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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

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

Purpose: The purpose of this project is to provide comprehensive cross-sectional and longitudinal data on function, needs, preferences, and satisfaction of Veterans and service members with major upper limb amputation.
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 reporting period (30 September 2020 - 29 September 2021) focused on data analyses and dissemination. We have completed 808 Aim 1 surveys, 585 Aim 2 surveys, 127 Aim 3 Visit 1 study visits, and 64 Aim 3 Visit 2 study visits. Data collection is complete for Aims 1, 2, and Aim 3. During this reporting period, we have published 2 papers and have 1 paper in press for Aims 1 & 2; and we have published 5 papers for Aim 3. We have a paper under construction. 1 Aim 1 abstract and 2 Aim 3 abstracts were presented at conferences.

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

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
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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. It is now time for 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. Our objective is to provide comprehensive cross-sectional and longitudinal data on function, needs, preferences, and satisfaction of Veterans and service members with major upper limb amputation.

2. **KEYWORDS:**

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

3. **ACCOMPLISHMENTS:**

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

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

Aim 1: Describe patterns of prosthesis use; identify the impact of amputation and prosthesis use on function, activities and participation; and identify unmet prosthetic needs.

Aim 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).

Aim 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		98%
	Dissemination	Month 36	Month 60		95%
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		95%
	Dissemination	Month 36	Month 72		90%

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

1 & 2: Specific objectives and major activities

Specific objectives and major activities accomplished during the Year 5 (NCE) reporting period (30th September 2020 – 29th September 2021) are described below:

Aims 1 & 2

Specific Objective 1: Maintain regulatory approvals (fully met)

Specific Objective 2: Identify Aim 1 & 2 sample (fully met)

Specific Objective 3: Complete Aim 1 data collection (fully met)

Specific Objective 4: Begin Aim 2 data collection (fully met, VA sample)

Specific Objective 5: Complete Aim 2 data collection (fully met, VA sample)

Specific Objective 6: Begin Aim 1 data analysis (fully met, VA sample and DoD sample)

Specific Objective 7: Complete Aim 1 data analysis (almost fully met VA sample, fully met DoD sample)
Major Activities:

- Data analysis 98% complete

Specific Objective 8: Disseminate Aim 1 results (partially met, VA sample)
Major Activities:

- 2 manuscripts were published (Aims 1 & 2)
- 1 manuscript is under construction
- 1 manuscript is in press (Aims 1 & 2)
- 1 conference abstract was presented
- 1 conference abstract was accepted for presentation
- Please refer to Tables 2 & 3 for a detailed description of Aim 1 dissemination activities for this year

Specific Objective 9: Complete Aim 2 data analysis (almost fully met, VA sample)
Major Activities:

- Data analysis 98% complete

Specific Objective 10: Disseminate Aim 2 results (partially met, VA sample)
Major Activities:

- 2 manuscripts were published (Aims 1 & 2)
- 1 manuscript is in press (Aims 1 & 2)
- Please refer to Tables 2 & 3 for a detailed description of Aim 2 dissemination activities for this year

Aim 3

Specific Objective 1: Maintain regulatory approvals for data collection sites (fully met)

Specific Objective 2: Complete Aim 3 Visit 1 data collection (fully met)

Specific Objective 3: Complete Aim 3 Visit 2 data collection (fully met)

Specific Objective 4: Continue Aim 3 analysis (partially met)
Major Activities:

- Continued analyses of Aim 3 Visit 1 data, analyses of psychometric properties of our outcome metrics were completed.
- Continued analyses of Aim 3 Visit 2 data

Specific Objective 5: Begin dissemination of Aim 3 results (partially met)
Major Activities:

- 5 manuscripts were published
- 2 conference abstracts were presented
- 2 conference abstracts were accepted for pending presentation
- 4 conference manuscripts were accepted for publication
- Please refer to Tables 2 & 3 for a detailed description of Aim 3 dissemination activities for this year

3) Significant Results or Key Outcomes

Data collection is complete for Aim 1, Aim 2 (VA sample) and for Aim 3.

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

Please refer to Tables 2 & 3 on the following pages which summarize the dissemination manuscripts and presentations across study aims.

Full citations for the manuscripts are listed in Section 6. Products

Table 2: Year 5 Manuscripts								
Author	**Title**	**Aim 1**	**Aim 2**	**Aim 3**	**Under construction**	**Under review (journal, date)**	**In press (journal)**	**Published (journal, date)**
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
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
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	
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
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
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
Resnik, L, Borgia, M, Cancio, J, Heckman, J, Highsmith, MJ,	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

Phillips, S, Webster, J.								
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			

Table 3: Year 5 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 was presented in 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 was 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 was presented in 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 to be 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 to be 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 to be 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 to be 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 to be 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 to be 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 to be published November 2021

4) Other Achievements

Infrastructure development

- Executed Year 5 subcontract award for Brown University.

- Continued regular communications to facilitate coordination and to ensure study fidelity, including:
    - Weekly PVAMC team meetings to ensure tracking of study deliverables

Data

- Please refer to Tables 2 & 3 above.

Stated goals not met

On August 12, 2021, we requested a 12 month No Cost Extension due to the impact the COVID 19 pandemic has had on manuscript review times and are awaiting a response from the Grants Specialist. Many journals have been significantly delayed in their review process. In normal times, the review process can be slow for a variety of reasons, including revision requests. Since the pandemic began, turnaround times have gotten much slower. We would like to have the opportunity to respond to journal reviewers' requests for revisions, as well as publish more manuscripts with our rich data.

1. Complete data analysis for Aim 3

   Goal – Month 36; Actual: February 2022 (Month 66)
   As mentioned above, we expect that we may need to conduct additional analyses in responses to reviewer comments and will not be complete until any additional papers are accepted for publication.

2. Complete dissemination for Aims 1, 2 & 3
   Goal – Month 36; Actual: September 2022 (Month 72)

   We have continued dissemination for Aims 1, 2 & 3 (Visit 1 and Visit 2), as mentioned above. During the next No Cost Extension year, we will continue our dissemination activities by submitting manuscripts for review and responding to reviewer comments. We will be presenting at several conferences and/or grand rounds (for example the AAPMR Assembly and ISPO World Conference in November 2021). We may need to conduct additional analyses in responses 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, has been working with our team on the analysis of data related to outcomes associated with concomitant lower limb amputation in persons with major upper limb amputation. She has presented one conference abstract on this topic and will present another at the AAPMR Assembly in November 2021. She will be a co-author on an upcoming manuscript related to this data.

Natalie Webster, a student from George Macon University, presented a conference abstract related to the Frequency, Severity and Implications of Shoulder Pain paper at the AAPMR Assembly in November 2020.

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

During this reporting period, we disseminated results at the following conferences and events:

1. American Academy of Physical Medicine and Rehabilitation (AAPMR) 2020 Assembly: Webster, N., Webster, J., Borgia, M., Resnik, J. Frequency and Severity of Shoulder Pain in Persons with Major Upper Limb Amputation who use prostheses: Results of a national study.

2. American Burn Association (ABA) National Conference: Cancio, JM., Borgia, M., Cancio, LC., Resnik, L. The impact of burn injury on upper extremity prosthesis users.

3. Virginia Commonwealth University Research Day: 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.

4. VA Amputation System of Care Grand Rounds, August 2021

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

Assuming that we are granted an additional 12 month No Cost Extension (Year 6), we plan to complete the following activities to meet the project goals and objectives:

Project Activity	Goal Completion Date
Complete analysis for Aims 3	Month 63
Complete dissemination for Aims 1, 2 & 3	Month 72
Submit 2 abstracts to national conferences	Month 72
Submit 4 publications to scientific journals	Month 72

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 report 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**

  Nothing new to report regarding delays. We are using remaining funds during the no cost extension period for data analysis and dissemination activities for Aims 1 – 3.

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.**

Accepted manuscripts:
Since the last Annual Report, we have published a total of 7 manuscripts and have 1 manuscript in press. These papers summarize selected results from the following Aims:

(Aims 1 & 2)
1. 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. 2021 Jan 11. Published Ahead of Print. doi: 10.1097/PHM.0000000000001694

2. 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. Fed Pract. 2021 Mar;38(3):110-120. doi: 10.12788/fp.0096. PMID: 33859462; PMCID: PMC8040957.

3. Resnik, L, Borgia, M, Clark, M. Contralateral Limb Pain is Prevalent, Persistent and Impacts Quality of Life of Veterans with Unilateral Upper Limb Amputation. Journal of Prosthetics and Orthotics, In Press.

(Aim 3)
1. Resnik, L, Borgia et al. Dexterity, Activity Performance, Disability, Quality of Life and Independence in Upper Limb Prosthesis Users: A normative study. Disabil Rehabil. 2020 Oct 18:1-12. doi: 10.1080/09638288.2020.1829106. Published ahead of print. PMID: 33073621.

2. Resnik, L, Borgia M, Delikat, J, Cancio, J et al. Psychometric evaluation of the Southampton Hand Assessment Procedure in a Sample of Upper Limb Prosthesis User. Journal of Hand Therapy, Journal of Hand Therapy. Published ahead of print. 2021 Jul 7. doi: 10.1016/j.jht.2021.07.003

3. Resnik, L, Borgia, M, Cancio, J, Heckman, J, Highsmith, J, Levy, C, Webster, J. Upper Limb Prosthesis Users: A Longitudinal Cohort, Prosthetics and Orthotics International. Published ahead of print. 2021 Aug 31. doi: 10.1097/PXR.0000000000000034

4. 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. PM R. Published ahead of print. 2021 Jul 4. doi: 10.1002/pmrj.12666. PMID: 34219397.

5. Resnik, L, Borgia, M, Cancio, j, Heckman, J, Highsmith, MJ, Levy, C, Phillips, S, Webster, J. Understanding Implications of Residual Limb Length, Strength and Range of Motion Impairments of Veterans with Upper Limb Amputation, American Journal of Physical Medicine & Rehabilitation. 2021 Aug 3. Published ahead of print, doi: 10.1097/PHM.0000000000001862. PMID: 34347631.

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

  Nothing to report.

- **Other publications, conference papers, and presentations.**

Our dissemination activities for this past year have also included 3 abstract presentations. In addition, 1 abstract and 4 conference manuscripts have been accepted for presentation at the upcoming World Congress of the International Society for Prosthetics and Orthotics (ISPO) in November 2021 and 1 abstract has been accepted for presentation at the upcoming AAPM&R Assembly in November 2021.

Abstracts presented:

1. 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. AAPMR, November 2020. (Aim 3)

2. Cancio, JM, Borgia, M., Cancio, LC, Resnik, L. The impact of burn injury on upper extremity prosthesis users. American Burn Association National Conference, Chicago, IL, April 2021 (virtual). (Aim 3)

3. 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. Virginia Commonwealth University (VCU) Residents & Fellows Research Day, June 2021. (Aim 1)

Abstracts accepted for presentation:

1. 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). ISPO Nov 2021 (Aim 3)

2. 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. ISPO Nov 2021 (Aim 3)

3. 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. AAPM&R Assembly Nov 2021 (Aim 1)

Conference manuscripts accepted for publication (All Aim 3):

1. Webster, J, Highsmith, M, Resnik, L. Pain conditions in Persons with Upper Limb Amputation: New Findings from the U.S. Dept of Veterans Affairs. ISPO Nov 2021

2. Highsmith, M, Webster, J, Resnik, L. Comparing dexterity, activity performance, disability, and quality of life, of body powered and myoelectric upper limb prosthesis users. ISPO Nov 2021

3. 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. ISPO Nov 2021

4. Resnik, L, Borgia, M, Cancio, J, Delikat, M. Alternative Scoring and Psychometric Evaluation of a Briefer Version of the Southampton Hand Assessment Procedure (SHAP). ISPO Nov 2021

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

  Nothing to report.

- **Technologies or techniques**

  Nothing to report.

- **Inventions, patent applications, and/or licenses**

  Nothing to report.

- **Other Products**

  Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

- **What individuals have worked on the project?**

Name:	Linda Resnik
Project Role:	Principal Investigator
Researcher Identifier (e.g., ORCID ID):	
Nearest person month worked:	1.0
Contribution to Project:	Dr. Resnik has performed work in the area of overall study oversight, 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 has performed work in the area of study coordination. She maintained the overall study budget and related tasks. In addition, Ms. Small was responsible for regulatory document preparation and submission. She has also assisted with manuscript preparation. the study. 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 has performed work to prepare study data for analysis and complete analyses for Aims 1, 2 & 3. He has assisted Dr. Resnik with preparing manuscripts for submission.
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 has performed work in the area of maintenance of study databases and preparation of study data, data cleaning and manuscript preparation
Funding Support:	*n/a*

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

There have been some changes to active support for the PI since Year 4 of our study. These changes are listed below. None of these changes have impacted level of effort on this project.

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

Title: Intelligent Spine Interface (PI: Borton)
Sponsor: Defense Advanced Research Projects Agency
Role: Co-Investigator
Time Commitment: 0.6 CM (Brown)
Period of Performance: 09/06/2020 – 09/24/2022 (NCE)
Amount Funded: $23,256
Project Goals/Specific Aims: The project proposes to build an Intelligent Spine Interface (ISI) capable of reading and writing simultaneously to, and from, the human spinal cord both above and below the site of spinal cord injury (SCI)

Title: The Role of Impaired Physical Function during Midlife on Predicting Future ADRD (PI: Bardenheier)
Sponsor: NIA 1R03AG070668-01
Role: Co-Investigator
Time Commitment: 0.24 CM (Brown)
Period of Performance: 03/01/2021 – 02/28/2023
Amount Funded: $308,176
Project Goals/Specific Aims: The study will ascertain the extent to which self-reported impairment in physical function during midlife, predicts future ADRD, thereby offering a new, efficient mechanism for early identification of ADRD

Completed

Title: Needs, Preferences and Functional Abilities of Veterans and Service Members with Upper Limb Amputation – Female Supplement
Sponsor: VA RR&D A2707-1
Contingent Upon VA RR&D A9264-S
Role: Principal Investigator
Time Commitment: 0.0 CM (VA Appt)
Period of Performance: 05/01/2017 – 04/30/2021
Amount Funded: $38,999
Project Goals/Specific Aims: The objective of this study is to provide comprehensive cross-sectional and longitudinal data on function, needs, preferences, and satisfaction of Veterans and service members with major upper limb amputation. This supplement will include a robust sample of female Veterans and allow comparisons of findings by gender.

- **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 attached – Copies of 8 accepted manuscripts

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 will provide cross-sectional and longitudinal survey and performance data. Data collection will be done through surveys and functional performance testing. Part 1 will be a cross-sectional survey. Part 2 is a one-year longitudinal follow-up survey of respondents from Part 1. Part 3 is an in-person study to collect performance-based measures of physical function at two time points, about one year apart.

Accomplishments: During Year 5, 2 manuscripts were published, and 1 manuscript is in press (Aims 1 & 2); 5 manuscripts were published (Aim 3); 1 conference abstract was presented (Aim 1) and 2 conference abstracts were presented (Aim 3).

Timeline and Cost

Activities - Project Year (PY)	Year 1	Year 2	Year 3	Year 4	Year 5
Identify sampling frame and train interviewers					
Data collection – Part 1					
Data collection – Part 2					
Data collection – Part 3					
Data analysis/dissemination					
Actual Expenses YR 1-4) (*estimated YR 5)	**$404,526**	**$810,622**	**$679,432**	**$376,039**	**$226,821**

Goals/Milestones

PY1 Goals – Study Launch – All goals met

PY2 Goals – Data collection and early analysis

- ✓ Part 2 surveys administered
- ✓ Gift cards issued Part 2
- ✓ Conduct analyses Aim 1, and preliminary analyses Aim 2

PY3 Goals – Data collection, preliminary analysis and dissemination

- ✓ Complete all data collection (Aims 1, 2 Aim 3 Visit 1)
- ✓ Analyze data Parts 1, 2 and 3 – in progress
- ✓ Submit abstracts and manuscripts – in progress

PY4 / PY5 (NCE Goals) – Data collection, analysis and dissemination

- √ Complete remainder of data collection (Aim 3 Visit 2)
- √ Complete data analysis for Parts 1, 2 (*partially complete Part 3)
- ❑ Complete dissemination for Parts 1, 2 and 3

PY5 Budget Expenditure to Date

Projected Expenditure: $2,497,440 (Cumulative, Y1+Y2+Y3 +Y4 + Projected Expenditure Y5 No Cost Extension)

Actual Expenditure: $2,446,685.10 as of 9/30/2021 (Cumulative, Y1+Y2+Y3 + Y4 + Y5 Actual Expenditure)

APPENDIX A:

Accepted Manuscripts

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

Linda Resnik, Matthew Borgia, and Melissa A. Clark

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

(*Am J Phys Med Rehabil* 2021;00:00–00)

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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Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (www.ajpmr.com).
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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 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 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 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.

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] AQ13

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 F1 F2 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 T1 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

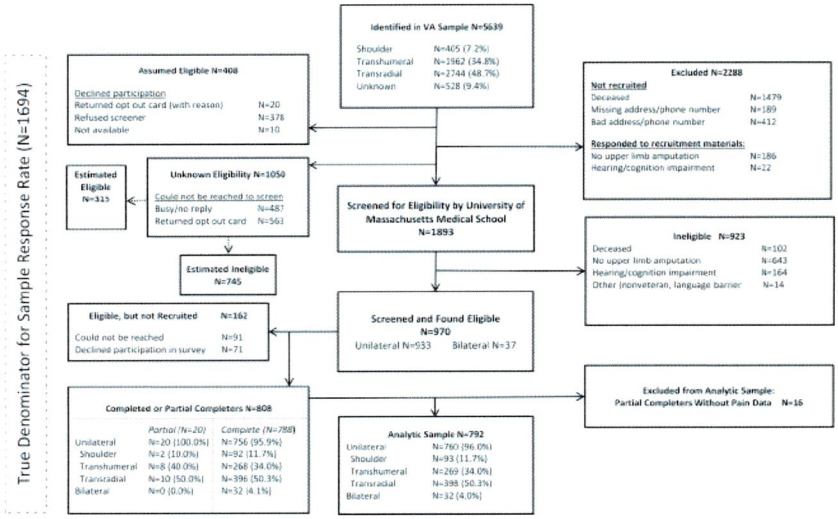

FIGURE 1. Flow diagram of baseline study recruitment.

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

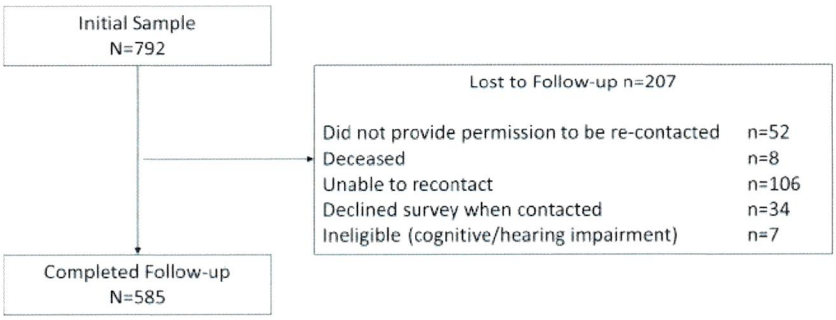

FIGURE 2. Flow diagram of loss to follow-up.

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

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)
Missing, n	0	0	4
Any neck pain (yes)	480 (60.6)	353 (60.3)	358 (61.5)
Missing, n	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

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)												

(Continued on next page)

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*
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
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				

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

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									
AQ15 SH/FQ	−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** AQ16
TH/ED	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
TR/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

(Continued on next page)

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	

AQ17 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.

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]

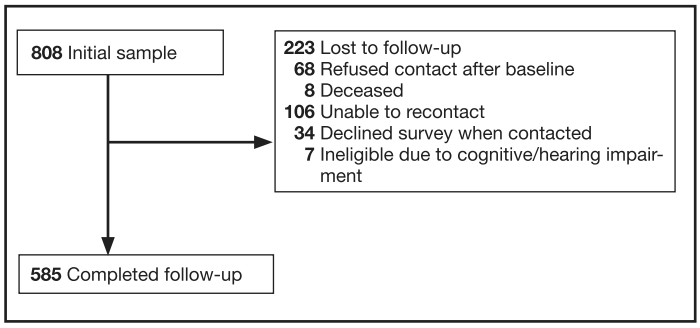
Earlier studies that examined the amputation rehabilitation services received by veterans with ULA pointed to quality gaps in care

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.

FIGURE Flow Diagram of Analytic Sample



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.

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)				Bilateral, mean (SD) (n = 29)	*P* Value[a]
		SH (n = 27)	TH (n = 121)	TR (n = 313)	All (n = 461)		
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 (Table 2 and eAppendix 2).

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

The opinions expressed herein are those of the authors and do not necessarily reflect those of *Federal Practitioner*, Frontline Medical Communications Inc., the US Government, or any of its agencies.

