AWARD NUMBER: W81XWH-16-2-0065

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

PRINCIPAL INVESTIGATOR: Dr. Linda Resnik, PhD, PT

CONTRACTING ORGANIZATION: Ocean State Research Institute
Providence, RI 02908

REPORT DATE: October 2019

TYPE OF REPORT: Annual Report

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

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
Oct 2019	Annual	9/30/18-9/29/19

4. TITLE AND SUBTITLE

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

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-16-2-0065

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

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

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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

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

10. SPONSOR/MONITOR'S ACRONYM(S)

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

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Purpose: 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 2018 - 29 September 2019) focused on data collection and preliminary data analyses. We have completed 808 Aim 1 surveys, 585 Aim 2 surveys, 127 Aim 3 Visit 1 study visits, and 50 Aim 3 Visit 2 study visits. Data collection is complete for Aims 1 and 2, and ongoing Aim 3 Visit 2. We have published 3 papers for Aim 1, and have several papers and presentations in progress.

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

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	85	19b. TELEPHONE NUMBER *(include area code)*

Standard Form 298 (Rev. 8-98)
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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		10%
	Conduct surveys (Aim 1)	Month 19	Month 19	June 2018	100%
	Conduct Aim 1 survey (DoD sample)	Month 19	Month 42		
	Conduct surveys (Aim 2)	Month 31	Month 31	June 2019	100%
	Data analysis (Aims1 & 2)	Month 33	Month 46		50%
	Dissemination	Month 36	Month 54		35?%
Aim 3	Regulatory approvals	Month 8	Month 8	July 2017	100%
	Prepare study staff	Ongoing	Ongoing		100%
	Study coordination	Month 33	Month 33		95%
	Data collection (Visit 1)	Month 21	Month 35	August 2019	100%
	Data collection (Visit 2)	Month 33	Month 42		66%
	Data Analysis	Month 36	Month 48		15%
	Dissemination	Month 36	Month 54		0%

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

1& 2) Specific objectives and major activities

Specific objectives and major activities accomplished during the Year 3 reporting period (30th September 2018 – 29th September 2019) are described below:

Aims 1 & 2

Specific Objective 1: Maintain regulatory approvals (fully met)
Major Activities:

- Submitted all study modifications, continuing reviews and closures to HRPO
- Obtained continuing review approval from the VA CIRB, FDA IRB, University of Massachusetts IRB

Specific Objective 2: Identify Aim 1 & 2 sample (Fully met: VA sample; Partially met: DoD sample)

Major Activities:

- Identified Aim 2 sample using Aim 1 participants who agreed to participate in additional study activities.
- Received a fully executed Data Use Agreement for access to EMED data from the NHRC, which will allow us to identify a DoD sample.

Specific Objective 3: Complete Aim 1 data collection (fully met, VA sample)
Major Activities:

- Nothing to report (Aim 1 met objective met during 2017-2018 reporting year, 808 Aim 1 participants)

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

- Assembled and mailed Aim 2 recruitment materials to Aim 1 participants who agreed to participate in additional study activities
- Began Aim 2 surveys July 2018

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

- Tracked participation and mailed gift cards to Aim 2 participants
- Completed Aim 2 data collection in June 2019 (585 Aim 2 participants)

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

- Identified and planned analyses for journal articles

Specific Objective 7: Disseminate Aim 1 results (partially met, VA sample)

- 3 manuscripts have been published
- 4 manuscripts have been submitted and are under review
- 2 additional manuscripts are under construction
- 2 Scientific Presentations for national conferences have been accepted

Specific Objective 8: Begin Aim 2 data analysis (fully met, VA sample)

- Cleaned Aim 2 database and created codebook
- Identified targeted analyses needed for Aim 2 manuscripts
- Data analysis in progress

Aim 3

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

- Submitted all study modifications to HRPO
- Obtained continuing review approval from the VA CIRB, FDA IRB, CFI, USF, and HRPO

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

- Tracked participation and provided gift cards to Aim 3 Visit 1 participants
- Completed Aim 3 Visit 1 data collection in August 2019 (127 Aim 3 participants)

Specific Objective 3: Continue Aim 3 Visit 2 data collection (fully met)
Major Activities:

- Tracked participation and provided gift cards to Aim 3 Visit 2 participants
- Continued Aim 3 (Visit 2) data collection, 50 completed as of 10/18/19

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

- Cleaned Aim 3 Visit 1 database and created codebook
- Conducted Aim 3 Visit 1 preliminary analyses
- Held weekly meetings with study prosthetists to analyze prosthetic description data
- Prepared residual limb and pain map data for analysis
- Held Aim 3 PI data meetings to discuss analysis and dissemination plans
- Analyses of Visit 1 data underway

