or more terminal devices	*n* = 334	*n* = 19	*n* = 20	*n* = 345	*n* = 18	*n* = 20
Primary type of terminal device used						
Body-powered hook	216 (64.7)	14 (73.7)	15 (75.0)	218 (63.2)	13 (72.2)	15 (75.0)
Greifer	6 (1.8)	0 (0.0)	0 (0.0)	8 (2.3)	0 (0.0)	0 (0.0)
Power hook (ETD)	11 (3.3)	0 (0.0)	3 (15.0)	16 (4.6)	0 (0.0)	1 (5.0)
Sensor speed hand	10 (3.0)	1 (5.3)	0 (0.0)	10 (2.9)	1 (5.6)	0 (0.0)
I-Limb	9 (2.7)	0 (0.0)	0 (0.0)	6 (1.7)	0 (0.0)	0 (0.0)
Michaelangelo hand	6 (1.8)	0 (0.0)	0 (0.0)	5 (1.5)	0 (0.0)	0 (0.0)
Bebionic hand	19 (5.7)	0 (0.0)	0 (0.0)	15 (4.4)	0 (0.0)	1 (5.0)
Other	51 (15.3)	4 (21.1)	2 (10.0)	65 (18.8)	4 (22.2)	3 (15.0)
Unknown	6 (1.8)	0 (0.0)	0 (0.0)	2 (0.6)	0 (0.0)	0 (0.0)
Missing (*n*)	2	0	0	2	0	0
Users of two or more prostheses	*n* = 121	*n* = 2	*n* = 6	*n* = 103	*n* = 4	*n* = 5
Secondary type of prosthesis used						
Body powered	56 (46.3)	0 (0.0)	2 (33.3)	44 (42.7)	1 (25.0)	1 (20.0)
Myoelectric	47 (38.8)	2 (100.0)	3 (50.0)	38 (36.9)	2 (50.0)	3 (60.0)
Hybrid	2 (1.7)	0 (0.0)	0 (0.0)	2 (1.9)	1 (25.0)	1 (20.0)
Cosmetic	2 (1.7)	0 (0.0)	1 (16.7)	4 (3.9)	0 (0.0)	0 (0.0)
Sports/recreation	10 (8.3)	0 (0.0)	0 (0.0)	15 (14.6)	0 (0.0)	0 (0.0)

significant differences in the proportion of respondents with unilateral vs bilateral amputation who used two or more prostheses at either baseline ($\chi^2 = 0.48$, $P = 0.49$) or at follow-up ($\chi^2 = 0.77$, $P = 0.38$).

About the same proportion of respondents used multiple terminal devices across the 1-year period. 36% of prosthesis users with unilateral amputation used two or more types of terminal devices at follow-up (40% at baseline). In contrast, 27% of prosthesis users with bilateral amputation used two or more terminal devices on at least one side at follow-up (14% at baseline). The proportions of those using two or more terminal devices

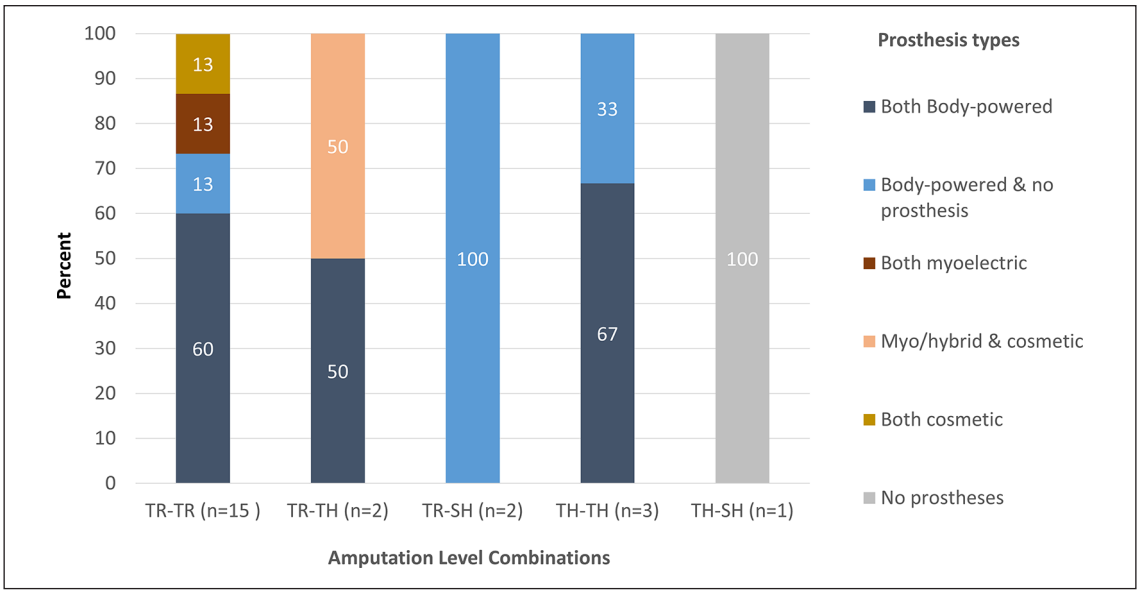

Figure 2. Amputation level and primary prostheses types used for persons with bilateral amputation ($n=23$).

Table 4. Comparison of frequency/intensity of prothesis use at baseline and follow-up for respondents who (1) abandoned a prosthesis, (2) continued using a prosthesis, and (3) started using a prosthesis.

	Baseline				Follow-up			
	Abandoned a prosthesis ($n=21$)	Continued prosthesis use ($n=337$)	Wilcoxon Mann-Whitney		Continued prosthesis use ($n=337$)	Started using a prosthesis ($n=30$)	Wilcoxon Mann-Whitney	
	n (%)	*n* (%)	W	*P* value	*n* (%)	*n* (%)	W	*P* value
Frequency of prosthesis use			4550	0.0096			7507	<0.0001
Daily	13 (61.9)	270 (81.1)			263 (78.3)	12 (40.0)		
Weekly	1 (4.8)	40 (12.0)			45 (14.4)	10 (33.3)		
Monthly	2 (9.5)	11 (3.3)			15 (4.5)	2 (6.7)		
Every few months	2 (9.5)	8 (2.4)			9 (2.7)	4 (13.3)		
1 to 2 times per year	3 (14.3)	4 (1.2)			4 (1.2)	2 (6.7)		
Intensity of prosthesis use			2664	0.0393			2984	<0.0001
<2 hours	8 (40.0)	57 (17.1)			43 (12.8)	10 (33.3)		
2 to <4 hours	1 (5.0)	26 (7.8)			47 (14.0)	11 (36.7)		
4 to <8 hours	3 (15.0)	62 (18.6)			59 (17.6)	4 (13.3)		
8 to <12 hours	4 (20.0)	69 (20.7)			65 (19.4)	3 (10.0)		
⩾12 hours	4 (20.0)	120 (35.9)			122 (36.3)	2 (6.7)		

was significantly different between those with unilateral vs bilateral amputation only at baseline ($\chi^2=6.23$, $P=0.01$).

Terminal device type and suspension method at follow-up were similar to those at baseline. At follow-up, the most common types of primary terminal devices were body-powered hooks (unilateral: 63%, bilateral: 72% left, 75% right). Multi-degree of freedom terminal devices (including the I-limb,[13] Michaelangelo Hand,[14] and Bebionic)[15] were used by 8% and 4.5% of those with unilateral and bilateral amputation, respectively.

Changes in prosthesis use in prior year

Table 4 shows comparisons of prosthesis use frequency and intensity for the separate sub-groups who (1) ceased using a prosthesis; (2) continued using a prosthesis; and (3) started using a prosthesis between baseline and follow-up. Prosthesis use as reported at baseline was less frequent and less intense among the 6% of prosthesis users who abandoned a prosthesis during the subsequent year as compared with those who did not ($P=0.01$). At follow-up, respondents who started using a prosthesis reported significantly less frequent prosthesis use, and fewer hours of

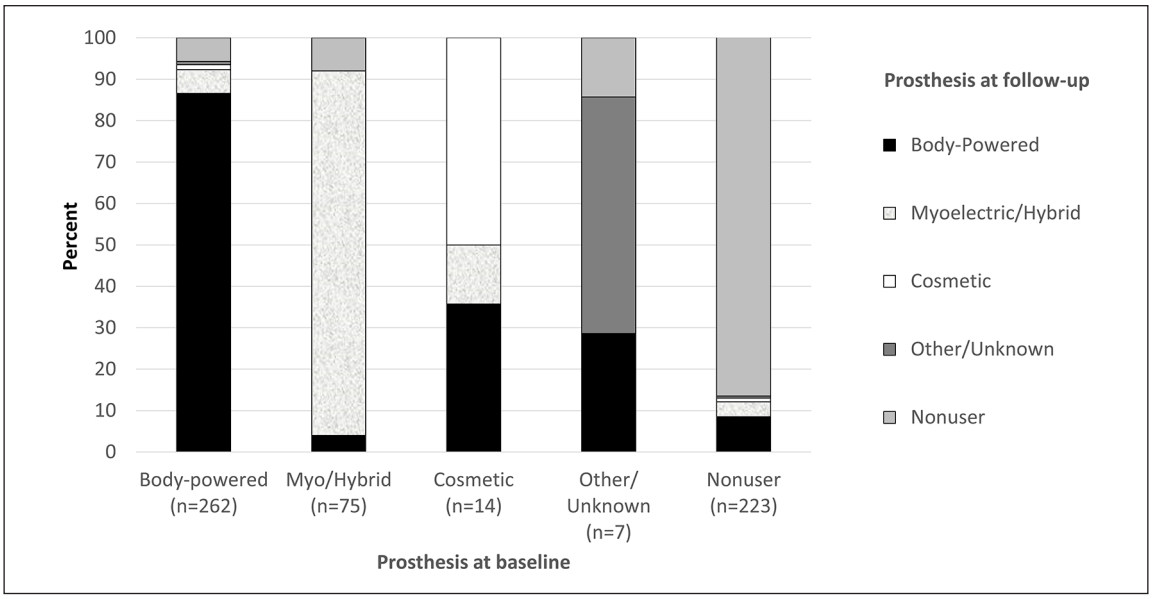

Figure 3. Primary prosthesis type at baseline and follow-up: respondents with unilateral or bilateral amputation ($n = 581$).

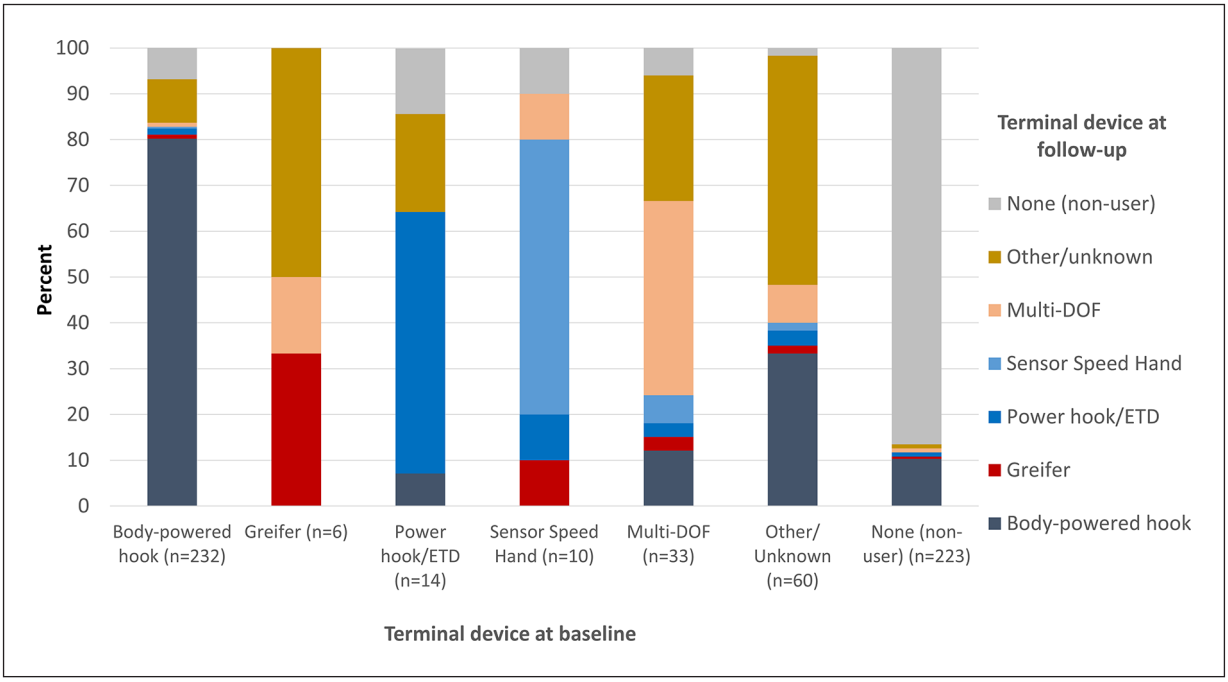

Figure 4. Primary terminal device type at baseline and follow-up: respondents with unilateral or bilateral amputation ($n = 578$).

prosthesis use compared with those who reported prosthesis use at both time points ($P < 0.0001$).

Transition to new type of prosthesis in prior year

The majority of participants with unilateral or bilateral amputation used the same type of primary prosthesis at baseline and follow-up (Figure 3). 12% of myoelectric/hybrid users and 13% of body-powered users reported changing primary prosthesis type between baseline and follow-up. In addition, half of the 14 cosmetic users switched to using either a body-powered (36%) or myoelectric (14%) prosthesis as their primary prosthesis type between baseline and follow-up.

Overall, 24.0% of respondents used a different primary terminal prosthesis type at follow-up and baseline (Figure 4). Specifically, 20% of body-powered users,

40% of sensor speed users, 43% of powered hook users, 50% of unknown type, 58% multi-degree of freedom (DOF) users, and 67% of Greifer users reported using a different type of terminal device at follow-up than baseline. A significantly higher proportion ($\chi^2 = 13.5$, $P = 0.0002$) of body-powered users transitioned to myoelectric devices as compared with myoelectric users transitioning to body-powered prosthesis.

Receipt of new prosthesis in prior year

At baseline, 15.1% ($n = 122$) of participants had received a new prosthesis in the prior year; at follow-up 14.4% ($n = 84$) had received a new prosthesis. Among follow-up participants who received a new prosthesis, 34.5% ($n = 29$) received a different prosthesis type than they reported using at baseline.

Training for new prosthesis recipients

Among those who received a new prosthesis at follow-up, rates of training with the new prosthesis were higher among those who received a prosthesis type that was different than any of the types they had reported using at baseline (52%) compared with those who received a previously reported type (31%); $\chi^2(1, 84) = 3.5$, $P = 0.0618$. However, the difference was not statistically significant.

Satisfaction with prostheses

TAPES scores were significantly higher at follow-up ($M = 4.0$, $SD = 0.7$) than at baseline ($M = 3.6$, $SD = 0.6$) for new prosthesis recipients (S = 466.5, $P = 0.002$). However, OPUS CSD scores were similar at follow-up ($M = 38.2$, $SD = 17.7$) and baseline ($M = 40.2$, $SD = 15.5$) with no significant difference (S = -115, $P = 0.34$). There were no differences in satisfaction scores between baseline and follow-up for those who used the same type of primary prosthesis at both time points (TAPES S = 1701.5, $P = 0.18$; CSD S = 549.5, $P = 0.58$). Those who ceased the use of a prosthesis between baseline and follow-up had 0.4 lower TAPES scores at baseline ($M = 3.5$, $SD = 0.8$) than those who continued to use a prosthesis at follow-up ($M = 3.9$, $SD = 0.6$; S = 2756, $P = 0.03$). There was no statistically significant difference in baseline OPUS CSD scores between prosthesis abandoners and continued users ($U = 4062$, $P = 0.11$).

Discussion

Many cross-sectional studies have examined prosthesis use and abandonment.[3,7,16,17] However, no prior study had followed a large cohort of persons with upper limb amputation (including 23 persons with bilateral upper limb loss) over time to observe changes in prosthesis use and satisfaction. Our study followed Veterans with upper limb amputation for 1 year to examine changes in prosthesis use, as well as rates of receipt of new prostheses and terminal devices.

We found that prosthesis use, use of more than one prosthesis, types of prostheses used, terminal device and suspension used, and rate of new prosthesis receipt were relatively stable over 1 year. However, a small proportion of body-powered and myoelectric users (12%–13%) switched primary prosthesis types and more than a third of cosmetic users began using a functional prosthesis. A higher proportion of body-powered users transitioned to myoelectric devices as compared with myoelectric users transitioning to body-powered prostheses. While the small numbers of respondents who transitioned device types precluded further analysis, we believe that studying transitions between prosthesis types may be of interest in future studies.

Respondents who received a new prosthesis type were more likely to receive prosthetic training as compared with those receiving a prosthesis of the same type. However, only 52% of persons receiving a new type of prosthesis received training, which is somewhat surprising, given that prosthetic training is fundamental to rehabilitation of persons with upper limb amputation.[18,19] We do not know whether respondents had been offered training and declined it, or if they were never offered training.

We found 14% to 15% of participants received a new prosthesis in the prior year. This figure is almost twice as high as the incidence rate estimated in an earlier study.[10] That study used VA national prosthetics prescription data from 2000 to 2010 and did not include any prostheses received from sources not associated with VA care.[10]

Although primary terminal device type was stable across all terminal device types, more than half of participants who reported using a multi-DOF terminal device and more than two-thirds of those who used a Greifer at baseline switched primary terminal device types during the 1-year period. The results related to Greifers should be interpreted cautiously due to the small sample size of Greifer users ($n = 6$). Given that multi-DOF terminal devices are costly, future studies examining satisfaction with these devices and reasons for discontinuing their use as the primary terminal device are needed.

Our prior analysis of baseline data found no significant differences in prosthesis satisfaction between persons who used body-powered and myoelectric/hybrid devices, and no differences in satisfaction ratings by terminal device used.[20] The current study adds to our understanding of prosthesis satisfaction and its impact on continued prosthesis use. We identified individuals who abandoned a prosthesis between baseline and follow-up and compared intensity of prosthesis use and prosthesis satisfaction with those who continued prosthesis use. Those with lower intensity prosthesis use or poorer device satisfaction scores

at baseline were more likely to report abandoning a prosthesis at follow-up. Together, these findings suggest that prosthesis abandonment may not be a sudden act, but instead, is predicated by dissatisfaction with the device, as well as irregular wearing patterns. If those at risk for prosthesis abandonment could be identified in advance, perhaps through regular prosthetic check-ups, targeted efforts to improve their prosthetic experience could be initiated.

Limitations

This is the first longitudinal study of upper limb prosthesis use and utilizes a large, and nationally representative US Veteran population. However, findings are limited to Veterans who received care at the VA and therefore may not be generalizable outside of the Veteran population and the VA system of care. Second, there are some limitations to the interpretation of prosthesis hours of use. Our survey question asked, "How many hours a day do you typically use a prosthesis?" We found that among persons who abandoned their prosthesis during the year, 40% reported using the prosthesis less than 2 hours per day, while 62% reported daily use. While it is evident that the device abandoners were less intense and less frequent prosthesis users, we cannot say with certainty how respondents interpreted this question: whether they reported the hours that they were wearing their device, or the hours that they were actively engaging their device during activities. Our study also did not examine the association between training receipt and outcomes. Future studies are needed to understand the impact of training to use a new prosthesis on prosthesis abandonment and prosthesis satisfaction.

Although we asked respondents about the receipt of a new prosthesis in the prior year, we did not collect data on why a new prosthesis was received, and do not have granular data on device make and model. We expect that many persons who received the same overall type of device had obtained the new device as a replacement for a device that was broken or worn out. However, new devices may have had new or different features and may have been obtained to offer improved or new functionality.

Conclusion

Rates of upper limb prosthesis use, frequency and intensity of use, and types of primary prostheses used by Veterans were stable over 1 year. At follow-up, 15% reported receiving a new prosthesis, 13% used a different primary prosthesis type, and 6% had discontinued prosthesis use. New prosthesis receipt resulted in improved prosthesis satisfaction. Findings suggest that prosthesis abandonment is predicated on dissatisfaction with the device, as well as irregular wearing patterns. These findings can be used to identify those at risk for prosthesis abandonment to improve their prosthesis experience.

Author contributions

The author(s) disclosed the following roles as contributors to this article: LR obtained the funding, designed study methodology, and led data analyses and manuscript draft and revision writing. MB assisted in study methodology, formal analysis and visualization, and wrote portions of the manuscript. SB assisted in study methodology, was responsible for project administration and supervision, and participated in discussions of data analyses and manuscript writing. MAC participated in study methodology, supervised data curation, and participated in data analyses and manuscript writing.

Declaration of conflicting interest

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Supplemental material

Supplemental material for this article is available online.