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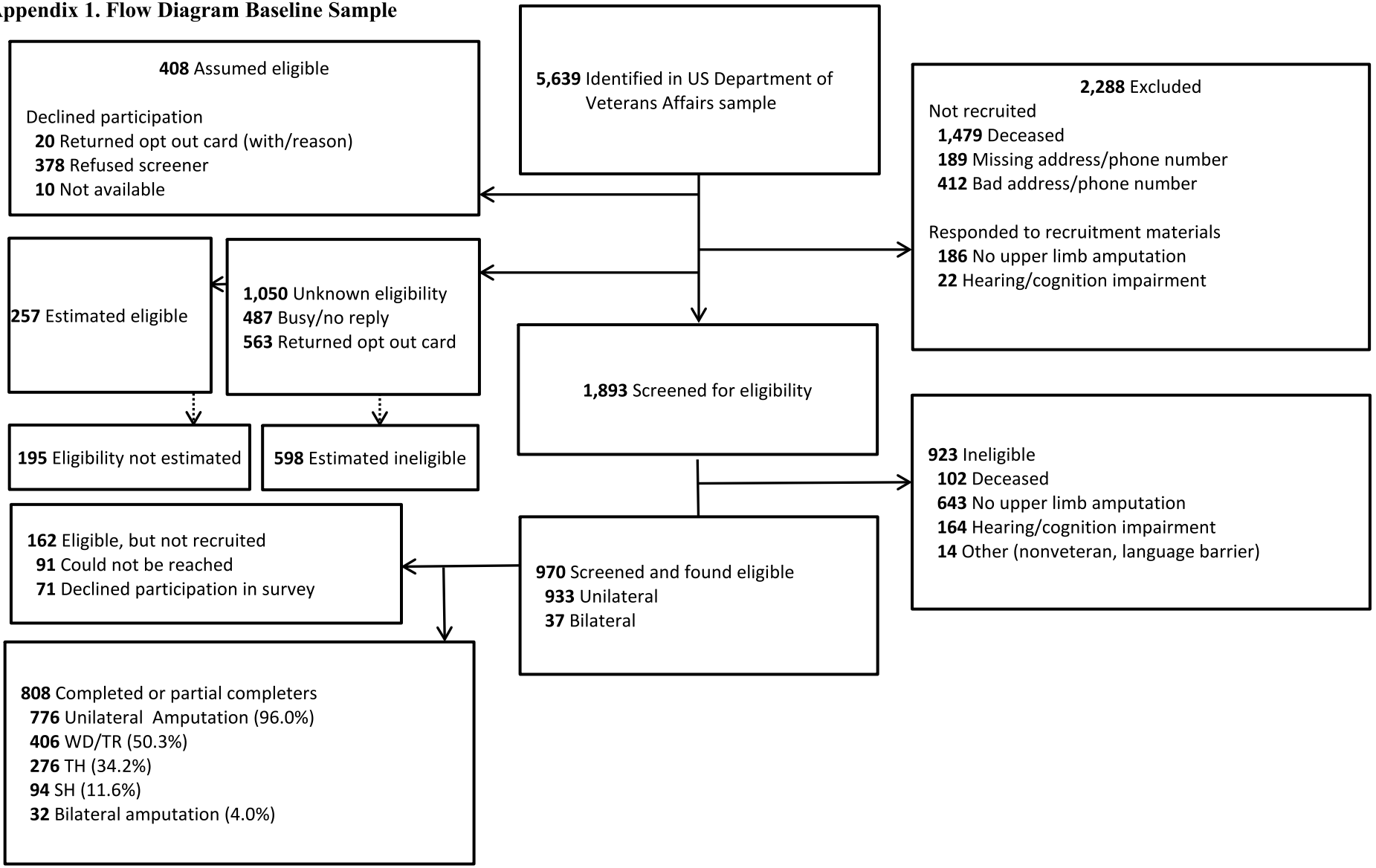
eAppendix 1. Flow Diagram Baseline Sample



Abbreviations: SH, shoulder; TH, transhumeral; TR, transradial; WD, wrist disarticulation.

eAppendix 2. Amputation Care Checklist Item Response Completion At Initial Visit (N = 808)

Checklist items	Completed		Missing/ Unknown/ Skipped	
	No.	%	No.	%
Quality of care				
Functional assessment in prior year	775	95.9	33	4.1
Amputation-related care in prior year	782	96.8	26	3.2
Prosthetic/amputation check up at the VA in prior year	785	97.2	23	2.9
Prosthetic/amputation check up by phone in prior year	785	97.2	23	2.9
Contacted by any care provider outside of appointments	783	96.9	25	3.1
Family or caregiver involved in care in prior year	783	96.9	25	3.1
Received information about amputation care in year	778	96.3	30	3.7
Pain management				
Well managed	511	63.2	297	36.8
Managed with medication	518	64.1	290	35.9
Managed with other strategy	516	63.9	292	36.1
Initial amputation care				
Family or caregiver involved in initial amputation management	768	95.1	40	5.0
Peer visit after amputation	739	91.5	69	8.5
Other				
Discussed amputation care goals in prior year	184	22.8	624	77.0
Worked to develop care plan in prior year	79	9.8	729	90.0
Providers helped to coordinate care after move	63	7.8	745	92.0

eAppendix 3. Linear Regression of Service Satisfaction Ratings, Separate Bivariate Models

Variables	OPUS Client Service Satisfaction	
	β	*P* Value
OPUS client device satisfaction	0.7	< .001
Trinity Amputation and Prosthetic Experience Scale	-15.6	< .001
Amputation level		
Shoulder	6.1	.13
Transhumeral	-2.7	.24
Transradial (ref)		
Bilateral	5.3	.23
Prothesis type		
Body-powered (ref)		
Myoelectric/Hybrid	0.1	.97
Cosmetic	11.7	.02
Amputation care in prior year		
No (ref)		
Yes	-6.8	.001
Age group		
18 to 44	1.3	.69
45 to 64 (ref)		
65 to 74	0.2	.95
75+	1.3	.71
Years since amputation	0.0	.91
Era of amputation		
Pre-Vietnam	0.8	.87
Vietnam War	-0.4	.88
Post-Vietnam through Gulf War	0.5	.88
Post-Gulf War to September 10, 2001	1.2	.74
September 11, 2001 to present(ref)		
Gender		
Male (ref)		
Female	-0.9	.92
Race		
White (ref)		
Black	8.6	.005
Other/Mixed	4.9	.27
Unknown	6.6	.08
Ethnicity		
Hispanic	3.4	.29
Not Hispanic (ref)		
Unknown	7.6	.29
Lower limb amputation		
No (ref)		
Yes	-0.8	.79
Geographic region		
Northeast	-5.0	.08
South (ref)		
Upper Midwest	-3.1	.25
West	-3.8	.16
Amputation etiology		
Combat	1.6	.41
Accident	-1.4	.50
Burn	-0.6	.86
Cancer	-9.0	.24
Diabetes	-10.7	.45
Infection	-0.9	.78

Abbreviation: Orthotics and Prosthetics User's Survey

eAppendix 4. Baseline and Follow-up CSS and Quality of Care for all Participants

	Baseline (N = 808)		Follow-up (n = 585)	
	Total, No.	**Mean (SD)**	**Total, No.**	**Mean (SD)**
OPUS CSS	402	36.2 (20.0)	301	35.2 (20.2)
Quality of Care Index	761	1.3 (1.5)	576	1.2 (1.5)
		No. (%)		**No. (%)**
Other quality of care items				
Pain is well-managed	511	342 (66.9)	357	246 (68.9)
Manage pain using medication	518	267 (51.50	364	178 (48.9)
Manage pain using other strategy	490	252 (48.8)	364	166 (45.6)
Family or caregiver involved in initial amputation management	768	366 (47.7)	570	275 (48.3)
Peer visit after amputation	739	187 (25.3)	557	140 (25.1)
Discussed amputation care goals in prior year	184	79 (42.9)	118	51 (43.2)
Worked to develop care plan in prior year	79	51 (64.6)	51	30 (58.8)
Providers helped to coordinate care after move	63	10 (15.9)	41	5 (12.2)

Abbreviations: CSS; client satisfaction survey; DoD, US Department of Defense; OPUS, Orthotics and Prosthetics User's Survey; VA, US Department of Veterans Affairs.

JPO: Journal of Prosthetics and Orthotics

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

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Abstract:	Introduction : Upper limb amputees (ULAs) 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 : 776 Veterans with unilateral ULA were surveyed at baseline and 562 were surveyed again at 1-year. Participants reported CLP frequency and intensity, and non-amputated limb conditions. Multivariable models examined factors associated with CLP, and associations between CLP intensity and HRQOL (physical component score [PCS] and mental component score [MCS]) and disability (QuickDASH). Results : CLP prevalence was 72.7% (baseline) and 71.6% (follow-up); 59.8% had persistent pain. Contralateral limb conditions, neck and residual limb pain were associated with higher odds of CLP. Black race (vs. white), back pain (vs. without), and age 45-65 (vs. 18-45) were associated with greater CLP intensity. Female sex (vs. male) and use of cosmetic prostheses (vs. body-powered) were associated with lower pain intensity. MCS was 2.7 and 6.6 points lower for moderate and severe CLP, respectively; PCS was 4.2 and 8.4 points lower for moderate and severe CLP; and disability was 9.4 and 20.7 points higher for moderate and severe CLP, compared to none to mild pain. Conclusions: CLP was prevalent and persistent in Veterans with ULA and was associated with black race, back pain and older age. Less pain intensity was associated with female sex and cosmetic prosthesis use. Moderate to severe CLP was associated with worse HRQOL and greater disability. Efforts are needed to prevent and treat ULA CLP pain. Further research is needed to understand if disparities in pain treatment exist by race.
Response to Reviewers:	Reviewer #1:

	First and Foremost, the "Conclusion" within the abstract is both misleading and negatively impactful to those seeking Upper Limb Prosthetic Care. Your study was conducted, or the particular variables of this paper extracted, from a broader study that does not clearly describe the reliance/over-reliance on the prosthesis. As the reference of your material/survey suggests, that information was gleaned from previous work that you had published in 2019. Daily use of a device, hours of use and tasks for using a prosthesis will clearly lead to whether or not the prosthesis is utilized. Reliance/Overreliance is not necessarily based on the factual nature of the prostheses being used, but could have been concluded based on "if" tasks could not have been accomplished without the prosthesis/prostheses. Even the population of individuals with bilateral, upper limb prostheses find ways of managing without prostheses entirely. The focus of this paper, that includes: presence, frequency, intensity of CLP and Hx of musculoskeletal limb conditions has no bearing on the reliance of the prosthesis. You may need to include other variables in this paper in order to even suggest such a conclusion. The statement of "CLP occurs regardless of (amputation level or) prosthesis use" is quite detrimental if taken in the wrong context. The individuals from whom you have gathered this information have CLP. There is no evidence to suggest that the addition of an upper limb prosthesis will reduce this pain as this is not directly addressed in your questioning. Therefore; concluding that "regardless of prosthesis use" individuals with ULA will have contralateral limb pain suggests that there is no utility in these devices; which is absolutely NOT the case. Additionally; the population that you have surveyed is quite skewed. Several variables come into play with regards to their CLP: Thank-you for these comments. We have edited the conclusion section, removing our discussion/speculation about over-reliance on a prosthesis. Individuals within the VA system (and other healthcare systems) are reliant on their care based on maintaining a "need" for services. Should these needs diminish or resolve, the care is no longer provided. The Reviewer makes an interesting point. It may be possible that those who had painful contralateral shoulder conditions were more likely to seek VA care. We have added to the discussion accordingly. Depending upon where your number for "participants" had arisen, either 51% of all Baseline Survey Group or 70% of Completion Group have some contralateral musculoskeletal limb conditions. If this truly is the case; wearing or not wearing a prosthesis will have little effect on resolution of the pain in several of these disorders, and may contribute toward the pain depending upon suspension design, etc. Table 1 shows that the prevalence of musculoskeletal limb conditions (at baseline) on the contralateral side was 51.2% for the full cohort and 52.7% for the longitudinal sample. Given that our survey asked whether participants had ever been diagnosed with a condition of the CLP, we were unable to assess whether change in a musculoskeletal condition occurred over the one year period. Additionally, as you had pointed out, these figures were taken from "self reported" disorders and not confirmed via Medical Records data. We clearly acknowledged the limitations of self-reported disorders in our study limitations on p. 13-14 Over 50% of your participants surveyed had their amputation occur prior to 1990. Thirty years of living with CLP will not likely resolve in the 12 months between your baseline inquiry and follow-up. We did not ask participants how long they had CLP pain and we have no reason to believe that they were living with CLP for 30 years. We agree that the generalizability of our findings may be limited for persons with more recent limb loss, we have added this limitation to our discussion of limitations on p. 13. Not sure that the percentages of individuals using upper limb prostheses has changed as dramatically as your comparison of a 2007 study (going 25 years retroactively) to your current collection of data. We do not make an assertions about whether the rates of prosthesis use have changed since 2007. We report on data collected in a national study of Veterans with upper limb amputation.

Your statement of the fact that ULP are "inefficient and uncomfortable ... contributing to altered body mechanics and compensatory movements..." is without question. The question arises as to whether or not these compensations are more or less detrimental if the task were to be performed without a prosthesis. That information is more important to know regarding the utilization of an ULP.
Thank-you for this comment, we agree that this is an important point. We have added to the introduction as follows, “Over-reliance on the sound side, due to non-use or limited use of a prosthesis, is likely to create altered body mechanisms and contribute to overuse injuries.”

Couple typos in "Other Variables" number of prosthesES currently used & intensiTY of prosthesis use (vs. intensiFY)
Thank you, we have corrected these typos.

Analytical Methods: Not sure about your list of Covariates in the logistic regression. Seems as if "combat and cancer amputation..." was supposed to be worded differently.
We have edited the sentence to read, “combat amputation etiology, cancer amputation etiology”, to be clear that both were separately added to the model.

A "mean age of 63.2" is certainly not representative of new users, nor individuals who may benefit from first prosthetic fitting that "may" help prevent them from acquiring the onset of CLP.
We agree that our findings have limited generalizability to persons with more recent amputation and have added this to the statement about limitations on p. 13.

"We did not observe an association between prosthesis use (or amputation level) and the likelihood of reporting CLP." This statement neither supports nor refutes your notion that "CLP occurs regardless of (amputation level or) prosthesis use".
As noted above, we have removed this text in the conclusion.

In your, overall, paper Conclusion, you did not discuss the dependency (or lack thereof) of CLP and prosthesis use; as you had suggested in your Abstract's - Conclusion.
As noted above, we have removed this text in the conclusion.

Reviewer #2:
Way, way too many abbreviations.
We have eliminated abbreviations for ‘Institutional Review Board’, ‘Operation Enduring Freedom’, and ‘Operation Iraqi Freedom’ as each were only used once. In the revised manuscript we use the following abbreviations for words that were used multiple times: ULA, CLP, MCS, PCS, HRQoL, VA.

Introduction would benefit from some reorganization to improve flow. Development of the rationale is sparse, especially first two paragraphs. Introduction would be stronger staying focused on contralateral limb pain.
Thank-you for this comment, we reorganized the introduction and believe that the flow has improved.

Line 12: "Veterans with ULA are at an even higher risk.2" seems like a sentence that needs to be finished. E.g, why are they at a higher risk, or they are at a higher risk than ???
We have edited the sentence to explicitly clarify that veterans with ULA are at even higher risk for CLP ‘than the general population of persons with ULAs’.

Lines 16-19: Similarly, these lines are rather global and leave the reader hanging. Can comparisons by level of amputation be made? More context to support the difference between VA and non-VA is needed.
The purpose of our introduction is to present a cogent rationale for the need for this study with some preliminary background on Veterans with ULA. We provide a general comparison of prosthesis use between Veteran and non-Veterans with upper limb amputation. We added the following sentence, “However, the reasons for the differences in prosthesis use are not well understood.”

	Lines 21-24: Citation is needed. We added a citation for this sentence. Lines 48-56: This language is typically in the Discussion not the Introduction. Rather than state studies are needed, consider introducing the purpose of the study from the perspective of the gap this study is filling. We have edited this text to read, “The prevalence of 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 are not well understood” Methods Design: Really this was both a cross-sectional and longitudinal study design since you did analyze the data for subject with no follow-up. We have updated the first sentence to now read: “A longitudinal study of Veterans with ULA was conducted, with cross-sectional data collected at baseline and longitudinal data collected at 1-year follow-up”. The first paragraph of the methods section could be improved with more detail on how Veterans with recruited and what variables were used in the sampling frame. This paragraph should include what happened during the telephone encounter, e.g., was a survey or interview performed? Were the HQoL and DASH measures administered over the phone? Were demographic and clinical variables collected at this time (Other variables) We revised the methods text to describe the method of data collection. All data were collected by telephone. Given word limitations, we cite another paper that contains more detailed description of the survey content. Lines 43-46, Heading Key Variables: I would probably move the length of interviews up to the previous paragraph. We have deleted the ‘key variables’ heading and moved the sentence up to be included in the previous paragraph. We agree this helps the methods text flow better and still leads into our variable descriptions. Line 24. Consider using either interview or survey rather than using these terms interchangeably. We have replaced the word “interview” with the word “survey” throughout. Analytic Methods are presented in detail Thank you. Results Line 51: Difference between the response and participation is not clear We have amended this sentence by correcting ‘participation’ to ‘cooperation’ and by adding a citation to the AAPOR guidelines used to calculate these rates. Much of the text in the results section is repetitious of the data presented in the tables and can be deleted We have deleted sentences describing the demographics in table 1 and have removed the reiteration of 95% Cis from the Table 6 text. We believe the remainder of our results are concise and give clear interpretation to the findings in our tables. Discussion Lines 14-16: "This prevalence rate is far greater than that reported in the general population of US adults, and in the civilian ULA population" should have citations so the readers can compare results of this study with the results of other studies similar to the nice comparison done in the following paragraph We have added citations to the discussion per Reviewer suggestion. Line 19 'Hardt' citation needs to be formatted We made this correction

April 13, 2021

Dr. Steven A. Gard
Editor-in-Chief
JPO: Journal of Prosthetics and Orthotics

Dear Dr Gard,

Thank-you for your favorable review of our paper titled, Contralateral Limb Pain is Prevalent, Persistent and Impacts Quality of Life of Veterans with Unilateral Upper Limb Amputation (JPO14-159). We appreciate the thoughtful Reviewer comments and have prepared a point by point response document.

We believe that the paper has been improved and are looking forward to its publication in JPO.

Sincerely,

Linda

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

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Running head: Contralateral Limb Pain in Upper Limb Amputation

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

Abstract

Introduction: Upper limb amputees (ULAs) 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: 776 Veterans with unilateral ULA were surveyed at baseline and 562 were surveyed again at 1-year. Participants reported CLP frequency and intensity, and non-amputated limb conditions. Multivariable models examined factors associated with CLP, and associations between CLP intensity and HRQOL (physical component score [PCS] and mental component score [MCS]) and disability (QuickDASH).

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

Conclusions: CLP was prevalent and persistent in Veterans with ULA and was associated with black race, back pain and older age. Less pain intensity was associated with female sex and cosmetic prosthesis use. Moderate to severe CLP was associated with worse HRQOL and greater

disability. Efforts are needed to prevent and treat ULA CLP pain. Further research is needed to understand if disparities in pain treatment exist by race.

Keywords: amputation, arm pain, upper extremity, Veteran, quality of life

Introduction

Upper limb amputees (ULAs) are at increased risk for contralateral limb pain (CLP) as compared to the general population, in part due to overreliance on the sound limb and increased susceptibility to overuse injuries.[1] Veterans with ULA are at an even higher risk of CLP than the general population of persons with ULAs.[2]

An estimated 36%-57% of persons with ULA report CLP.[1, 8, 9-11] In a nationally representative study of U.S. adults, prevalence estimates of CLP were: 19.9% for shoulder, 16.8% for hand, 9.8% for wrist, and 1.2% for arm.[12] Chronic pain of the upper limb was reported in 4.1% in a U.S. population with ULA.[13] Furthermore, almost one third of persons with ULA in the Washington state area of the U.S reported CLP lasting at least 3 months.[14] The rates of CLP in U.S. Veterans with ULA exceed rates previously reported, with 71% experiencing CLP.[2] The persistence of CLP in Veterans has not been previously examined.

Approximately 80% of adults with ULAs in the U.S., the U.K., and Canada utilize a prosthesis.[3] In comparison, only 60% of the overall population of U.S. Veterans with unilateral ULA utilize a prosthesis.[2] However, the reasons for the differences in prosthesis use are not well understood.

Those with unilateral amputation depend on their sound limb for daily activities, regardless of whether or not they use a prosthesis. [4] 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 that do use them.[5, 6, 7] Over-reliance on the sound side, due to non-use or limited use of a prosthesis is likely to create altered body mechanisms and contribute to overuse injuries.

The prevalence of 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 are not well understood. 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 one year; 2) identify factors associated with CLP; and 3) quantify the associations between CLP, health-related quality of life (HRQoL) and disability among a sample of Veterans with ULA.

Methods

A study of Veterans with ULA was conducted, with cross-sectional data collected at baseline and longitudinal data collected at 1-year follow-up through telephone surveys. This study was approved by the VA Central Institutional Review Board. The sampling frame included Veterans with major upper limb amputation who received VA care between 2010-2015. To maximize generalizability to Veterans with ULA, the sampling frame was identified from VA Corporate data warehouse sources.[2] All non-deceased Veterans with valid addresses and phone numbers were mailed recruitment materials.