3) Significant Results or Key Outcomes

Data collection is complete for Aim 1 & Aim 2 (VA sample) and ongoing for Aim 3
Aim 1: 808 complete (final N)
Aim 2: 585 complete (final N)
Aim 3 Visit 1: 127 complete (final N)
Aim 3 Visit 2: 50 completed as of 10/18/2019

Aim 1 survey methods are summarized in the paper titled "A national study of Veterans with major upper limb amputation: Survey methods, participants, and summary findings". The results from the Aim 1 risk-benefit analyses are summarized in the papers titled "Patient perspectives on benefits and risks of implantable interfaces for upper limb prostheses: a national survey" and Patient Perspectives on Osseointegration: A National Survey of Veterans with Upper Limb Amputation. Full citations for these papers are listed on page 12 and full manuscripts are attached.

4) Other Achievements

Infrastructure development

- Executed Year 3 subcontract awards for the 5 VA sites (Seattle, Richmond, Tampa, Gainesville, San Antonio), University of Massachusetts, Center for the Intrepid, and University of South Florida

- Continued regular communications to facilitate coordination and insure study fidelity, including:
    - Regular phone meetings held with the overall study coordinator and staff at Aim 3 data collection sites
    - Monthly Aim 3 local site coordinator meetings
    - Quarterly Aim 3 study assessor meetings
    - Monthly Aim 2 study staff meetings (PVAMC and University of Massachusetts)

Data

- As discussed in previous reports, we have had delays with identifying the DoD sample. Identifying the DoD study population for Aims 1 and 2 required data use agreements (DUA) with two different DoD agencies. The DUA with the Naval Health Research Center (NHRC) was fully executed in October 2019, and we expect to obtain access to data in early December 2019. As previously reported, we have also worked with the DaVINCI team to identify DoD participants in DaVINCI databases, but we are unable to obtain contact information for this sample so will not be able to move forward with surveying participants identified using DaVinci. Our plan is to use the NHRC data to identify our DoD sample, and then determine if there are any unique participants who have not transitioned into VA care, and attempt to recruit those participants for the Aim 1 survey.

- We have held three Aim 3 PI data meetings to discuss analyses and prepare for dissemination (meetings held 2/4/19, 4/26/19 & 9/26/19). During these meetings we presented preliminary Aim 3 Visit 1 findings, and discussed key questions with Aim 3 local site investigators.

- To date, 3 manuscripts have been published and 4 additional manuscripts have been submitted and are under review, and two are under construction. We have had two abstracts accepted for national meetings. We have started analyzing Aim 2 and Aim 3 Visit 1 data, but have not yet submitted any manuscripts related to these study Aims.

Stated goals not met

While we have made significant progress, we have experienced some challenges in meeting stated goals:

1. Prepare study data (DoD population)
    a. Goal - By Month 7; Actual – Anticipated December 2019 (Month 39)

As described above, we experienced delays in accessing Department of Defense data for this project. We are pleased to report that our EMED data use agreement with the NHRC was fully executed in October 2019 and we expect to receive data in early December 2019. We received data from DaVINCI, but we are unable to obtain contact information using this database so will

not be able to contact participants. As discussed above, we will move forward with identifying a DoD sample using NHRC data, but will not be able to move forward with DaVINCI data.

2. Complete Aim 3 Visit 2 data collection
    a. Goal – Month 33: Actual: We anticipate completing Visit 2 data collection in March 2020 (Month 42)

Aim 3 Visit 2 data collection activities are ongoing because Visit 1 data collection extended into Year 3 of the award in order to meet recruitment goals, and Visit 2 happens ~12 months after Visit 1. We need to extend our timeline for Visit 2 because we extended Visit 1 data collection activities into Year 3. As of 10/18/19, we have enrolled 50 Visit 2 participants. Since we have been awarded a one-year no cost extension, we will expect to complete additional Visit 2 study sessions through March 2020 (Month 42), and then we will begin analysis and dissemination activities for Aim 3 Visit 2.

3. Complete data analysis for Aims 1 & 2
    a. Goal – Month 33; Actual: We anticipate completing data analysis for Aim 1 by April 2020 (Month 43) and for Aim 2 by July 2020 (Month 46)

The final dataset for Aim 2 was prepared during the summer 2019, and we are now in the process of completing initial analyses and planning for manuscripts. We anticipate we will complete planned analyses by July 2020 (Month 46).