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Original Research

Frequency and Severity of Phantom Limb Pain in Veterans with Major Upper Limb Amputation: Results of a National Survey

Ellie Balakhanlou, MD, Joseph Webster, MD, Matthew Borgia, MA, Linda Resnik, PT, PhD

Abstract

Objective: To describe the frequency and severity of phantom limb pain (PLP) in veterans with major upper limb amputation and determine the association between PLP and person, amputation, and prosthesis characteristics.
Design: Cross-sectional design.
Setting: National survey of veterans living in the community.
Participants: U.S. military veterans (N = 776) with major upper limb amputations.
Main Outcome Measures: Frequency and intensity of PLP, person characteristics such as age and gender, amputation characteristics such as level and etiology, and prosthesis characteristics such as type and intensity of prosthesis use.
Results: Respondents were 97% male with a mean age of 63 years and a mean time since amputation of 31 years. The most common amputation level was transradial (36%) and 62% reported accident as the amputation etiology. 73% of amputees reported PLP with a mean intensity score of 4.2 (standard deviation 3.4). PLP frequency in the daily to always category was reported in 42% of amputees. Weekly and more frequent residual limb pain was associated with having any PLP. Amputation at the shoulder (odds ratio [OR] 3.78 [1.93, 7.39]), amputation at the transhumeral level (OR 1.76 [1.10,2.81]), and amputation due to cancer (OR 5.33 [1.15, 24.81]) were also associated with any PLP. Moderate (β = 1.34, P = < .001) and severe (β = 3.31, P < .001) residual limb pain intensity was associated with higher PLP intensity among those with pain. Amputation at the shoulder level was associated with a 1.5 points higher average pain intensity score (P < .001) compared to the transradial level. Multivariable models failed to show an association between PLP prevalence and amputation of the dominant limb (P = .08) and PLP was not associated with intensity of daily prosthesis use in bivariate analyses.
Conclusion: This study of a large cohort of veterans with major upper limb amputation highlights the long-term persistence of moderate frequency and intensity PLP.

Introduction

There are two types of amputation-related pain that frequently occur following limb amputation. Residual limb pain (RLP) is pain that is perceived to originate from the remaining portion of the amputated limb.[1-3] Phantom limb pain (PLP) is a condition in which pain is perceived in the amputated limb that is no longer present.[2-6] Persons with limb loss often report both PLP and RLP, but RLP is more common in the acute and subacute periods after amputation whereas PLP can be more predominant months after amputation.[1] The prevalence of PLP previously reported in the literature has a wide range from 40% to 80%.[3-11] The prevalence of PLP in persons with upper extremity amputation has been reported to be in the 40%-50% range,[3,4,12,13] whereas PLP following lower limb amputation has been reported to be as high as 70%-80%.[3,4,9,14-16] For some, the intensity and frequency of PLP may subside with time, but PLP may persist indefinitely and result in significant pain interference, impairment, and disability.[3,4,9,14-16] Most research to date has focused on lower limb loss and PLP, perhaps because of the higher occurrence rate or the larger population of individuals with lower limb amputation. Consequently, the prevalence and factors associated with PLP in persons with upper extremity amputation have been less well described.

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There are incomplete data available in the literature regarding risk factors associated with PLP especially in those with upper limb amputation. Chronic PLP has been previously associated with preoperative pain, residual limb pain, and time period since amputation.[3,4,7,9,17,18] Persons with upper limb amputation who experience phantom limb sensation also have an increased risk of PLP with a relative risk for PLP of 11.3.[7] Hanley et al demonstrated that those who wore a prosthesis were more likely to have chronic PLP, but the authors could not deduce whether using a prosthesis contributed to pain or if the prosthesis was used to help relieve pain.[2] Additional studies have found that individuals who reported using a prosthesis were significantly more likely to have PLP; however, these studies have not explored the relationship between PLP and intensity of daily prosthesis use.[2,7]

In those with upper limb loss, more proximal amputation levels (amputations above the elbow and more proximal compared to amputations below the elbow) have been associated with an increased risk of PLP.[4,10] Smith et al showed that amputation of the dominant limb was associated with greater PLP, but use of the prosthesis on the dominant side was not associated with change in pain symptoms.[19] Others have not been able to establish a relationship between limb dominance and PLP.[7] Depressive symptoms have predicted higher levels of PLP intensity and bothersomeness whereas other psychological factors including stress and catastrophizing have been noted to play a role in maintaining or aggravating PLP.[5,20] In those with lower limb amputation, a positive association between PLP and low back pain has been noted.[12]

Leveraging survey results from a large sample of veterans with upper limb amputation, the purposes of this article are to describe the frequency and severity of phantom limb pain (PLP) in veterans with major upper limb amputation and quantify the association between PLP and person, amputation, and prosthesis characteristics.

Methods

Data for this study were derived from a larger, survey study (described in this paper) that collected comprehensive data on function, needs, preferences, and prosthetic satisfaction in a large cohort of veterans with major upper limb amputation. Our analyses include the subset of respondents who had unilateral major upper limb amputation.

Survey Recruitment and Data Collection

The veteran sample was identified through the Veterans Affairs (VA) Corporate Data Warehouse (CDW). Participants included all veterans with major upper limb amputation who received care at the VA between 2010 and 2016. Major upper limb amputation levels were defined in our study as amputation at the forequarter, shoulder disarticulation, transhumeral (TH), elbow disarticulation (ED), transradial (TR), or wrist disarticulation (WD) level. The sampling frame was identified from VA CDW sources including inpatient, outpatient, and fee domains; the main source for information regarding Veterans Health Administration benefit compensation and pension benefits paid to veterans and their beneficiaries; and Veterans Benefits Administration (VBA) disability ratings. A list of diagnosis and procedure codes used to identify the sample has been provided in a separate publication.[21]

All nondeceased veterans with valid addresses and phone numbers were sent an initial recruitment package containing an invitation letter, a study information sheet explaining the study, and a card with stamped envelope to return if they wished to opt out of participation. Veterans who did not opt out of study participation by returning the postcard or calling the study telephone number within 30 days were contacted by the study interviewers. To maximize study recruitment, up to 10 attempts were made to contact potential participants. All participants provided oral informed consent to participate. A waiver of documentation of informed consent was obtained from the VA Central Institutional Review Board. All surveys were conducted via telephone by trained interviewers and were approximately 45 minutes in length. The analyses presented in this paper utilize data from respondents with unilateral limb loss. Persons with bilateral upper limb amputation were excluded.

Measures

The survey instrument was comprehensive in nature and included questions designed to obtain data related to person-level characteristics, amputation-specific characteristics (including amputation level, years since amputation, and etiology of amputation), and prosthesis use characteristics. Respondents indicated all etiologies of amputation that applied and thus may have indicated more than one etiology. Pain-related questions were used to assess PLP and residual limb pain. In order to facilitate participant's understanding, phantom limb was defined as feeling of the presence of limb that was lost. Residual limb was defined as portion of the limb remaining after the amputation.

Pain Frequency

Participants were asked to rate their pain frequency in the past 4 weeks: never, only once or twice, about once per week, two to three times per week, four to six times per week, several times every day, all the time or almost all the time. For the purposes of data analysis, pain frequency was categorized into 4 levels: never, weekly or less frequent, 2 to 6 times per week, and daily to always.

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Pain Intensity

Participants were also asked to rate their phantom and residual limb pain intensity over the past 4-week time period. Pain intensity was scored on a 10-point scale with 0 representing no pain and 10 representing the worst possible pain. Pain intensity was recategorized into 4 levels: never had pain, none to mild (0-3), moderate (5-8), and severe (9-11).

Amputation Level

For the purposes of data analysis, amputation levels were consolidated into three amputation level categories. The transradial level includes those with wrist disarticulation, transhumeral level includes those with elbow disarticulation, and shoulder level includes forequarter and shoulder disarticulation amputation levels.

Statistical Methods

We examined descriptive statistics to characterize respondents by amputation level. We used bivariate analyses to examine the relationships of covariates with PLP prevalence (using chi-square and two-tailed Fisher's exact tests) and PLP intensity (using Kruskal-Wallis tests because the assumption of normality was rejected by the Shapiro-Wilk test). The purpose of the bivariate analyses was to identify possible associations between covariates and PLP prevalence and intensity that would be added to our multivariable models. We then used a two-part multivariable model; first using logistic regression predicting any PLP and then using linear regression predicting PLP intensity for those with any pain. Covariates that were statistically significant at $P < .1$ in bivariate analysis were added to the multivariable logistic and linear regressions to control for potential confounding and to identify other factors that were independent predictors of PLP intensity and frequency.

Results

Study Participants

Seven hundred fifty-five male participants and 21 female participants with unilateral major upper limb amputation completed some or all of the telephone survey. There were 20 participants who did not complete all items in the survey; 16 of these did not complete the items addressing pain frequency and intensity. Further details regarding the person, amputation, and prosthesis characteristics of the study population by amputation level are included in Table 1. The average age was 63.2 years, 97.3% were males and 75.1% reported their race as White. The average time since amputation was 31.3 years. Approximately half of the participants (50.6%) reported amputation involving the dominant side. Transradial amputation was the most common level at 36%. Sixty-two percent of the sample reported accident as the etiology of amputation. Among those who reported wearing a prosthesis (N = 461; 59%), the majority (70.7%) reported using a body-powered prosthesis and 42.1% reported using a prosthesis for more than 8 hours per day.

Frequency and Severity of Pain Syndromes

Table 2 shows the reported frequency of both PLP and RLP in study participants. PLP frequency in the "daily to always" category was reported in 42% of the sample. 27% of participants reported that they never had PLP in the past 4 weeks. RLP frequency in the "daily to always" category was reported by 29.6%. Prevalence of PLP in the "daily to always" frequency category was higher in respondents with more proximal amputation levels; 47.9% at transhumeral level and 57.0% at the shoulder level compared to 34.6% at the transradial level (Figure 1).

Table 3 details the reported levels of pain intensity. In our sample, 73% reported some PLP with a mean pain intensity of 4.2 (SD 3.4). Only about a quarter of participants reported PLP intensity in the "never" category. Similar to RLP frequency, pain intensity in the "moderate" and "severe" categories was also commonly reported in the residual limb. Again, similar to PLP frequency, PLP intensity in the "moderate" and "severe" categories was more prevalent in those with more proximal amputation levels; 65.5% at transhumeral level and 67.4% at the shoulder level compared to 48.6% at the transradial level (Figure 2). Of note, about 23% of the veterans rated their PLP intensity in the "severe" category, which is significantly higher compared to the residual limb (13%).

Associations Between Person, Amputation, and Prosthesis Characteristics and PLP

In bivariate analyses of PLP frequency, the following variables were statistically significant at $P \leq .1$: race, amputation of dominant side, age, time since amputation, amputation level, amputation etiology (from combat, burns, and cancer), residual limb and neck pain frequency and intensity, and self-suspension prothesis types (Appendix S1 Table 1). In bivariate analyses of PLP intensity (for those with any pain), the following variables were statistically significant at $P \leq .1$: race, ethnicity, age, amputation level, residual limb and neck pain frequency and intensity, and prothesis types using harnessing (Appendix S1 Table 2).

In multivariable models (Table 4), we found that those who had residual limb pain "weekly or less frequent" (odds ratio [OR] 3.32 [1.77, 6.20]), "2 to 6 times per week" (OR 6.55 [2.78, 15.44]), and "daily to always" (OR 8.75 [3.52, 21.79]), had significantly higher odds of having any PLP compared to those who never had residual limb pain in the prior 4 weeks. Amputation at shoulder level (OR 3.78 [1.93, 7.39]), amputation at transhumeral

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Table 1
Characteristics of study participants (N = 776)

Person Characteristics	Transradial (N = 406) Mn (SD)	Transhumeral (N = 276) Mn (SD)	Shoulder/Forequarter (N = 94) Mn (SD)
Age (y)	63.6 (14.2)	62.8 (13.4)	63.0 (15.5)
	N (%)	**N (%)**	**N (%)**
Gender			
Male	397 (97.8)	266 (96.4)	92 (97.9)
Female	9 (2.2)	10 (3.6)	2 (2.1)
Race			
White	320 (78.8)	194 (70.3)	69 (73.4)
Black	36 (8.9)	34 (12.3)	16 (17.0)
Unknown	35 (8.6)	31 (11.2)	6 (6.4)
Other/mixed	15 (4.7)	17 (6.2)	3 (3.2)
Hispanic			
Yes	27 (6.7)	30 (10.9)	5 (5.3)
No	360 (88.7)	231 (83.7)	87 (92.6)
Don't know/unsure	19 (4.7)	15 (5.4)	2 (2.1)
Amputation characteristics	**Mn (SD)**	**Mn (SD)**	**Mn (SD)**
Years since amputation	32.4 (18.5)	31.3 (17.8)	26.4 (18.7)
Age at time of amputation	31.1 (13.1)	31.7 (13.3)	36.4 (16.6)
	N (%)	**N (%)**	**N (%)**
Amputation level			
Forequarter	0 (0.0)	0 (0.0)	23 (24.5)
Shoulder disarticulation	0 (0.0)	0 (0.0)	71 (75.5)
Transhumeral	0 (0.0)	236 (85.5)	0 (0.0)
Elbow disarticulation	0 (0.0)	40 (14.5)	0 (0.0)
Transradial	280 (69.0)	0 (0.0)	0 (0.0)
Wrist disarticulation	126 (31.0)	0 (0.0)	0 (0.0)
Amputation etiology			
Combat injury	161 (39.7)	89 (32.3)	25 (26.6)
Accident	261 (64.3)	168 (60.9)	54 (57.5)
Burn	57 (14.0)	19 (6.9)	5 (5.3)
Cancer	7 (1.7)	7 (2.5)	16 (17.0)
Diabetes	5 (1.2)	5 (1.8)	1 (1.1)
Infection	32 (7.9)	40 (14.5)	14 (14.9)
Amputation of dominant side			
Yes	221 (54.4)	127 (46.0)	45 (47.9)
No	182 (44.8)	148 (53.6)	48 (51.1)
Unknown	3 (0.7)	1 (0.4)	1 (1.1)
Prosthetic users	**TR (N = 313)**	**TH (N = 121)**	**SH (N = 27)**
Prosthesis characteristics	**N (%)**	**N (%)**	**N (%)**
Type of primary prosthesis			
Body powered	217 (69.3)	95 (78.5)	14 (51.9)
Myoelectric	71 (22.7)	17 (14.0)	8 (29.6)
Hybrid	3 (1.0)	2 (1.7)	1 (3.7)
Cosmetic	14 (4.5)	4 (3.3)	4 (14.8)
Sports/recreation	4 (1.3)	2 (1.7)	0 (0.0)
Unknown	4 (1.3)	1 (0.8)	0 (0.0)
Type suspension			
Suction	105 (33.6)	45 (37.2)	6 (22.2)
Gel or silicone liner with pin	60 (19.2)	25 (20.7)	6 (22.2)
Vacuum	32 (10.2)	17 (14.1)	2 (74)
Self-suspending	123 (39.3)	41 (33.9)	8 (29.6)
Harnessing	210 (67.1)	109 (90.1)	26 (96.3)
External sleeve	42 (13.4)	18 (14.9)	2 (7.4)
Intensity of daily prosthesis use			
Less than 2 h	49 (15.7)	32 (26.5)	7 (25.9)
2 to less than 4 h	20 (6.4)	15 (12.4)	7 (25.9)
4 to less than 8 h	54 (17.3)	25 (20.7)	6 (22.2)
8 to less than 12 h	67 (21.4)	19 (15.7)	2 (7.4)
12 h or more	121 (38.7)	26 (21.5)	5 (18.5)
Don't know/unsure	2 (0.6)	4 (3.3)	0 (0.0)

TR = transradial; TH = transhumeral; SH = shoulder/forequarter.

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Table 2
Pain frequency in study participants by amputation level (N = 776)

Pain Frequency*	Transradial (N = 406) N (%)	Transhumeral (N = 276) N (%)	Shoulder/Forequarter (N = 94) N (%)
Phantom limb pain			
Never	128 (32.3)	54 (20.2)	19 (20.4)
Weekly or less frequent	72 (18.2)	43 (16.1)	13 (14.0)
2 to 6 times per week	59 (14.9)	42 (15.7)	8 (8.6)
Daily/always	137 (34.6)	128 (47.9)	53 (57.0)
Residual limb pain			
Never	151 (38.0)	80 (30.1)	
Weekly or less frequent	81 (20.4)	56 (21.1)	
2 to 6 times per week	66 (16.6)	33 (12.4)	
Daily/always	99 (24.9)	97 (36.5)	

*Pain frequency in last 4 weeks classified as never = "never"; weekly or less frequent = "only once or twice" and "about once per week"; 2 to 6 times per week = "2 to 3 times per week" and "4 to 6 times per week"; and daily/always = "several times every day" and "all the time or almost all the time."

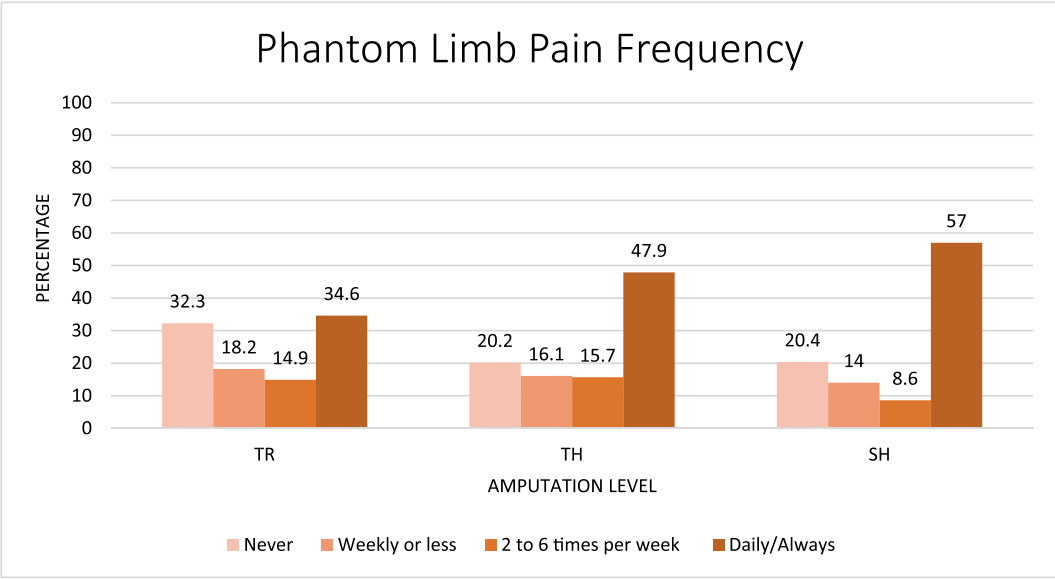

Figure 1. Phantom limb pain frequency by amputation level. *TR = transradial; TH = transhumeral; SH = shoulder/forequarter. **Pain frequency in last 4 weeks classified as never = "never"; weekly or less frequent = "only once or twice" and "about once per week"; 2 to 6 times per week = "2 to 3 times per week" and "4 to 6 times per week"; and daily/always = "several times every day" and "all the time or almost all the time".

Table 3
Pain intensity in study participants by amputation level (N = 776)

Pain Intensity	Transradial (N = 406)	Transhumeral (N = 276)	Shoulder/Forequarter (N = 94)
Phantom limb pain			
Never had pain	128 (32.4)	54 (20.5)	19 (20.7)
None to mild	75 (19.0)	37 (14.0)	11 (12.0)
Moderate	124 (31.4)	99 (37.5)	33 (35.9)
Severe	68 (17.2)	74 (28.0)	29 (31.5)
Residual limb pain			
Never had pain	151 (38.0)	80 (30.1)	
None to mild	72 (18.1)	41 (15.4)	
Moderate	135 (34.0)	98 (36.8)	
Severe	39 (9.8)	47 (17.7)	

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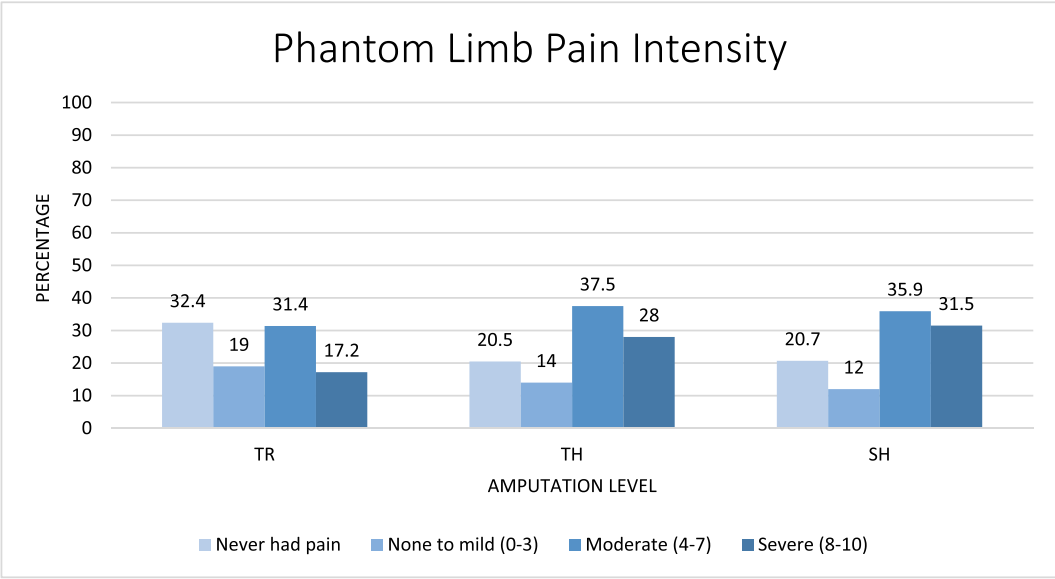

*TR= Transradial, TH= Transhumeral, SH= Shoulder/Forequarter

Figure 2. Phantom limb pain intensity by amputation level. *TR = transradial; TH = transhumeral; SH = shoulder/forequarter.

level (OR 1.76 [1.10, 2.81]), etiology of cancer (OR 5.33 [1.15, 24.81]), and use of self-suspending prostheses (OR 1.79 [1.06, 3.03]) were also associated with any PLP. Amputation etiology of combat injury (OR 0.62 [0.40, 0.97]) and burn (OR 0.50 [0.26, 0.94]) were associated with reduced occurrence of PLP.