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

Telephone Survey

Surveys lasted approximately 45 minutes and covered a wide range of topics (including demographics and outcome measures). The baseline survey has been described in detail elsewhere,[2] and is summarized briefly below.

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 non-amputated 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 to 3 times per week", "4 to 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 categorical variable with 4 categories ("never", "weekly or less frequent", "2 to 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"). Respondents were asked whether they had ever been diagnosed with any of 9 common conditions in the non-amputated 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.[4]

Outcomes

Health-related quality of life (HRQoL) was assessed using the VR-12 Physical Component Score (PCS) and the 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), gender, 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, intensity 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), 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/ANOVAs). We used findings from these analyses to construct two 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). We utilized 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 amputation etiology, cancer amputation etiology, presence of musculoskeletal sound side conditions and presence of any back, neck, residual limb and phantom limb pain. Covariates in the linear regression model included: age, gender, 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 three sets of multivariable general linear regression models (GLMs) to examine the association of CLP intensity with HRQoL (2 models) 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 cooperation rates[18] 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, mean age of 63.2 (sd 14.1) with 31.3 (sd 18.4) years since amputation. Accidents (63.1%) and combat injury (35.4%) were the most common amputation etiology. Characteristics of the baseline and longitudinal samples were similar (Table 1).

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 1/3 of participants in the baseline and longitudinal samples experienced daily or more frequent pain. For the longitudinal sample, 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.

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

Results of multivariable linear regression for baseline contralateral limb pain intensity are also shown in Table 5. Respondents of black race (compared to white) had, on average, 1.2 points greater CLP intensity and those with back pain (compared to without) had 0.7 points greater CLP intensity. Respondents age 18-45 (compared to 45-65) had 0.9 points lower intensity CLP. Female respondents (compared to male) had 1.4 points lower intensity CLP, and those using cosmetic prosthesis (compared to body-powered) had 1.7 points lower intensity CLP.

Table 6 shows the crude relationship between intensity of CLP, HRQoL and Disability scores. Health-related quality of life as measured by mean MCS scores ranged from 53.4 for the sub-group with no CLP to 44.7 for the sub-group with severe CLP. Mean PCS ranged from 43.5 to 33.5, and disability as measured by the QuickDASH ranged from 26.1 to 52.5. Crude differences between sub-groups were diminished after adjusting for potential confounders. Fully adjusted GLMs (Table 7) showed that on average, MCS scores were 2.8 and 6.6 points lower for those reporting moderate and severe CLP, respectively, compared to none to mild CLP. On average, PCS scores were 4.2 and 8.4 points lower for those with moderate and severe CLP, respectively, compared to none to mild CLP. Compared to those with none to mild CLP, those with moderate and severe pain experienced greater disability; QuickDASH scores were 9.3 and 20.5 points higher, respectively. Full results of multivariable linear regressions of health-related quality of life and disability are provided in Supplementary Digital Content Table 2.

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 more than 70% of Veterans with unilateral ULA had 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,[12] and in the civilian ULA population. [1, 8, 9-11] 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.

We 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 who reported that overuse problems did not vary by amputation level or type of prosthesis used.[19] A study of Vietnam and Operation Enduring Freedom and Operation Iraqi Freedom Veterans reported that 28-36% of those with unilateral ULA utilized their prosthesis for the majority of daily tasks, 40-43% utilized their prosthesis in a minority of daily tasks, and 24-30% did not use a prosthesis.[4] 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.[4]

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 non-amputated 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.[20, 21]

Mean pain intensity in our sample was about 0.8 points higher than previously reported in persons with ULA.[14] We found a relationship between older age and CLP intensity but not prevalence, with persons ages 45-64 reporting more intense pain as compared to those younger than 45. This is different from a study of chronic pain in the U.S. population which found that pain prevalence increased from younger to middle ages and then decreased with older age. [13] 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,[22] and greater pain intensity in black Americans as compared to white Americans.[23] The literature points to disparities in chronic pain management,[23] and pain screening processes in the VA.[24] Further research is needed to understand if 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 non-amputated 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 non-amputated side.

We found that moderate to severe CLP was associated with poorer mental and physical health, and greater disability. HRQOL scores in our study for those with severe CLP are comparable to those previously described.[14] Hanley 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 examined impact of CLP on disability days, we did not find previous studies that examined the impact of CLP in ULA's on QuickDASH scores. [14]

Limitations:

The majority of our analyses utilized data from the full baseline sample of respondents. Given the relatively high response rate, we believe this sample is generalizable to the population of Veterans with ULA who receive care at the VA. Although we observed minor differences in the longitudinal sample, as compared to those lost to follow-up (Supplementary Digital Content Table 3), 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 amputation etiology. We acknowledge that our results may have more limited generalizability to the civilian population with upper limb loss, and to persons with more recent 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 non-amputated arm, there are limitations to our estimates. First, respondents were asked to self-report whether they had ever been diagnosed with a condition of the non-amputated 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 to 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 (43%),[19], but higher than in

those experiencing symptoms suggestive of carpal tunnel syndrome reported by Datta (26.1%).[11] Another limitation was that our list of common conditions was limited and based on the list of conditions utilized in prior research.[4] Almost 50% of respondents indicated that they had "other" types of conditions and described the condition to the interviewer. Our research team reviewed these responses, re-categorized them into existing conditions whenever possible, or created several new categories to represent unique conditions that were reported by at least four people.

Conclusion

CLP 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 (compared to younger age) was 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 self-reported disability. Efforts are needed to prevent and treat CLP pain in the Veteran ULA population.

Figure legends

Figure 1. Lost to follow-up flowchart

Conflicts of Interest

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List of Supplementary Digital Content

Supplementary Digital Content Table 1. Factors associated with contralateral limb pain frequency and intensity at baseline among persons with unilateral upper limb amputation

Supplementary Digital Content Table 2. Factors associated with health-related quality of life and disability

Supplementary Digital Content Table 3. Lost to follow-up comparison of characteristics at baseline

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Table

	Baseline Sample (N=776)	Longitudinal Sample (N=562)
	Mean (sd)	**Mean (sd)**
Age (Years)	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 (%)**
Gender		
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 more than one)		
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)
Number of prostheses used		
One	291 (63.1)	215 (64.0)
Two or more	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		
Less than 2 hours	68 (19.1)	64 (18.8)
2 to less than 4 hours	42 (9.1)	26 (7.7)
4 to less than 8 hours	85 (18.4)	62 (18.5)
8 to less than 12 hours	88 (19.1)	68 (20.2)
12 hours or more	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)

Table 1. Characteristics of Respondents in the Baseline and Longitudinal Samples (Unilateral amputees only

sd, standard deviation

	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 to 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)
	Mn (sd)	**Mn (sd)**	**Mn (sd)**
Contralateral upper limb pain intensity (for those with any pain)	5.0 (2.3)	4.9 (2.3)	4.8 (2.2)

Table 2. Prevalence, frequency and intensity of contralateral upper limb pain: Baseline and Longitudinal Samples (Unilateral only)

	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)**
	N (%)
Improved	81 (24.4)
No change	187 (56.3)
Worsened	64 (19.3)

Table 3. Change in contralateral limb pain prevalence and intensity

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

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 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)

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

	Logistic Regression: Any contralateral limb pain (yes/no) N=746			Linear Regression: Contralateral limb pain intensity (0-10) N=507		
Characteristic	**OR**	**95%CI**	**p**	**β**	**95%CI**	**p**
Amputation Level						
Shoulder/FQ	1.82	0.98, 3.36	0.0578	0.35	-0.39, 1.10	0.3517
Transhumeral/ED	1.04	0.69, 1.57	0.8358	-0.17	-0.61, 0.28	0.4641
Transradial/WD (ref)						
Gender						
Male (ref)						
Female				-1.39	-2.60, -0.17	**0.0253**
Race						
White (ref)						
Black				1.17	0.55, 1.80	**0.0003**
Unknown				0.74	-0.06, 1.54	0.0693
Other/Mixed				0.40	-0.53, 1.33	0.3931
Age at time of study						.
18 to 44				-0.85	-1.50, -0.20	**0.0104**
45 to 64 (ref)						
65 to 74				0.32	-0.15, 0.79	0.1824
75+				-0.12	-0.80, 0.56	0.7229
Amputation Etiology						
Combat injury						
Yes	1.31	0.88, 1.94	0.1830			
No (ref)						
Cancer						
Yes						
No (ref)						
Diabetes						
Yes				-1.81	-0.40, 4.01	0.1086
No (ref)						

Any musculoskeletal condition of the sound side						
Yes	4.19	2.86, 6.14	**<0.0001**			
No (ref)						
Any Back Pain						
Yes				0.65	0.20, 1.10	**0.0044**
No (ref)						
Any Neck Pain						
Yes	3.78	2.59, 5.51	**<0.0001**			
No (ref)						
Any Phantom Lim Pain						
Yes	1.43	0.94, 2.20	0.0988			
No (ref)						
Any Residual Limb Pain						
Yes	2.41	1.57, 3.72	**<0.0001**	0.48	-0.01, 0.98	0.0545
No (ref)						
Current Prosthesis Use						
Yes				0.36	-0.10, 0.81	0.1244
No (ref)						
Primary Prosthesis Type						
Body-powered (ref)						
Myoelectric/Hybrid				-0.12	-0.76, 0.53	0.7231
Cosmetic				-1.65	-0.28, -0.47	**0.0064**
R^2					0.11	

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

OR, odds ratio; 95%CI, 95% confidence interval; FQ, forequarter; ED, elbow disarticulation; WD, wrist disarticulation.

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

		Health-Related Quality of Life		
		MCS	**PCS**	**Disability**
	N	**Mn (sd)**	**Mn (sd)**	**Mn (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)

Table 6. Health-Related Quality of Life and Disability among the baseline sample (N=776)
MCS, Mental Component Score; PCS, Physical Component Score; Disability measured with the QuickDASH, Quick version of the Disabilities of the Arm Shoulder and Hand Questionnaire; sd, standard deviation; CLP, contralateral limb pain.

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

Table 7. Association of contralateral limb pain with health-related quality of life (MCS and PCS) and disability (QuickDASH).
GLM, general linear regression model; 95%CI, 95% confidence interval; MCS, Mental Component Score; PCS, Physical Component Score; QuickDASH, Quick version of the Disabilities of the Arm Shoulder and Hand Questionnaire; CLP, contralateral limb pain; Adj-R^2, adjusted-R^2.

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, number of prostheses.

***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, number of prostheses

Figure

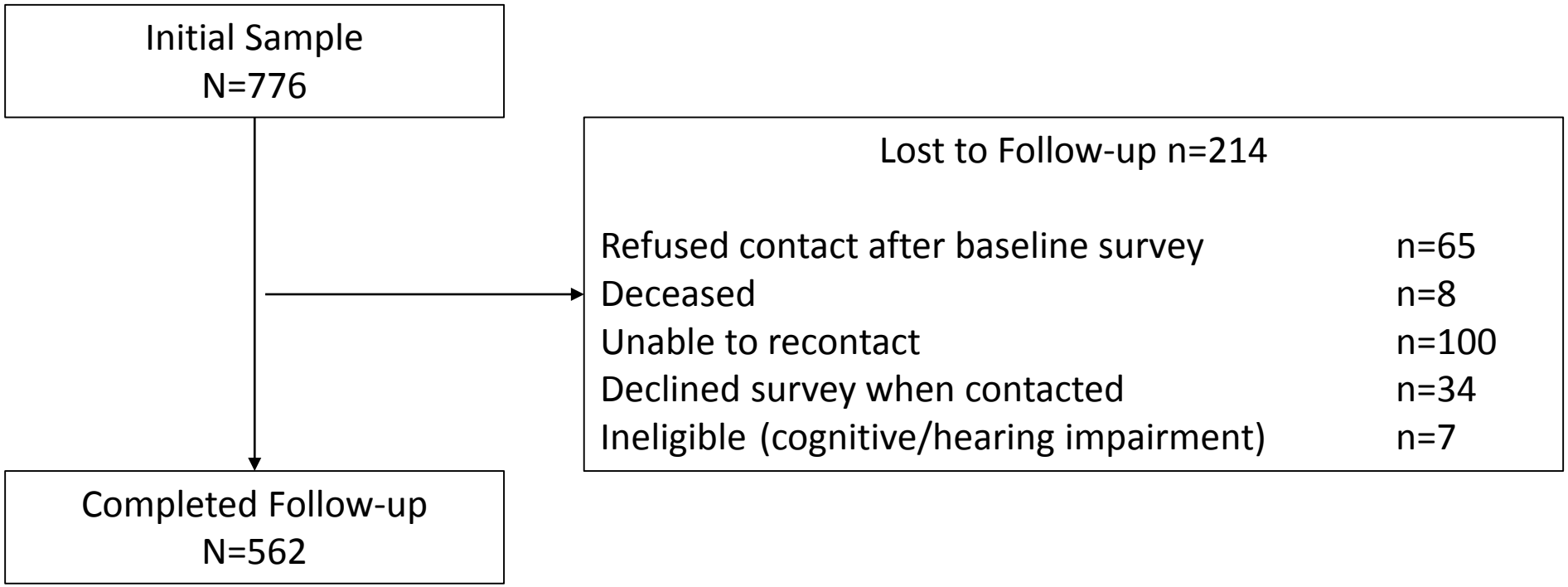
Initial Sample
N=776
Lost to Follow-up n=214
Refused contact after baseline survey n=65
Deceased n=8
Unable to recontact n=100
Declined survey when contacted n=34
Ineligible (cognitive/hearing impairment) n=7
Completed Follow-up
N=562

Figure Legends

Main manuscript with track changes

Disability and Rehabilitation

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ORIGINAL ARTICLE

Dexterity, activity performance, disability, quality of life, and independence in upper limb Veteran prosthesis users: a normative study

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ABSTRACT

Purpose: To present population data on standardized measures of dexterity, activity performance, disability, health-related quality of life (HRQoL) and community integration for persons with upper limb amputation (ULA), compare outcomes to normative values, and examine differences by prosthesis type and laterality (unilateral vs. bilateral amputation).

Materials and methods: Multi-site, cross-sectional design, with in-person evaluations, functional performance, and self-report measures. Descriptive and comparative analyses were performed by amputation level and prosthesis type, data were compared for unilateral and bilateral amputation.

Results: One hundred and twenty-seven individuals participated; mean age 57 years, 59% percent body-powered prostheses users. All measures of dexterity differed ($p < 0.05$) by amputation level and by laterality. All measures of activity differed by amputation level with the best scores in transradial (TR) amputation groups. Comparisons of body-powered users with TR amputation found that dexterity was better for those with bilateral compared to unilateral amputation.

Conclusions: Dexterity is markedly impaired in persons with ULA. Individuals with more proximal ULA levels are most impacted. HRQoL and community participation are less impacted and more equivalent to unimpaired persons. Further research is needed to examine differences by terminal device type and determine how best to match persons with ULA to the optimal prosthesis type and componentry, based on individual characteristics.

➤ IMPLICATIONS FOR REHABILITATION

- This study provides population-based, comparative data on dexterity, activity performance, disability, quality of life, and independence in upper limb prosthesis users.
- The study provides preliminary analyses comparing the effectiveness of body-powered devices, myoelectric devices with single degree of freedom and multi-degree of freedom terminal devices.
- The data presented in this study can be used to benchmark outcomes in patients who are upper limb prosthesis users.
- The data will also be useful to inform comparative evaluations of existing and emerging prosthetic technology.

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Introduction

A National Academy of Sciences report concluded that "despite advances in prosthetic designs and research, currently available upper extremity prostheses (UEPs) are limited in their ability to mitigate impairments related to limb loss" [1]. However, the extent of limitation associated with prosthesis use and the impact of contextual factors on these limitations is not fully understood. There are a wide variety of devices and components available to persons with upper limb amputation (ULA), but little data comparing outcomes for populations of users at differing amputation levels, users with single or

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bilateral upper limb loss, or users of various device types. Such data would inform patients and clinicians and could enable benchmarking of outcomes to realistic expectations for prosthetic rehabilitation. These data can also be used to facilitate comparative effectiveness evaluations of existing prosthetic componentry and as newer technology becomes available.

The most prevalent types of UEPs are body-powered (cable harnesses operated), and externally powered (myoelectric) – most commonly operated by surface myoelectrodes. A recent systematic review that compared body-powered and myoelectric prostheses found no clear superiority by device type, and called for additional research to compare prostheses types [2].

In the past decade, new and more costly types of prostheses and components have become available, making the need for additional research even more pressing. A variety of multi-degree of freedom (DOF) prosthetic terminal devices that enable multiple grip patterns are now commercially available and – according to a national study of Veterans with major ULA – are used by nearly 11% of Veterans who use upper limb prostheses [3]. Although multiple grip terminal devices are penetrating the market, and are desired by consumers [4,5], it is unclear what benefit patients or clinicians can expect from these devices. There have been few studies comparing single- vs. multi-degree DOF terminal devices, or other terminal device types. Small studies, for instance, did not show a clear advantage of any particular type of terminal device [6–11].

Our recently completed national survey of Veterans with major upper limb loss did not identify differences by device or terminal device type in perceived difficulty with activities, likelihood of needing assistance with activities of daily living (ADL), self-reported disability or health-related quality of life (HRQoL) [12]. However, that study was limited because prosthesis and terminal device type, and function were self-reported and were therefore subject to potential misclassification of device type, and to recall bias. Further research utilizing in-person assessment of prosthesis configuration and performance measures of dexterity and function are needed to compare outcomes of users of different types of prostheses and terminal devices to confirm or refute these findings.

To help address the clinical and research gaps, an in-person, multi-site study of upper limb prosthesis users was conducted which allowed verification of prosthesis and terminal device type and the ability to quantify a wide variety of outcomes. The purposes of this manuscript are to: (1) describe the methods of this study; (2) present normative and comparative data on outcomes by amputation level and prosthesis type; and compare outcomes to prior studies; and (3) compare outcomes for unilateral and bilateral upper limb amputees, with the overarching goal of assisting policy makers, clinicians, and patients to better match individual upper limb amputees with the most appropriate devices and components.

Methods

Study design

The study used a cross-sectional, observational design with data collected at five study sites across the U.S. The study was approved by the Veterans Administration (VA) Central Institutional Review Board (IRB), Regional Health Command-Central IRB and by the Human Research Protection Office (HRPO). All participants provided voluntary informed consent.

Sample

We enrolled a convenience sample of 127 persons with major ULA (defined as having at least one amputation at or proximal to the level of wrist disarticulation), who used an active prosthesis (body-powered, myoelectric, hybrid or Life Under Kinetic Evolution (LUKE Arm) [13]. Participants with unilateral or bilateral amputations were included. Participants who could not tolerate wearing a prosthesis for at least 3 h and those with a severe health condition that might limit their ability to participate in study assessment activities were excluded. Veteran participants who participated in an earlier survey study [3] and who agreed to future study contact were invited to participate. Other participants were recruited through clinical contacts, advertisements, and word of mouth.

Data collection

Participants attended an in-person study visit at a data collection site. Physical or occupational therapists, assisted by a research coordinator, assessed participants. Study visits lasted approximately 3–4 h with rest breaks provided as needed. Study visits included collection of demographic data (age, race, ethnicity, employment), history of the participant's amputation and prosthesis use (military status, amputation etiology, history of amputation-related rehabilitation, prosthesis use), and a physical examination (weight, height, limb length, residual limb inspection). During the prosthetic evaluation, the device and its components were described by the assessor and the prosthesis and terminal device were photographed. Measures of functional performance were collected by the study assessor to quantify dexterity and activity performance. Self-reported measures, which were interviewer administered, addressed satisfaction with the prostheses, disability, HRQoL, community integration, and need for assistance with ADL. A brief description of the collected standardized measures is provided in Table 1.

Key independent variables

To allow robust comparisons, given the small sample sizes, we collapsed categories of amputation level into three categories: transradial (TR), which included persons with wrist disarticulation and TR amputation; transhumeral (TH), which included persons with elbow disarticulation and TH amputation; and shoulder (SH), which included persons with SH disarticulation and interscapulothoracic amputation. We also compared persons with unilateral and bilateral amputation.

A three-level categorical variable to classify the prostheses types used based on prosthesis and terminal device type DOF was developed. The three categories were: body-powered, myoelectric single DOF terminal device, and myoelectric multi-DOF terminal device. Assessors first characterized the prosthesis as either body-powered, myoelectric, hybrid, or LUKE Arm. LUKE Arm was categorized as myoelectric, and hybrid devices were categorized based on the function of their terminal devices (body-powered or myoelectric). The type of terminal device utilized was documented by the study assessor and verified by the study prosthetist who viewed photographs of the device. Myoelectric terminal device categories were categorized based on their DOF. Electronic terminal devices (ETDs), Greifers [14] and sensor speed hands [15] were categorized as single DOF; I-Limb [16], Michelangelo [17], Bebionic [18], and LUKE hands [13] were categorized as multi-DOF.

Table 1. Brief description of key outcome measures.