4. Complete data analysis for Aim 3
    a. Goal – Month 36; Actual: We anticipate completing data analysis for Aim 3 by September 2020 (Month 48)

We are planning to end Aim 3 Visit 2 activities by March 2020 (month 42) so that analysis and dissemination activities can take place. Aim 3 Visit 1 analysis is in progress, and we will begin Aim 3 Visit 2 analysis in April 2020 (month 43). We expect these activities will extend at least through September 2020 (month 48), the end of our current no cost extension.

5. Complete dissemination for Aims 1, 2 & 3
    a. Goal – Month 36; Actual: September 2020 and beyond (Month 54)

We have begun dissemination for Aim 1 as mentioned above. We anticipate beginning dissemination for Aim 2 by July 2020. Because we will be collecting for Aim 3 until the end of March 2020 (Month 42), followed by data analysis, we anticipate beginning dissemination for Aim 3 by Sept 2020 (Month 48). These activities will likely extend beyond the period of our current no cost extension. We anticipate we will need to request an additional no cost extension to complete analysis and dissemination activities.

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

Nothing to report.

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

Nothing to report.

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

During the next reporting period (Year 4, No Cost Extension period), we anticipate accomplishing the following activities to meet the project goals and objectives:

Project Activity	Goal Completion Date
Receive NHRC data, and identify unique DoD amputees, recruit and administer Aim 1 survey to those individuals	Month 42
Identify and plan analyses for Aim 2 data	Month 42
Complete Aim 3 Visit 2 data collection	Month 42
Complete Analysis for Aim 1	Month 43
Complete Analysis for Aim 2	Month 46
Perform and interpret analyses for Aim 3 Visit 1 Data	Month 48
Perform and interpret analyses for Aim 3 Visit 2 Data	Month 48
Begin dissemination for Aim #3	Month 48
Submit 2 abstracts to national conferences	Month 48
Submit 4 publications to scientific journals	Month 48

4. **IMPACT:**

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

Nothing to report.

- **What was the impact on other disciplines?**

Nothing to report.

- **What was the impact on technology transfer?**

Nothing to report.

- **What was the impact on society beyond science and technology?**

Nothing to report.

5. **CHANGES/PROBLEMS:**

- **Changes in approach and reasons for change**

During Year 3, we made the following changes to the study approach:

- Due to scheduling problems and slow recruitment, we closed the Gainesville site in July 2019. Gainesville Aim 3 Visit 2s are being completed at the Tampa site. We submitted required closing documents to the VA CIRB and HRPO.

- We added the San Antonio VA site so that we are able to enroll civilians in San Antonio. We were unable to enroll civilians to date at the CFI data collection site, and in order to meet recruitment goals we expanded to include data collection at the San Antonio VA. The study assessor and study coordinator from the CFI will collect data at the CFI and at the San Antonio VA.

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

As mentioned above, recruitment into Aim 3 was slower than anticipated which extended Visit 1 data collection into Year 3 and delayed the planned completion of Visit 2 data collection. Because we have received a no cost extension, we will be able to continue Visit 2 data collection.

We continued to experience problems with access to DoD. At this time we have a fully executed DUA with the NHRC, and expect to get data soon to allow us to identify a DoD population using this sample.

- **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 to support continued study coordination, data collection for the Aim 1 DoD sample, data collection for Aim 3, and 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:

1. Resnik L, Benz H, Borgia M, Clark MA. Patient perspectives on benefits and risks of implantable interfaces for upper limb prostheses: a national survey. Expert Rev Med Devices. 2019;16(6):515-40. doi: 10.1080/17434440.2019.1619453. PubMed PMID: 31090461.

2. Resnik L, Ekerholm S, Borgia M, Clark MA. A national study of Veterans with major upper limb amputation: Survey methods, participants, and summary findings. PLoS One. 2019;14(3):e0213578. doi: 10.1371/journal.pone.0213578. PubMed PMID: 30870496; PubMed Central PMCID: PMCPMC6417699

3. Resnik L, Benz H, Borgia M, Clark MA. Patient Perspectives on Osseointegration: A National Survey of Veterans with Upper Limb Amputation. PM R. 2019. doi: 10.1002/pmrj.12147. PubMed PMID: 30784201.

Manuscripts under review:

1. Resnik, L, Borgia, M, Heinneman, A, Clark, M. Prosthesis Satisfaction in a National Sample of Veterans with Upper Limb Amputation, Submitted July, 2019

2. Resnik, L. Borgia, M, Highsmith, J. Randolph BJ, Webster, J. Veteran experience and perceptions with upper limb amputation and prosthetic care services, Submitted March, 2019

3. Resnik, L, Borgia, M, Clark, M, A National Survey of Prosthesis Use in Veterans with Major Upper Limb Amputation: Comparisons by Gender, Submitted September, 2019

4. Resnik, L. et al. Function and quality of life of upper limb amputees: Impact of prosthesis use and type, Submitted September 2019

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

Nothing to report.