Moderate (β = 1.34, P = < .001) and severe (β = 3.31, P < .001) residual limb pain intensity was associated with higher PLP intensity among those with pain. However, those who had neck pain "daily to always" had lower (β = −077, P = .03) PLP intensity than those who never had neck pain. Amputation at the shoulder level was associated with a 1.5 points higher pain scores (P < .001) compared to at the transradial level. Multivariable models failed to show an association between PLP and amputation of the dominant limb. Bivariate analyses did not indicate any statistically significant relationship between PLP and type of prosthesis or intensity of daily prosthesis use.

Discussion

Major upper limb amputation has the potential to result in significant alterations in physical performance, body image, and activity participation.[21] Phantom limb pain is an important consideration following upper limb amputation because it is both frequently occurring and long lasting. Appropriate awareness and identification of PLP is also critical because of its potential associated functional implications. [2,3,14-16,22,23]

The pathophysiology underlying PLP is complex and multifaceted.[3,9,24-28] Although several different theories exist, the etiology of phantom phenomena has been categorized primarily into three anatomical locations and mechanisms: supraspinal, spinal, and peripheral.[3,24-28] The supraspinal mechanism focuses on reorganization of somatosensory cortex surrounding the area representing deafferented limb.[1,3,24-30] The spinal mechanism focuses on functional changes in the dorsal horn due to deafferentation from peripheral nerve injury.[1,3,29,30] Finally, the peripheral mechanism describes axonal nerve damage during amputation and the downstream effects of inflammation and regenerative sprouting.[1,3,29,30] Inevitably, pain after amputation is likely a combination of multiple different mechanisms and the contribution from each mechanism may vary by individual.

Although prior studies have examined the frequency of phantom limb pain following amputation, there is variability in the previously reported prevalence and a limited body of investigations specific to individuals with upper limb amputation.[3-11] Many prior studies have also been limited by small sample sizes and incomplete descriptions of PLP chronicity, intensity, and frequency. In addition, the pathophysiology underlying PLP is complex as described previously, so understanding of the factors associated with pain frequency and intensity may provide insights into the management of those factors that are modifiable. For example, addressing RLP may have the potential to affectt the intensity and frequency of PLP. The currently available literature has not clearly delineated these variables associated with PLP.[3-11,31]

The findings from this study are significant for several reasons. This investigation involved a large cohort and specifically addresses the population of veterans with upper limb amputation. This cohort represents a broad sample of veterans with upper limb amputation who received any type of care in the Department of Veterans Affairs. The study adds to the previously reported literature on the prevalence of PLP, confirming that PLP is a very common condition and that the prevalence may be higher than previous reports. The accuracy of our

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Table 4
Separate multivariable models of presence of phantom limb pain and phantom limb pain intensity

	Logistic Regression: Any Phantom Limb Pain (yes/no) N = 710		Linear Regression: Intensity (0-10) N = 541	
	Odds Ratio (95% CI)	*P*	B (95% CI)	*P*
Race				
White (ref) (n = 583)				
Black (n = 86)	1.77 (0.84, 3.71)	.13	0.18 (−0.41, 0.77)	.55
Unknown (n = 72)	1.16 (0.50, 2.68)	.73	0.85 (−0.09, 1.79)	.08
Other/mixed (n = 35)	1.07 (0.35, 3.20)	.91	0.38 (−0.48, 1.23)	.39
Hispanic				
Yes (n = 62)			0.51 (−0.29, 1.31)	.21
No (ref) (n = 678)				
Don't know/unsure (n = 36)			−0.18 (−1.87, 1.52)	.84
Amputation of dominant side				
Yes (n = 393)	0.70 (0.48, 1.04)	.08		
No (ref) (n = 376)				
Age at time of study				
[18,45) (ref) (n = 99)				
[45,65) (n = 207)	0.99 (0.44, 2.22)	.97	0.16 (−0.48, 0.79)	.63
[65,75) (n = 340)	0.91 (0.40, 2.05)	.82	−0.10 (−0.70, 0.51)	.76
75+ (n = 106)	0.79 (0.30, 2.05)	.63	−0.43 (−1.21, 0.35)	.28
Time since amputation				
[0.20) (ref) (n = 264)				
[20,50) (n = 391)	0.80 (0.45, 1.42)	.45		
50+ (n = 100)	0.89 (0.40, 1.97)	.78		
Amputation level				
Shoulder/forequarter (n = 94)	3.78 (1.93, 7.39)	.001	1.54 (0.79, 2.30)	<.001
Transhumeral/elbow disarticulation (n = 276)	1.76 (1.10, 2.81)	.01	0.21 (−0.24, 0.67)	.35
Transradial/wrist disarticulation (ref) (n = 406)				
Residual limb pain frequency				
Never had pain (ref) (n = 325)				
Weekly or less frequent (n = 137)	3.32 (1.77, 6.20)	<.001	−0.34 (−1.04, 0.36)	.34
2 to 6 times per week (n = 99)	6.55 (2.78, 15.44)	<.001	−0.18 (−0.97, 0.61)	.65
Daily/always (n = 196)	8.75 (3.52, 21.79)	<.001	−0.41 (−1.20, 0.38)	.30
Residual limb pain intensity				
None to mild (ref) (n = 113)				
Moderate (n = 233)	1.39 (0.68, 2.85)	.37	1.34 (0.74, 1.93)	<.001
Severe (n = 86)	1.15 (0.42, 3.14)	.79	3.31 (2.50, 4.11)	<.001
Neck pain frequency				
Never had pain (ref) (n = 303)				
Weekly or less frequent (n = 151)	1.13 (0.62, 2.06)	.69	−0.65 (−1.31, 0.01)	.05
2 to 6 times per week (n = 111)	1.04 (0.50, 2.19)	.91	−0.73 (−1.49, 0.03)	.06
Daily/always (n = 195)	1.20 (0.55, 2.59)	.65	−0.77 (−1.50, −0.05)	.03
Neck pain intensity				
None to mild (ref) (n = 115)				
Moderate (n = 254)	1.64 (0.88, 3.06)	.12	1.37 (0.76, 1.98)	<.001
Severe (n = 88)	1.48 (0.55, 4.02)	.44	1.90 (1.09, 2.71)	<.001
Amputation etiology				
Combat injury				
Yes (n = 275)	0.62 (0.40, 0.97)	.03		
No (ref) (n = 500)				
Burn				
Yes (n = 81)	0.50 (0.26, 0.94)	.03		
No (ref) (n = 693)				
Cancer				
Yes (n = 30)	5.33 (1.15, 24.81)	.03		
No (ref) (n = 744)				
Prosthesis use				
Yes (n = 461)	0.97 (0.60, 1.56)	.88	−0.65 (−1.30, 0.00)	.04
No (ref) (n = 306)				
Suspension type				
Self-suspending				
Yes (n = 172)	1.79 (1.06, 3.03)	.03		
No (ref) (n = 273)				

(Continues)

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Table 4.
Continued

	Logistic Regression: Any Phantom Limb Pain (yes/no) N = 710		Linear Regression: Intensity (0-10) N = 541	
	Odds Ratio (95% CI)	*P*	B (95% CI)	*P*
Harnessing				
Yes (n = 345)			0.33 (−0.27, 0.94)	.28
No (ref) (n = 113)				

Empty cells indicate variables that were not significant at $P < .1$ in bivariate analyses and were not included in the models.

prevalence estimates is strengthened by the large sample size and representativeness of the sample. Findings also supports the commonly held belief that PLP symptoms are frequently chronic in those with upper limb amputation as the average time since amputation in our sample was 31 years. Providers should be aware of the chronicity of PLP and continue to recognize signs and symptoms of this phenomena.

The results of our study may also provide clinicians a greater appreciation of the relationship between patient, amputation, and prosthesis characteristics and PLP. Despite our original hypotheses, we found no significant association between PLP and amputation of dominant limb, intensity of prosthesis use, or type of prosthesis used in bivariate analyses and did not add these variables to the multivariable models. Our study adds to the literature reporting an association between frequency and intensity of PLP and amputation level with veterans with more proximal upper limb amputation being more likely to have higher intensity and frequency PLP. This is an important finding for clinicians to take into consideration in the counseling and management of persons with more proximal amputation levels. Similar to prior investigations, this study found an association between moderate intensity residual limb pain and any PLP as well as higher PLP intensity among those with worse residual limb pain intensity.[9] The finding that participants with neck pain in our study experienced lower PLP intensity is interesting and might be explained by the pain signals in the more proximal neck segment creating a modulating effect on the more distal PLP signals. This finding should be explored further in the future.

When comparing amputations due to cancer to amputations not due to cancer, we found that amputation due to cancer was associated with PLP. This finding is consistent with reports from prior studies that found that PLP was highly prevalent in individuals with amputation due to cancer.[10,32] These prior studies also reported that PLP was more common than residual limb or stump pain in persons with amputation due to cancer.[10,32] Higher PLP in persons with an amputation etiology of cancer could be secondary to hypersensitization of nerves in setting of the malignancy or perhaps because of adjunct therapies such as chemotherapy and/or radiation. The finding that burn amputation etiology is associated with a reduced occurrence of PLP is novel and the underlying mechanism for this finding is not clear. These findings should be interpreted with some caution because the etiology of amputation was determined by self-report and participants were able to identify more than one etiology. Thus, it was unclear in these cases which etiology was primary. Further studies should be performed to help delineate the association between cause of amputation and PLP.

This investigation has several limitations. Survey respondents were all veterans who received some care in the Department of Veterans Affairs, which may limit the generalizability of findings to a wider population of persons with upper limb amputation. Our data were collected through telephone survey and pain-related questions asked participants to rate their pain level over a 4-week time period. It is possible that some participants did not recall their pain accurately over this time period. This methodology differs from some previously published studies that used self-applied questionnaires instead of interviews.[7,14] Our survey instrument was long, and it is possible that some respondents became fatigued during interviews and that this adversely affected their recall. Because of the cross-sectional nature of this study, we were not able to characterize changes in PLP intensity or frequency over time. Our sample was primarily male, and findings may not generalize well to females with limb loss. Finally, the observational study design identifies factors associated with PLP and cannot be used to demonstrate causality.

Conclusion

This study found that moderate intensity PLP and daily to constant PLP is common in veterans with upper limb amputation. It also found an association between PLP and residual limb pain, proximal amputation levels, and amputation due to cancer. The study found no significant association between PLP and amputation of dominant limb, intensity of daily prosthesis use, or type of prosthesis used.

Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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Disclosure

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Psychometric evaluation of the Southampton hand assessment procedure (SHAP) in a sample of upper limb prosthesis users

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ABSTRACT

Background: The 26-item Southampton Hand Assessment Protocol (SHAP) is a test of prosthetic hand function that generates an Index of Functionality (IOF), and prehensile pattern (PP) scores. Prior researchers identified potential issues in SHAP scoring, proposing alternative scoring methods (LIF and W-LIF).
Study design: Cross-sectional study.
Purpose: Evaluate the psychometric properties of the SHAP IOF, LIF, and W-LIF and PP scores and develop the Prosthesis Index of Functionality (P-IOF).
Methods: We examined item completion, floor andceiling effects, concurrent, discriminant, construct and structural validity. The P-IOF used increased boundary limits and information from item completion and completion time. Calibration used a nonlinear mixed model. Scores were estimated using maximum a posteriori Bayesian estimation. Mixed integer linear programing (MILP) informed development of a shorter measure. Validity analyses were repeated using the P-IOF.
Results: 126 persons, mean age 57 (sd 15.8), 69% with transradial amputation were included. Floors effects were observed in 18.3%-19.1% for the IOF, LIF, and W-LIF. Ten items were not completed by >15% of participants. Boundary limits were problematic for all but 1 item. Correlations with dexterity measures were strong ($r =$ 0.54-0.73). Scores differed by amputation level ($p > .0001$). Factor analysis did not support use of PP scores. The P-IOF used expanded boundary limits to decrease floor effects. MILP identified 10 items that could be dropped. The 26-item P-IOF and 16-item P-IOF had reduced floor effects (<7.5%), strong evidence of concurrent and discriminant validity, and construct validity. P-IOF reduced administrative burden by 9.5 (sd 5.6) minutes.
Discussion: Floor effects limit a measure's ability to distinguish between persons with low function.
Conclusion: Analyses supported the validity of the SHAP IOF, LIF, and W-LIF, but identified large floor effects, as well as issues with structural validity of the PP scores. The 16-item P-IOF minimizes floor effects and reduces administrative burden.

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Introduction

Assessment of terminal device function in upper limb prosthesis users is critically important to understand functionality of prosthetic devices, evaluate the impact of prosthetic training, and evaluate the comparative effectiveness of devices, control, and suspension methods. However, few performance measures have been developed specifically for upper limb prosthesis users, and those that have been developed have not been studied thoroughly. This manuscript will focus on 1 such measure, the Southampton Hand Assessment Protocol (SHAP).[1]

The SHAP is a test of hand function developed for the assessment of upper limb prostheses use consisting of 26 timed

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tasks which include 12 tasks with abstract light and heavy objects (eg 'Heavy sphere') and 14 activities of daily living (ADLs).[1] The task item scores are grouped to generate 6 prehensile pattern (PP) scores (spherical, tripod, power, lateral, tip and extension grip types), and produce an overall Index of Functionality (IOF) score.

Use of the SHAP in outcomes research has steadily increased in the past decade. To date, the SHAP has been utilized in studies of persons with major upper limb amputation,[2-17] partial hand amputation,[18-21] bionic reconstruction,[21] and in able-bodied persons using prosthesis simulators.[22-29] The measure has also been adapted for use in children.[30] Most studies employ the IOF, with about a third also reporting use of the PP scores.

SHAP use in research appears to be growing, despite limited data on the measure's validity, the need to pay for online scoring, and the substantial burden of administration. Several research studies have identified potential issues in SHAP scoring. These studies recommended additional research to determine appropriate time limits for SHAP tasks and to evaluate whether certain items should be eliminated.[31]

The exact SHAP scoring algorithm is proprietary, with scoring only available through the online SHAP test center (with an associated fee for usage) . Thus, there are challenges in replicating the precise scoring algorithm outside of the test center. Burgerhof and colleagues explored alternative methods of scoring the SHAP activities.[31] Using data from a sample of 27 "experienced" myoelectric prosthesis users and employing previously reported normative values, they developed the linear index of function (LIF) and LIF PP scores (LIF-PP) using direct linear transformations of item completion times to a score between 0 and 100. Because some tasks are assigned to more than 1 PP and thus are counted in the LIF and (likely) in the IOF more than once, this research team also developed a weighted version (W-LIF). Their analyses found that the IOF, LIF, and W-LIF were very highly correlated, with the W-LIF, and IOF most strongly correlated.[31] Accordingly, they concluded that any of these approaches would yield mostly comparable results. However, Burgerhof also identified several issues in the SHAP scoring which, we believe, extend to the LIF, and W-LIF.

The first issue relates to the use of normative values and boundary limits. For each SHAP task, a time limit or "boundary condition" of 8 times the normative value for that task is imposed in scoring. The boundary limits for the SHAP tasks were based upon early research that reported that myoelectric prosthesis users took approximately 6 times as long to complete a task as did subjects with natural hand function; and twice as long as persons using a body-powered prosthesis (3) The SHAP developers chose a more liberal boundary of 8 times the normative value. Burgerdorf reported that in a sample of 27 persons (85% with transradial [TR] amputation) boundary limits were exceeded by 22-45% for certain tasks, such as pick up coins, undo buttons, food cutting and rotate a screw, suggesting that even more liberal boundary limits may be indicated.[31] No study has evaluated the boundary limits with samples that included robust numbers of persons with transhumeral (TH) and shoulder (SH) amputation, though it is likely that the proportions exceeding the boundary limits would be larger. Any SHAP task that is not completed within the boundary limit is reassigned a score of 100 seconds, which is then transformed to 0. This essentially creates a floor effect for all persons who score more than 8 times the boundary limits, and limits the ability to differentiate between persons who complete tasks more slowly than 8 times the limit.

Other aspects of SHAP scoring procedures may also contribute to a floor effect. Any SHAP task that is not completed or is not attempted is assigned a score of 100 seconds (later transformed to 0). This procedure results in equal scores for those not attempting or completing an item, and those completing an item outside the boundary limits.

Another concern about the SHAP relates to the validity of the PP scores. Prehensile Pattern scores are calculated for groups of tasks that are typically performed with specific grasp patterns by unimpaired individuals. It is unclear whether these PP categories are valid for prosthesis users, who do not have the same options for grasp patterns. To date, no investigations of the structural validity (eg the factor structure) of the SHAP items have been reported, and no evidence to support the factor structure of the PP scores. Recent studies to develop a taxonomy of prosthesis grasp use in upper limb amputees identified 5 prehensile patterns: ower, pinch between forefingers, pinch with palm rest, pinch between fingers and thumb, and other.[32] These categories do not fully overlap with the PP patterns used as the basis for the SHAP, challenging the appropriateness of using the SHAP PPs for prosthesis users.

Therefore, the overall purposes of this study were to evaluate the psychometric properties of the SHAP IOF, LIF, and W-LIF and their associated PP scores and use that information to make recommendations for revised scoring. Specifically, we 1) evaluated whether the measures had floor or ceiling effects and examined content validity by quantifying task completion rates and rates of exceeding boundary limits; 2) examined construct, concurrent, and discriminant validity; 3) utilized the findings from these psychometric analyses to inform the development and testing of an alternative scoring method which utilizes only those items of the SHAP that were most informative in generating the total score. We call this measure the Prosthesis Index of Functionality (P-IOF).

Methods

Study design

Data from this study was collected as part of a cross-sectional, observational cohort study, approved by the XXX. All participants provided voluntary informed consent. Data was collected at 5 participating study sites.

Sample

Study participants were a convenience sample of users of active upper limb prostheses users (body powered, myoelectric, hybrid or LUKE Arm) who had at least 1 amputation at the wrist disarticulation level or above. Eligible participants reported that they could tolerate wearing a prosthesis for at least 3 hours and had no severe health condition (as determined by the study PI) that would impact study activities. A convenience sample of participants was recruited including persons who had participated in an earlier study[33] and agreed to be contacted about future study activities, through clinical contacts, advertisements, and word of mouth. One hundred twenty-seven persons participated in data collection activities. One participant was excluded from the analyses presented here because his prosthesis broke during SHAP testing.

Data collection

Participants attended a single ~3.5 hour in-person study visit and were evaluated by study assessors who were physical or occupational therapists. During the study visit, data was collected on demographics (age, race, ethnicity, and employment), and history (military status, amputation etiology and years since amputation). The assessor conducted a physical examination (results not reported here), evaluated the prosthesis and terminal device used

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in testing, and administered the SHAP and other measures of dexterity, disability, and quality of life.

Data analyses

We characterized the sample and the prostheses used during testing with descriptive statistics and examined SHAP IOF, LIF and W-LIF scores. We used the SHAP online test center to obtain SHAP IOF and PP scores and utilized the formulae reported by Burgerdorf to calculate LIF and W-LIF scores.[31] Histograms and descriptive statistics were utilized to examine distributions of scores to identify potential floor or ceiling effects. To evaluate whether there were problematic floor or ceiling effects (greater than 15%), we described the percent of participants who scored at the bottom end of the scale (0-5). We also recalculated the LIF and W-LIF scores using 12x normative values for boundary limits to observe the impact on IOF and PP distributions.

Content validity

To examine content validity of the SHAP items, we examined task completion rates, quantifying the proportion of participants who did not complete a task, did not attempt a task as well as those who scored outside the established boundaries for each task (all scores which would be transformed to 0 in the scoring algorithm).

Construct validity

We examined construct validity of the IOF, LIF, W-LIF, and PPs by comparing scores of sub-groups of subjects. Scores were compared first by amputation level (TR vs TH or SH) using t-tests. Given the small number of persons with amputation at the SH level, we combined SH, and TH for these analyses. Additionally, we stratified the TR subsample by type of prosthesis used (body-powered, myoelectric single-DOF terminal device, or myoelectric multi-DOF terminal device) and compared differences in scores by group using Kruskal-Wallis tests. To determine if there might be differences by individual items that were obscured in calculation of PP and total scores, we also compared raw scores for individual SHAP items by prosthesis type for TR amputees using Kruskal-Wallis tests. We established the following apriori hypotheses related to construct validity of the measures. First, we expected that there would be statistically significant differences in scores by amputation level; with persons with TR amputation having better overall and PP scores as compared to those with TH and/or SH level. Second, based on clinical experience, we hypothesized that persons using body-powered prostheses would have better overall scores, and better scores on most PP, as compared to than those using myoelectric devices. However, we expected persons using multi-DOF terminal devices would have better scores on PP which require spherical grasp, given that most of these terminal devices allow the user to move the thumb into a variety of positions.

Convergent and divergent validity

We used Pearson correlations to examine relationships between scores of the SHAP (IOF, LIF and W-LIF) and associated PP scores and scores of the modified Jebsen-Taylor Hand Function Test (JTHFT) subtests,[34] the Box and Block,[35] the Nine-Hole Peg Test,[36] the VR-12 MCS and PCS,[37] and the QuickDASH.[38] We established a priori hypotheses related to concurrent and discriminant validity, expecting that summary scores (IOF, LIF and W-LIF) would be strongly correlated with the majority of other timed measures of dexterity: Box and Block, JTHFT, and the Nine-Hole Peg Test; but weakly correlated at best with the VR-12 (a measure of emotional functioning) or the QuickDASH, (an upper limb specific measure of disability).

Structural validity

First, we calculated Cronbach Alpha for the 26 continuous item scores. Next, we conducted exploratory factor analyses of the SHAP items using scores transformed using 8x normative values, as per SHAP scoring protocol.