	Construct	Item content	Rating criteria	Interpretation
Functional performance				
Dexterity				
Jebsen-Taylor Hand Function (JTHF)	Dexterity	7 separate tests of fine motor activities: writing, page turning, small objects, eating, placing checkers, light cans, heavy cans	Performance speed; items per second (modified scoring)	Higher scores indicate better dexterity
Nine Hole Peg (NHP)	Dexterity	Accurately place and remove 9 plastic pegs into a pegboard	Timed measure (time limited to 6 min), score calculated as items/second (modified scoring)	Higher scores indicate faster speed, better dexterity
Box and Block	Dexterity	Number of wooden blocks transported in 60 s	Performance speed; total number of blocks transported	Higher scores indicate better performance
Southampton Hand Assessment Procedure (SHAP)	Dexterity/index of function	26 unilateral timed tasks of hand function: 12 abstract tasks and 14 activities of daily (such as zipping, pouring, buttoning)	Performance speed	Higher scores indicate better dexterity
Activity performance				
Activities Measure for Upper Limb Amputation (AM-ULA)	Activity performance	18-everyday tasks: brush/comb hair, don t-shirt, doff t-shirt, button shirt, zip jacket, don socks, tie shoes, drink from a cup, use fork, use spoon, pour 12 oz can, write, use scissors, turn doorknob, hammer nail, fold towel, use phone, reach overhead	Each item is rated on task completion: speed, movement quality, skillfulness of prosthesis use and independence. Total score is the average score $\times 10$.	Higher scores indicate better activity performance
Brief Activities Measure for Upper Limb Amputation (BAM-ULA)	Activity performance	10 everyday tasks: tuck in shirt, lift 20 lbs, open and drink from water bottle, remove wallet from back pocket, replace wallet, lift gallon jug, open and pour jug, brush/comb hair, use a fork, open door with round knob	Ability to complete each task (yes/no). Total score is the number of activities that were completed.	Higher scores indicate better activity performance
Timed Measure of Activity Performance (T-MAP)	Activity performance	5 everyday activities: drink from a cup, wash face, food preparation, eating, dressing	Timed Measure: sum of time to complete each activity	Lower scores indicate faster speed, less difficulty
Self-report measures				
Device satisfaction				
Trinity Amputation and Prosthesis Experience Satisfaction Scale (TAPES)	Prosthetic satisfaction	10 items satisfaction with prosthesis: color, shape, noise, appearance, weight, usefulness, reliability, fit, comfort, and overall satisfaction	Satisfaction	Higher scores indicate greater prosthetic satisfaction
Quick Disability of the Arm, Shoulder, and Hand (QuickDASH)	Disability	Self-reported functional difficulty (8 items), 3 items about sleep, sensation and pain	Performance difficulty and impairment severity	Higher scores indicate greater disability
HRQoL				
Veterans RAND 12-Item Health Survey Mental Composite Score (VR-12 MCS)	Quality of life	Measure for Mental Health Component Summary	Self-rated quality of life	Higher scores indicate greater satisfaction
Veterans RAND 12-Item Health Survey Physical Composite Score (VR-12 PCS)	Quality of life	Measure for Physical Health Component Summary	Self-rated quality of life	Higher scores indicate greater satisfaction
Community Reintegration of Injured Service Members-Computer Adapted-Test (CRIS-CAT)	Extent of participation	Computer adaptive testing measuring participation in life roles	Frequency and amount of participation	Higher scores indicate better community integration
CRIS-CAT	Perceived difficulty	Computer adaptive testing measuring participation in life roles	Perceived limitations in participation	Higher scores indicate better community integration
CRIS-CAT	Satisfaction	Computer adaptive testing measuring participation in life roles	Satisfaction with participation	Higher scores indicate better community integration
Need for ADL help	Independence	Any need for help with daily activities	Yes/no	No required help indicates greater independence

Data analyses

We described participant characteristics, and prosthesis type for unilateral and bilateral amputation and by amputation level. Outcomes were compared by amputation level and laterality using the Kruskal–Wallis and Wilcoxon Mann–Whitney non-parametric tests due to small sample sizes. To establish normative values and test for differences by prosthesis type, the sample was stratified by amputation level to allow comparison of outcomes by prosthesis type for individuals with TR and TH amputations using Kruskal Wallis tests. Analyses of individuals with SH-level amputation were not included due to their small sample size ($n = 5$). Subsequent analyses were stratified by amputation level and age categories, and by prosthesis type and age categories to allow for comparison of outcomes by age group.

To contextualize the magnitude of outcome impairment, we compared our findings to data available on normative (unimpaired) samples. To facilitate comparison, we stratified our sample into three subgroups by age (18–44, 45–64, and $\geq$65 years) and compared to similar general population age cohorts when possible. Since our sample was predominantly male, when possible we compared them to males in the general population. Finally, when possible, we used normative values for the non-dominant side for comparison, given that upper limb prostheses are used typically as the "helper hand", not the dominant hand, in persons with unilateral amputation. For dexterity measures, we compared population values of the Jebsen Taylor Hand Function (JTHF) test [19,20], Box and Blocks test [21], Nine Hole Peg (NHP) [22,23], and Southampton Assessment Procedure (SHAP) [10,24] to values in our sample. As it was not possible to obtain exact data from prior publications due to our revised scoring method for JTHF and the NHP test, we instead transformed reported average timed scores to items completed per second, using the maximum number of items for each specific task.

Given that Activities Measure for Upper Limb Amputation (AM-ULA) [25], Brief Activities Measure for Upper Limb Amputation (BAM-ULA) [26], and Timed Measure of Activity Performance (T-MAP) [27] are amputation-specific measures, comparisons to unimpaired samples were not possible. Instead, we compared our data to values previously published on Quick Disability of the Arm, Shoulder, and Hand (QuickDASH), Veterans RAND 12-Item Health Survey Mental Composite Score (MCS), and Physical Composite Score (PCS). As there are no published population normative values available for the Community Reintegration of Injured Service Members-Computer Adapted-Test (CRIS-CAT) [28] measures for persons in their mid-50s (the mean age of our sample), we compared the scores reported for employed Veterans with no history of mental illness or substance abuse (who had a mean age of 47.7 years; range 25–60) [29]. Scores of the VR-12 MCS and PCS were compared to age-matched norms [30].

Given that dexterity measures involve single hand (or prosthesis) use, data were first combined from those with bilateral and unilateral amputation and dexterity scores were compared by amputation level and prosthesis type. Comparisons for persons with unilateral amputation only were then repeated. For activity performance measures, which involve bimanual tasks, as well as prosthesis satisfaction, self-report disability measures, HRQoL, and community integration we compared scores of persons with unilateral amputation by amputation level.

We controlled for multiple comparisons to adjust for false discovery rates in "families" or categories of tests using the Benjamini–Hochberg method to maintain a false discovery rate of 0.10 within each test category [31]. The following categories were used: dexterity (10 measures), activity performance (three measures), and self-reported function, disability, HRQoL, and community integration (six measures). Prothesis satisfaction was evaluated only by the Trinity Amputation and Prosthesis Experience Satisfaction Scale (TAPES) [32].

Wilcoxon Mann–Whitney tests were used to compare dexterity scores for persons with unilateral TR and persons with bilateral amputation who had TR amputation on their dominant side (our largest sub-group).

Results

Demographics and prosthesis characteristics are provided in Table 2. The sample was 97% male, 75% white, 85% Veterans, with a mean age of 56.9 (SD 16.5). The most common self-reported etiologies of amputation were traumatic; with 55% indicating accident and 36% combat injury (participants could indicate more than one etiology). The prosthesis that subjects wore for testing was mostly body-powered prostheses (59%) with some myoelectric single DOF (21%) and myoelectric multi-DOF (20%) devices. Prosthesis weight was 3.9 lbs (SD 2.3). One-quarter of the sample had received prosthesis training for the device used in testing. All hybrid devices in our sample were classified as myoelectric (two single DOF terminal device, five multi-DOF terminal device).

Amputation level

All measures of dexterity (JTHF tasks [33], Box and Blocks [21], NHP [22], and SHAP IOF [10]) were significantly different ($p < 0.05$) by amputation level (Table 3) and remained statistically significant after Benjamini–Hochberg adjustments. Persons with TR amputation had the best dexterity, followed persons with TH and SH amputation. Three measures of activity performance, the AM-UL, BAM-ULA, and T-MAP were significantly different by amputation level after Benjamini–Hochberg adjustment (Table 3). Those with TR amputation had the best scores for all three measures of activity.

Unilateral versus bilateral amputation

Those with bilateral amputation had better dexterity scores of all measures as compared to those with unilateral amputation, and differences remained significant after adjustment for multiple comparisons (Table 3). Those with unilateral amputation had faster ($p = 0.003$) T-MAP scores (mn 4.8) than those with bilateral amputation (8.9) even after adjustment for multiple activity measure comparisons (Table 3). Those with bilateral amputation had better CRIS-CAT scores on the extent of limitation subscale ($p = 0.048$), though this difference was no longer significant after correction for multiple comparisons. Normative values by age group are shown in Appendix.

Comparison of outcomes of persons with and without upper limb amputation

Table 4 provides comparative data to contextualize the magnitude of outcome impairment. In summary, the sub-group of persons with unilateral TR amputation ages 18–44 had JTHF scores that were 0.09–0.62 times that of unimpaired males aged 20–55. The subsample with TR unilateral amputation aged 45–64 had 0.07–0.97 times the JTHF scores of unimpaired males aged 60–69. The subsample of TRs who were 65 years or older had 0.05–0.82 times the JTHF scores of unimpaired males aged 70–89. The least amount of impairment across all age categories was in the writing

Table 2. Demographics and prosthesis characteristics of participants by amputation level ($N = 127$).

	Unilateral amputation ($N = 112$)				Bilateral amputation ($N = 15$)	All ($N = 127$)
	WD/TR ($N = 75$) Mn (SD)	ED/TH ($N = 32$) Mn (SD)	SH/FQ ($N = 5$ Mn (SD)	Total ($N = 112$) Mn (SD)	Mn (SD)	Mn (SD)
Age (years)	56.6 (17.3)	57.1 (16.3)	55.1 (23.4)	56.7 (17.1)	58.5 (10.7)	56.9 (16.5)
Years since amputation	24.2 (19.7)	18.5 (16.1)	23.3 (23.6)	22.5 (18.9)	23.1 (18.8)	22.6 (18.9)
Prosthesis weight (lbs)	3.2 (1.6)	5.2 (2.5)	6.9 (2.9)	3.9 (2.2)	4.1 (2.6)	3.9 (2.3)
	N (%)	*N* (%)	*N* (%)	*N* (%)	*N* (%)	*N* (%)
Age category						
$18 \leq$ age < 45	22 (29.3)	5 (15.6)	2 (40.0)	29 (25.9)	2 (13.3)	31 (24.4)
$46 \leq$ age < 65	20 (26.7)	16 (50.0)	0 (0.0)	36 (32.1)	9 (60.0)	45 (35.4)
$66 \leq$ age < 75	26 (34.7)	10 (31.3)	3 (60.0)	39 (34.8)	4 (26.7)	43 (33.9)
75+	7 (9.3)	1 (3.1)	0 (0.0)	8 (7.1)	0 (0.0)	8 (6.3)
Gender						
Male	73 (97.3)	31 (96.9)	5 (100.0)	109 (97.3)	14 (93.3)	123 (96.9)
Female	2 (2.7)	1 (3.1)	0 (0.0)	3 (2.7)	1 (6.7)	4 (3.2)
Race						
White	58 (77.3)	20 (62.5)	5 (100.0)	83 (74.1)	12 (80.0)	95 (74.8)
Black	8 (10.7)	5 (15.6)	0 (0.0)	13 (11.6)	1 (6.7)	14 (11.0)
Mixed/other	9 (12.0)	7 (21.9)	0 (0.0)	16 (14.3)	2 (13.3)	18 (14.2)
Ethnicity						
Hispanic	8 (10.7)	7 (21.9)	0 (0.0)	15 (13.4)	1 (6.7)	16 (12.6)
Not Hispanic	63 (84.0)	25 (78.1)	5 (100.0)	93 (83.0)	14 (93.3)	107 (84.3)
Unknown	4 (5.3)	0 (0.0)	0 (0.0)	4 (3.6)	0 (0.0)	4 (3.2)
Employment status[a]						
Employed full-time	15 (20.0)	6 (18.8)	0 (0.0)	21 (18.8)	1 (6.7)	22 (17.3)
Employed part-time	2 (2.7)	2 (6.3)	0 (0.0)	4 (3.6)	1 (6.7)	5 (3.9)
Student	2 (2.7)	4 (12.5)	0 (0.0)	6 (5.4)	0 (0.0)	6 (4.7)
Retired, employed after amputation	30 (40.0)	10 (31.3)	1 (20.0)	41 (36.6)	5 (33.3)	46 (36.2)
Retired, not employed after amputation	9 (12.0)	3 (9.4)	2 (40.0)	14 (12.5)	4 (26.7)	18 (14.2)
Medical leave	1 (1.3)	2 (6.3)	1 (20.0)	4 (3.6)	3 (20.0)	7 (5.5)
Unknown	16 (21.3)	5 (15.6)	1 (20.0)	22 (19.6)	1 (6.7)	23 (18.1)
Military status						
Active duty	2 (2.7)	0 (0.0)	0 (0.0)	2 (1.8)	0 (0.0)	2 (1.6)
Veteran	66 (88.0)	28 (87.5)	5 (100.0)	99 (88.4)	9 (60.0)	108 (85.0)
Civilian	7 (9.3)	4 (12.5)	0 (0.0)	11 (9.8)	6 (40.0)	17 (13.4)
Etiology of amputation[a]						
Congenital	3 (13.0)	0 (0.0)	0 (0.0)	3 (8.6)	1 (10.0)	4 (8.9)
Combat	27 (44.3)	8 (29.6)	1 (25.0)	36 (39.1)	2 (14.3)	38 (35,9)
Accident	30 (49.2)	15 (55.6)	4 (100.0)	49 (53.3)	9 (64.3)	58 (54.7)
Burn	4 (6.6)	2 (7.4)	0 (0.0)	6 (6.5)	4 (28.6)	10 (9.4)
Cancer	4 (6.6)	1 (3.7)	0 (0.0)	5 (5.4)	0 (0.0)	5 (4.7)
Diabetes	1 (1.6)	0 (0.0)	0 (0.0)	1 (1.1)	0 (0.0)	1 (0.9)
Infection	8 (13.1)	4 (14.8)	0 (0.0)	12 (13.0)	3 (21.4)	15 (14.2)
Prosthesis type						
Body powered	45 (60.0)	18 (56.3)	2 (40.0)	65 (58.0)	10 (66.7)	75 (59.1)
Myoelectric single DOF terminal device	12 (16.0)	9 (28.1)	2 (40.0)	23 (20.5)	4 (26.7)	27 (21.3)
Myoelectric multi-DOF terminal device	18 (24.0)	5 (15.6)	1 (20.0)	24 (21.4)	1 (6.7)	25 (19.7)
Terminal device type						
Body-powered hook	45 (60.0)	18 (56.3)	2 (40.0)	65 (58.0)	10 (66.7)	75 (59.1)
Externally powered prehensors	7 (9.3)	5 (15.6)	1 (20.0)	13 (11.6)	3 (20.0)	16 (12.6)
Multi-DOF Myo hand	18 (24.0)	5 (15.6)	1 (20.0)	24 (21.4)	1 (6.7)	25 (19.7)
Single-DOF Myo hand	5 (6.7)	4 (12.5)	1 (20.0)	10 (8.9)	1 (6.7)	11 (8.7)
Receipt of any training to use current prosthesis						
Yes	20 (26.7)	6 (18.8)	1 (20.0)	27 (24.1)	6 (40.0)	33 (26.0)
No	55 (73.3)	26 (81.3)	4 (80.0)	85 (75.9)	9 (60.0)	94 (74.0)

[a]Etiology of amputation: respondents could indicate multiple etiologies.

task. All three subgroups, by age, of subjects with TR amputation had 0.20–0.26 the Box and Blocks scores compared to unimpaired male groups (left or right hands, approximately same age groups). The youngest group with TR amputation had NHP scores 0.08 of age matched norms, and older sub-groups scores were 0.11–0.16 that of age matched norms. The average SHAP IOF scores of those with TR amputation was 0.43–0.44 times that of unimpaired males, with little difference in age sub-group.

Compared to normative values [34], those with TR amputation aged 18–44 have 3.94 times the QuickDASH scores as unimpaired aged 20–49 (higher scores indicate greater disability). Persons with TR amputation aged 45–64 and 65+ had 2.52 and 1.49 times higher QuickDASH scores as unimpaired males aged 50–69 and 70+, respectively, demonstrating that the magnitude of disability is greater for younger persons with TR amputation. Compared to age-matched normative samples, those with TR amputation had 1.11–1.27 greater MCS scores. PCS scores in our sample were higher than age matched norms in the persons ages 18–44 and 45–64 (1.17 and 1.40, respectively), but lower 0.91 in the group 65 and older. Our sample with TR amputation aged 18–44 and 45–65 had 0.81–0.92 times the CRIS-CAT scores than the normative comparison group, indicating worse community integration.

Outcomes by prosthesis type

Comparison of dexterity measures by amputation level (unilateral and bilateral amputation groups combined) (Table 5) revealed significant differences by prosthesis type for those with TR

Table 3. Outcomes by amputation laterality, amputation level.

	Unilateral amputation ($N = 112$)				All amputation ($N = 127$)		
	WD/TR ($N = 75$) Mn (SD)	ED/TH ($N = 32$) Mn (SD)	SH/FQ ($N = 5$) Mn (SD)	Kruskal–Wallis p Value	Unilateral ($N = 112$) Mn (SD)	Bilateral ($N = 15$) Mn (SD)	WMW p Value
Dexterity measures							
JTHFT							
Writing	0.48 (0.29)	0.26 (0.22)	0.13 (0.14	**0.0004***	0.41 (0.29)	0.86 (0.23)	**<0.0001***
Page turning	0.13 (0.09)	0.05 (0.05)	0.01 (0.02)	**<0.0001***	0.10 (0.09)	0.26 (0.16)	**<0.0001***
Small objects	0.10 (0.08)	0.04 (0.05)	0.01 (0.02)	**<0.0001***	0.08 (0.08)	0.22 (0.15)	**<0.0001***
Eating	0.17 (0.11)	0.07 (0.07)	0.00 (0.00)	**<0.0001***	0.13 (0.11)	0.22 (0.10)	**0.0021***
Checkers	0.09 (0.07)	0.05 (0.06)	0.01 (0.01)	**0.0004***	0.07 (0.07)	0.20 (0.14)	**0.0001***
Light cans	0.22 (0.13)	0.10 (0.08)	0.06 (0.01)	**<0.0001***	0.18 (0.13)	0.40 (0.25)	**0.0005***
Heavy cans	0.22 (0.16)	0.09 (0.10)	0.07 (0.04)	**<0.0001***	0.18 (0.15)	0.39 (0.23)	**0.0002***
Box and Blocks	17.2 (8.4)	8.2 (8.1)	0.8 (1.8)	**<0.0001***	13.9 (9.5)	25.7 (7.5)	**<0.0001***
9-Hole peg	0.05 (0.05)	0.02 (0.04)	0.0 (.)	**0.0205***	0.04 (0.05)	0.13 (0.07)	**<0.0001***
SHAP IOF	41.4 (18.3)	11.3 (13.9)	0.6 (1.3)	**<0.0001***	31.0 (22.4)	46.2 (21.2)	**<0.0001***
Activity measures							
AM-ULA	15.3 (6.0)	11.4 (5.2)	9.1 (6.5)	**0.0006***	13.9 (6.1)	15.4 (6.9)	0.3659
BAM-ULA	7.3 (2.1)	4.2 (2.8)	.	**0.0027***	6.8 (2.5)	8.4 (1.5)	0.1155
T-MAP (min)	4.5 (1.6)	5.5 (2.3)	.	0.0829*	4.8 (1.8)	8.9 (4.5)	**0.0027***
Prosthesis satisfaction							
TAPES	3.9 (0.7)	3.6 (0.7)	2.7 (1.5)	0.0538	3.8 0.8)	3.9 (0.7)	0.5800
Disability, HRQoL, and community integration							
QuickDASH	28.8 (18.4)	31.8 (17.7)	30.0 (19.0)	0.7263	29.7 (18.1)	30.1 (15.6)	0.7514
VR-12 MCS	52.1 (11.1)	50.9 (12.7)	53.9 (8.0)	0.8073	51.8 (11.4)	54.7 (7.2)	0.5958
VR-12 PCS	39.3 (8.7)	38.2 (11.4)	31.6 (13.5)	0.4089	38.6 (9.8)	39.7 (11.5)	0.6115
CRIS-CAT extent	49.1 (9.0)	47.9 (9.4)	46.1 (10.1)	0.6520	48.6 (9.1)	53.6 (7.7)	**0.0482**
CRIS-CAT perceived	49.0 (7.4)	47.2 (6.0)	44.0 (5.3)	0.1838	48.3 (7.0)	51.2 (9.0)	0.1873
CRIS-CAT satisfaction	50.3 (9.3)	46.6 (5.6)	46.8 (9.0)	0.1543	49.1 (8.5)	52.3 (10.8)	0.2771
	N (%)	*N* (%)	*N* (%)	Exact p	*N* (%)	*N* (%)	Exact p
Need for ADL help	12 (22.6)	6 (25.0)	2 (50.0)	1.0000	20 (24.7)	7 (58.3)	**0.0353**

*Significant after Benjamini–Hochberg adjustment with false discovery rate = 0.1. Bold values are those that are statistically significant at $p < 0.05$.

amputation in the JTHF small objects tasks ($p < 0.05$), Box and Blocks ($p < 0.05$), and the NHP test ($p < 0.001$). Differences in Box and Blocks and NHP remained after correction for multiple comparisons. For the TH group, statistically significant differences were observed before ($p < 0.05$), but not after adjustment for multiple comparison, by prosthesis type for JTHF small objects and NHP test. In all cases, body powered users had the best dexterity scores.

Comparisons of outcomes for persons with unilateral amputation only found similar patterns in differences in dexterity scores (Table 6). Significant differences in dexterity were observed in the TR group by device type for JTHF small objects and heavy cans ($p < 0.05$), and for NHP ($p < 0.001$). Only NHP differences remained after adjustment for multiple comparisons. In the TH group, significant differences were observed before and after adjustment for multiple comparisons in JTHF small objects and NHP. In all cases, those using BP devices had better dexterity scores.

Activity measures differed significantly by prothesis type before and after adjustment for multiple comparisons in the TR group for the BAM-ULA ($p < 0.01$), with body-powered users completing the fewest BAM-ULA items. No differences in activity scores by prosthesis type were observed for the TH group. TAPES satisfaction scores did not differ by prothesis type. Among the remaining measures, the CRIS-CAT perceived limitations scores in the TR group showed significant differences by prothesis type after adjustment for multiple comparisons. No differences in QuickDASH or VR-12 scores were observed. A greater proportion of TR and TH participants who used myoelectric single-DOF devices reported needing assistance with everyday activities as compared to other groups, but these differences were not statistically significant.

Comparisons of outcomes of unilateral and bilateral amputation groups by prosthesis type

Comparisons of participants with bilateral and unilateral TR amputation who used body-powered devices found significant differences in all dexterity measures except the SHAP ($p < 0.01$) (Appendix, Table A3). Dexterity was better for those with bilateral amputation as compared to unilateral amputation in all cases. When adjusted for multiple comparisons, all measures, including the SHAP IOF were statistically significantly different for groups with unilateral and bilateral amputation. Additionally, those with bilateral amputation completed significantly more BAM-ULA items than those with unilateral amputation, even after adjustment for multiple comparisons. No measures of satisfaction, disability, HRQoL, or community integration differed significantly for persons with unilateral and bilateral amputation using body powered devices.

Discussion

This study reported normative values for dexterity, activity performance, prosthesis satisfaction disability, HRQoL, and community integration in persons with ULA by amputation level and prosthesis type. This work builds on prior observational studies that reported on many of the same outcome measures by amputation level, but did not compare outcomes by device type [25–27,33,35]. Findings confirm results reported in earlier studies that dexterity, as measured by standardized tests, is significantly impaired in upper limb prosthesis users and that impairment is greater in prosthesis users with more proximal level limb loss.

We compared normative data on activity performance by amputation level but were unable to compare activity scores to

Table 4. Outcomes of unilateral TR amputation group and normative values of standardized tests.

	Unimpaired males[c]			TR unilateral amputations (prothesis side)		
	Age group	Side	Mn	Age group	Mn	Ratio of scores
JTHFT (item/s)						
Writing	20–59	NonDom	0.74[a]	18–44	0.46	0.62
Writing	60–69	NonDom	0.66[a]	45–64	0.64	0.97
Writing	70–89	NonDom	0.50[a]	65+	0.41	0.82
Page turning	20–59	NonDom	0.90[a]	18–44	0.11	0.12
Page turning	60–69	NonDom	1.14[a]	45–64	0.17	0.15
Page turning	70–89	NonDom	1.40[a]	65+	0.12	0.09
Small objects	20–59	NonDom	1.03[a]	18–44	0.10	0.10
Small objects	60–69	NonDom	1.25[a]	45–64	0.09	0.07
Small objects	70–89	NonDom	1.35[a]	65+	0.10	0.07
Eating	20–59	NonDom	1.58[a]	18–44	0.15	0.09
Eating	60–69	NonDom	1.85[a]	45–64	0.19	0.10
Eating	70–89	NonDom	2.05[a]	65+	0.16	0.08
Checkers	20–59	NonDom	0.95[a]	18–44	0.12	0.13
Checkers	60–69	NonDom	1.37[a]	45–64	0.09	0.07
Checkers	70–89	NonDom	1.47[a]	65+	0.07	0.05
Light cans	20–59	NonDom	0.64[a]	18–44	0.27	0.42
Light cans	60–69	NonDom	0.79[a]	45–64	0.24	0.30
Light cans	70–89	NonDom	0.97[a]	65+	0.18	0.19
Heavy cans	20–59	NonDom	0.62[a]	18–44	0.26	0.42
Heavy cans	60–69	NonDom	0.81[a]	45–64	0.24	0.30
Heavy cans	70–89	NonDom	0.95[a]	65+	0.18	0.19
Box and Blocks	20–44	Left	82.4	18–44	16.9[b]	0.21
Box and Blocks	45–64	Left	74.4	45–64	19.3[b]	0.26
Box and Blocks	65+	Left	64.4	65+	16.0[b]	0.25
Box and Blocks	20–44	Right	84.1	18–44	16.9[b]	0.20
Box and Blocks	45–64	Right	75.7	45–64	19.3[b]	0.25
Box and Blocks	65+	Right	66.0	65+	16.0[b]	0.24
Nine hole peg (item/s)	21–45	Left	0.50[a]	18–44	0.04[b]	0.08
Nine hole peg (item/s)	46–65	Left	0.44[a]	45–64	0.07[b]	0.16
Nine hole peg (item/s)	66+	Left	0.37[a]	65+	0.04[b]	0.11
Nine hole peg (item/s)	21–45	Right	0.52[a]	18–44	0.04[b]	0.08
Nine hole peg (item/s)	46–65	Right	0.46[a]	45–64	0.07[b]	0.15
Nine hole peg (item/s)	66+	Right	0.37[a]	65+	0.04[b]	0.11
SHAP IOF	18–45	Not specified	98.8	18–44	42.9	0.43
SHAP IOF	46–65	Not specified	98.0	45–64	43.6	0.44
SHAP IOF	66–75	Not specified	92.0	65+	39.1	0.43
QuickDASH	20–49	Not applicable	8.0	18–44	31.5	3.94
QuickDASH	50–69	Not applicable	11.5	45–64	28.9	2.52
QuickDASH	70+	Not applicable	18.0	65+	26.8	1.49
VR12 MCS	18–44	Not applicable	38.3	18–44	48.1	1.25
VR12 MCS	45–64	Not applicable	38.8	45–64	49.3	1.27
VR12 MCS	65+	Not applicable	50.9	65+	56.5	1.11
VR12 PCS	18–44	Not applicable	35.3	18–44	41.3	1.17
VR12 PCS	45–64	Not applicable	28.9	45–64	40.4	1.40
VR12 PCS	65+	Not applicable	40.7	65+	37.2	0.91
CRIS-CAT extent	25–60	Not applicable	55.8	18–44	45.4	0.81
CRIS-CAT extent	25–60	Not applicable	55.8	45–64	48.5	0.87
CRIS-CAT perceived	25–60	Not applicable	56.6	18–44	48.1	0.85
CRIS-CAT perceived	25–60	Not applicable	56.6	45–64	48.2	0.85
CRIS-CAT satisfaction	25–60	Not applicable	54.9	18–44	47.9	0.87
CRIS-CAT satisfaction	25–60	Not applicable	54.9	45–64	50.4	0.92

[a]Calculation of average items/s is not mathematically exact – instead we use the maximum items possible/average time.
[b]Prosthetic side tested.
[c]Used only male data when possible (some studies are a mostly male mix).

unimpaired persons. Although it would be inappropriate to compare scores of the AM-ULA to unimpaired persons because it is an amputation-specific measure, we can compare our findings to those previously reported. An earlier study with a smaller ($N = 46$) and younger (mean age 45.8 ± 16.5) sample reported AM-ULA scores of 19–22 for those with TR amputation and 14–16 for those with TH amputation [25]. The lower AM-ULA scores we observed in the current study (TR mn 15.8, TH mn 11.4) may be explained by differences in age as our sample was older (mn 56.7 vs. 45.8), proportion of Veterans in the samples, or by unobserved differences in health of the samples. Normative values of the T-MAP and BAM-ULA which, in theory, could be comparable because the scoring is not amputation specific, are not yet available. BAM-ULA scores in the current study (TR mn 7.3, TH 4.2) were roughly equivalent to that reported by Resnik et al. (mn 6.3) in a sample consisting of 57% TR and 37% TH amputation [26]. T-MAP values reported in the current study (TR mn 4.5, TH mn 5.5) were faster than earlier reported values (mn 6.2 min) [27]. However, the earlier study did not stratify scores by amputation level and included 27 TR and 21 TH amputees [27].

QuickDASH scores confirm that ULA results in significant disability, and disability is greater for those with more proximal amputation levels [36–38]. The ratio of QuickDASH scores compared to normative values differed by age group; those in the

Table 5. Dexterity outcomes by amputation level and device type (all subjects; bilateral amputation classified by dominant side).

	Transradial				Transhumeral			
	Body powered ($N = 53$) Mn (SD)	Myo-single DOF ($N = 15$) Mn (SD)	Myo multi-DOF ($N = 19$) Mn (SD)	K–W p	Body powered ($N = 20$) Mn (SD)	Myo-single DOF ($N = 10$) Mn (SD)	Myo multi-DOF ($N = 5$) Mn (SD)	K–W p
Dexterity								
JTHF								
Writing	0.56 (0.33)	0.47 (0.27)	0.53 (0.29)	0.5301	0.38 (0.35)	0.23 (0.20)	0.25 (0.17)	0.6274
Page turning	0.17 (0.13)	0.15 (0.09)	0.12 (0.07)	0.2945	0.07 (0.06)	0.04 (0.07)	0.04 (0.04)	0.2432
Small objects	0.13 (0.11)	0.12 (0.12)	0.08 (0.09)	**0.0176**	0.07 (0.06)	0.03 (0.06)	0.02 (0.02)	**0.0110**
Eating	0.19 (0.11)	0.17 (0.13)	0.13 (0.09)	0.1275	0.09 (0.09)	0.07 (0.08)	0.04 (0.04)	0.4514
Checkers	0.09 (0.08)	0.13 (0.14)	0.12 (0.08)	0.2988	0.07 (0.07)	0.05 (0.07)	0.03 (0.03)	0.7279
Light cans	0.25 (0.19)	0.23 (0.12)	0.27 (0.15)	0.6802	0.14 (0.11)	0.09 (0.10)	0.11 (0.05)	0.3597
Heavy cans	0.25 (0.22)	0.27 (0.12)	0.25 (0.13)	0.2398	0.09 (0.10)	0.09 (0.10)	0.15 (0.08)	0.2419
Box and Blocks	20.6 (9.2)	15.1 (9.1)	15.4 (6.0)	**0.0209***	11.8 (9.8)	5.2 (5.7)	7.6 (6.5)	0.2118
9 hole peg	0.07 (0.06)	0.06 (0.06)	0.01 (0.01)	**0.0001***	0.05 (0.06)	0.01 (0.03)	0.00 (0.00)	**0.0312**
SHAP IOF	44.0 (19.6)	41.0 (21.1)	39.6 (14.8)	0.5697	14.4 (15.3)	10.8 (16.6)	12.8 (12.7)	0.6742

*Significant after Benjamini–Hochberg adjustment with false discovery rate = 0.1. Bold values in this table indicate values statistically significant at $p < 0.05$.

youngest age group reported disability scores that were relatively worse than those in the older age groups. Whereas, scores of MCS and PCS, both measures of HRQoL were not impaired in our sample as compared to age-matched norms except among those aged 65 and over. In fact, it appears that participants in our sample rated their overall mental health (MCS) higher in all age groups, and their physical related HRQoL (PCS) higher than age matched norms in the groups under ages 65. The reasons for these differences should be explored in future research. Our comparison groups came from a single large study [30].

Our study failed to find statistically significant differences in dexterity or activity performance by prosthesis type. This may be because our measures lack sensitivity to subtle differences, or because other factors are confounding this relationship and need to be accounted for when making direct comparisons. It is also possible that prosthesis type is not associated with these outcomes. Future, larger studies will be needed to examine these factors. Future studies may also explore the impact of prosthesis weight on satisfaction.

An interesting finding was that dexterity was significantly better for those who had bilateral amputation as compared to those who had unilateral amputation. This suggests that increased prosthesis engagement, as would be expected in persons with bilateral amputation, results in better prosthetic function. Persons with bilateral amputation, however, did have worse scores on measures of ADL performance with a higher proportion requiring assistance with ADL.

Limitations

Our study utilized a convenience sample and consisted predominantly of Veterans. Thus, there are limits to the generalizability of findings to the entire civilian population. Although our study was one of the largest outcome studies of persons with ULA to date, the sample sizes in some subgroups (e.g., SH disarticulation and interscapulothoracic amputation; myoelectric single and multi-DOF device users, particularly at the TH level) were small, and this likely affected the precision of our estimates, and resulted in underpowered comparisons. Further research is needed to accrue larger samples and generate more precise estimates of normative values by prosthesis type and level. Our sample was limited to prosthesis users with amputation at the wrist or above. Findings are not generalizable to prosthesis users with partial hand amputation. Future research is needed to understand dexterity, activity performance, prosthesis satisfaction disability, HRQoL, and community integration of persons with partial hand amputation.

Our analyses of the impact of prosthesis type compared outcomes by amputation level but did not attempt to adjust for other factors which could potentially confound outcomes; including experience with prosthesis use and training to use the device. Although we believe that these factors should be examined in future work, the vast majority of participants in our study had been using their prostheses for many years because participants had, on average, had their amputation for more than 20 years. However, only 26% of our sample reported that they had received training to use the prosthesis that they used in testing. We did not collect data on receipt of initial prosthesis training during our in-person data collection. There are limits to the interpretability of our findings based on study design, as our subjects were not randomly assigned to their prosthesis configuration. Instead, devices had been prescribed and/or selected based on personal preferences and needs. It is possible that persons with lower levels of function are prescribed more complex devices with the expectation that they would receive the most benefit from them, or more simple devices that are easier to learn and control. Future studies which follow subjects who transition from one type of a prosthesis to another are needed.

Not all possible relationships were deemed to be in the scope of this investigation. Although we compared prosthesis type, we did not conduct more granular analyses of the impact of myoelectric terminal device type (single DOF vs. multi-DOF), due to small sample sizes. Although, we grouped all body powered terminal devices together, we acknowledge that there may be differences between types of body powered terminal devices that we were not able to discern. Our study did not have a sufficient number of participants who were using voluntary closing terminal devices, or prehensors to enable comparisons. We did not attempt to compare makes or brands of terminal devices within the categories of single and multi-DOF myoelectric devices, because of small sample sizes. Future studies, which include larger numbers of subjects would be needed to make robust comparisons. However, these studies will likely face the challenge of recruiting the needed participation, due to the relative rarity of upper limb and SH amputations. Furthermore, our study did not examine prosthesis characteristics, such as weight, or other factors associated with device satisfaction or wear time. However, prosthesis weight is included in Table 2. Such data are needed to understand drivers of satisfaction.

Table 6. Functional and self-report outcomes by amputation level and device type (unilateral amputation group only).

	Transradial				Transhumeral			
	Body powered ($N = 45$)	Myo-single DOF ($N = 12$)	Myo multi-DOF ($N = 18$)	K–W	Body powered ($N = 18$)	Myo-single DOF ($N = 9$)	Myo multi-DOF ($N = 5$)	K–W
	Mn (SD)	Mn (SD)	Mn (SD)	*p*	Mn (SD)	Mn (SD)	Mn (SD)	*p*
Dexterity								
JTHF								
Writing	0.49 (0.30)	0.41 (0.26)	0.52 (0.30)	0.4274	0.29 (0.26)	0.21 (0.20)	0.25 (0.17)	0.8279
Page turning	0.13 (0.09)	0.14 (0.10)	0.12 (0.07)	0.8182	0.06 (0.05)	0.02 (0.03)	0.04 (0.04)	0.1505
Small objects	0.11 (0.07)	0.11 (0.11)	0.07 (0.09)	**0.0288**	0.07 (0.06)	0.01 (0.02)	0.02 (0.02)	**0.0053***
Eating	0.18 (0.12)	0.17 (0.14)	0.14 (0.09)	0.4160	0.08 (0.09)	0.05 (0.06)	0.04 (0.04)	0.5489
Checkers	0.08 (0.06)	0.08 (0.09)	0.12 (0.08)	0.0957	0.06 (0.07)	0.03 (0.05)	0.03 (0.03)	0.5968
Light cans	0.20 (0.13)	0.22 (0.11)	0.28 (0.15)	0.2995	0.12 (0.09)	0.06 (0.07)	0.11 (0.05)	0.2330
Heavy cans	0.20 (0.17)	0.26 (0.12)	0.25 (0.14)	**0. 0481**	0.08 (0.11)	0.08 (0.09)	0.15 (0.08)	0.1519
Box and Blocks	19.00 (8.73)	14.27 (7.88)	15.28 (6.19)	0.0645	10.53 (9.34)	4.00 (4.47)	7.60 (6.50)	0.2154
9 hole peg	0.06 (0.05)	0.06 (0.06)	0.01 (0.01)	**0.0008***	0.04 (0.04)	0.00 (0.00)	0.00 (0.00)	**0.0194***
SHAP IOF	42.4 (18.4)	39.3 (23.1)	40.2 (15.0)	0.8298	13.4 (16.2)	6.6 (10.3)	12.8 (12.7)	0.5407
Activity measures								
AM-ULA	14.9 (5.3)	14.9 (7.7)	16.4 (6.5)	0.6800	12.3 (6.2)	9.4 (4.2)	11.9 (1.8)	0.2335
BAM-ULA	6.6 (2.1)	9.2 (1.0)	8.0 (1.6)	**0.0023***	4.5 (3.4)	4.0 (.)	3.5 (0.7)	0.8307
T-MAP (min)	5.0 (1.8)	3.9 (0.6)	3.9 (0.9)	0.0810	4.6 (1.7)	4.9 (1.2)	7.4 (3.0)	0.1824
Prosthesis satisfaction								
TAPES	4.0 (0.7)	3.5 (0.7)	3.8 (0.7)	0.0514	3.7 (0.9)	3.5 (0.5)	3.7 (0.5)	0.6402
Disability, HRQoL, and community integration								
QuickDASH	29.2 (19.4)	30.9 (15.8)	26.3 (18.1)	0.7196	34.0 (20.7)	28.2 (13.8)	30.5 (13.3)	0.8488
VR-12 MCS	53.5 (10.1)	46.3 (12.8)	52.4 (11.5)	0.0854	50.4 (13.1)	50.6 (14.6)	52.9 (9.4)	0.9820
VR-12 PCS	37.5 (8.9)	43.2 (6.9)	41.1 (8.2)	0.0854	34.7 (13.2)	41.9 (5.6)	44.0 (8.1)	0.1719
CRIS-CAT extent	50.1 (8.7)	44.6 (9.6)	49.5 (8.8)	0.2424	45.4 (8.3)	50.1 (10.9)	53.2 (8.6)	0.1312
CRIS-CAT perceived	49.4 (6.8)	44.3 (4.7)	51.1 (9.1)	**0.0333**	46.2 (5.0)	48.3 (7.1)	48.8 (7.9)	0.8735
CRIS-CAT satisfaction	51.2 (9.2)	46.9 (7.7)	50.2 (10.5)	0.3651	45.6 (4.9)	47.9 (5.8)	47.7 (7.9)	0.5518
	N (%)	*N* (%)	*N* (%)	exact p	*N* (%)	*N* (%)	*N* (%)	exact p
Need for ADL help	7 (21.2)	3 (37.5)	2 (16.7)	0.5738	3 (25.0)	2 (28.6)	1 (20.0)	1.0000

*Significant after Benjamini–Hochberg adjustment with false discovery rate = 0.1. Bold values in this table indicate values statistically significant at $p < 0.05$.

Responsiveness of the prostheses was not independently measured but rather subsumed in dexterity measures. Dexterity, in this context, results from the speed or responsiveness of prosthesis movement, the grip options, the shape of the prosthesis terminal device, and the need to switch between grips or other movements to orient the terminal device to perform an activity. Another worthy topic outside the scope of this study is whether any particular componentry or prosthetic model offers notable benefits or limitations compared to others in the same class.