Creation of a modified scoring system

Given the improvements in floor effects that we observed when increasing item boundary limits to 12 times normative values, we elected to use this approach to create the Prosthesis Index of Functionality (P-IOF). Item scores were linearly transformed into 0-100 scores with means of the normative sample being considered the best possible time (100), and 12 times the mean time of the normative sample or non–completion of tasks considered the worst possible (0) for individual tasks. Higher scores in the transformed item score indicate better function. In order to utilize information about items that were not completed or not attempted we recoded each into 2 items: 1) a dichotomous item (0 indicates a uncompleted task - or 1 with a transformed item score of 0, 1 indicates a completed task); and 2) a continuous item (equal to transformed item score if the dichotomous item is coded as 1, otherwise the value of this item is coded as missing). Those who completed tasks above the time limits thus had 1 for the dichotomous item and 0 for transformed item scores.

We then conducted confirmatory factor analyses (CFAs) of the P-IOF with weighted least square, mean and variance adjustment to evaluate the unidimensionality of this approach. The analyses were done in Mplus.

Model calibration

A nonlinear mixed model[39] was used to calibrate the data with mixed response formats, using a 2-parameter item response model for the dichotomous items and a Gaussian linear regression model[40] for the continuous items. In the nonlinear mixed model, the random effect (or the latent variable) at the person level accounts for the correlation across continuous and dichotomous items; the fixed effects include the discriminant and difficulty parameters for dichotomous items, and the slope, intercept and residual parameters for continuous items. The difficulty parameter in the dichotomous item model is the level of the person score in which the person has a 50% chance to complete this activity; the intercept parameter in the continuous item model represents the average score in the continuous item for a person score of 0. The discrimination and slope parameters represent the magnitude of changes in probability of the dichotomous items or in the score of continuous items when person score changes by 1 unit. Thus, a higher value in discrimination and slope parameters means a higher capability of the items to differentiate between persons with higher and lower functions. These analyses were done in Mplus.[41]

Person score estimation

The maximum a posteriori (MAP) Bayesian estimation method [42] was applied to estimate the person scores. The posterior distribution of the person score is the combination of the likelihood functions for responses of the dichotomous and continuous items, and the standardized normal distribution as the priori distribution. [43] The Newton-Raphson iteration procedure[44] was used to estimate the person score which maximizes the posteriori distribution. The standard error of the person score estimate is the second derivative in Newton-Raphson iteration method. The estimate process was implemented in SAS. We replicated the same scoring algorithm using Visual Basic for Applications language and created an easy-to-use scoring system in Excel for persons in the field.

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Selection of items

Mixed integer linear programming (MILP) was used to identify items that were most informative in generating the overall score.[45] The MILP procedure maximizes or minimizes the objective function under a set of constraints. The objective function in shortening the scale is to minimize the number of selected items. After examining the test information function of all dichotomous items, the following constraints were applied in MILP process: The information value must be greater than 10 at person score levels of -1.5, -1, -0.5, 0, and 0.5. Test information greater than 10 corresponds to score reliability greater than 0.9. The analyses were done in R.

We used this information to create a 16-item (Short-Form) P-IOF measure and we transformed the estimated person score from a Z score to a 0-100 score for easy interpretation. For this transformation, we assigned a 0 to a hypothetical person who could not complete all items, and a 100 to a person who could complete all items at or faster than the normative mean value. We then compared the standard errors for the full 26-item P-IOF and the 16-item version of the measure. To determine the impact of reducing the number of test items on administrative burden, we estimated the mean time to administer the full 26-item test and then subtracted the time it took to complete the 10 items that were dropped. We used data from data collection forms, and viewed a sample of 10 videos of participants at the TR, TH and SH level (chosen at random from those with useable data), measuring the time it took for individual item administration including reading of test instructions, allowance of practice time etc. This information was used to estimate administrative burden. We also created a score calculator in Excel which allows users to automatically transform raw scores to generate a P-IOF short form score. A summary of statistical analyses and their purposes is shown in Appendix D.

Validation of the revised metric

We examined the distribution of the short form P-IOF to evaluate the presence of floor or ceiling effects in our new measure. We then repeated analyses of construct and convergent validity using the scores of the 16 items metric.

Results

Participants included 126 persons, 88% unilateral, 12% bilateral amputees, 97% male, 75% white, and mean age was 57.0 (sd 15.8) (Table 1). Sixty-nine percent had amputation at the TR (or wrist) level, 27% at the TH (or elbow) level and 4% at the SH level. Nearly 60% used a body-powered prosthesis, 21% used a myoelectric single-DOF terminal device, and 20% used a myoelectric with a multi-DOF terminal device.

There were 18.3-19.1% of participants with scores at the floor of the IOF, LIF, and W-LIF scales (Fig. 1). Floor effects were the largest for tip grip (33%), smallest for extension, but above 15% for all (Fig. 2). Floor effects were less noticeable for the sub-group of participants with TR amputation (Appendix A, Fig. 1) for most prehensile patterns (4-16%) and for overall IOF, LIF and W-LIF scores (4.6%). Distribution of the LIF and W-LIF mirrored the IOF. Distributions in Figure 3 show that using 12x normative values for boundary limits brought the floor effects down to 15% for the LIF and W-LIF.

Figure 4 shows the proportion of participants who did not complete, did not attempt, and exceeded the boundary limits for each task. The range of percent not attempted for items was between 6.4%-23.0%. There were 8 items that were not attempted by more than 15% (jar lid, carton pouring, full jar, screwdriver, food cutting, buttons, rotate key, and jug pouring). Range of non–completion of items was from 1.6-26.2. There were 10 items not completed by more than 15% (spherical heavy, jar lid, screwdriver, food cutting, buttons, tip light, tip heavy, coins, zipper, and jug pouring). The range of completion in times exceeding the boundary limit was 4.8%-36.5%. Only 1 item (tray lift) had less than 5% of the sample outside the boundary limit. Items with the most problematic boundary limits included coins (exceeded by 35%), and food cutting and tripod heavy (exceeded by 25%).

A comparison of SHAP IOF, LIF and W-LIF scores by amputation level is shown in Table 2. SHAP IOF scores differed significantly

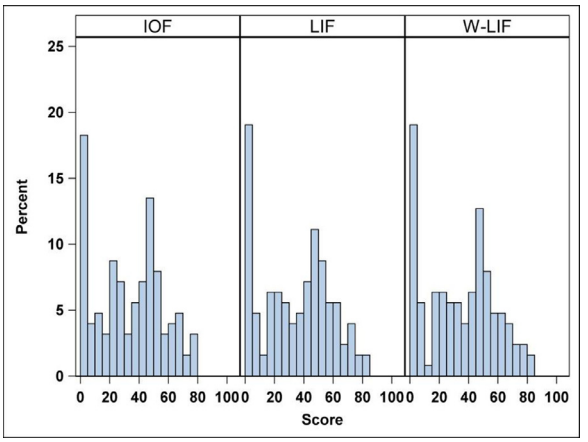

Fig. 1. Distribution of SHAP IOF, LIF and W-LIF scores.

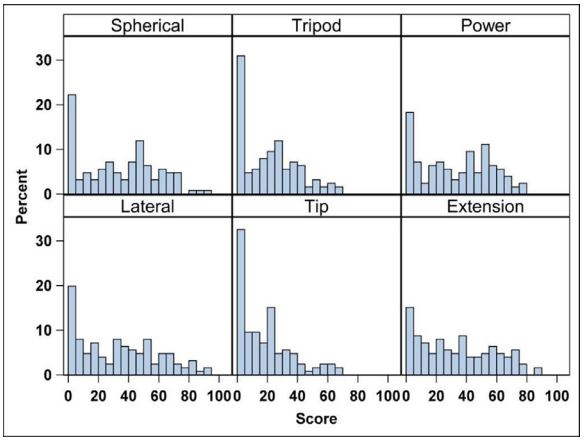

Fig. 2. Distribution of SHAP prehensile pattern scores.

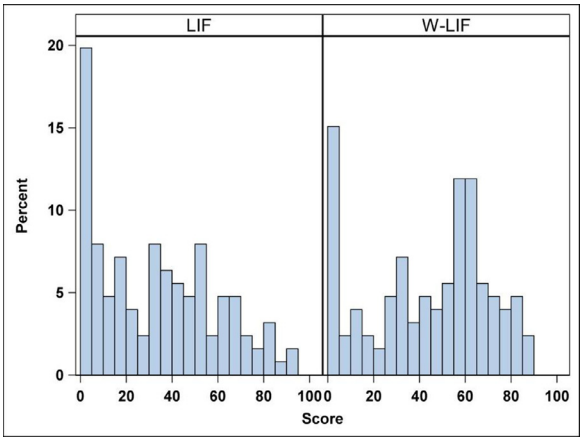

Fig. 3. Distribution of LIF and W-LIF with scores calculated using 12x boundary limits.

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Table 1
Participant characteristics.

Laterality:	Unilateral (N = 111) Mn (sd)	Bilateral (N = 15) Mn (sd)	All (N = 126) Mn (sd)
Age	56.8 (16.4)	58.5 (10.7)	57.0 (15.8)
Years since amputation	22.3 (19.1)	23.1 (18.8)	23.3 (19.0)
	N (%)	*N* (%)	*N* (%)
Sex			
Male	108 (96.8)	14 (93.3)	122 (96.8)
Female	3 (3.2)	1 (6.7)	4 (3.2)
Race			
White	82 (74.6)	12 (80.0)	94 (74.6)
Black	13 (11.1)	1 (6.7)	14 (11.1)
Mixed and/or other	16 (14.3)	2 (13.3)	18 (14.3)
Ethnicity			
Hispanic	15 (13.5)	1 (6.7)	16 (12.7)
Not Hispanic	92 (82.9)	14 (93.3)	106 (84.1)
Unknown	4 (3.6)	0 (0.0)	4 (3.2)
Amputation level			
Shoulder Disarticulation	5 (4.5)	0 (0.0)	5 (4.0)
Transhumeral	31 (27.9)	3 (20.0)	34 (27.0)
Transradial	75 (67.6)	12 (80.0)	87 (69.1)
Prosthesis type			
Body powered	64 (57.7)	10 (66.7)	74 (58.7)
Myoelectric, single DOF terminal device	23 (20.7)	4 (26.7)	27 (21.4)
Myoelectric, multi-DOF terminal device	24 (21.6)	1 (6.7)	25 (19.8)
Terminal device type			
Body-powered hand	1 (0.9)	0 (0.0)	1 90.8)
Body-powered hook	60 (54.1)	10 (66.7)	70 (55.6)
Body-powered prehenser	3 (2.7)	0 (0.0)	2 9(2.4)
Externally powered prehenser	13 (11.7)	3 (20.0)	16 (12.7)
Single-DOF myoelectric hand	10 (9.0)	1 (6.7)	11 (8.7)
Multi-DOF myoelectric hand	24 (21.6)	1 (6.7)	25 (19.8)
Etiology of amputation			
Congenital	3 (8.6)	1 (10.0)	4 (8.9)
Combat	36 (39.6)	2 (14.3)	38 (36.2)
Accident	52 (57.1)	9 (64.3)	61 (58.1)
Burn	6 (6.5)	4 (28.6)	10 (9.5)
Cancer	5 (5.5)	0 (0.0)	5 (4.8)
Diabetes	1 (1.1)	0 (0.0)	1 (0.9)
Infection	12 (13.2)	3 (21.4)	15 (14.3)

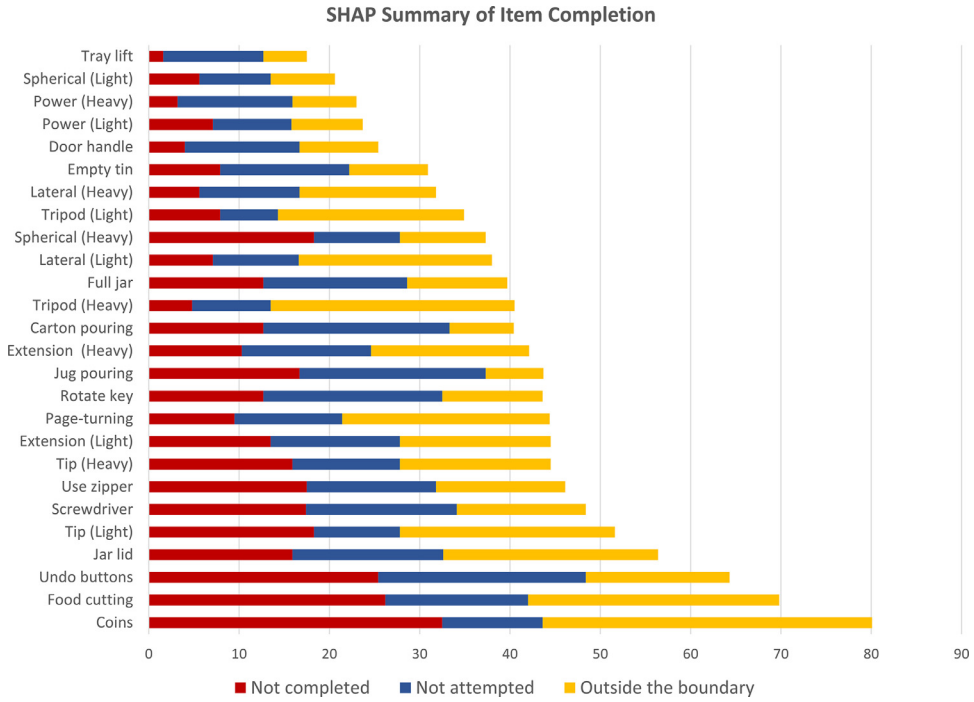

Fig. 4. Proportion of participants who did not complete, did not attempt, and exceeded the boundary limits for each task.

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Table 2
Comparison of scores by amputation level.

	Transhumeral / Shoulder ($N = 39$) Mn (sd)	Transradial ($N = 87$) Mn (sd)	t-test *P*	Effect Size
Overall measures				
SHAP IOF	11.6 (14.8)	42.5 (18.8)	<.001	1.8
LIF	12.0 (15.4)	44.5 (19.7)	<.001	1.8
W-LIF	11.9 (15.1)	44.0 (19.5)	<.001	1.8
SHAP prehensile patterns				
Spherical	10.4 (14.8)	43.4 (21.7)	<.001	1.7
Tripod	6.4 (9.4)	26.8 (18.1)	<.001	1.3
Power	10.6 (14.4)	42.1 (20.0)	<.001	1.7
Lateral	10.3 (16.4)	42.9 (23.4)	<.001	1.5
Tip	4.5 (8.8)	23.7 (17.5)	<.001	1.3
Extension	13.9 (17.8)	41.3 (22.7)	<.001	1.3
16-item P-IOF Score (12x Norms used)	27.1 (22.4)	62.6 (17.4)	<.001	1.8

Table 3
Comparison of scores by prosthesis type (transradial amputees only).

	Body powered ($N = 53$) Mn (sd)	Myo single DOF ($N = 15$) Mn (sd)	Myo multi-DOF ($N = 19$) Mn (sd)	Kruskal-Wallis *P*
Overall measures				
SHAP IOF	44.0 (19.6)	41.0 (21.1)	39.6 (14.8)	.5697
LIF	44.7 (20.4)	44.3 (22.0)	43.9 (16.7)	.8624
W-LIF	44.8 (20.3)	43.3 (21.8)	42.2 (15.9)	.8011
SHAP prehensile patterns				
Spherical	42.0 (22.8)	42.7 (23.0)	47.7 (17.7)	.3913
Tripod	27.7 (18.4)	30.3 (21.1)	21.6 (14.3)	.3442
Power	42.2 (20.1)	42.3 (24.1)	41.9 (17.3)	.8832
Lateral	44.7 (24.9)	41.3 (23.4)	39.3 (19.5)	.7118
Tip	24.1 (18.8)	28.2 (18.1)	18.9 (12.3)	.2885
Extension	40.2 (23.9)	44.5 (22.8)	41.6 (19.9)	.7874
16-item P-IOF Score (12x Norms used)	63.6 (17.5)	59.8 (22.6)	62.1 (12.6)	.7407

($P < .0001$) for those with TH and/or SH amputation (mn 11.6 sd 14.8) and those with TR amputation (mn 42.5 sd 18.8); PP scores, LIF, W-LIF were all also higher for those with TR amputation ($P < .0001$).

A comparison of scores by prosthesis type (those with TR amputation only) is shown in Table 3. No between group differences were observed in IOF, LIF, W-LIF, or PP scores. We did observe differences in raw scores of several SHAP items (screwdriver, buttons, using zipper, tray lift) for TR amputees by prosthesis type, with body powered users having shortest times in all cases (Table 4).

Correlations between the SHAP IOF, LIF, W-LIF, and other measures are shown in Figure 5. Correlations between IOF, LIF, W-LIF and other dexterity measures were 0.54-0.79. Correlation between individual PP and other dexterity measures were somewhat lower (0.42-0.73); the strongest associations were between lateral PP and JTHFT feeding ($r = 0.72$), and between Box and Blocks and all PP scales (0.68-0.73). Correlations with discriminant measures were weak (below 0.30) except for CRIS-CAT extent of limitation and perceived limitations - correlations with IOF/LIF/W-LIF were 0.30.

The Cronbach alpha for the original SHAP IOF measure was 0.967, indicating excellent internal consistency. EFA revealed that a 1 factor solution for all SHAP items was marginally acceptable as a unidimensional factor with comparative fit index (CFI) = 0.87, Tucker Lewis Index (TLI) = 0.861, root mean square error of approximation (RMSEA) = 0.91.However. there was no evidence in support of separate factors for PP scores – items did not load onto factors related to prehensile patterns.

Confirmatory factor analyses of our modified scoring method (P-IOF) – which used information from the dichotomous and continuous items and an increased boundary limit of 12x normative values – found acceptable fit (TLI ≥0.9, RMSEA <0.08). Only 7.5% of the sample had P-IOF scores at the lower end of the scale (results not shown).

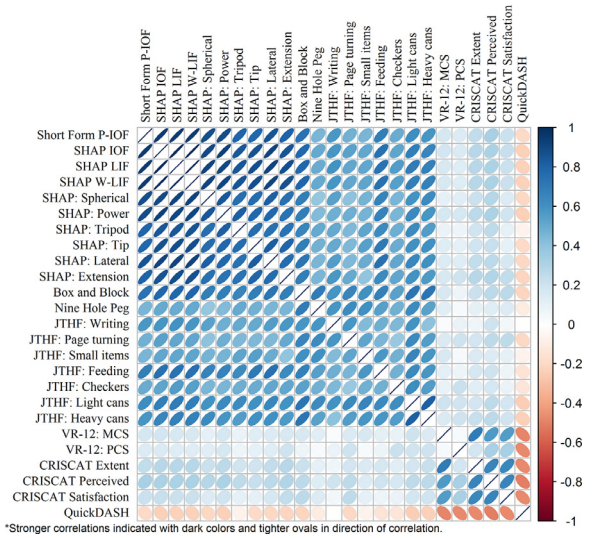

Fig. 5. Correlations between the SHAP IOF, LIF, W-LIF and other measures.

Mixed integer linear programming identified 10 items that did not contribute meaningfully to the calculation of the total score: Jar lid, carton pouring, full jar, door handle, tripod (light), tip (heavy), jug pouring, extension (light), extension (heavy) and page turning. Table 5 shows the administration time of the full item set, the 16-item set, and the 10 items that we dropped. On average, administration of the full 26-item set took 30.3 minutes (sd 14.7). In contrast, administration of the 16-item set took 20.7 minutes (sd 10.8) and the 10 items that were dropped took 9.5 minutes (sd 5.6). The Short Form P-IOF score calculator is provided

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Table 4
Comparison of individual items (raw time in seconds) by prosthesis type (transradial amputees only) for task completers only.

	Body powered (N = 53) Mn (sd)	Myo single DOF (N = 15) Mn (sd)	Myo multi-DOF (N = 19) Mn (sd)	Kruskal-Wallis P
SHAP item times				
Spherical (Light)	5.8 (2.6)	8.4 (5.5)	5.5 (2.1)	.1190
Spherical (Heavy)	7.4 (3.7)	8.3 (9.9)	13.1 (25.9)	.7480
Jar lid	17.6 (16.0)	15.1 (9.5)	17.3 (12.4)	.9812
Carton Pouring	23.8 (15.3)	24.1 (9.1)	25.9 (12.8)	.5050
Power (Light)	5.7 (3.3)	5.5 (2.3)	5.4 (2.5)	.9611
Power (Heavy)	7.4 (6.3)	6.1 (3.5)	5.3 (2.4)	.4577
Full jar	8.2 (5.9)	11.7 (14.4)	20.0 (49.3)	.8285
Empty tin	7.4 (7.8)	7.5 (4.8)	11.4 (29.3)	.1470
Screwdriver	21.4 (16.0)	27.4 (16.8)	34.7 (35.8)	.0296
Door handle	4.7 (3.3)	7.9 (12.2)	5.2 (2.5)	.3445
Food Cutting	26.7 (24.4)	28.1 (16.9)	28.1 (13.3)	.3080
Tripod (Light)	11.1 (10.9)	9.8 (6.5)	9.6 (7.8)	.9309
Tripod (Heavy)	10.9 (9.0)	7.9 (5.8)	10.2 (9.0)	.6194
Undo Buttons	41.2 (28.3)	54.3 (31.0)	97.7 (84.0)	.0007
Tip (Light)	13.1 (11.9)	7.6 (5.2)	8.7 (6.7)	.3250
Tip (Heavy)	14.3 (25.6)	8.6 (6.8)	11.7 (11.9)	.6961
Coins	59.3 (48.0)	51.0 (34.5)	80.4 (103.8)	.7331
Rotate Key	7.4 (5.0)	11.3 (12.2)	9.9 (9.7)	.2731
Use Zip	15.0 (20.9)	7.7 (2.1)	23.7 (27.2)	.0269
Lateral (Light)	8.0 (5.4)	7.9 (5.3)	10.0 (7.7)	.8223
Lateral (Heavy)	8.5 (6.5)	7.4 (4.5)	11.1 (9.6)	.6546
Jug pouring	21.7 (17.8)	27.1 (27.2)	21.2 (8.0)	.4600
Tray lift	8.2 (4.4)	11.5 (4.7)	8.8 (4.2)	.0184
Extension (Light)	13.4 (22.3)	15.6 (30.7)	18.1 (34.6)	.3953
Extension (Heavy)	10.3 (8.5)	6.6 (2.8)	8.0 (6.4)	.1244
Page-turning	11.1 (8.2)	13.3 (10.6)	20.5 (19.7)	.0505

Table 5
Completion times (minutes) for 26 SHAP items, 10 dropped items and 16-item P-IOF in random sample (N = 10).