Our comparisons of normative data for those with TR amputation to unimpaired samples was limited by the data available in current literature. Not all age groups matched perfectly. We did not find age-stratified nondominant hand data for the SHAP, thus some of the difference between those with TR amputation and the unimpaired sample may be due to use of a dominant hand. Non-dominant hand data were also not available for the Box and Block or NHP tests; however. we were able to compare to both left- and right-hand data for unimpaired groups. It was not possible to identify age-grouped data in a completely male sample for the VR-12, so some bias by gender may exist given that only 3% of our sample were women. Calculations of JTHF and NHP average items/second were not mathematically exact – instead we had to use the maximum items completed divided by the average times taken. However, given the low variance in reported times for unimpaired samples, we believe our comparisons to those with TR amputation are accurate.

Conclusions

This study estimated normative values by amputation level for standardized measures of dexterity, activity performance, disability, HRQoL, and community integration and estimated magnitude of impairment of these outcomes. We found that dexterity is markedly impaired in prosthesis users with ULA and that there is substantial upper limb related disability at all levels of ULA. Persons with more proximal amputation levels are most impacted. In contrast, HRQoL of life and community participation appear to be less impacted and more equivalent to that of unimpaired

persons. Furthermore, this study estimated normative values for three prosthesis configurations (body-powered, myoelectric with single DOF terminal, and myoelectric devices with multi-DOF terminal devices) by amputation level. These data may inform clinicians and researchers and help them create benchmarks for these standardized measures by amputation level and prosthesis types.

This study did not detect differences in dexterity, activity performance, disability, HRQoL, or community integration by overall type of prosthesis used, suggesting that that more complex, expensive devices (such as myoelectric multi-DOF terminal devices) do not offer clear advantages for the average person with ULA. Further research with larger sample sizes or different designs, is needed to confirm or refute these findings, to explore whether there are differences by specific terminal device brands or functionality, and to determine how best to match prosthesis type to person based on individual characteristics.

Disclosure statement

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Appendix

Table A1. Normative values for transradial and transhumeral unilateral amputation by age category.

	Unilateral amputation WD/TR			Unilateral amputation ED/TH		
	(*N* = 75)			(*N* = 32)		
	18 to <45 (*N* = 22) Mn (SD)	45 to <65 (*N* = 20) Mn (SD)	65+ (*N* = 33) Mn (SD)	18 to <45 (*N* = 5) Mn (SD)	45 to <65 (*N* = 16) Mn (SD)	65+ (*N* = 11) Mn (SD)
Dexterity measures						
JTHFT						
Writing	0.46 (0.23)	0.64 (0.35)	0.41 (0.26)	0.11 (0.16)	0.30 (0.22)	0.29 (0.24)
Page turning	0.11 (0.07)	0.17 (0.08)	0.12 (0.10)	0.03 (0.05)	0.06 (0.05)	0.05 (0.05)
Small objects	0.10 (0.10)	0.09 (0.07)	0.10 (0.08)	0.02 (0.02)	0.04 (0.05)	0.06 (0.06)
Eating	0.15 (0.10)	0.19 (0.12)	0.16 (0.12)	0.05 (0.05)	0.05 (0.07)	0.10 (0.09)
Checkers	0.12 (0.08)	0.09 (0.07)	0.07 (0.05)	0.06 (0.10)	0.05 (0.06)	0.04 (0.03)
Light cans	0.27 (0.10)	0.25 (0.15)	0.18 (0.13)	0.05 (0.08)	0.10 (0.08)	0.12 (0.09)
Heavy cans	0.26 (0.12)	0.24 (0.16)	0.18 (0.17)	0.05 (0.04)	0.12 (0.11)	0.08 (0.09)
Box and Blocks	16.9 (6.9)	19.3 (8.2)	16.0 (9.3)	3.6 (4.4)	7.7 (7.3)	10.9 (9.8)
9-Hole peg	0.04 (0.04)	0.07 (0.05)	0.04 (0.05)	0.02 (0.04)	0.02 (0.04)	0.03 (0.03)
SHAP IOF	42.9 (15.5)	43.6 (20.1)	39.1 (19.1)	5.8 (8.8)	13.0 (12.9)	11.3 (17.2)
Activity measures						
AM-ULA	19.0 (6.5)	16.6 (6.6)	13.2 (5.2)	11.8 (5.0)	11.3 (6.1)	11.3 (4.9)
BAM-ULA	8.5 (1.6)	7.6 (2.3)	6.3 (1.7)	8.0 (.)	2.8 (1.9)	4.8 (3.0)
T-MAP (min)	4.0 (1.0)	4.3 (2.1)	5.1 (1.3)	5.5 (0.9)	5.9 (2.7)	3.2 (0.5)
Prosthesis satisfaction						
TAPES	3.8 (0.8)	3.7 (0.7)	4.0 (0.7)	3.8 (0.8)	3.7 (0.8)	3.5 (0.7)
Disability, HRQOL and community integration						
QuickDASH	31.5 (18.3)	28.9 (18.8)	26.8 (18.5)	31.6 (19.4)	31.6 (18.3)	32.3 (17.8)
VR-12 MCS	50.0 (13.7)	51.2 (13.0)	59.2 (6.0)	45.8 (13.6)	54.2 (10.8)	50.1 (16.6)
VR-12 PCS	44.2 (8.6)	43.4 (7.2)	40.9 (8.3)	44.8 (12.3)	41.9 (11.6)	39.1 (12.3)
VR-12 MCS imputed	48.1 (13.3)	49.3 (12.8)	56.5 (5.8)	48.8 (14.2)	52.2 (10.4)	49.8 (15.9)
VR-12 PCS imputed	41.3 (8.6)	40.4 (7.2)	37.2 (9.3)	41.5 (10.0)	38.5 (11.9)	36.2 (11.7)
CRIS-CAT extent	45.4 (10.7)	48.5 (9.6)	52.0 (6.1)	44.9 (13.4)	48.2 (9.1)	48.9 (8.4)
CRIS-CAT perceived	48.1 (9.3)	48.2 (7.9)	50.1 (5.4)	45.7 (5.6)	47.6 (6.8)	47.2 (5.4)
CRIS-CAT satisfaction	47.9 (10.3)	50.4 (9.5)	51.8 (8.5)	45.8 (7.2)	47.4 (5.9)	45.9 (4.8)
	N (%)	*N* (%)	*N* (%)	*N* (%)	*N* (%)	*N* (%)
Need for ADL help	5 (35.7)	3 (20.0)	4 (16.7)	2 (50.0)	2 (15.4)	2 (28.6)

Table A2. Functional and self-report outcomes by age category and device type (unilateral, transradial amputation only).

	Body powered ($N = 45$)			Myo-single DOF ($N = 12$)			Myo multi-DOF ($N = 18$)		
	18–<45 ($N = 6$)	45–<65 ($N = 11$)	66+ ($N = 28$)	18–<45 ($N = 7$)	45–<65 ($N = 3$)	66+ ($N = 2$)	18–<45 ($N = 9$)	45–<65 ($N = 6$)	66+ ($N = 3$)
	Mn (SD)	Mn (SD)	Mn (SD)	Mn (SD)	Mn (SD)	Mn (SD)	Mn (SD)	Mn (SD)	Mn (SD)
Dexterity									
JTHF	0.43 (0.24)	0.70 (0.33)	0.42 (0.27)	0.48 (0.28)	0.38 (0.13)	0.21 (0.30)	0.46 (0.20)	0.65 (0.44)	0.43 (0.12)
Writing	0.12 (0.09)	0.18 (0.08)	0.12 (0.09)	0.12 (0.07)	0.19 (0.12)	0.15 (0.21)	0.10 (0.05)	0.14 (0.07)	0.14 (0.11)
Page turning	0.08 (0.05)	0.10 (0.07)	0.12 (0.08)	0.15 (0.11)	0.06 (0.09)	0.02 (0.01)	0.09 (0.11)	0.06 (0.08)	0.03 (0.03)
Small objects	0.11 (0.07)	0.21 (0.10)	0.18 (0.12)	0.18 (0.13)	0.20 (0.19)	0.10 (0.10)	0.16 (0.08)	0.14 (0.11)	0.07 (0.04)
Eating	0.10 (0.07)	0.09 (0.06)	0.07 (0.06)	0.10 (0.09)	0.08 (0.12)	0.02 (0.02)	0.15 (0.09)	0.10 (0.08)	0.09 (0.04)
Checkers	0.19 (0.10)	0.23 (0.14)	0.20 (0.13)	0.27 (0.07)	0.20 (0.18)	0.09 (0.04)	0.32 (0.11)	0.30 (0.19)	0.11 (0.03)
Light cans	0.16 (0.10)	0.24 (0.19)	0.19 (0.18)	0.29 (0.06)	0.25 (0.22)	0.15 (0.01)	0.32 (0.13)	0.24 (0.10)	0.10 (0.10)
Heavy cans	18.0 (7.9)	23.1 (7.3)	17.6 (9.1)	15.7 (7.2)	12.7 (11.7)	4.5 (4.9)	17.1 (6.7)	15.7 (4.7)	9.0 (4.0)
Box and Blocks	0.04 (0.03)	0.09 (0.04)	0.05 (0.05)	0.07 (0.06)	0.07 (0.07)	0.00 (0.00)	0.01 (0.02)	0.00 (0.00)	0.00 (0.00)
9 hole peg	39.7 (21.2)	46.0 (17.5)	41.6 (18.6)	43.3 (18.1)	37.7 (34.6)	27.5 (33.2)	44.7 (9.7)	42.0 (20.0)	23.3 (2.1)
SHAP IOF									
Activity measures									
AM-ULA	16.1 (1.4)	17.5 (6.3)	13.7 (5.1)	18.3 (5.8)	11.5 (10.3)	7.8 (3.1)	18.9 (6.7)	15.1 (6.5)	11.3 (2.8)
BAM-ULA	7.5 (0.7)	7.1 (2.8)	6.1 (1.8)	9.2 (1.1)	9.0 (.)	. (.)	8.3 (2.2)	8.0 (1.4)	7.5 (0.7)
T-MAP (min)	4.4 (1.4)	4.7 (2.6)	5.3 (1.4)	3.8 (0.5)	3.5 (0.3)	4.3 (0.8)	3.8 (0.9)	3.8 (1.2)	4.3 (0.2)
Prosthesis satisfaction									
TAPES	4.2 (0.6)	3.8 (0.8)	4.1 (0.7)	3.4 (0.9)	3.6 (0.3)	3.9 (0.2)	4.0 (0.7)	3.6 (0.7)	3.7 (0.8)
Disability, HRQOL, and community integration									
QuickDASH	27.7 (14.6)	34.1 (21.4)	27.6 (19.7)	39.0 (9.7)	22.0 (22.8)	15.9 (3.2)	28.3 (24.5)	23.0 (9.6)	27.3 (10.4)
VR-12 MCS	52.5 (9.3)	49.6 (15.4)	59.4 (6.5)	44.4 (15.4)	50.2 (6.6)	55.8 (1.0)	52.7 (14.8)	54.5 (11.2)	59.7 (1.8)
VR-12 PCS	45.6 (8.0)	41.8 (7.8)	39.3 (8.1)	**45.9 (6.9)**	44.9 (8.9)	49.4 (8.6)	41.8 (10.4)	45.8 (5.8)	47.5 (4.8)
VR-12 MCS imputed	50.4 (8.8)	47.5 (15.4)	56.6 (6.3)	42.7 (15.7)	49.6 (6.5)	5.4 (0.0)	50.7 (13.9)	52.4 (10.8)	57.5 (2.6)
VR-12 PCS imputed	42.8 (8.2)	38.7 (7.7)	35.8 (9.2)	43.1 (6.6)	41.5 (8.9)	46.1 (8.3)	39.0 (10.4)	43.0 (5.6)	43.7 (5.4)
CRIS-CAT extent	46.1 (12.7)	47.6 (10.8)	52.0 (6.3)	40.2 (8.9)	49.9 (8.5)	52.2 (7.3)	49.1 (10.0)	49.4 (9.2)	51.3 (5.6)
CRIS-CAT perceived	48.6 (7.4)	47.7 (9.0)	50.3 (5.7)	43.1 (5.4)	45.2 (4.2)	47.0 (3.2)	51.6 (11.7)	50.8 (7.5)	50.6 (4.0)
CRIS-CAT satisfaction	47.7 (7.9)	49.1 (10.9)	52.8 (8.7)	44.2 (7.8)	53.4 (7.1)	46.5 (2.5)	50.9 (13.1)	51.3 (8.5)	45.8 (5.4)
	N (%)	*N* (%)	*N* (%)	*N* (%)	*N* (%)	*N* (%)	*N* (%)	*N* (%)	*N* (%)
Need for ADL help	2 (33.3)	2 (28.6)	3 (15.0)	2 (66.7)	1 (33.3)	0 (0.0)	1 (20..0)	0 (0.0)	1 (50.0)

Table A3. Comparison of function participants with unilateral and bilateral amputation: TR body-powered users only.

	Unilateral WD/TR ($N = 45$) Mn (SD)	Bilateral WD/TR ($N = 8$) Mn (SD)	WMW *p* Value
Dexterity measures			
JTHFT			
Writing	0.49 (0.30)	0.93 (0.2)	**0.0008***
Page turning	0.13 (0.09)	0.36 (0.15)	**0.0012***
Eating	0.11 (0.07)	0.27 (0.18)	**0.0094***
Small objects	0.18 (0.12)	0.27 (0.08)	**0.0287***
Checkers	0.08 (0.06)	0.19 (0.13)	**0.0083***
Light cans	0.20 (0.13)	0.51 (0.28)	**0.0059***
Heavy cans	0.20 (0.17)	0.53 (0.22)	**0.0010***
Box and Blocks	19.0 (8.7)	29.8 (6.2)	**0.0035***
9-Hole peg	0.06 (0.05)	0.15 (0.08)	**0.0036***
SHAP IOF	42.4 (18.4)	52.9 (25.1)	0.0878*
Activity measures			
AM-ULA	14.9 (5.3)	16.8 (5.9)	0.2334
BAM-ULA	6.6 (2.1)	9.0 (0.8)	**0.0124***
T-MAP	5.0 (1.8)	7.6 (3.7)	0.0826
Prosthesis satisfaction measures			
TAPES	4.0 (0.7)	4.2 (0.4)	0.8044
Disability, HRQoL, and community integration			
QuickDASH	29.2 (19.4)	22.7 (13.2)	0.5339
VR-12 MCS	55.8 (10.7)	56.6 (8.9)	0.9569
VR-12 PCS	40.9 (8.1)	46.8 (9.5)	0.0787
VR-12 MCS imputed	53.5 (10.1)	55.2 (8.2)	0.8424
VR-12 PCS imputed	37.5 (8.9)	43.6 (9.1)	0.0865
CRIS-CAT extent	50.2 (8.7)	55.4 (5.9)	0.1265
CRIS-CAT perceived	49.4 (6.8)	53.6 (11.0)	0.2634
CRIS-CAT satisfaction	51.2 (9.2)	52.8 (7.1)	0.4446
	N (%)	*N* (%)	Exact *p*
Need for ADL help	7 (21.2)	3 (60.0)	0.1026

*Significant after Benjamini–Hochberg adjustment with false discovery rate = 0.1. Bold values in this table indicate values statistically significant at $p < 0.05$.

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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

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

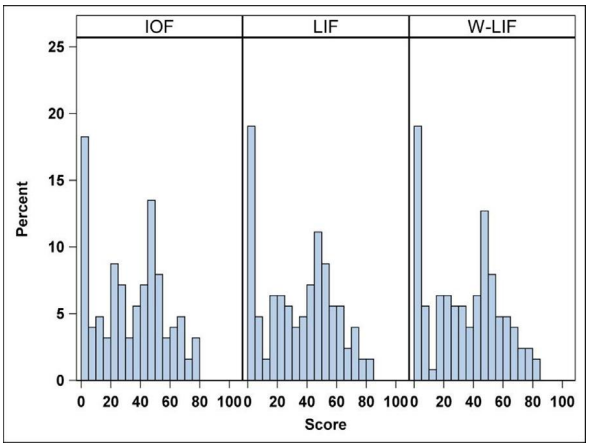

Fig. 1. Distribution of SHAP IOF, LIF and W-LIF scores.

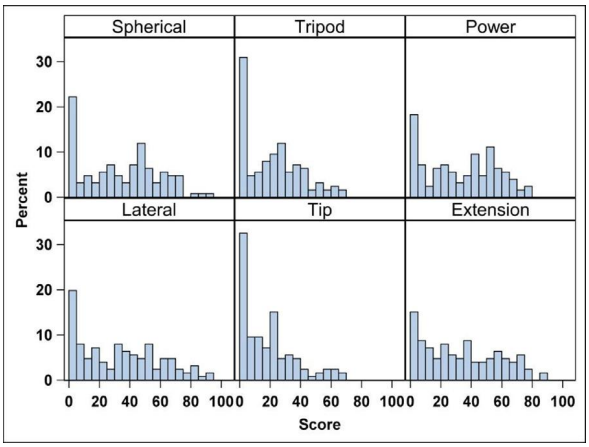

Fig. 2. Distribution of SHAP prehensile pattern scores.

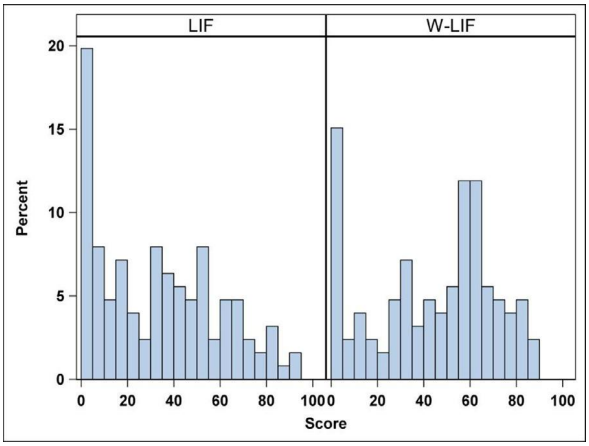

Fig. 3. Distribution of LIF and W-LIF with scores calculated using 12x boundary limits.

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)

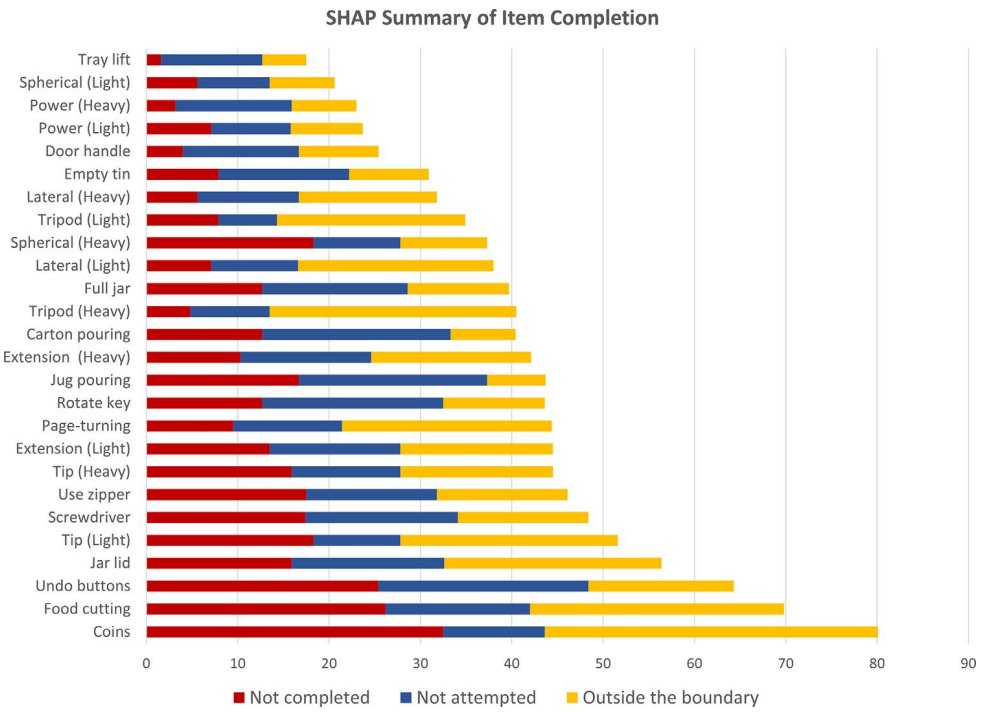

Fig. 4. Proportion of participants who did not complete, did not attempt, and exceeded the boundary limits for each task.

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).

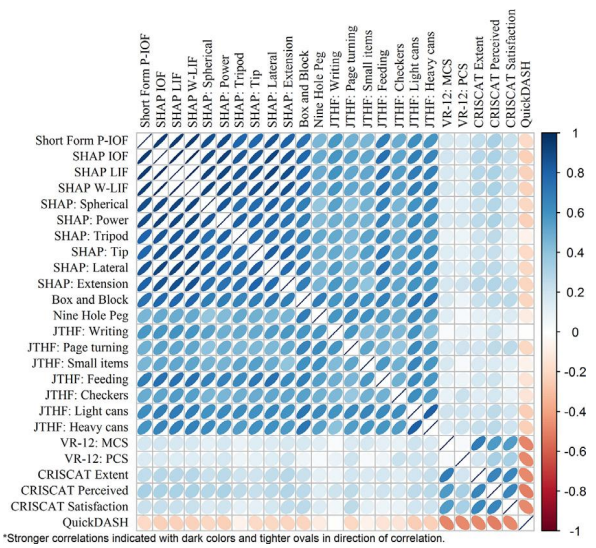

Fig. 5. Correlations between the SHAP IOF, LIF, W-LIF and other measures.