Items	Mean	SD	Median	Min	Max
Original 26 items of SHAP	30.3	14.7	26.6	16.1	60.8
Dropped 10 items	9.5	5.6	8.9	1.6	20.6
16 items of Short Form P-IOF	20.7	10.8	19.9	4.6	40.2

in Appendix B, and the code for score calculation is provided in Appendix C.

Statistically significant differences in Short Form P-IOF scores were observed between participants with TR and those with TH or SH amputation (Table 2), with significantly higher scores (P < .001) among the TR group (mn 27.1 sd 22.4) than the TH group (mn 62.6 sd 17.4). No differences were observed by device type for TR amputees (Table 3).

The 16-item measure had strong correlations with concurrent measures (0.55-0.77), low correlations with discriminant measures (0.16-0.31) and very high correlations with SHAP IOF, LIF, W-LIF (0.97-0.98) (Fig. 5). Figure 6 shows the distribution of the Short Form P-IOF. Validity analyses of short form P-IOF revealed similar patterns as before, however fewer than 7.5% of subjects scored in the bottom 0-5 points range. There was a 0.99 correlation between the 26-item and 16 item P-IOF, and comparisons of standard errors show comparable precision around score estimates (Fig. 7).

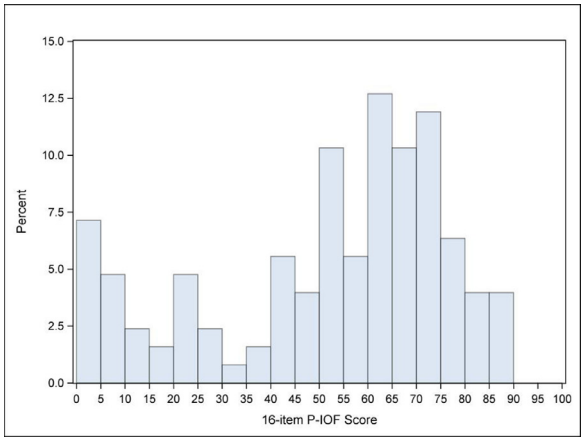

Fig. 6. Distribution of the 16- item P-IOF scores.

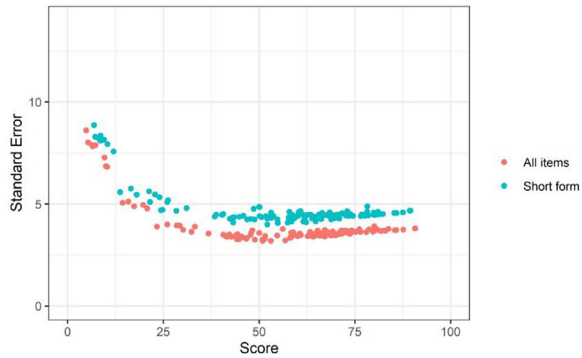

Fig. 7. Comparison of standard errors of the 26 item and 16 item P-IOF.

Discussion

We conducted the largest study of the SHAP in prosthesis users and performed a thorough analysis of the validity of the SHAP. We identified several strengths as well as weaknesses of the measure that led us to develop a modified measure which we called the P-IOF. Overall, our analyses supported the internal validity, construct and concurrent and discriminant validity of the SHAP mea-

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sure (and associated variations on scoring (LIF, W-LIF), but identified a large floor effect, as well as issues with structural validity of the IOF and the PP scores. The substantial floor effect we observed suggested that the SHAP measure and its PPs are not appropriately targeted to persons with major upper limb amputation. Although our exploratory factor analyses supported the unidimensionality of the IOF scoring, it did not support the grouping of SHAP items into prehensile patterns.

We believe that the SHAP's substantial floor effects are attributable to the large proportion of persons in our sample who could not complete, did not attempt, or exceeded boundary limits for many items; all of whom received the same item scoring. The original sample used to develop the SHAP scoring algorithm was predominantly persons with TR amputation (age not reported), all of whom were able to complete tasks within the 8x normative value boundary limits. In contrast, our sample included a great proportion of persons with TH (27.6 %) and SH (3.9%) amputation, subgroups that were less able to complete tasks and required more time to complete. That said, concerns about the proportion of persons with upper limb amputation who exceeded the established boundary limits were also noted in a study of 27 prosthesis users (24 with TR or WD level amputation).[31]

However, this does not fully explain why our sample had lower IOF scores than previously reported studies.[2-5,7,8,10,12,13,15-17,31,46] Our sub-group of 87 participants with TR amputation had lower IOF scores (mn 42.5 sd 18.8) than reported in previous studies of predominantly persons with TR amputation. These differences may be explained by older age of our TR sample (mn 56.8 sd 16.6), as compared to those in prior studies. A robust comparison of our findings with those previously reported for persons with major upper limb amputation is shown in Appendix Table 1. Only 2 studies included more than 8 participants. Median scores in the 27 person Burgerdorf sample, for example, were 62.0, however that sample was younger (median age 47).[31] Similarly, Salminger's study of 17 persons with TR amputation (mn age 26) reported mean IOF scores of 65.1.

The average PP scores in our sample were also lower (spherical: 43.4, tripod: 26.8, power: 42.1, lateral: 42.9, tip: 23.7, and extension: 41.3) than that reported in earlier studies[2,4,15,16,46] (Appendix Table 2). However, all studies reporting PP scores had very small samples. For example, Segil's study of 4 TR amputees utilizing a modified Bebionic hand reported overall higher average PP scores (spherical: 81, tripod: 22, power: 49, lateral: 63, tip: 29, and extension: 71), with the exception of the tripod PP. The sample was younger than our sample with a reported mean age of 44 (sd 16).[15] Another study of 6 experienced TR prosthetic users (mn age 36) also reported higher PP scores (spherical: 62, tripod: 36, power: 47, lateral: 54, tip: 31, and extension: 60).[4]

Ours was the first study to examine the structural validity of the SHAP PP scores, and analyses did not support grouping of items into these grasp categories. This finding is not surprising given that the vast majority prosthesis users do not have the option to utilize the 6 grasp patterns commonly used by persons with intact hands. We did not find differences in SHAP IOF or PP scores by prosthesis and/or terminal device type. Our findings mirror those in several prior small studies that used the SHAP to compare prosthetic terminal device and control type.[2-8,10,12,16,47] Exclusive use of the IOF and PP pattern scores instead of individual items may obscure differences between prostheses and terminal devices with differing capabilities. We found differences in raw scores of specific items by device type (screwdriver, buttons, zipper, tray lift). These 4 items were retained (based on MILP information value) in our revised measure and we recommend that future studies consider using the raw scores of these items to compare performance with different types of devices, if desired.

Given the above findings, we recognized that an opportunity existed to improve the measurement of prosthetic hand function, by reducing the floor effects and minimizing the administrative burden seen in the SHAP measure and associated alternative scoring of that measure, the LIF and W-LIF. We utilized a novel approach to measurement construction that utilized information on item completion as well as time to complete tasks to capture lower levels of performance. To better distinguish between persons at the slower end of task performance, we extended the boundary limits of each task to 12x normative values for each task. We reduced administrative burden of the measure by selecting only those tasks that contributed meaningfully to the overall score, eliminating 10 items. We then developed a simple method of score calculation for use by researchers and clinicians in the field, free of charge. The end result is a new measure, the P-IOF which can be administered in two-third of the time as the original measure, and which can be scored using our Excel macro. Furthermore, our scoring process is fully transparent, with coding available to allow others to apply the process to their data. Furthermore, the scoring of the P-IOF if easier to derive than the LIF and W-LIF scores (which also can be calculated without incurring extra costs) .

One advantage of our MAP Bayesian modeling approach is that we can utilize the subject's total score to predict the probability of completion of specific tasks, as well as the time it would take to complete that task, if it was completed. For example, a subject whose score was 30 would have a 40% probability of completing the heavy sphere task, and those who completed would have a predicted time of 13.5 seconds. In contrast, a subject with a score of 50 would have a 76% probability of completing the heavy sphere task, and completers would have a predicted time of 10.0 seconds. Subjects with a score of 70 would have a 94% probably of completing the heavy sphere task, and completers would complete the task in 6.5 seconds.

Limitations

Our sample of prosthesis users remains small compared to the overall population of prosthesis users. However, relative to the very small samples in previous studies of prosthetic function, we believe our findings are very generalizable to prosthesis users. Given the very small sample of persons with amputation at the SH level, we combined this subgroup with the TH subgroup in our analyses. We conducted sensitivity analyses to determine how this approach influenced our findings of difference in scores by amputation level. We removed the 5 SH level participants and repeated all analyses. Statistically significant findings were unchanged.

Although we have produced a new measure with improved psychometrics, we acknowledge that the P-IOF score does not entirely eliminate the floor effects, and future improvements to measurement of prosthesis function may be possible through the addition of easier items.

Conclusion

Our analyses supported the validity of the SHAP IOF, as well as the LIF, and W-LIF, both of which are alternative scorings for SHAP items. We described the proportion of participants who could not complete, did not attempt, or exceeded the boundary limits of each item; noting items that were problematic. We also identified large floor effects in all of these measures, suggesting that the test would not be able to detect differences between groups or changes within persons at the lower end of function. Structural validity was investigated with factor analyses which did not support the use of the PP scores. We developed a new way of scoring

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the 26 SHAP items which we called the Prosthesis Index of Functionality (P-IOF) and a 16-item P-IOF, both of which minimized the floor effects and had good evidence of validity. Finally, we developed an easy to use, publicly available scoring algorithm. Use of the 16-item P-IOF reduces administrative burden while improving precision of measurement of prosthesis hand function.

Declaration of competing interest

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Supplementary materials

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Prosthetics and Orthotics International

Upper limb prosthesis users: A longitudinal cohort study

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Abstract

Background: No previous studies have followed prosthesis users with upper limb loss or limb deficiency using their own prostheses to assess change over time.

Objectives: (1) To describe prostheses and terminal device types used at baseline and 1-year follow-up; (2) to examine changes in functional outcomes and device satisfaction over time; and (3) to examine whether changes in outcomes varied across level of amputation and type of prosthesis used.

Study Design: Multisite, observational time series design with in-person functional performance and self-report data collected at baseline and 1-year follow-up.

Methods: Baseline and follow-up outcome scores were compared using Wilcoxon signed-rank tests. Analyses were stratified by amputation level, time since amputation, prosthesis type, and change in device type. Published minimal detectable change (MDC) values were used to determine whether detectable change in outcome measures occurred.

Results: The longitudinal cohort consisted of 64 participants (mean age 64 years, 56% body-powered users). The only significant differences in outcome measures between baseline and follow-up (after adjustment for false discovery) were hours/day of prosthesis use, which increased from 6.0 (4.4) to 7.3 (5.3) hours ($P = 0.0022$). Differences in prosthesis use intensity remained significant in analyses stratified by amputation level, time since amputation, prosthesis type, and change in device type. Between 14 and 20% of the sample had change in one or more outcome measures that was greater than the known MDC.

Conclusions: Most participants had stable outcomes over a year's time, whereas 14–20% experienced either improvement or decline in one or more tests indicating the importance of annual follow-up visits.

Keywords

upper limb amputation, upper limb prosthesis, longitudinal study, outcomes

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Background

Normative values of dexterity, activity performance, prosthesis satisfaction, disability, health-related quality of life (HRQoL), and community integration for upper limb (UL) prosthesis users were recently published.[1] These values were derived from a cross-sectional study that examined a multitude of important outcomes at a single time point, providing benchmarks for clinician and researcher use when comparing patients/participants to age-matched prosthesis users, by amputation level, using specific device types.

While valuable, the cross-sectional design of previous work precludes tracking key outcomes over time. Much of the existing data quantifying function and disability of UL prosthesis users are derived from survey studies, the majority cross-sectional.[2–8] When functional performance data have been reported, studies were cross-sectional with no longitudinal follow-up 1 or involved small samples focused on evaluating prosthesis training or specific prosthetic intervention.[9] At this time, there are no data available on functional performance of established UL prosthesis users over time. It is unclear whether performance remains stable or changes year to year.

It is reasonable to expect that persons with more recent amputation are more likely to experience considerable change over 1 year. Healing and maturation of the residual limb to begin

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prosthesis fitting can take weeks to months depending on the complexity of the surgical intervention and comorbid conditions.[10–12] Prosthesis fitting and training also typically requires several months. Although clinical recommendations are to fit individuals with prostheses as soon as possible following amputation, there is limited evidence detailing long-term outcomes associated with early compared with delayed fitting.[10,12,13] Persons with more proximal UL amputations are commonly challenged to incorporate more complex prosthesis control strategies requiring greater training intensity and duration. Outcomes following UL amputation also vary according to comorbidities (such as traumatic brain injury) and amputation level.[13,14]

Enhanced understanding regarding patterns of key outcomes over time could inform clinical care, alerting providers to clinically relevant changes. Enhanced understanding of timing, during which change is anticipated, could also inform when to schedule follow-up appointments. Understanding outcomes over time under normal, nonexperimental conditions may also be useful for researchers conducting longitudinal studies of novel device use, where outcome measures are repeatedly administered, and some amount of change might be attributable to prior history, experience, and maturation.

Some research studies have followed users of novel or experimental prostheses over time to evaluate changes in outcomes.[15–18] Others have followed persons with incident amputation longitudinally through surveys to make comparisons between amputation and limb salvage and amputation and hand replantation.[19] In addition, limited data are available comparing outcomes in persons with UL amputation undergoing vascularized composite allotransplantation with those undergoing prosthetic rehabilitation.[20] To our knowledge, no previous studies have followed a cohort of established UL prostheses users to assess if and how they changed. Such information could provide valuable information for clinicians, patients, purchasers, and policy makers. Therefore, the overall objective of this study was to follow UL prosthesis users over 1 year to describe any changes in prosthesis use, satisfaction, function, and HRQoL. Specifically, we aimed to (1) describe prosthesis and terminal device (TD) type used at baseline and follow-up; (2) examine changes in functional outcomes and device satisfaction over time; and (3) examine whether changes in outcomes varied across level of amputation and type of prostheses used.

Methods

Study design

The study used a cross-sectional, observational time series design with data collected at baseline and 1-year follow-up. Data collection occurred at one of five study sites in the United States. The study was approved by the Veterans Administration Central Institutional Review Board (IRB), Regional Health Command Central IRB, and by the Human research Protection Office. Participants provided written informed consent.

Sample

Participants were a convenience sample of individuals, primarily Veterans, with major UL amputations or limb deficiency. Veterans who were participants in an earlier survey study and who agreed to be contacted for potential involvement in future study activities were invited to participate. Others were recruited through clinical contacts, advertisements, e-blasts, and word of mouth.

All participants used an active prosthesis (body powered or externally powered—including myoelectric and Life Under Kinetic Evolution [LUKE Arm] or hybrid).[21] Persons who could not tolerate wearing a prosthesis for 3 hours and/or those who had a health condition that might limit their ability to participate in study assessment activities were excluded. Participants were recruited from a variety of sources.

Data collection

Participants attended in-person study visits at a data collection site. Data were collected by physical or occupational therapists, assisted by research coordinators. Each of the study visits lasted approximately 3–4 hours with rest breaks provided as needed. During study visits, data were collected on demographic characteristics (age, race, ethnicity, and military/Veteran status), history of the amputations, and prosthesis use (prostheses type and hours and days of prostheses use). Assessors inspected, described, and photographed the prosthetic device and its components and TD. Participants also described any additional prostheses and TDs that they currently own and use (besides those used in testing). Study staff reviewed text descriptions of additional device types for classification of additional prostheses and TDs.

Descriptions of all outcome measures are provided in Table 1. Measures of dexterity and activity performance were administered by study assessors. Self-reported measures addressed satisfaction with the prostheses, disability, HRQoL, community integration, and need for assistance with activities of daily living (ADL). Study assessors also administered the Trinity Amputation and Prosthesis Experience Scale (TAPES) to measure prosthesis satisfaction.[22]

Data analyses

Demographics and physical characteristics of the longitudinal cohort were described by amputation level/laterality. To examine potential bias in the longitudinal cohort, sample characteristics and outcome measures were compared between the longitudinal cohort and those lost to follow-up (LTF) using nonparametric Wilcoxon-Mann-Whitney tests and Fisher exact tests because normality assumptions required for parametric tests were rejected by the Shapiro-Wilk test.

The type of device and TD used at baseline and follow-up were described. All continuous and dichotomous outcome measures at baseline and 1-year follow-up were compared using Wilcoxon signed-rank and McNemar tests. Outcomes for individuals with unilateral UL amputation were stratified by amputation level, and Wilcoxon signed-rank analyses were repeated for subgroups with transradial (TR) and transhumeral (TH) amputation. Given that we expected that functional outcomes would be more likely to change for those with more recent amputation and that we found that those with more recent amputations were more likely to switch TD types between baseline and follow-up, we repeated these comparisons for the subgroup who had sustained amputations within the prior 5 years using Wilcoxon signed-rank tests. Wilcoxon signed-rank tests comparing outcome measures at

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Table 1. Brief description of key outcome measures.

	Construct	Rating Criteria	Interpretation
Functional performance			
Dexterity			
JTHFT	Dexterity	Performance speed; items per second (modified scoring)	Higher scores indicate better dexterity
NHP	Dexterity	Timed measure (time limited to 6 minutes), score calculated as items/second (modified scoring)	Higher scores indicate faster speed, better dexterity
Box and Block	Dexterity	Performance speed; total number of blocks transported	Higher scores indicate better performance
SHAP	Dexterity/index of function	Performance speed	Higher scores indicate better dexterity
Activity performance			
AM-ULA	Activity performance	Each item is rated on task completion: speed, movement quality, skillfulness of prosthesis use, and independence. Total score is the average score ×10	Higher scores indicate better activity performance
BAM-ULA	Activity performance	Ability to complete each task (yes/no). Total score is the number of activities that were completed	Higher scores indicate better activity performance
T-MAP	Activity performance	Timed measure: sum of time to complete each activity	Lower scores indicate faster speed, less difficulty
Self-report			
Device satisfaction			
TAPES	Prosthetic satisfaction	Satisfaction	Higher scores indicate greater prosthetic satisfaction
QuickDASH	Disability	Performance difficulty and impairment severity	Higher scores indicate greater disability
HRQoL			
VR-12 MCS	Quality of life	Self-rated quality of life	Higher scores indicate greater satisfaction
VR-12 PCS	Quality of life	Self-rated quality of life	Higher scores indicate greater satisfaction
CRIS-CAT	Extent of participation	Frequency and amount of participation	Higher scores indicate better community integration
CRIS-CAT	Perceived difficulty	Perceived limitations in participation	Higher scores indicate better community integration
CRIS-CAT	Satisfaction	Satisfaction with participation	Higher scores indicate better community integration
Need for activities of daily living help	Independence	Yes/no	No required help indicates greater independence

Abbreviations: ADL, activities of daily living; AM-ULA, Activities Measure for Upper Limb Amputation; BAM-ULA, Brief Activities Measure for Upper Limb Amputation; CRIS-CAT, Community Reintegration of Injured Service Members–Computer Adapted Test; HRQoL, health-related quality of life; JTHFT, Jebsen-Taylor Hand Function Test; NHP, Nine Hole Peg; QuickDASH, Quick Disability of the Arm, Shoulder, and Hand; SHAP, Southampton Hand Assessment Procedure; TAPES, Trinity Amputation and Prosthesis Experience Scale; TH, transhumeral; T-MAP, Timed Measure of Activity Performance; TR, transradial; VR-12 MCS, Veterans RAND 12-Item Health Survey Mental Composite Score; VR-12 PCS, Veterans RAND 12-Item Health Survey Physical Composite Score; WSR, Wilcoxon signed rank.

baseline to follow-up were also repeated for the subgroups using body-powered and myoelectric devices and the subgroups who had switched device types and who had used the same device type throughout the study. These analyses controlled for multiple comparisons using the Benjamini-Hochberg method.[23] This method adjusted for false discovery rates in major categories of tests to maintain a false discovery rate of 0.10 within each test category.[23] The following categories were used: dexterity (10 measures), activity performance (three measures), and self-reported function, disability, HRQoL, community integration (six measures), and prosthesis use frequency (two measures).

To determine the proportion of participants whose outcomes achieved a minimally detectable change (MDC), we used published MDC 90% values to classify change from baseline to follow-up as "worsened by the MDC", "within the MDC," and "improved by the MDC" and described the distribution of change above MDC in outcome measures.

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Table 2. Demographics and prosthesis characteristics of the longitudinal cohort by amputation level.

	SH (N = 1)	TH (N = 18)	TR (N = 39)	Bilateral[a] (N = 6)	Total (N = 64)
	Mn	Mn (sd)	Mn (sd)	Mn (sd)	Mn (sd)
Age	27.5	54.5 (11.7)	57.5 (16.3)	56.3 (12.4)	56.1 (15.0)
Years since amputation	6.0	18.9 (13.9)	25.0 (19.3)	14.1 (14.9)	21.9 (17.7)
Years with specific device used in testing (baseline)	6.0	4.1 (3.9)	4.6 (5.9)	2.7 (3.0)	4.3 (5.1)
Years with specific device used in testing (follow-up)	7.0	3.7 (3.9)	6.1 (10.7)	7.9 (10.7)	5.6 (9.1)
Years with general type of device used in testing (baseline)	6.0	14.7 (14.5)	18.9 (19.3)	11.7 (11.8)	16.8 (17.3)
Years with general type of device used in testing (follow-up)	7.0	16.2 (15.5)	20.9 (19.4)	9.8 (12.8)	18.3 (17.9)
Weeks of training with baseline device	9.0	15.4 (31.7)	4.1 (5.7)	7.5 (14.2)	7.7 (18.2)
Weeks of training with follow-up device	9.0	17.7 (31.8)	4.3 (6.6)	6.7 (14.5)	8.4 (18.7)
	N (%)	N (%)	N (%)	N (%)	N (%)
Receipt of any training to use current prosthesis					
No	0 (0.0)	3 (16.7)	11 (28.2)	3 (50.0)	17 (26.5)
Yes	1 (100.0)	15 (83.3)	28 (71.8)	3 (50.0)	47 (73.4)
Years since amputation					
<5 years	0 (0.0)	1 (5.6)	4 (10.3)	2 (33.3)	7 (10.9)
5 years or more	1 (100.0)	17 (94.4)	35 (89.7)	4 (66.7)	57 (89.1)
Age category					
18≤ age <45	1 (100.0)	3 (16.7)	9 (23.1)	1 (16.7)	14 (21.9)
46≤ age <65	0 (0.0)	12 (66.7)	12 (30.8)	3 (50.0)	27 (42.2)
66≤ age <75	0 (0.0)	3 (16.7)	15 (38.5)	2 (33.3)	20 (31.3)
75+	0 (0.0)	0 (0.0)	3 (7.6)	0 (0.0)	3 (4.7)
Sex					
Male	1 (100.0)	18 (100.0)	38 (97.4)	6 (100.0)	83 (98.4)
Female	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	1 (1.6)
Race					
White	1 (100.0)	10 (55.6)	29 (74.4)	3 (50.0)	43 (67.2)
Black	0 (0.0)	5 (27.8)	5 (12.8)	1 (16.7)	11 (17.2)
Mixed/other	0 (0.0)	3 (16.7)	3 (16.7)	2 (33.3)	10 (15.6)
Ethnicity					
Hispanic	0 (0.0)	4 (22.2)	4 (10.3)	1 (16.7)	9 (14.1)
Non-Hispanic	1 (100.0)	14 (77.8)	34 (87.2)	5 (83.3)	54 (84.4)
Unknown	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	1 (1.6)
Prosthesis type					
Body powered	0 (0.0)	9 (50.0)	22 (56.4)	5 (83.3)	36 (56.3)
Myoelectric single DOF TD	1 (100.0)	5 (27.8)	7 (18.0)	1 (16.7)	14 (21.9)
Myoelectric multi-DOF TD	0 (0.0)	4 (22.2)	10 (25.6)	0 (0.0)	14 (21.9)
TD type					
Body-powered hook	0 (0.0)	9 (50.0)	21 (53.9)	5 (83.3)	35 (54.7)
Body-powered prehenser	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	1 (1.6)
Externally powered prehensers	0 (0.0)	2 (11.1)	5 (12.8)	1 (16.7)	8 (12.5)
Multi-DOF Myo Hand	0 (0.0)	4 (22.2)	10 (25.6)	0 (0.0)	14 (21.9)
Single-DOF Myo Hand	0 (0.0)	3 (16.7)	2 (5.1)	0 (0.0)	6 (9.4)

[a]*All bilateral amputees had TR amputation on the tested side.*
Abbreviations: DOF, degrees of freedom; SH, shoulder; TD, terminal device; TH, transhumeral; TR, transradial.

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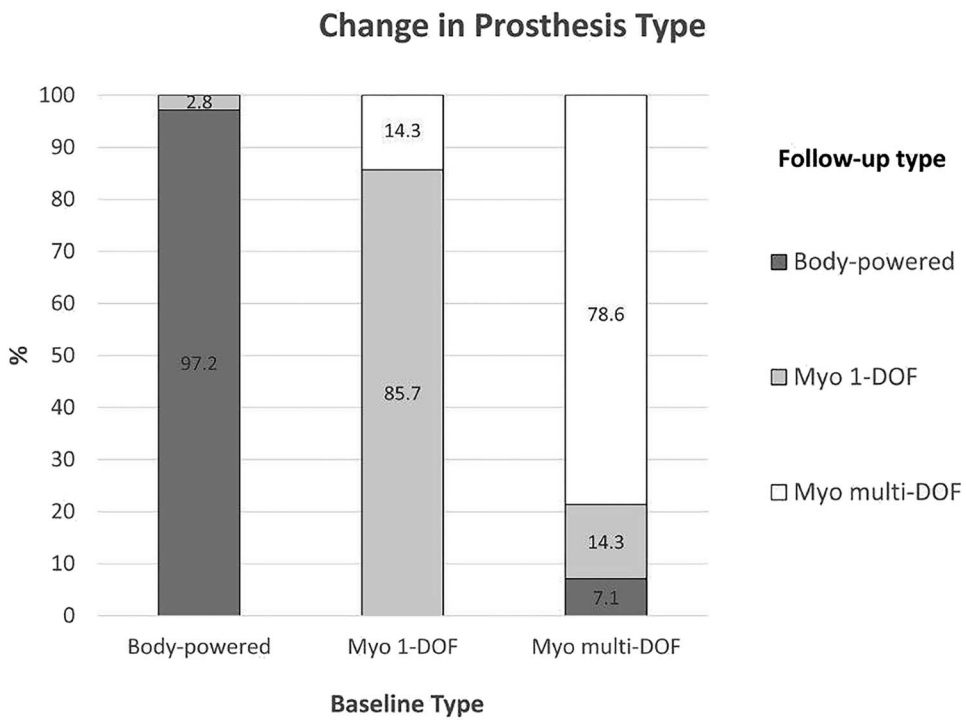

Figure 1. Change in prosthesis type from baseline to follow-up.

Results

One hundred and twenty-seven individuals with UL prosthesis experience were recruited to participate in this study. Sixty-three (50%) participants who completed the baseline assessment were LTF. There were no statistically significant differences in baseline demographics or amputation characteristics of the longitudinal sample and those LTF (Appendix Table 1, Supplemental Digital Content 1, http://links.lww.com/POI/A45). There were significant differences in several baseline outcome measures (Appendix Table 2, Supplemental Digital Content 1, http://links.lww.com/POI/A45). Those LTF performed worse on the Jebsen-Taylor Hand Function Test page-turning (completed significantly fewer items per second) ($P = 0.02$) and heavy cans ($P = 0.05$) tasks compared with the longitudinal cohort. A greater percent of those LTF (31.8%) reported needing ADL help compared with the longitudinal cohort (10.9%) ($P < 0.01$), with most of those LTF requiring <4 hours/day of ADL help.

Sixty-four participants completed both the baseline and follow-up data collection visits. Baseline demographics and prosthesis characteristics of the sample, stratified by amputation level, are provided in Table 2. The sample was 98% male, 67% White, 88% Veteran, and had a mean age of 56.1 (SD 15.0) years. On average, participants had sustained their amputation 21.9 (SD 17.7) years before baseline, had been using their baseline testing device for 4.3 (SD 6.1) years, and had 16.8 (SD 17.3) years of experience using that general type of device (by category). A small percentage of participants (N = 7, 11%) sustained their amputation within 5 years of baseline testing. Body-powered devices were used by most (56.2%) at baseline testing, followed by myoelectric single-degree of freedom (DOF) (21.9%) and multi-DOF devices (21.9%). Seventy-three percent of participants reported receiving training with their current prostheses.

Most participants were tested with the same prosthesis type at follow-up. Change in prosthesis type between baseline and follow-up is shown in Figure 1. In the full longitudinal cohort, the only significant differences in outcome measures between baseline and follow-up (after adjustment for false discovery) were hours/day of prosthesis use, which increased from 6.0 (4.4) to 7.3 (5.3) hours ($P = 0.002$) (Appendix Table 3, Supplemental Digital Content 1, http://links.lww.com/POI/A45). In the TR subgroup (Table 3), the only statistically significant difference after adjustment for false discovery was frequency of prosthesis use (days/week), which decreased from 5.4 (2.0) to 4.9 (2.3) days per week from Visit 1 to Visit 2. Among the TH group, hours/day of prosthesis use increased from baseline 4.0 (3.4) hours per day to follow-up 5.7 (4.7) hours per day ($P = 0.04$), and this difference remained significant after adjustment for false discovery.

Analyses stratified by years since amputation (Appendix Table 4, Supplemental Digital Content 1, http://links.lww.com/POI/A45) showed significant differences after adjustment for false discovery in hours/day of prosthesis use, which increased from 5.6 (3.6) to 8.6 (5.0) ($P = 0.047$) among those with amputation in the prior 5 years and from 6.0 (4.6) to 7.1 (5.3) hours ($P = 0.02$) among those with less recent amputation. After stratifying by prosthesis type and adjusting for false discovery (Appendix Table 5, Supplemental Digital Content 1, http://links.lww.com/POI/A45), there was a significant difference among body-powered device users in hours/day prosthesis use, which increased from 6.3 (4.6) to 7.6 (5.4) ($P = 0.01$).

Analyses stratified by change in prosthesis used are shown in Appendix Table 6 (Supplemental Digital Content 1, http://links.lww.com/POI/A45). There were no statistically significant

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Table 3. Outcomes over time, stratified by amputation level: unilateral amputation only.

	TR (N = 39)				TH (N = 18)			
		Baseline	Follow-up	WSR		Baseline	Follow-up	WSR
Dexterity measures	N	Mn (sd)	Mn (sd)	*P*	N	Mn (sd)	Mn (sd)	*P*
JTHFT								
Writing	38	0.49 (0.35)	0.52 (0.28)	0.2236	16	0.34 (0.22)	0.38 (0.17)	0.6788
Page turning	39	0.16 (0.09)	0.15 (0.09)	0.4254	17	0.06 (0.05)	0.06 (0.05)	0.9632
Small objects	38	0.10 (0.09)	0.10 (0.07)	0.8758	17	0.05 (0.06)	0.05 (0.05)	0.4257
Eating	39	0.19 (0.13)	0.20 (0.11)	0.5448	17	0.09 (0.08)	0.08 (0.06)	0.8394
Checkers	39	0.10 (0.08)	0.10 (0.09)	0.8534	17	0.07 (0.07)	0.07 (0.06)	0.7057
Light cans	39	0.23 (0.14)	0.25 (0.17)	0.4719	16	0.13 (0.09)	0.15 (0.11)	0.4037
Heavy cans	38	0.26 (0.18)	0.27 (0.19)	0.5191	16	0.13 (0.12)	0.15 (0.13)	0.4212
Box and Blocks	38	18.8 (8.8)	19.0 (9.2)	0.6825	18	9.1 (9.0)	9.9 (7.1)	0.5933
Nine-Hole Peg	36	0.06 (0.05)	0.06 (0.05)	0.7394	13	0.02 (0.05)	0.03 (0.04)	0.5625
SHAP IOF	38	43.9 (18.2)	43.8 (20.7)	0.6483	17	16.1 (15.9)	17.7 (17.8)	0.4118
Activity measures								
AM-ULA	39	15.8 (6.6)	15.6 (6.8)	0.7842	18	11.2 (4.2)	11.0 (3.9)	0.5089
BAM-ULA	15	8.1 (2.2)	7.93 (2.8)	0.8621	4	3.8 (3.3)	5.0 (2.7)	0.3750
T-MAP (mins)	28	4.5 (1.7)	4.20 (1.5)	0.2623	11	4.9 (1.58)	4.8 (1.4)	0.9854
Prosthesis Satisfaction								
TAPES	39	3.89 (0.62)	3.87 (0.62)	0.9939	18	3.84 (0.55)	3.9 (0.5)	0.7042
Disability, HRQOL, and community integration								
QuickDASH	36	28.8 (19.7)	31.4 (19.4)	0.4143	18	26.2 (14.2)	28.3 (15.5)	0.4488
VR-12 MCS	38	54.3 (12.0)	52.6 (11.1)	0.0973	16	56.0 (10.5)	55.7 (9.8)	0.7057
VR-12 PCS	38	43.5 (7.1)	41.8 (9.2)	0.2542	16	42.9 (12.0)	42.40(11.6)	0.6322
CRIS-CAT Extent	37	49.3 (9.3)	48.7 (7.6)	0.5414	17	48.6 (9.0)	49.2 (8.2)	0.4307
CRIS-CAT Perceived	37	48.8 (7.8)	48.4 (7.3)	0.6003	17	48.5 (5.3)	48.9 (5.3)	0.6777
CRIS-CAT Satisfaction	37	51.4 (10.9)	48.6 (7.7)	**0.0421**	17	47.9 (5.2)	48.6 (5.2)	0.5171
Prosthesis use								
Hours of prosthesis use per day	39	6.1 (4.2)	7.2 (5.0)	0.0628	18	4.0 (3.4)	5.7 (4.7)	**0.0372**[a]
Frequency of prosthesis use (days per week)	39	5.4 (2.0)	4.9 (2.3)	0.0837[a]	18	5.6 (2.1)	5.7 (2.0)	0.9609
		N (%)	N (%)	McNemar *P*		N (%)	N (%)	McNemar *P*
Need for ADL help	22	19 (86.4)	19 (86.4)	1.0000	12	11 (91.7)	10 (83.3)	1.0000

[a]*Bold indicates significant at p<0.05 after Benjamini-Hochberg adjustment with false discovery rate=0.1.*
Abbreviations: ADL, activities of daily living; AM-ULA, Activities Measure for Upper Limb Amputation; BAM-ULA, Brief Activities Measure for Upper Limb Amputation; CRIS-CAT, Community Reintegration of Injured Service Members–Computer Adapted Test; HRQoL, health-related quality of life; JTHFT, Jebsen-Taylor Hand Function Test; QuickDASH, Quick Disability of the Arm, Shoulder, and Hand; SHAP, Southampton Hand Assessment Procedure; TAPES, Trinity Amputation and Prosthesis Experience Scale; TH, transhumeral; T-MAP, Timed Measure of Activity Performance; TR, transradial; VR-12 MCS, Veterans RAND 12-Item Health Survey Mental Composite Score; VR-12 PCS, Veterans RAND 12-Item Health Survey Physical Composite Score; WSR, Wilcoxon signed rank.

differences after adjustment for false discovery for those who switched device types between baseline and follow-up. However, among those who did not switch device type, hours/day of prosthesis use increased from 6.1 (4.5) at baseline to 7.4 (5.4) at follow-up ($P = 0.01$), and prosthesis use per week decreased from 5.6 (2.1) days/week at baseline to 5.2 (2.3) at follow-up ($P = 0.048$).

The proportions of participants who experienced a change in outcome scores that was greater than or less than the known MDC 90 of the measure are shown in Table 4. Most (65–95%) did not experience any change in outcomes. Twenty percent of participants improved more than the MDC in the Brief Activities Measure for Upper Limb Amputation (BAM-ULA scores), 17% in Jebsen writing task, and 16% in Activities Measure for Upper Limb Amputation (AM-ULA) scores. Whereas, 15% worsened more than the MDC in the BAM-ULA and QuickDASH and 14% worsened more than MDC in the AM-ULA.

Discussion

We conducted a longitudinal cohort study of UL prosthesis users and evaluated whether there were changes in prosthesis use, dexterity, activity performance, HRQoL, and disability over 1 year. We also examined whether there were differences in

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Table 4. Change in measures over time above MDC.

			Change over 1 year		
			Worsened by MDC	Within MDC	Improved by MDC
	MDC90	N	N (%)	N (%)	N (%)
Dexterity measures					
JTHFT					
Writing	0.18	60	6 (10.0)	44 (73.3)	10 (16.7)
Page turning	0.11	63	7 (11.1)	52 (82.5)	4 (6.4)
Small objects	0.09	62	6 (9.7)	52 (83.9)	4 (6.5)
Eating	0.10	62	5 (8.10	51 (82.3)	6 (9.7)
Checkers	0.11	62	5 (8.1)	51 (82.3)	6 (9.7)
Light cans	0.15	62	3 (4.8)	54 (87.1)	5 (8.1)
Heavy cans	0.13	61	8 (13.1)	46 (75.4)	7 (11.5)
Box and Blocks	6.49	62	5 (8.1)	50 (80.7)	7 (11.3)
Nine-Hole Peg	NA				
SHAP IOF	NA				
Activity measures					
AM-ULA	3.72	63	9 (14.3)	44 (69.8)	10 (15.9)
BAM-ULA	1.9	20	3 (15.0)	13 (65.0)	4 (20.0)
T-MAP (mins)	130.7	42	0 (0.0)	40 (95.2)	2 (4.8)
Prosthesis satisfaction					
TAPES	0.79	54	7 (10.9)	51 (79.7)	6 (9.4)
Disability, HRQoL, and community integration					
QuickDASH	13.9	61	9 (14.8)	47 (77.1)	5 (8.2)
			MDC not available		
VR-12 PCS	Not Available				
CRIS-CAT Extent of Limitations	NA				
CRIS-CAT Perceived Limitations	NA				
CRIS-CAT Satisfaction	NA				
Prosthesis use					
Hours of prosthesis use per day	NA				
Frequency of prosthesis use (days per week)	NA				

Abbreviations: AM-ULA, Activities Measure for Upper Limb Amputation; BAM-ULA, Brief Activities Measure for Upper Limb Amputation; CRIS-CAT, Community Reintegration of Injured Service Members–Computer Adapted Test; HRQoL, health-related quality of life; JTHFT, Jebsen-Taylor Hand Function Test; MDC, minimal detectable change; SHAP, Southampton Hand Assessment Procedure; TAPES, Trinity Amputation and Prosthesis Experience Scale; T-MAP, Timed Measure of Activity Performance; VR-12 PCS, Veterans RAND 12-Item Health Survey Physical Composite Score; WSR, Wilcoxon signed rank.

outcomes over time by amputation level, years since amputation, baseline type of prosthesis used, and for those who switched device types between baseline and follow-up. The significance of this study is strengthened by the relatively large sample size and broad spectrum of outcome measures collected 1 year apart.

Overall, we found that dexterity and activity performance outcomes, HRQoL, and perceived disability were remarkably stable over time, with little difference by subgroup. These findings suggest that persons with TR and TH amputation are equally stable over time and that key outcomes plateau in the first 5 years following amputation. Outcomes were also stable for subgroups tested with body-powered and myoelectric devices, demonstrating that once trained and experienced in using the prosthesis, performance with either type of device can be consistent over time. Although average functional performance remained stable, our analyses of the proportion of persons who changed more than the MDC revealed small proportions of participants who declined (14–15%) or improved in performance (16–20%) over 1 year. This finding emphasizes the potential value of routine/annual follow-up visits to monitor function and identify potentially reversible causes of functional decline.

Most of our sample used the same prosthesis for testing at baseline and follow-up, a finding that is not surprising, given that most Veterans with UL amputation are prescribed a new device at rates of 0.19–0.33/year and 89% of the sample was 5 years or more out from their amputation.[24] We did not find group differences between those who tested with a different type of device at baseline and follow-up. This may be because the "new device type" used at

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follow-up were devices that were not, in fact, new to the participant. At baseline, 74% of the sample indicated that they owned a secondary device. Participants who switched device types indicated that they had been using the device they tested with at follow-up for an average of 2.3 (SD 2.4) years and that general device type for an average of 14.2 (SD 20.4) years. This suggests that participants were testing with an alternate device they already owned at baseline, but which, at that time, was not considered their primary device type.

We did observe that for the full sample, and for most subgroup analyses, the hours of prosthesis use increased over time, whereas the reported frequency of use decreased. We observed that, on average, those with more recent amputation, increased their usage by 3 hours/day compared with an increase of 1.1 hours/day for those with less recent amputation. The reason for this change and the clinical significance of this finding are unclear as these differences in usage were not reflected in change in functional performance and might be explained by recall bias and limitations of self-reporting prosthesis use. It is also possible that participants increased their usage in preparation for their second study visit.

Limitations

Our findings are limited to older Veterans, most of whom were long-term prosthesis users. Further studies are needed to identify whether non-Veterans and younger persons show the same pattern of stable outcomes over 1 year's time. There are also limitations to our study because of the 50% loss to follow-up. There are several explanations for this high attrition rate. Many participants traveled long distances to study data collection sites to participate in testing sessions, and for some, this required overnight stays and/or flights (both payed for by the study). This burden of participation may have been too much for those who were employed or who required a companion to assist in ADL or were experiencing health challenges or functional decline. Several participants retired from the military and moved. To assess potential bias due to loss to follow-up, we compared baseline scores of participants LTF and those that were retained. Those LTF were very similar to the longitudinal cohort on most measures, but had worse scores on two of ten dexterity tests, which may suggest worse dexterity and a greater likelihood of need for help with ADL. These differences suggest that our longitudinal cohort may have been more independent and thus more easily able to travel to study sites for testing without the need for a companion. However, we do not know how this difference may have impacted the findings regarding change over time. Because of a change in data collection protocol, data on the need for ADL help were not collected in 27% of participants. Given that this information was missing in similar proportions in those retained and those LTF, we do not think that this biased our analyses.