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

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).

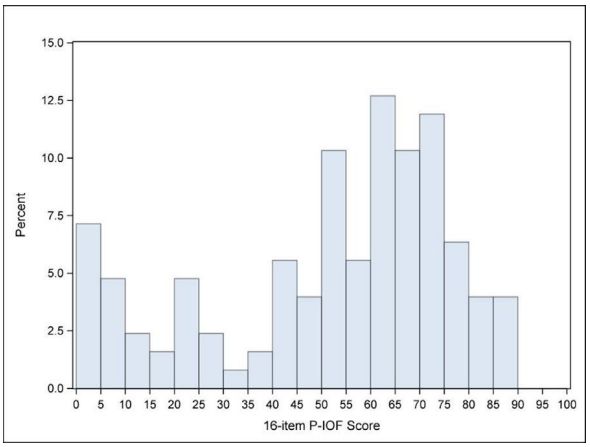

Fig. 6. Distribution of the 16- item P-IOF scores.

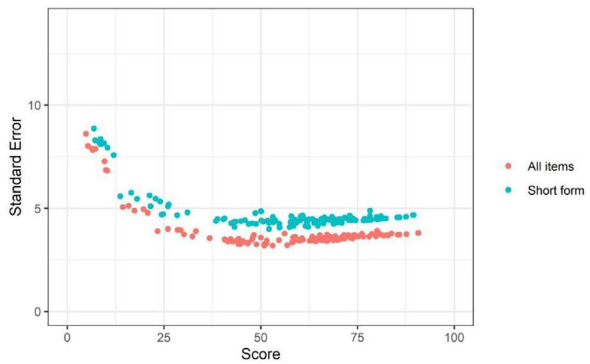

Fig. 7. Comparison of standard errors of the 26 item and 16 item P-IOF.

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-

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

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

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jht.2021.07.003.

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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

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

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.

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.

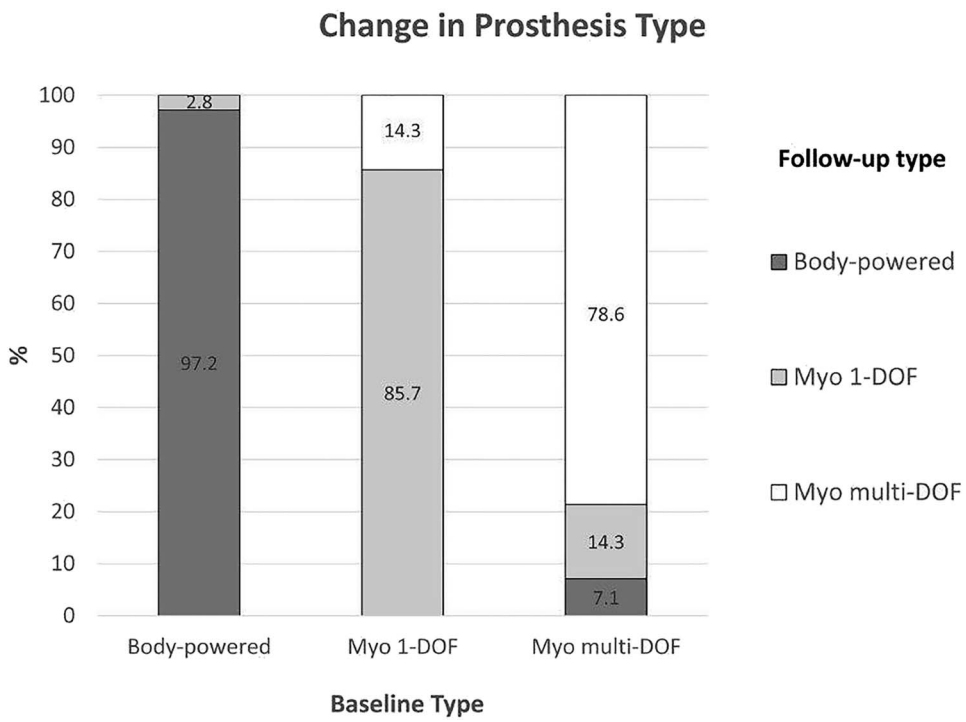

Figure 1. Change in prosthesis type from baseline to follow-up.

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

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

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

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 AQ7 study conforms to all STROBE 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

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 3, Supplemental Digital Content 2, http://links.lww.com/PHM/B361). AQ8

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-DOF (21.5%) and single-DOF devices (19.6%). T1 AQ9

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%). T2

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

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 MCS 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 PCS 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

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				

[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

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*						

[a]Below elbow includes TR and WD levels.
[b]Above elbow includes TH and ED levels.

AQ13

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

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 available.

TABLE 5. Linear regression of outcome measures on impairment covariates

	AM-ULA (n = 101)			MCS (n = 97)			TAPES (n = 103)			AQ15
	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	AQ13
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)										

[a]Below elbow includes TR and WD levels.

[b]Above elbow includes TH and ED levels.

CI, confidence interval; 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

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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ORIGINAL RESEARCH

PM&R

Frequency, severity, and implications of shoulder pain in people with major upper limb amputation who use prostheses: Results of a National Study

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Abstract

Background: People with upper limb amputation are potentially at increased risk of shoulder pain because they often perform compensatory movements to operate their prostheses and rely more heavily on their nonamputated limb for everyday activities.

Objective: To describe the frequency, severity, associated factors, and implications of shoulder pain in people with unilateral major upper limb amputation who use prostheses.

Design: Cross-sectional, observational design.

Setting: National recruitment of people living in the community.

Participants: U.S. veterans and civilians (N = 107) with unilateral major upper limb amputation.

Interventions: Not applicable.

Main Outcome Measures: Shoulder pain (any, ipsilateral and contralateral to amputation), activity performance (Activities Measure for Upper Limb Amputation), health-related quality of life (Veterans RAND 12-Item Health Survey mental component summary [MCS] and physical component summary [PCS]), and disability (Quick Version of the Disabilities of the Arm, Shoulder and Hand Score [QuickDASH]).

Results: All participants completed a comprehensive in-person assessment. Participants were 97% male with a mean age of 57.1 years and a mean time since amputation of 23.4 years. The prevalence of any shoulder pain was 30% (15% ipsilateral, 25% contralateral, 10% bilateral). Shoulder pain intensity (0 to 10 scale) was moderate for both ipsilateral (mean 4.9, SD 2.0) and contralateral (mean 4.2, SD 2.0) pain. No significant difference in shoulder pain frequency was observed by amputation level. The prevalence of any shoulder pain was greater in those using a body-powered prosthesis (38% compared to 18% in externally powered users). Each additional year since amputation was associated with an increased likelihood of having contralateral shoulder pain (odds ratio: 1.05, confidence interval: 1.01, 1.10). In linear regression models, those with contralateral shoulder pain had worse PCS ($\beta = -7.07$, $p = .008$) and worse QuickDASH ($\beta = 18.25$, $p < .001$) scores.

Conclusions: In our sample of predominantly male veterans with major upper limb amputation, shoulder pain was a common condition associated with functional and quality of life implications. Among prosthesis users, the shoulder contralateral to the amputation was at greatest risk, with risk increasing with every year since amputation.

INTRODUCTION

Shoulder pain is considered a relatively common condition in the general adult population, although rates reported in the literature vary widely from 4% to 26%.[1-8] The frequency of shoulder pain in those with major upper limb amputation has been reported to be as high as 59% with an average pain severity in the slightly to rather bothersome range (3.5) as assessed by a 5-point ordinal scale ranging from "no pain" to "very bothersome pain."[9] Although prior studies examining this topic have not identified differences between prosthesis users and nonusers in pain frequency,[9-11] individuals with upper limb amputation who use prostheses are potentially at increased risk of shoulder pain compared to prosthesis nonusers because they often perform compensatory movements with proximal joints to operate their prosthesis.[12-14] Because prosthetic limbs vary greatly in terms of weight, suspension mechanism, and control strategy, it is also possible that certain prosthetic limb types are more likely to be associated with shoulder pain. Most people who require upper limb amputation have a long postamputation life expectancy[15-17] and based on longitudinal studies of overuse syndromes and other painful conditions, it is plausible that the compensatory movements used to operate prosthetic limbs have a cumulative effect over time.[2,5,7,18,19]

Upper limb amputation also has the potential to contribute to musculoskeletal conditions and pain on the nonamputated side. Individuals with unilateral upper limb loss commonly rely more heavily on their nonamputated limb for the performance of functional tasks including lifting and carrying.[9-11,13-14] This reliance, in combination with the bilateral compensatory movements used for prosthesis use, might result in overuse syndromes and pain in the proximal joints of the amputated limb as well as the nonamputated upper limb.[9-11,14,20] Prior studies have reported an increased rate of overuse syndromes and other painful musculoskeletal conditions in people with upper limb amputation,[21-26] including those with distal amputations at the hand or finger level.[27] High pain intensity levels and pain interference in the nonamputated limb and neck region of those with upper limb amputation has also been described.[10-11,23-25]

Although prior studies reported an increased risk of musculoskeletal conditions including shoulder pain in those with upper limb amputation, these studies have not fully characterized the factors associated with shoulder pain, the pain location (contralateral vs ipsilateral to the amputation), or the association between shoulder pain and function. Obtaining a better understanding of shoulder pain frequency and intensity as well as those at greatest risk could influence strategies aimed at maintaining functional independence and general health outcomes in those with upper limb loss and may also inform new prosthesis designs and rehabilitation strategies for prevention. Therefore, the objectives of this study were to (1) describe the frequency and severity of shoulder pain in people with unilateral major upper limb amputation who use prostheses; (2) determine the association between pain and specific person, amputation, and prosthesis characteristics; (3) quantify the association between shoulder pain and activity performance, disability, and health-related quality of life (HRQOL).

METHODS

Study design

The study employed a cross-sectional study design. Community dwelling people with major upper limb amputation were recruited from the Department of Veterans Affairs and from the community. Data collection took place at five study sites across the United States. The study was approved by the Veterans Administration Central Institutional Review Board, Regional Health Command-Central Institutional Review Board, and by the Human Research Protection Office. All participants provided voluntary informed consent.

Sample

The analytic sample was a subset of participants who participated in a larger study of people with major upper limb amputation (amputation at or proximal to the wrist level) who used an active prosthesis.[28] An active prosthesis was defined as a prosthetic limb that used either a body-powered or an externally powered control system to provide active motion in at least the prosthetic terminal device. The analyses presented here were limited to people with unilateral upper limb amputation at the wrist disarticulation (WD), transradial (TR), elbow disarticulation (ED), or transhumeral level (TH). Participants with bilateral upper limb amputation ($N = 15$) were excluded to create a more homogeneous group. Participants with shoulder disarticulation or forequarter amputation ($N = 5$) were excluded given that the shoulder joint on the side of the amputation was absent. Participants who at the time of screening were not actively using a prosthesis or could not tolerate wearing a prosthesis for at least 3 hours and those with a severe health condition that would limit their ability to participate in study assessment activities were excluded.

Data collection

Participants were assessed by a physical or occupational therapist, assisted by a research coordinator.

Study visits included collection of demographic data, collection of amputation and prosthesis use history, and performance of a directed physical examination. Self-report and functional performance measures were collected by the study assessor to quantify HRQOL, upper limb disability, and activity performance. Assessors underwent rigorous training in the administration of all outcome measures. The script used by the assessors to instruct participants in the performance of each measure was standardized and used by all assessors at all sites. All participant assessments were videotaped, and assessments were reviewed by the study investigators to ensure that all measures were reliably performed according to the provided script and that ratings were performed consistently across participants and sites.

Primary outcome

Participant pain symptoms and pain location were obtained by the study assessor during the study visit. Using a pain map diagram, participants were instructed to identify and mark all painful areas and rate the level of pain for each area on a scale from 0 (not painful) to 10 (extremely painful). Following the study visit, research team members abstracted pain information from data collection forms using a structured abstraction tool developed by the research team. The pain maps were divided into 10 regions of the body including the shoulder. The 10 regions of the body that were used for the structured data abstraction are included in Table S1. Tables with all 10 regions were used to record location of pain and pain intensity rating on a scale of 0–10 for any location where the participant reported pain. As previously reported, pain intensity was recategorized and reported in four levels: Never had Pain, None to Mild (0–3), Moderate (4–7), and Severe (8–10).[29] We examined shoulder pain prevalence as a dichotomous variable (present or absent). Shoulder pain was categorized by location depending on whether the pain was located on the same side as the amputation (ipsilateral), on the side opposite from the amputation (contralateral), both sides (bilateral) or on either side or both sides (any).

Secondary outcomes

We measured activity performance using the Activities Measure for Upper Limb Amputation (AM-ULA), a performance measure that includes 18 everyday tasks.[30] Higher AM-ULA scores indicate better activity performance. The AM-ULA has strong interrater reliability (reported intraclass correlation coefficients of 0.84–0.89), internal consistency (Cronbach alphas of 0.89–0.91), and known groups validity and evidence of responsiveness to change in people with upper limb amputation.[30,31] HRQOL was assessed using the generic Veterans RAND 12-Item Health Survey (VR-12), which is scored as the physical component summary (PCS) and mental component summary (MCS).[32] Normative values for the VR-12 scales are available.[32] Higher scores indicate better HRQOL. The Quick Version of the Disability of Arm, Shoulder, and Hand (QuickDASH) measure assessed difficulty performing activities, amount of limitation, extent of interference with activities, and extent of arm, shoulder, and hand pain and tingling.[33,34] Higher QuickDASH scores indicate greater disability. The QuickDASH, examined in a sample of upper limb amputees, had a Cronbach alpha of 0.83 and test-retest intraclass correlation coefficient of 0.87.[34]

Other measures

Categories of amputation level were collapsed into two categories: TR, which included people with wrist disarticulation and TR amputation; and TH, which included people with elbow disarticulation and TH amputation. Participant age in years was calculated based on date of birth. Time since amputation was analyzed as a continuous variable, indicated in years as reported by the participant. Time since amputation was also classified into three categories (less than 10 years since amputation, between 10 and 20 years, and greater than 20 years). Prosthesis type was classified as body powered or externally powered (eg, myoelectric). Participants indicated the average hours/day of prosthesis use as well as the average number of days/week that they typically used their prosthesis. Amputation etiology data was obtained by participant self-report. Participants were asked to select the etiology of their amputation from a list including the following options: congenital, combat, accident, burn, cancer, diabetes, and infection. Participants were able to select more than one amputation etiology. Employment data were also collected by self-report. Participants were asked to select from a list of employment options including the following: working, student, retired, medical leave, or other. Response options were collapsed in our analyses into a working/student category and a retired/medical leave/other category owing to small subgroup sizes.

Residual limb length was measured by the study assessor. We collapsed categorizes of limb length identified by Kelly.[35] For those with TH level amputation, we used length from acromion to the distal bone end on the amputated side and divided by the length from acromion to the lateral epicondyle on the sound side to obtain an estimate of the proportion of the residual limb remaining. We then categorized this fraction as short (<0.5) or standard/long above elbow (0.5 or

more). For those with TR level amputation, we used the length from lateral humeral epicondyle to the distal bone end on the amputated side and divided by the length from the humeral epicondyle to radial styloid on the sound side. We categorized the proportion of the limb remaining as very short/short (<0.55) or standard/long (0.55 or more).

Data analyses

We compared participant characteristics by presence of any shoulder pain with bivariate analyses (*t*-tests, chi-square, and Fisher's exact tests). Bivariate analyses also compared the prevalence (using chi-square and Fisher's exact tests) and intensity (*t*-tests and Wilcoxon Mann-Whitney *U* tests) of shoulder pain (ipsilateral, contralateral, any) by amputation level and prosthesis type. *T*-tests were used to compare QuickDASH, AM-ULA, and VR-12 PCS and MCS scores for those with and without ipsilateral, contralateral, and any shoulder pain.

To identify the independent predictors of contralateral and ipsilateral shoulder pain, we developed two separate logistic regression models. These models controlled for potential confounders that we believed, based on prior work, might be associated with shoulder pain[36] and any additional variables that were significantly associated (at $p < .1$) with any shoulder pain in our bivariate analyses. Variables included in the model were years since amputation and prosthesis type, age, amputation level, race, residual limb length, and combat and accident amputation etiologies. To quantify the association between shoulder pain and activity performance, HRQOL, and disability, we created four separate linear regression models to identify the association between presence of ipsilateral, contralateral, or any shoulder pain and key outcome measures (AM-ULA, PCS, MCS, and QuickDASH). These models also controlled for years since amputation, age, amputation level, prosthesis type, residual limb length, and combat and accident amputation etiologies. Participants with missing data for combat and accident amputation etiologies were classified as "no data" for regression analyses; those missing outcomes data were excluded from analyses.

RESULTS

Participants (N = 107) completed the in-person assessment at one of the five study sites. Table 1 provides the demographic, amputation, and prosthesis characteristics of participants by presence of any shoulder pain. Participants were 97% male with a mean age of 57.1 years and a mean time since amputation of 23.4 years. On average, those with shoulder pain were 7.2 years older ($p = .03$), had sustained an amputation 10.5 years earlier ($p = .01$), and were more likely to report a body-powered prosthesis (75.0% compared to 52.0%) as their current device ($p = .03$) as compared to participants without shoulder pain. Bivariate analyses revealed no other statistically significant differences in any other participant, amputation, and prosthesis characteristics. Additional descriptive statistics (Table S2) showed comparable prosthesis use intensity between those with and without shoulder pain by laterality (ipsilateral or contralateral) or between those using body-powered prostheses compared to externally powered prostheses. Nineteen participants had missing data for amputation etiology. Table S3 provides participant characteristics for subgroups with ipsilateral and contralateral shoulder pain.

As shown in Table 2, the prevalence of any shoulder pain was 30%; pain in both shoulders (bilateral shoulder pain) was present in 10% (N = 11). Mean shoulder pain was rated as moderate intensity on both the ipsilateral (mean 4.9) and contralateral (mean 4.2) sides. Bivariate analyses found that the prevalence of shoulder pain and shoulder pain intensity were not statistically significantly different by amputation level. Prevalence of any shoulder pain was significantly ($p = .03$) greater for those using a body-powered prosthesis (38%) compared to externally powered prosthesis (18%). Contralateral shoulder pain was significantly more prevalent among body-powered users than among externally powered prosthesis users ($p = .02$) (Figure 1). Ipsilateral shoulder pain was also more prevalent for body-powered users, but the difference was not statistically significant ($p = .16$). There were no statistically significant differences in ipsilateral ($p = .13$) or contralateral ($p = .91$) shoulder pain intensity by prosthesis type (results not shown).

The relationship between shoulder pain frequency and time since amputation is shown in Figure 2. The figure shows that the frequency of both ipsilateral and contralateral shoulder pain was similar for people throughout the first 20 years after amputation. The prevalence of ipsilateral shoulder pain frequency did not increase in people who had their amputation for more than 20 years. The frequency of both any and contralateral shoulder pain was higher in those who were more than 20 years past amputation.