Although we included non-Veterans to increase our sample size, most participants were Veterans. Because the sample was a convenience sample, our results should be interpreted cautiously, as they may not accurately characterize the change in outcomes that occurs in non-Veterans, those with newer amputation, younger persons with UL amputation, those who do not use a prosthesis, and those with differing etiologies.

Our study, though large for this population, is limited by sample size. We conducted a post hoc power analysis with G*Power 3.1.9.7.[25] For our full sample of 64 participants with follow-up data we had 80% power at alpha = 0.05 to detect effect sizes of 0.364 and higher in Wilcoxon signed-rank tests. Power was lower for subsamples. Thus, we may have been limited in detecting smaller effect sizes. Another limitation in our study is that we were unable to control for a variety of potentially confounding factors (e.g. living environment, occupation/hobbies, and climate), which may have influenced outcomes. Although we observed differences in hours/day of prosthesis use and frequency of prosthesis use over time, these findings should also be interpreted cautiously. The survey questions addressing hours and frequency of prosthesis use asked participants to provide information for one point in time rather than for an average use over a period of time. The accuracy of this type of information has not been previously examined and may have been impacted by a variety of factors such as seasonal variations in activity levels and prosthesis use.[26]

Although we saw comparable patterns in persons with more recent (<5 years) and less recent amputations, our sample included few persons having very recent amputation. Additional studies are needed with larger samples and individuals with less time since amputation to identify the trajectory of outcomes in the first 5 years after amputation.

Finally, although we classified participants as having changed by at least the MDC on several measures, there were not published MDCs for all outcome measures. Furthermore, it is unknown whether the MDC represents clinically meaningful change. Additional research is needed to establish the minimal clinical important difference of outcome measures for persons with UL amputation.

Conclusion

This longitudinal study of persons with UL amputation with a considerable history of prosthetic use found that most had stable functional performance and perceived disability and HRQoL over a year's time. Stability was consistent across amputation level and prosthesis type. Although most participants demonstrated stable performance, results revealed some variation in function (both improvement and decline) over a year's time indicating the importance of an annual visit for amputation care. Further research in this patient population is warranted to understand whether strategies to optimize engagement (and minimize LTF) are indicated for a longitudinal cohort.

Disclosure

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Declaration of conflicting interests

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Supplemental material

Supplemental material is available via direct URL citations in the HTML and PDF versions of this article on the website (www.POIjournal.org).

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Understanding Implications of Residual Limb Length, Strength, and Range-of-Motion Impairments of Veterans With Upper Limb Amputation

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Objective: The aim of the study was to describe and quantify the relationship between limb impairment variables to key functional outcomes.
Design: This was an observational study of 107 participants with unilateral above/at-elbow or below-elbow/wrist amputation. Demographics, prosthesis characteristics, residual limb length, and prevalence of passive range-of-motion restrictions, and strength impairments were described. Correlations between impairment variables were estimated. Linear regressions examined associations between impairment variables and activity performance, health-related quality of life, disability, and prosthesis satisfaction.
Results: Prevalence of short/very short below- and above-elbow residua was 25.7% and 12.5%, respectively. Shorter below-elbow/wrist residual limb length was correlated with elbow flexion weakness ($r = 0.30$) and prevalence of passive range of motion ($r = 0.25$). Shoulder prevalence of passive range-of-motion restrictions were correlated with shoulder ($r = 0.27$–0.51) and elbow weakness ($r = 0.25$–0.46). In regressions, activity performance was worse for those with shoulder flexion prevalence of passive range-of-motion restrictions ($B = -5.0$, $P = 0.03$) and better for those with flexion restrictions ($B = 3.3$, $P = 0.04$) compared with normal prevalence of passive range of motion. Prosthetic satisfaction was lower for those with limited elbow prevalence of passive range of motion.
Conclusions: Short below-elbow residual limb length was correlated with impairment of elbow flexion strength and prevalence of passive range of motion. Prevalence of passive range-of-motion restrictions were most prevalent at the shoulder and were strongly correlated with weakness in the same planes of motion. Few significant associations were found between impairment variables and outcomes.

Key Words: Upper Limb Amputation, Upper Limb Prosthesis, Prosthesis Use, Disability Evaluation, Veteran, Outcomes

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What Is Known

- Prosthetic and functional implications of transhumeral and transradial amputation are well documented.
- Variability exists in residual limb length, strength, and passive range-of-motion (PROM) impairments.
- Measurement of these impairments and their effect on outcomes require further study.

What Is New

- Shoulder abduction and shoulder flexion PROM restrictions were strongly correlated. Although other PROM restrictions of the shoulder and elbow were weakly to moderately correlated with each other, PROM restrictions were most prevalent at the shoulder joint and were strongly correlated with weakness in the same planes of motion.
- This study establishes a framework for consistent measurement, evaluation, and outcomes assessment in ULA research.

Prosthetic and functional implications of upper limb amputation (ULA) are well documented in the literature[1,2]; however, variability of residual limb length (RLL), strength and range of motion (ROM) impairments, and functional outcomes have not been described. Clinically, many practitioners have observed the impact that RLL has on the functional abilities of individuals with and without a prosthesis. However, the relationships between RLL and outcome measures of prosthetic satisfaction and quality of life have not been reported.

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In addition to influencing amputation level and RLL, traumatic events resulting in ULA frequently result in injuries to the soft tissues, joints, and neurovascular structures in the residual limb.[3,4] As a result of these injuries, persons with amputations may develop soft tissue and skin scarring, joint contractures, sensory loss, pain, and weakness.[3–5] Despite the apparent frequency of these findings clinically, little information has been published describing the ROM limitations and strength deficits in persons with ULA. Although multiple previous studies have documented the high rate of prosthetic abandonment in persons with ULA,[6–10] understanding of the relationship between RLL and ROM and strength impairments remains limited.

Our overall purposes were to understand the prevalence and relationships of RLL, ROM, and strength impairments in prosthesis users with ULA. Specifically, the study aimed to (1) describe prevalence of ROM impairments into joint contracture categories; (2) describe prevalence of gross strength deficits; (3) describe prevalence of various RLL after ULA to identify those with average, long, or short residua; and (4) quantify the association between strength and passive ROM (PROM) impairments, RLL, prosthetic satisfaction, disability, health-related quality of life (HRQoL) and activity performance.

METHODS

Study Design

The study used an observational cross-sectional design. Data were collected at one of five study sites in the United States. The study was approved by the Veterans Affairs Central Institutional Review Board, Regional Health Command-Central Institutional Review Board, and Human Research Protection Office. This study conforms to all Strengthening the Reporting of Observational Studies in Epidemiology guidelines and reports the required information accordingly (see Supplementary Checklist, Supplemental Digital Content 1, http://links.lww.com/PHM/B360).

Sample

Participants in this analytic subsample were a subset of the sample recruited for a more comprehensive parent study described elsewhere.[2] These subjects were a convenience sample of service members, veterans, and civilians who had unilateral major ULA or limb deficiency at the above-elbow (AE) or below-elbow (BE) level. The AE levels included elbow disarticulation (ED) and transhumeral (TH) levels. The BE levels included transradial (TR) and wrist disarticulation (WD) levels. Participants who used an active prosthesis (body-powered, myoelectric, hybrid or Life Under Kinetic Evolution [LUKE Arm]) were included.[11] Persons who used only a cosmetic prostheses, those who could not tolerate wearing their prostheses for at least 3 hrs/d, and/or those who had health conditions that might limit their abilities to participate in study assessment activities were excluded. Participants were recruited from an earlier phase of this study[12] through clinical contacts, advertisements, e-blasts, and word of mouth. For these analyses, only persons with unilateral amputation below the level of the shoulder were included.

Data Collection

Data were collected in 3- to 4-hr, in-person study visits at one of the data collection sites. All participants provided written informed consent to in-person study visits, and the study was approved by the Veterans Affairs Central Institutional Review Board. Study assessors were physical or occupational therapists, assisted by a research coordinator. Rest breaks were provided to participants as needed. Assessors collected demographic data (age, race, ethnicity, employment) and information on each participant's amputation and prosthesis use (years since amputation, etiology, prosthesis type). Amputation etiology items were added after the study had begun and thus were missing for some participants. Some veterans had participated in a previous survey phase of the study and had etiology data available. However, data on congenital amputation were not collected in the earlier phase. Nineteen participants had no etiology data, and 34 lacked congenital amputation data.

The assessors inspected and described the prosthetic device and components and documented each prosthesis and terminal device with photographs. During the physical examination, the study assessor measured PROM and gross strength of the upper limbs at all remaining joints proximal to the amputation. Assessors also performed length measurements of the residual amputated and sound limbs using anatomical landmarks and documented on a standard prosthetic upper limb measurement form. The primary independent variables in our analyses (impairment variables) were PROM impairment, gross strength, and RLL. Each of these variables is described hereinafter.

Joint Contracture (PROM Impairment)

Joint contracture was assessed using PROM measurements of each joint proximal to the amputation taken with the prosthesis off, using a goniometer. The PROM impairment was classified by the study team based on the amount of end-range passive movement available at each joint, with initial descriptive categories of impairment consistent with those previously described.[13] Shoulder flexion and abduction PROM measurements were classified as normal if maximal PROM was 180 degrees, mild contracture if maximal PROM was 120 to less than 180 degrees, moderate contracture if maximal PROM was 60 to less than 120 degrees, and severe contracture if maximal PROM was less than 60 degrees. Shoulder extension was classified as normal (≥50 degrees), mild contracture (32 to <50 degrees), moderate contracture (16 to <32 degrees), and severe contracture (<16 degrees). Shoulder adduction was classified as normal or less than full based on the assessors' judgments as to whether the upper limb (or prosthesis) could be adducted to touch the ipsilateral side of the torso. Elbow flexion was classified as normal (140–180 degrees), mild contracture (93 to <140 degrees), moderate contracture (46 to <93 degrees), and severe contracture (<46 degrees). Given that there were very few participants with elbow extension restriction, this variable was dichotomized, classifying PROM as normal if the elbow joint could be extended to −15 degrees or more (i.e., at least 15 degrees of flexion) or restriction if the elbow could not be extended to at least −15 degrees. In subsequent correlation analyses and models, all PROM variables were dichotomized as normal versus any amount of restriction.

Gross Strength

Given that there are no standardized, validated methods of measuring strength in persons with ULA, a gross strength measurement was used for this study. Gross strength was assessed

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with participants wearing their prostheses, with the objective of identifying whether participants were able to lift their limbs against gravity to the full ROM available with passive assistance. Assessors asked participants to move their limbs in specified directions and observed whether they were able to move their limbs through their available, previously measured, PROM. Strength was classified as grossly normal if the participant was able to move their limb fully within their available PROM against gravity and impaired if they could not.

Residual Limb Length

Given the interest in the association between RLL and function, and that a universal standard is lacking to characterize BE residua by length, a hybrid approach was used to classify residual length. Only persons with documented WD were classified as such. For others with BE amputation, the thresholds previously identified[14] for RLL based on measurements of limb length (from acromion to the distal boney end on the amputated side) were used for descriptive analyses; the categories "very short" and "short" were combined in other analyses because of small sample sizes. Categorization of RLL was "very short/short" (0 to <13.97 cm), "medium" (13.97–20.32 cm), and "long" (≥20.32 cm).

Lacking published precedents to classify RLL in AE amputation into the categories of "short," "standard," and "long" by residua length alone, the proportions of remaining limb were estimated as previously reported by Edwards and Panchbhavi.[15] Only persons with documented ED were classified as such. For others with AE level amputation, the length from acromion to the distal boney end on the amputated side was used and divided by the length from acromion to the lateral humeral epicondyle on the sound side. This fraction was then categorized as "short" AE (<0.5), "standard" AE (0.5 to <0.9), and "long" AE (≥0.9). To identify the length of AE residua categorized as short, standard, and long (based on proportion), the mean and standard deviation of RLLs in centimeters was calculated (Appendix Table 3, Supplemental Digital Content 2, http://links.lww.com/PHM/B361).

Outcome Measures

We selected key outcome measures, which we believed were patient centered and important as global measures of activity performance, disability, and quality of life. Activity performance was evaluated with the Activities Measure for ULA (AM-ULA), an 18-item measure of performance on everyday tasks.[16] Health-related quality of life was assessed using the Veterans RAND 12-Item Health Survey.[17] The Quick Version of the Disability of Arm, Shoulder, and Hand assessed self-perceived difficulties in function and symptoms.[18–20] Satisfaction with prostheses was evaluated with the Trinity Amputee Prosthetic Experience Satisfaction Scale,[21] a 10-item scale rating satisfaction with the color, shape, noise, appearance, weight, usefulness, reliability, fit, and comfort, as well overall prosthetic satisfaction.

Data Analyses

Demographics, prosthesis characteristics, RLL categories, and prevalence of PROM and gross strength deficits were described by amputation level. Spearman and point-biserial correlations were estimated to examine the relationships between impairment variables (RLL, PROM, and strength). The following thresholds were used to interpret the strength of correlations that reached statistical significance ($P < 0.05$): small = 0.1 to less than 0.3, medium = 0.3 to less than 0.5, and large = 0.5–1.0.[22]

Separate linear regression models were developed to quantify the association between impairment variables and outcome measures (activity performance, HRQoL, disability, and prosthesis satisfaction). Explanatory variables included all impairment variables (all PROM restrictions, strength deficits, and RLL), and potential confounders included amputation level and prosthesis type. Missing data were displayed in descriptive tables and excluded from correlation, and regression analysis R^2 was examined to assess model fit. We performed residual diagnostics for these models; *Q-Q* plots confirmed normality of residuals and predicted versus residual plots did not indicate heteroscedasticity or any nonlinear relationship. Variable inflation factors were greater than 0.1 and tolerance values were less than 10 for all covariates, so all were retained in regression models.

RESULTS

The sample consisted of 107 participants, 75 (70%) with BE amputation and 32 (30%) with AE amputation. Demographics and prosthesis characteristics, stratified by amputation level, are provided in Table 1. The sample was 97% male, 73% White, 88% veteran, and had a mean age of 57.1 yrs (SD = 16.1 yrs). Body-powered devices were used most (58.9%), followed by myoelectric multi degrees of freedom (DOF) (21.5%) and single-DOF devices (19.6%).

Table 2 provides descriptive data on the simplified categories of RLL and PROM variables used in our correlations and linear regression analyses, with data stratified by amputation level and prosthesis type. A smaller proportion of participants with AE as compared with BE had short/very short residua (12.5% vs. 25.7%) or long residua (31.3% vs. 39.2%). The distribution by RLL varied for body-powered and myoelectric device users. Fifty percent of BE myoelectric users had long residua, as compared with only 14.3% of AE myoelectric users. A smaller proportion of myoelectric AE users had short or very short RLL as compared with BE myoelectric users (14.3% vs. 23.3%).

Most body-powered users with BE amputation had shoulder flexion (78%) and shoulder abduction (73%) PROM restrictions. In comparison, 50% of myoelectric users had shoulder flexion PROM restrictions, and 57% had shoulder abduction PROM restrictions. The majority of body-powered and myoelectric users with BE amputation had normal shoulder extension (84% and 83% respectively), normal shoulder adduction (98% and 100%), normal elbow flexion (60% and 60%), and normal elbow extension (96% and 86%) PROM.

In the AE group, most body-powered and myoelectric users had some shoulder flexion PROM restrictions (89% and 86%, respectively) and shoulder abduction PROM restriction (89% and 93%). In contrast, most had normal shoulder extension PROM (72% and 86%), and all had normal shoulder adduction. Additional, more detailed characterization of RLL and PROM is provided in Appendix Table 1 (Supplemental Digital Content 2, http://links.lww.com/PHM/B361). Because

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TABLE 1. Baseline demographics and prosthesis characteristics for full sample and longitudinal cohort, stratified by amputation level

	Full Sample		
	BE[a] (*n* = 75)	AE[b] (*n* = 32)	All (*N* = 107)
	Mean (SD)	Mean (SD)	Mean (SD)
Age	56.6 (17.3)	58.2 (13.2)	57.1 (16.1)
Years since amputation	24.8 (19.7)	20.1 (16.7)	23.4 (18.9)
	n (%)	*n* (%)	*n* (%)
Age category			
18 ≤ age <45	22 (29.3)	5 (15.6)	27 (25.2)
46 ≤ age <65	20 (26.7)	16 (50.0)	36 (33.6)
66 ≤ age <75	26 (34.7)	10 (31.3)	36 (33.6)
>75	7 (9.3)	1 (3.1)	8 (7.5)
Sex			
Male	73 (97.3)	31 (96.9)	104 (97.2)
Female	2 (2.7)	1 (3.1)	3 (2.8)
Race			
White	58 (77.3)	20 (62.5)	78 (72.9)
Black	8 (10.7)	5 (15.6)	13 (12.2)
Mixed/other	9 (12.0)	7 (21.9)	16 (15.0)
Ethnicity			
Hispanic	8 (10.7)	7 (21.9)	15 (14.0)
Not Hispanic	63 (84.0)	25 (78.1)	88 (82.2)
Unknown	4 (5.3)	0 (0.0)	4 (3.7)
Employment status			
Working/student	19 (25.3)	12 (37.5)	31 (29.0)
Retired	39 (52.0)	13 (40.6)	52 (48.6)
Medical leave/other	1 (1.3)	2 (6.3)	3 (2.8)
Unknown	16 (21.3)	5 (15.6)	21 (19.6)
Military status			
Active duty	2 (2.7)	0 (0.0)	2 (1.9)
Veteran	66 (88.0)	28 (87.5)	94 (87.9)
Civilian	7 (9.3)	4 (12.5)	11 (10.3)
Etiology of amputation[c]			
Congenital	3 (13.0)	0 (0.0)	3 (8.8)
Combat	27 (44.3)	8 (29.6)	35 (39.8)
Accident	30 (49.2)	15 (55.6)	45 (51.1)
Burn	4 (6.6)	2 (7.4)	6 (6.8)
Cancer	4 (6.6)	1 (3.7)	5 (5.7)
Diabetes	1 (1.6)	0 (0.0)	1 (1.1)
Infection	8 (13.1)	4 (14.8)	12 (13.6)
Prosthesis type			
Body powered	45 (60.0)	18 (56.3)	63 (58.9)
Myoelectric single-DOF terminal device	12 (16.0)	9 (28.1)	21 (19.6)
Myoelectric multi-DOF terminal device[d]	18 (24.0)	5 (15.6)	23 (21.5)

[a] Below elbow includes TR and WD levels.
[b] Above elbow includes TH and ED levels.
[c] Etiology of amputation: respondents could indicate multiple etiologies.
[d] Includes 1 participant with LUKE prosthesis.

only one participant in the entire sample had shoulder adduction restrictions, this variable was not included in further analyses.

The prevalence of strength deficits for both the amputated and sound sides is shown in Table 3, stratified by amputation level. The BE group had a lower prevalence of gross strength impairment on the amputated side than the AE group in shoulder flexion (37% vs. 75%), shoulder extension (20% vs. 44%), and shoulder abduction (37% vs. 84%). However, the BE group had slightly a higher prevalence of gross strength impairment on the sound side than the AE group in shoulder flexion (15% vs. 9%), shoulder extension (8% vs. 6%), shoulder abduction (16.0% vs. 15.6%), and active elbow flexion/extension (9% vs. 4%).

Spearman and point-biserial correlation between impairment variables are provided in Table 4. Shorter BE RLL was weakly correlated with elbow flexion PROM restriction ($r = 0.25$) gross strength impairment in elbow flexion ($r = 0.30$). There was no significant correlation between RLL and any other impairment variable in persons with AE/ED amputation. Shoulder abduction and shoulder flexion PROM restrictions were strongly correlated ($r = 0.79$). All other PROM measures of the shoulder and elbow were weakly or moderately correlated with each other ($r = 0.26$–0.42). Shoulder PROM restrictions were moderately or strongly correlated with shoulder weakness ($r = 0.27$–0.51) and weakly/moderately correlated with elbow weakness ($r = 0.25$–0.46). For persons with BE amputation, elbow flexion PROM restriction was significantly correlated with elbow flexion weakness ($r = 0.29$). Weakness of shoulder flexion, abduction, and extension were strongly correlated ($r = 0.54$–0.83), suggesting a pattern of gross strength impairment throughout the shoulder musculature. On the other hand, weakness of elbow flexion was weakly correlated with shoulder flexion ($r = 0.32$) and abduction ($r = 0.32$) weakness.

Multiple linear regression found that AM-ULA scores were worse for those with shoulder flexion PROM restrictions ($B = -5.0$, $P = 0.03$) compared with normal PROM. The AM-ULA scores were better for those with elbow flexion ($B = 3.3$, $P = 0.04$) restrictions as compared with those with normal PROM (Table 5). The Veterans RAND 12-Item Health Survey Mental Component Score scores were worse on average for those with an elbow flexion ($B = -8.4$, $P = 0.03$) restriction (Table 5). The Trinity Amputee Prosthetic Experience Satisfaction Scale scores were also worse for those with elbow flexion ($B = -0.5$, $P = 0.03$) restriction. No impairment variable was a significant predictor of the Veterans RAND 12-Item Health Survey Physical Component Score or Quick Version of the Disability of Arm, Shoulder, and Hand scores; regression results are shown in Appendix Table 2 (Supplemental Digital Content 2, http://links.lww.com/PHM/B361). R^2 was between 0.17 and 0.24 for all regression models.

DISCUSSION

To our knowledge, this is the first study that provides classification and description for RLL, joint contracture, and strength deficits of service member and veteran prosthesis users with unilateral AE and BE amputation and examines relationships between these impairments of body function and structure and key outcome variables (activity performance, HRQoL, and perceived disability and prosthesis satisfaction).

This study found that a smaller proportion of participants with AE as compared with BE amputation had either short/very short residua (12.5 vs. 25.7%). This finding is consistent with clinical observations that it is more difficult to achieve adequate socket suspension for persons with shorter AE amputation than it is for those with shorter BE amputations. We also observed

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TABLE 2. Descriptive data on RLL and PROM restrictions

	BE[a] (n = 75)				Above Elbow[b] (n = 32)			
	Body Powered (n = 45)	**Myoelectric (n = 30)**	**Fisher Exact Test**	**All**	**Body Powered (n = 18)**	**Myoelectric (n = 14)**	**Fisher Exact Test**	**All**
Residual Limb Length	***n* (%)**	***n* (%)**	***P***	***n* (%)**	***n* (%)**	***n* (%)**	***P***	***n* (%)**
BE			0.2704					
Short/very short	12 (27.3)	7 (23.3)		19 (25.7)				
Medium	18 (40.9)	8 (26.7)		26 (35.1)				
Long/wrist	14 (31.8)	15 (50.0)		29 (39.2)				
Missing, *n*	1	0		1				
AE							0.2087	
Short/very short					2 (11.1)	2 (14.3)		4 (12.5)
Standard					8 (44.4)	10 (71.4)		18 (56.3)
Long/elbow					8 (44.4)	2 (14.3)		10 (31.3)
PROM								
Shoulder flexion			**0.0233**				1.0000	
Normal (180 degrees)	10 (22.2)	15 (50.0)		25 (33.3)	2 (11.1)	2 (14.3)		4 (12.5)
Restricted (<180 degrees)	35 (77.8)	15 (50.0)		50 (66.7)	16 (88.9)	12 (85.7)		28 (87.5)
Shoulder extension			1.0000				0.4264	
Normal (50–180 degrees)	38 (84.4)	25 (83.3)		63 (84.0)	13 (72.2)	12 (85.7)		25 (78.1)
Restricted (<180 degrees)	7 (15.6)	5 (16.7)		12 (16.0)	5 (27.8)	2 (14.3)		7 (21.9)
Shoulder abduction			0.1444				1.0000	
Normal (180 degrees)	12 (26.7)	13 (43.4)		25 (33.3)	2 (11.1)	1 (7.1)		3 (9.4)
Restricted (<180 degrees)	33 (73.3)	17 (56.7)		50 (66.7)	16 (88.9)	13 (92.9)		29 (90.6)
Shoulder adduction			1.0000				NA	
Normal (on visual inspection)	44 (97.8)	30 (100.0)		74 (98.7)	18 (100.0)	14 (100.0)		32 (100.0)
Restricted (<full)	1 (2.2)	0 (0.0)		1 (1.3)	0 (0.0)	0 (0.0)		0 (0.0)
Elbow flexion			1.0000					
Normal (140–180 degrees)	27 (61.4)	18 (64.3)		45 (62.5)				
Restricted (<140 degrees)	17 (38.6)	10 (35.7)		27 (37.5)				
Missing, *n*	1	2		3				
Elbow extension			0.1992					
Normal (>−15 degrees)	42 (95.5)	24 (85.7)		66 (91.7)				
Restricted (≤−15 degrees)	2 (4.6)	4 (14.3)		6 (8.3)				
Missing, *n*	1	2		3				

Bold font highlights statistical significance at $P < 0.05$.

[a] Below elbow includes TR and WD levels.

[b] Above elbow includes TH and ED levels.

that a smaller proportion of participants with AE as compared with BE had long residual (31.3% vs. 39.2%). However, the distribution by RLL varied for body-powered and myoelectric device users. Half of BE myoelectric users had long residua, as compared with only 14.3% of AE myoelectric users. This may be due to challenges in fitting a prosthetic elbow in persons with long AE amputations, which may be associated with cosmetically unacceptable or longer prosthetic limbs. It is also possible that clinic teams are trained to believe that persons with longer BE RLL may be better candidates for a myoelectric system and thus do not consider these devices for those with shorter RLL. A smaller proportion of myoelectric AE users had short or very short RLLs as compared with BE myoelectric users (14.3% vs. 23.3%). This may be because heavier weight myoelectric devices are more problematic for persons with short AE residuum due to shoulder weakness. However, the sample of AE participants was small, and further research is needed to confirm these findings in prosthesis users.

Fewer persons with BE amputation (as compared with those with AE) had strength deficits of the shoulder on the amputated side. The AE amputation requires the resection of biceps and triceps brachii muscles that span the shoulder, which may explain differences in shoulder strength between the AE and the BE. In addition, traumatic injury resulting in AE amputation (as compared with BE amputation) may be more extensive and more likely to involve injury to key shoulder musculature. Furthermore, it is possible that the involved shoulder in those with BE amputation continues to be highly involved with function, thus contributing to sustained strength compared with the involved shoulder of those with AE amputation. In contrast, the BE group had a higher prevalence of shoulder and elbow strength deficit on the sound side. One possible explanation for this finding is that a greater proportion of participants in the BE subgroup had combat etiology, and this may have initially involved traumatic injury to both upper limb. These findings would need to be examined in future studies of combat

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TABLE 3. Gross strength and shoulder pain on amputated and sound sides

	BE[a] (n = 75)			AE[b] (n = 32)		
	Body Powered (n = 45)	Myoelectric (n = 30)	Fisher Exact Test	Body Powered (n = 18)	Myoelectric (n = 14)	Fisher Exact Test
Strength	n (%)	n (%)	P	n (%)	n (%)	P
Amputated side (ipsilateral)						
Shoulder flexion			0.1476			1.0000
Impaired	20 (44.4)	8 (26.6)		13 (72.2)	11 (78.6)	
Grossly normal	25 (55.6)	22 (73.3)		5 (27.8)	3 (21.4)	
Shoulder extension			0.3774			1.0000
Impaired	11 (24.4)	4 (13.3)		8 (44.4)	6 (42.9)	
Grossly normal	34 (75.6)	26 (86.7)		10 (55.6)	8 (57.1)	
Shoulder abduction			0.3356			1.0000
Impaired	19 (42.2)	9 (30.0)		15 (83.3)	12 (85.7)	
Grossly normal	26 (57.8)	21 (70.0)		3 (16.7)	2 (14.3)	
Active elbow flexion/extension			0.8102			
Impaired	28 (62.2)	17 (68.6)				
Grossly normal	17 (37.8)	12 (41.4)				
Missing, n						
Nonamputated side (contralateral)						
Shoulder flexion			**0.0417**			1.0000
Impaired	10 (22.2)	1 (3.3)		2 (11.1)	1 (7.1)	
Grossly normal	35 (77.8)	29 (96.7)		16 (88.9)	13 (92.9)	
Shoulder extension			0.3920			1.0000
Impaired	5 (11.1)	1 (3.3)		1 (5.6)	1 (7.1)	
Grossly normal	40 (88.9)	29 (96.7)		17 (94.4)	131 (92.9)	
Shoulder abduction			0.1083			1.0000
Impaired	10 (22.2)	2 (6.7)		3 (16.7)	2 (14.3)	
Grossly normal	35 (77.8)	28 (93.3)		15 (83.3)	12 (85.7)	
Active elbow flexion/extension			0.2315			1.0000
Impaired	6 (13.3)	1 (3.3)		1 (7.7)	0 (0.0)	
Grossly normal	39 (86.7)	29 (96.7)		12 (92.3)	12 (100.0)	
Missing, n						

Bold font highlights statistical significance at $P < 0.05$.

[a] Below elbow includes TR and WD levels.

[b] Above elbow includes TH and ED levels.

and noncombat amputation, which collected data on initial injury characteristics.

Although others have discussed the disadvantages of shorter residuum in terms of challenges in socket fitting and reduced lever arms for muscular attachments,[14,23] to our knowledge, no previous report examined the association between RLL, PROM, and strength. This study identified an association between having short BE residua and restriction in elbow extension PROM and weakness of elbow flexion, but no relationships between short AE residua and restriction in PROM or gross strength.

Passive range-of-motion restrictions of shoulder flexion and abduction were most strongly correlated; however, PROM restriction in all movements except elbow extension was weakly to moderately correlated with each other. This demonstrates that PROM restriction, when present, impacted strength of multiple movements of the amputated limb. Interestingly, PROM restrictions were more prevalent among persons with BE amputation who used a body-powered prosthesis than in those with BE who used a myoelectric prosthesis. This finding may be explained by the fact that terminal devices of body-powered prostheses are difficult to operate with the shoulder elevated and harnessing may be uncomfortable or restrictive in elevated positions. Thus, these participants may not have had reason to move their shoulders into elevated (flexed/abducted) positions. Clinically, it is possible that myoelectric prosthesis prescription is associated with prosthesis use in a larger functional envelope (as compared with body-powered prosthesis use), preserving shoulder PROM; further research in this area is needed.

Strong correlations were observed between muscle weakness in shoulder abduction, flexion and extension, and mild to moderate correlations between shoulder and elbow weakness. These findings demonstrate that for persons with BE amputation, weakness on the amputated side is likely to involve the whole shoulder and elbow joints. Overall, shoulder muscle weakness was more than twice as prevalent in persons with AE as compared with BE amputation. This finding makes sense, given that we would expect that muscles of the shoulder girdle are more likely to be intact in persons with BE.

No association was found between RLL and measures of activity performance, HRQoL, self-reported disability, or prosthetic

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TABLE 4. Spearman/point-biserial correlations between impairment variables

		Residual Limb Length		PROM Restriction					Muscle Weakness			
		Shorter BE	Shorter AE	Shoulder Flexion	Shoulder Extension	Shoulder Abduction	Elbow Flexion	Elbow Extension	Shoulder Flexion	Shoulder Extension	Shoulder Abduction	Elbow Flexion
		r (95% CI)	*r* (95% CI)	*r* (95% CI)	*r* (95% CI)	*r* (95% CI)	*r* (95% CI)	*r* (95% CI)	*r* (95% CI)	*r* (95% CI)	*r* (95% CI)	*r* (95% CI)
Residual limb length	Shorter BE	1										
	Shorter AE	NA	1									
PROM restriction	Shoulder flexion	0.00 (−0.23 to 0.23)	−0.14 (−0.46 to 0.22)	1								
	Shoulder extension	0.17 (−0.06 to 0.39)	0.04 (−0.31 to 0.38)	**0.28 (0.10 to 0.45)**	1							
	Shoulder abduction	0.00 (−0.23 to 0.23)	0.07 (−0.29 to 0.40)	**0.79 (0.70. 0.85)**	**0.28 (0.09 to 0.44)**	1						
	Elbow flexion	**0.25 (0.01 to 0.45)**	NA	**0.26 (0.03 to 0.47)**	**0.44 (0.22 to 0.50)**	**0.32 (0.10 to 0.43)**	1					
	Elbow extension	0.07 (−0.16 to 0.30)	NA	0.22 (−0.01 to 0.43)	0.17 (−0.07 to 0.39)	0.22 (−0.01 to 0.43)	**0.29 (0.06 to 0.48)**	1				
Muscle weakness	Shoulder flexion	0.06 (−0.17 to 0.29)	0.16 (0.20 to 0.48	**0.51 (0.35 to 0.64)**	**0.33 (0.15 to 0.49)**	**0.41 (0.24 to 0.55)**	0.16 (−0.08 to 0.38)	0.20 (−0.03 to 0.41)	1			
	Shoulder extension	−0.05 (−0.27 to 0.18)	0.25 (−0.11 to 0.55	**0.32 (0.14 to 0.48)**	**0.32 (0.14 to 0.48)**	**0.27 (0.08 to 0.43)**	0.04 (−0.20 to 0.27)	0.00 (−0.23 to 0.23)	**0.54 (0.39 to 0.66)**	1		
	Shoulder abduction	0.03 (−0.20 to 0.26)	0.28 (−0.08 to 0.57	**0.46 (0.29 to 0.60)**	**0.31 (0.12 to 0.47)**	**0.44 (0.27 to 0.58)**	0.22 (−0.02 to 0.43)	0.20 (−0.03 to 0.41)	**0.83 (0.76 to 0.88)**	**0.55 (0.40 to 0.67)**	1	
	Elbow flexion	**0.30 (0.08 to 0.50)**	NA	**0.36 (0.13 to 0.54)**	**0.26 (0.03 to 0.46)**	**0.25 (0.02 to 0.44)**	**0.29 (0.06 to 0.48)**	0.15 (−0.09 to 0.36)	**0.32 (0.10 to 0.51)**	0.18 (−0.06 to 0.39)	**0.32 (0.08 to 0.51)**	1

Bold text indicates statistically significant relationships, and shaded boxes indicate correlations that are medium (0.3) or greater.

NA, not applicable.

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TABLE 5. Linear regression of outcome measures on impairment covariates

	AM-ULA (n = 101)			MCS (n = 97)			TAPES (n = 103)		
	0.26			0.18			0.18		
R^2	β	95% CI	P	β	95% CI	P	β	95% CI	P
Amputation level									
BE[a] (ref)									
AE[b]	−2.35	−6.46 to 1.76	0.2583	−6.03	−15.32 to 3.26	0.2001	−0.57	−1.09 to −0.05	**0.0331**
Prosthesis type									
Body powered (ref)									
Myoelectric	−0.55	−2.98 to 1.88	0.6534	−3.01	−8.40 to 2.39	0.2706	−0.27	−0.58 to 0.04	0.0901
BE RLL									
Short/very short	−3.34	−7.06 to 0.38	0.0777	−3.64	−12.23 to 4.96	0.4026	0.09	−0.39 to 0.56	0.7233
Medium	−1.78	−5.04 to 1.48	0.2815	0.25	−7.14 to 7.64	0.9466	0.10	−0.32 to 0.52	0.6464
Long/wrist (ref)									
AE RLL									
Short/very short	−5.58	−11.71 to 0.56	0.0742	−3.53	−16.99 to 9.93	0.6028	−0.19	−0.97 to 0.60	0.6392
Standard (ref)									
Long/elbow	−0.58	−5.27 to 4.11	0.8056	4.59	−5.72 to 14.89	0.3784	−0.02	−0.60 to 0.56	0.9527
PROM									
Shoulder flexion									
Normal (180 degrees, ref)									
Restricted (<180 degrees)	−5.01	−9.40 to −0.62	**0.0259**	4.04	−5.77 to 13.86	0.4147	−0.02	−0.59 to 0.54	0.9364
Shoulder extension									
Normal (≥50 degrees, ref)									
Restricted (<50 degrees)	0.10	−3.20 to 3.39	0.9542	0.39	−7.19 to 7.96	0.9190	0.33	−0.09 to 0.75	0.1269
Shoulder abduction									
Normal (180 degrees, ref)									
Restricted (<180 degrees)	1.97	−2.13 to 6.06	0.3427	−3.63	−12.67 to 5.42	0.4271	0.08	−0.45 to 0.61	0.7699
Elbow flexion									
Normal (140–180 degrees, ref)									
Restricted (<140 degrees)	3.34	0.14 to 6.53	**0.0408**	−8.36	−15.67 to −1.05	**0.0255**	−0.46	−0.87 to −0.04	**0.0306**
Elbow extension									
Normal (>−15 degrees, ref)									
Restricted (≤−15 degrees)	0.35	−4.70 to 5.40	0.8905	11.04	−0.16 to 22.24	0.0533	−0.08	−0.73 to 0.56	0.8034
Strength									
Shoulder flexion									
Impaired	0.21	−3.91 to 4.34	0.9181	−1.10	−10.27 to 8.08	0.8129	−0.15	−0.68 to 0.38	0.5690
Grossly normal (ref)									
Shoulder extension									
Impaired	0.07	−3.07 to 3.20	0.9657	−3.17	−10.17 to 3.83	0.3699	−0.29	−0.69 to 0.11	0.1481
Grossly normal (ref)									
Shoulder abduction									
Impaired	−0.12	−4.37 to 4.12	0.9543	0.87	−8.63 to 10.37	0.8560	0.31	−0.24 to 0.85	0.2686
Grossly normal (ref)									
Active elbow flexion/extension									
Impaired	0.93	−2.15 to 4.02	0.5483	−1.67	−8.98 to 5.64	0.6503	−0.31	−0.71 to 0.09	0.1261
Grossly normal (ref)									

Bold font highlights statistical significance at $P < 0.05$.

[a] Below elbow includes TR and WD levels.

[b] Above elbow includes TH and ED levels.

CI, confidence interval; MCS, Mental Component Score; TAPES, Trinity Amputee Prosthetic Experience Satisfaction Scale.

satisfaction. It is possible that HRQoL is determined more by nonprosthetic factors. Prosthetic satisfaction is strongly related to prosthesis fit and its comfort, which may have more to do with the character of the overlying integument, the presence or absence of scars or wounds, and the expertise and the bond between the person with the amputation and their prosthetist. The lack of association between activity and disability may be explained by the fact that persons with limb loss may have adjusted by performing tasks primarily with the intact limb, for example. That said, the sample of persons with AE amputation

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was small. The point estimates between AM-ULA scores and RLL for AE amputation did show a trend toward worse activity function for persons with short RLL ($P = 0.07$). Future research involving larger sample sizes is needed to confirm or refute these findings.

Linear regression found that AM-ULA scores were worse for those with shoulder flexion PROM restrictions ($B = -5.0$, $P = 0.03$) compared with normal PROM. This may be because of the amount of body compensation required for persons with restricted shoulder flexion movement to complete some of the AM-ULA tasks, as the scoring rubric of the AM-ULA considers the amount of body compensation required in task performance. However, elbow flexion PROM restrictions were associated with better activity performance. Further research is needed to understand these findings.

Although elbow flexion restriction was associated with better AM-ULA scores, these restrictions were associated with worse mental health and lower prosthesis satisfaction. This may be because some persons with elbow flexion PROM restrictions are limited in using their amputated side in midline activities and in eating and grooming activities, and this negatively impacts their prosthesis satisfaction, self-perception, and body image. This study was innovative in the use of a hybrid approach to categorize RLL at the BE and AE level. Data on RLL measurement in the proportion remaining approach may be informative for future researchers exploring RLL. Further discussion of the advantages and limitations of these approaches to RLL categorization is provided in Appendix B (Supplemental Digital Content 3, http://links.lww.com/PHM/B362).

LIMITATIONS

There are limits to the generalizability of our findings to nonveterans and service members. Most participants in this study were veterans who had participated in a survey of veterans with amputation. There may be selection bias where those drawn from the previous study differ from the general population. In addition, our findings cannot be generalized to nonprosthesis users and to prosthesis users who do not tolerate wearing a device a minimum of 3 hrs. Persons who could not be successfully or comfortably fit with a prosthesis were not included in this study. It is possible that those with very short RLL who could not be successfully fit with a prosthesis would be different. Further research to quantify the function and HRQoL of persons who do not use a prosthesis is needed.

Overall, we detected few significant relationships between the impairment variables and outcomes. This may be attributable to our limited sample size. We conducted a post hoc power analysis and found that the minimal effect size f^2 that our model could have detected (with $\alpha = 0.05$, and 80% power) was 0.187, which is moderate size. Therefore, we believe that we were powered to detect a moderate or larger effect size difference in our covariates. Future studies with larger sample sizes are needed to detect smaller effect size differences. It is also possible that our methods for assessing and categorizing for gross strength were not sensitive enough to detect more subtle impairments.

In addition, findings should be interpreted cautiously, given that the sample was predominantly male veterans with a mean time since amputation of more than 20 years. It is unclear whether amputation surgery practices have changed in the United States and how this could impact RLL of persons with more recent amputation. Given the long time since amputation, it is also possible that lifestyle, health maintenance behaviors, and the insidious development of chronic comorbidities are also confounding factors. Furthermore, the sample had a high proportion of persons with combat-related amputation (34%), and thus, rates of PROM restriction and weakness may not be generalizable to samples with smaller proportions of combat-related amputation with lower rates of combat-related comorbidities.

This study used gross measurements of PROM restriction and muscle weakness that were collected by study therapists at multiple locations. The PROM measurements were collected using goniometers and strength assessments were made by observation. Categories were purposefully collapsed to characterize the presence or absence of impairment to strengthen the face validity of these measures. Measures were taken by a single rater at each site. No data are available on the intrareliability or interreliability of this approach. Future studies might evaluate the reliability of these types of gross assessments or use alternative approaches to strength measurement.

Last, our regression models explained between 17% and 24% of the variance in outcomes, suggesting that there are other unmeasured factors that influence activity performance, prosthesis satisfaction, disability, and quality of life.

CONCLUSIONS

This exploratory study is the first to provide detailed descriptions and classification of RLL, PROM impairment, and gross strength deficits in a large cohort of veterans with major ULA. Passive ROM restrictions were identified most commonly at the shoulder joint in persons with both BE- and AE amputation and were strongly correlated with weakness in the same planes of motion. Short BE RLL was more common than short AE RLL and was correlated with impairment of both elbow flexion strength and PROM. Perhaps because of greater reliance on the contralateral limb for functional activities, few statistically significant relationships were observed between RLL, ROM impairment, and strength deficits with measures of activity performance, health-related quality of life, and prosthesis satisfaction. However, those with elbow flexion restrictions had significantly better activity performance but worse HRQoL and prosthesis satisfaction.

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