Mean outcome measure scores are compared for those with and without any, ipsilateral, and contralateral shoulder pain in Table 3. Analytic sample sizes varied for each outcome measure because of missing data: QuickDASH (N = 107), AM-ULA (N = 105), PCS (N = 101), and MCS (N = 101). QuickDASH scores were significantly higher (worse disability) for those with any shoulder pain (mean 38.5) than for those without pain (mean 26.1) ($p = .001$) and for those with

TABLE 1 Demographics and participant characteristics by presence of shoulder pain

	No shoulder pain (N = 75) Mean (SD)	**Any shoulder pain (N = 32) Mean (SD)**	***t*-test *p***	**Total (N = 107) Mean (SD)**
Age (y)	54.9 (16.2)	62.1 (15.0)	**.034**	57.1 (16.1)
Years since amputation	20.3 (17.6)	30.8 (20.3)	**.008**	23.4 (18.9)
Hours prosthesis use/day	5.9 (4.7)	6.1 (4.9)	.155	6.0 (4.7)
Days/week prosthesis used	5.3 (2.4)	5.8 (1.6)	.883	5.4 (2.2)
	N (%)	**N (%)**	**χ^2/Fisher's *p***	**N (%)**
Amputation level			.843	
Transhumeral/elbow	22 (29.3)	10 (31.3)		22 (29.9)
Transradial/wrist	53 (70.7)	22 (68.8)		75 (70.1)
Gender			.212	
Male	74 (98.7)	30 (93.8)		104 (97.2)
Female	1 (1.3)	2 (6.3)		3 (2.8)
Race			.089	
White	50 (66.7)	28 (87.5)		78 (72.9)
Black	11 (14.7)	2 (6.3)		13 (12.2)
Mixed/other	14 (18.7)	2 (6.3)		16 (15.0)
Ethnicity			.218	
Hispanic	13 (17.3)	2 (6.3)		15 (14.0)
Not Hispanic	60 (80.0)	28 (87.5)		88 (82.2)
Unknown	2 (2.7)	2 (6.3)		4 (3.7)
Employment status			.148	
Working/student	25 (33.3)	6 (18.8)		31 (29.0)
Retired/medical leave/other	34 (45.3)	21 (65.6)		55 (51.4)
Unknown	16 (21.3)	5 (15.6)		21 (19.6)
Military status			.869	
Active duty	1 (1.3)	1 (3.1)		2 (1.9)
Veteran	66 (88.0)	28 (87.5)		94 (87.9)
Civilian	8 (10.7)	3 (9.4)		11 (10.3)
Prosthesis type			**.027**	
Body powered	39 (52.0)	24 (75.0)		63 (58.9)
Externally powered	36 (48.0)	8 (25.0)		44 (41.1)
Residual limb length			.132	
Short	24 (32.0)	5 (15.6)		29 (27.1)
Standard or long	47 (62.7)	23 (71.9)		70 (65.4)
Unknown	4 (5.3)	4 (12.5)		8 (7.5)
Etiology of amputation[a]	N = 61	N = 27		N = 88
Congenital	3 (11.5)	0 (0.0)	>.99	3 (8.8)
Combat	24 (39.3)	11 (40.7)	>.99	35 (39.8)
Accident	30 (49.2)	15 (44.4)	.648	45 (51.1)
Burn	5 (8.2)	1 (3.7)	.662	6 (6.8)
Cancer	4 (6.6)	1 (3.7)	>.99	5 (5.7)
Diabetes	1 (1.5)	0 (0.0)	>.99	1 (1.1)
Infection	8 (13.1)	4 (14.8)	>.99	12 (13.6)

[a]Etiology of amputation: respondents could indicate multiple etiologies; however, 19 participants are missing all etiology data and 73 are missing data on congenital etiology.

contralateral shoulder pain (39.7 vs 26.5, $p = .001$) than those without contralateral shoulder pain. Significant differences in PCS scores were also noted for those with any shoulder pain (36.4 vs 44.8, $p < .001$) compared to those without any shoulder pain, for those with ipsilateral shoulder pain (35.8 vs 43.4, $p = .003$)

TABLE 2 Shoulder pain prevalence and intensity by amputation level

	WD/TR (N = 75)		ED/TH (N = 32)				All (N = 107)	
	N	%	N	%	$\chi^2 p$	Exact *p*	N	%
Shoulder pain prevalence								
Ipsilateral	10	13.3	6	18.8	.472	.556	16	15.0
Contralateral	19	25.3	8	25.0	.971	>.99	27	25.2
Any shoulder pain	22	29.3	10	31.3	.843	.822	32	29.9
	N	**Mean (SD)**	**N**	**Mean (SD)**	**T-test *p***	**WMW *p***	**N**	**Mean (SD)**
Shoulder pain intensity								
Ipsilateral	10	5.1 (2.0)	5	4.6 (2.1)	.662	.506	15	4.9 (2.0)
Missing	0		1				1	
Contralateral	17	4.4 (2.0)	5	3.6 (2.1)	.433	.533	22	4.2 (2.0)
Missing	2		3				5	

Abbreviations: ED, elbow disarticulation; TH, transhumeral; TR, transradial; WD, wrist disarticulation; WMW, wilcoxon mann-whitney.

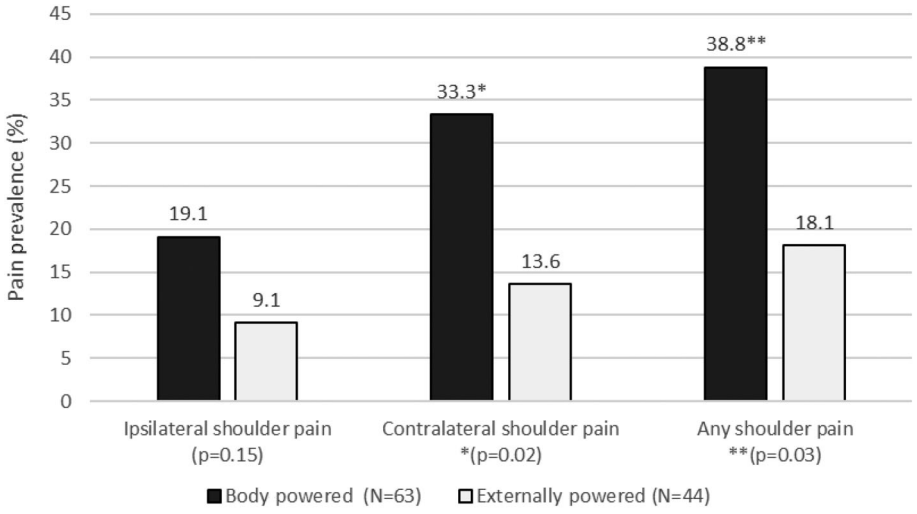

FIGURE 1 Shoulder pain prevalence by prosthesis type

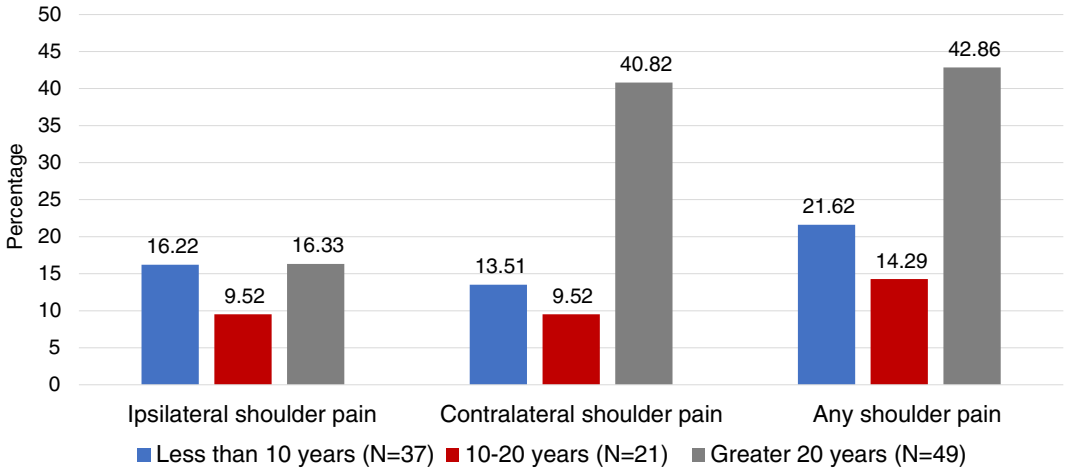

FIGURE 2 Shoulder pain frequency by years since amputation

compared to those without ipsilateral shoulder pain, and for those with contralateral shoulder pain (35.9 vs 44.4, $p < .001$) compared to those without contralateral shoulder pain. There were no significant differences found in AM-ULA or MCS scores for those with and without shoulder pain in bivariate analysis.

TABLE 3 Comparison of disability, activity performance and HRQOL in participants with and without shoulder pain

	Any shoulder pain			Ipsilateral shoulder pain			Contralateral shoulder pain		
	No (N = 75) Mean (SD)	Yes (N = 32) Mean (SD)	*t*-test *p*	No (N = 91) Mn (sd)	Yes (N = 16) Mn (sd)	*t*-test *p*	No (N = 80) Mn (sd)	Yes (N = 27) Mn (sd)	*t*-test *p*
QuickDASH	26.1 (17.3)	38.5 (17.4)	**.001**	28.4 (18.1)	37.2 (17.2)	.073	26.5 (17.2)	39.7 (17.5)	**.001**
AM-ULA	14.3 (5.9)	13.8 (6.3)	.725	14.4 (6.1)	12.4 (5.1)	.215	14.0 (6.0)	14.6 (6.1)	.630
VR-12 PCS	44.8 (8.3)	36.4 (8.9)	**<.001**	43.4 (8.9)	35.8 (8.9)	**.003**	44.4 (8.3)	35.9 (9.3)	**<.001**
VR-12 MCS	54.5 (11.6)	50.9 (13.0)	.173	53.9 (12.2)	50.2 (11.1)	.276	54.0 (11.8)	51.6 (12.8)	.392

Abbreviations: AM-ULA, Activities Measure for Upper Limb Amputation; HRQOL, health-related quality of life; QuickDASH, Quick Version of the Disabilities of the Arm, Shoulder and Hand Score; VR-12 MCS, Veterans RAND 12-Item Health Survey mental component summary; VR-12 PCS, Veterans RAND 12-Item Health Survey physical component summary.

TABLE 4 Logistic regression models of contralateral and ipsilateral shoulder pain (N = 99)

	Contralateral shoulder pain		Ipsilateral shoulder pain	
	OR (95% CI)	*p*	OR (95% CI)	*p*
Intercept	3.58 (0.16, 78.38)	.402	0.22 (0.02, 7.55)	.499
Years since amputation	1.06 (1.01, 1.11)	**.017**	1.00 (0.96, 1.04)	.958
Age	0.95 (0.89, 1.01)	.101	1.00 (0.95, 1.06)	.893
Amputation level				
Transradial (ref)				
Transhumeral	1.31 (0.39, 4.35)	.664	1.70 (0.45, 6.44)	.432
Race				
White (ref)				
Black	0.94 (0.15, 5.95)	.946	0.41 (0.04, 3.95)	.441
Mixed/other	0.12 (0.01, 1.25)	.077	0.31 (0.03, 2.91)	.306
Prosthesis type				
Body powered (ref)				
Externally powered	0.25 (0.06, 0.99)	**.049**	0.43 (0.11, 1.79)	.248
Amputation etiology				
Not combat/accident (ref)				
Accident (not combat)	1.27 (0.14, 11.74)	.833	0.76 (0.11, 5.40)	.785
Combat	1.26 (0.13, 12.07)	.840	0.18 (0.02, 1.97)	.159
No data	0.81 (0.06, 10.12)	.867	0.74 (0.08, 6.74)	.790
Residual limb length				
Short	0.14 (0.03, 0.65)	**.012**	0.87 (0.19, 3.98)	.860
Not short (ref)				
Cox-Snell R^2	0.22		0.08	

Abbreviations: CI, confidence interval; OR, odds ratio.

The results of the multivariable logistic regression models of contralateral and ipsilateral shoulder pain presence are shown in Table 4. The odds of reporting contralateral shoulder pain were 1.06 times higher ($p = .02$) for each additional year since amputation, 0.25 times lower ($p = .049$) for externally powered prosthesis users (compared to body powered), and 0.14 times lower ($p = .01$) for those with short residual limb length (compared to "not short"). There were no statistically significant predictors of ipsilateral shoulder pain in the logistic regression model. Cox-Snell R^2 of models was 0.08 for ipsilateral shoulder pain and 0.22 for contralateral pain.

The results of multivariable linear regression models examining predictors of outcome measure performance are shown in Table 5. Presence of ipsilateral or contralateral shoulder pain did not have a significant effect on AM-ULA scores. On average, AM-ULA scores were

TABLE 5 Linear regression of outcome measures on impairment covariates

	AM-ULA (N = 97)		PCS (N = 94)		MCS (N = 94)		QuickDASH (N = 98)	
	β (95% CI)	*p*	β (95% CI)	*p*	β (95% CI)	*p*	β (95% CI)	*p*
Intercept	27.11 (21.48, 32.74)	**<.001**	47.31 (38.01, 56.61)	**<.001**	52.92 (40.14, 65.70)	**<.001**	20.78 (2.84, 38.71)	**.024**
Shoulder pain								
Ipsilateral	−2.15 (−5.72, 1.43)	.236	−4.08 (−9.91, 1.76)	.168	−2.75 (−10.76, 5.26)	.497	0.50 (−10.80, 11.79)	.931
Contralateral	1.36 (−1.75, 4.47)	.388	−7.07 (−12.21, −1.94)	**.008**	−4.44 (−11.50, 2.61)	.214	18.25 (8.36, 28.14)	**<.001**
Years since amputation	−0.03 (−0.12, 0.05)	.411	0.06 (−0.07, 0.20)	.363	0.17 (−0.03, 0.36)	.497	−0.37 (−0.63, −0.11)	.930
Age	−0.14 (−0.23, −0.04)	**.005**	−0.08 (−0.23, 0.08)	.340	0.07 (−0.14, 0.29)	.088	0.17 (−0.13, 0.47)	.262
Amputation level								
Transradial (ref)								
Transhumeral	−4.72 (−7.17, −2.28)	**<.001**	−0.54 (−4.59, 3.51)	.791	−3.29 (−8.85, 2.27)	.494	2.27 (−5.39, 9.92)	.557
Prosthesis type								
Body-powered (ref)								
Externally powered	−2.71 (−5.21, −0.21)	**.034**	2.12 (−2.04, 6.29)	.314	−0.08 (−5.8, 5.65)	.243	−2.55 (−10.45, 5.35)	.523
Residual limb								
Short	−3.91 (−6.47, −1.36)	**.003**	0.08 (−4.23, 4.39)	.972	−3.45 (−9.37, 2.47)	.979	5.56 (−2.56, 13.68)	.177
Not short (ref)								
Amputation etiology								
Not combat/accident (ref)								
Accident (not combat)	−1.10 (−5.01, 2.80)	.575	0.54 (−5.89, 6.96)	.868	−3.78 (−12.61, 5.04)	.396	0.98 (−11.43, 13.39)	.875
Combat	−0.64 (−4.70, 3.42)	.754	−3.42 (−10.21, 3.38)	.320	−3.95 (−13.29, 5.38)	.402	2.01 (−10.90, 14.92)	.758
No etiology data	−0.01 (−4.29, 4.28)	.997	0.06 (−6.98, 7.10)	.986	−5.63 (−15.31, 4.04)	.250	8.64 (−4.84, 22.11)	.206
R^2	0.33		0.26		0.14		0.23	

Abbreviations: AM-ULA, Activities Measure for Upper Limb Amputation; QuickDASH, Quick Version of the Disabilities of the Arm, Shoulder and Hand Score; MCS, VR-12 mental component summary; PCS, VR-12 physical component summary.

lower (worse) in participants with increased age ($\beta = -0.14$, $p = .005$), transhumeral amputation ($\beta = -4.72$, $p < .001$), externally powered prosthesis use ($\beta = -2.71$, $p = .03$), and short residual limbs ($\beta = -3.91$, $p = .003$). PCS scores were significantly worse for those with contralateral shoulder pain ($\beta = -7.07$, $p = .008$). Worse performance on the QuickDASH was found in those with contralateral shoulder pain ($\beta = 18.25$, $p < .001$). Linear regression R^2 values ranged from 0.14 to 0.33.

DISCUSSION

This study highlights shoulder pain as an important condition in people with upper limb amputation who use prosthetic limbs. The frequency of shoulder pain in our study is higher than rates reported in the general adult population, which ranges from 4% to 26%. Although the overall shoulder pain frequency and intensity are consistent with prior studies in people with upper limb amputation,[9-11] our investigation adds to the existing literature by identifying a higher frequency of pain in the shoulder opposite from the amputation and that shoulder pain of moderate intensity is present even many years after amputation. Our finding of greater frequency of shoulder pain contralateral to the amputation especially in those using body-powered prostheses may be explained, in part, by the fact that our population consisted mostly of people with acquired amputations, all of whom used an active prosthesis type. In contrast, prior studies that reported similar or greater rates of shoulder pain in the ipsilateral shoulder were conducted with samples that were predominantly individuals with congenital limb deficiency including those with finger or hand deficiencies, the majority of whom did not use prosthetic limbs.[24,25] Most body-powered prostheses use harness systems that require specific compensatory movements to be performed in the contralateral shoulder for prosthetic limb control and these compensatory movements are typically not similarly performed in those not using a prosthesis.

It is possible that the higher frequency of pain in the contralateral shoulder is related to both the compensatory strategies that are used by prosthesis users as well as the heavy reliance on the nonamputated upper extremity for heavy lifting and carrying activities. This concept is supported by our finding that myoelectric users had lower odds for having contralateral pain than body-powered users. Individuals who use body-powered prosthesis control strategies involve both shoulders, whereas externally powered users do not involve the contralateral limb in prosthesis control. This finding alerts clinicians and upper limb amputation prosthesis users to the importance of shoulder joint protection strategies on the side opposite of the amputation when performing activities both with and without the prosthesis.[10,11,14]

One of the strengths of our study is that it offers an opportunity to better understand the relationship between time since amputation and shoulder pain. Prior studies that found no correlation between shoulder pain and time since amputation examined mixed populations with both congenital limb deficiency and acquired limb amputation,[10,21] and only 25% of the participants in the study by Burger et al were active prosthesis users.[10] Another study addressing time since amputation by Hanley et al did not specifically address shoulder pain and participants had an average time since amputation of 7.0 years, as compared to our population with a mean time since amputation of 23.4 years.[11] Our study found the frequency of both any and contralateral shoulder pain was at least twice as high in those who were more than 20 years past amputation. Our study findings support the concept that the compensatory movements used to operate prosthetic limbs have cumulative effects over time.[9-11,14] Our research found significant increases in contralateral shoulder pain prevalence over time with a 5% increased odds of contralateral shoulder pain for every year following amputation. This finding suggests that the cumulative effects on shoulder pain are greater in the contralateral shoulder.

Consistent with prior investigations, this study found no significant differences in shoulder pain frequency in those with transhumeral level amputation compared to the transradial level.[21-25] This suggests that although people with different amputation levels may use unique compensatory strategies for prosthesis use and completion on activities of daily living, all types of compensatory movements likely contribute to shoulder girdle and/or rotator cuff overuse syndromes and the development of chronically painful conditions. This finding also helps to inform clinicians that strategies to prevent and manage shoulder pain are important in all patients with major upper limb amputation who use prostheses, regardless of amputation level. Our finding that those with shorter residual limbs experienced less contralateral shoulder pain is of unclear significance as it might be anticipated that those with shorter residual limbs would require greater compensatory movements for prosthesis control and subsequently have a stronger association with contralateral shoulder pain. However, it is possible that those with shorter residual limbs actually had lower prosthesis use intensity over the long term, which could reduce the risk of contralateral shoulder pain. In this study, those with shorter residual limbs had worse functional performance as measured by the AM-ULA, which suggests that shorter residual limbs make it more difficult complete functional tasks while using the prosthesis. It is also possible that those with shorter residual limbs have a greater reliance on the nonamputated limb for activity performance, given that

items on the AM-ULA are scored lower if the prosthesis is used passively or not at all.[27]

Although not statistically significant across all domains, our study indicates that shoulder pain in the moderate intensity range is associated with functional performance and HRQOL outcomes in long-term upper limb prosthesis users. Our study specifically found a negative correlation coefficient between contralateral shoulder pain and measures of upper limb disability and the physical component of HRQOL. To our knowledge, this finding has not been previously reported. The finding that pain in the contralateral shoulder was associated with worse function as measured by the QuickDASH and worse physical HRQOL as measured by the PCS supports the assertion that people with upper limb amputation rely upon the nonamputated limb and that focused prevention strategies are critical. The lack of association between shoulder pain and activity performance as measured by the AM-ULA suggests that either the pain was not severe enough to interfere with functional performance or that individuals were able compensate for the pain to maintain their functional performance.

Conclusions based on our study findings are limited in several respects. Some subgroups (such as myoelectric users) are small, which may have limited our ability to detect statistically significant differences with small or moderate effect sizes. For *t*-tests comparing groups with and without "any shoulder pain," we had 80% power at alpha = .05 significance to detect effect sizes ≥0.597 or more. Whereas we had 80% power to detect effect sizes ≥0.767 for groups with and without ipsilateral shoulder pain and an effect size ≥0.629 for groups with and without contralateral shoulder pain. Our identification and measurement of shoulder pain were based on a one-time visit and may not accurately reflect the frequency, intensity, and impact of this condition over a longer time period. We did not collect data on the status of the shoulder before amputation and we have no data to determine whether the initial traumatic injury involved damage to either shoulder. It is possible that variations in shoulder pain etiology, additional lifestyle, and/or occupation-related factors not explored in this study contributed to shoulder pain and confounded our results. Our results should be interpreted cautiously given that our study did not collect additional diagnostic data (physical examination finding or radiographic studies) that may have been able to further elucidate the shoulder pain etiology. Given that our sample consisted primarily of male veterans who were long-term prosthesis users, our findings may not be generalizable to other cohorts of people (eg, nonveterans, those with more recent amputation). Our sample was limited to unilateral amputees with limb loss distal to the shoulder joint. Future research to build upon our findings should consider the study of larger samples, the collection of more detailed employment and activity data, the incorporation of additional diagnostic evaluations, and examination of the potential impact of prevention strategies on pain and functional performance. Additional research detailing the influence of prosthesis characteristics such as weight, terminal device type, and suspension strategy is also recommended.

CONCLUSION

Shoulder pain was found to be a common condition associated with functional and quality of life implications in our sample of mainly male veterans with major upper limb amputation who use a prosthesis. The shoulder contralateral to the amputation was found to be at greatest risk, especially in those with a longer time since amputation and who were body-powered prosthesis users. No association was found between shoulder pain and level of amputation. These findings emphasize the potential cumulative effects of prosthesis use and the importance of lifelong prevention strategies for the shoulder opposite from the amputation. These findings may not generalize to others with upper limb amputation who do not use prostheses, nonveteran populations, or those with different demographic characteristics.

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DISCLOSURES

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SUPPORTING INFORMATION

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

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