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

Planned scientific presentations:

1. Resnik, L, Heckman, J, Phillips, S, Balakhanlou, E. Methods and Highlights From the National Study of Veterans With Upper Limb Amputation. American Congress of Rehabilitation Medicine (ACRM), Chicago, IL, November, 2019

2. Balakhanlou, E, Webster, J, Borgia, M, Resnik, L. Frequency and Severity of Phantom Limb Pain in Veterans with Major Upper Limb Amputations: Results of a National Survey (Research Abstract) American Academy of Physical Medicine & Rehabilitation (AAPM&R), San Antonio, TX, November, 2019

- **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:	4
Contribution to Project:	Dr. Resnik has performed work in the area of overall study overnight, data quality monitoring, data analysis, manuscript preparation and oversight for the work of Ms. Biester (Ekerholm), Mr. Borgia and Ms. Gill.
Funding Support:	*n/a*

Name:	Sarah Biester (Ekerholm)
Project Role:	Project Manger
Researcher Identifier (e.g. ORCID ID):	n/a
Nearest person month worked:	6
Contribution to Project:	Ms. Biester has performed work in the area of study coordination across all study sites, regulatory document preparation and submission, and other reporting requirements. Ms. Biester has also coordinated the submission of data use agreements, maintains the overall study budget, approves invoices, prepares HR and contracting paperwork, and other administrative tasks as required.
Funding Support:	*n/a*

Name:	Anisha Gill
Project Role:	Deputy Project Coordinator
Researcher Identifier (e.g. ORCID ID):	n/a
Nearest person month worked:	6
Contribution to Project:	Ms. Gill has performed work in the area of maintenance of study databases and preparation of study data, data cleaning, mailings for Aims 1 & 2, and quality control reviews for Aim 3 data collection. In addition, she has assisted Ms. Biester with study coordination, and provided technical support to Aim 3 local site coordinators in data collection and entry procedures.
Funding Support:	*n/a*

Name:	Matthew Borgia
Project Role:	Biostatistician/Analyst

Researcher Identifier (e.g. ORCID ID):	n/a
Nearest person month worked:	4
Contribution to Project:	Mr. Borgia has performed work to, clean and update contact information and prepare study data for Aim 2 mailings, create codebooks for study data, clean data and conduct analyses for Aim 1, 2 and 3 data.
Funding Support:	n/a

Name:	Eileen Small
Project Role:	Project Coordinator
Researcher Identifier (e.g. ORCID ID):	n/a
Nearest person month worked:	2
Contribution to Project:	Ms. Small was hired to take on study coordination duties. She is currently being trained on study coordination and does not have specific duties.
Funding Support:	*n/a*

Name:	Akosua Adu-Boahene
Project Role:	Project Coordinator
Researcher Identifier (e.g. ORCID ID):	n/a
Nearest person month worked:	6
Contribution to Project:	Ms. Adu-Boahene was being trained to take over study coordination duties, however, she left her role with the VA in April 2019.
Funding Support:	n/a

Name:	Josephine Airoldi
Project Role:	Research Assistant
Researcher Identifier (e.g. ORCID ID):	n/a
Nearest person month worked:	5
Contribution to Project:	Ms. Airoldi was hired to replace Ms. Gill. She managed the pain map and residual limb project for Aim 3, and took on responsibility for Ms. Gill's duties (Aim 3 data management, quality control, etc)
Funding Support:	n/a

Name:	Jacqueline Siven
Project Role:	Research Assistant/Coordinator (Tampa)
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	6
Contribution to Project:	Ms. Siven has coordinated data collection activities for the Tampa site, including subject recruitment, travel, reimbursement, tracking, data collection and data entry. In addition, Ms. Siven has coordinated required regulatory submissions for the Tampa site and assisted with prosthetic description data dissemination planning.
Funding Support:	*n/a*

Name:	Matthew Jerrell
Project Role:	Research Assistant/Coordinator (Seattle)
Researcher Identifier (e.g. ORCID ID):	

Nearest person month worked:	6
Contribution to Project:	Mr. Jerrell has coordinated data collection activities for the Seattle site, including subject recruitment, travel, reimbursement, tracking, data collection and data entry. In addition, Mr. Jerrell has coordinated required regulatory submissions for the Seattle site.
Funding Support:	*n/a*

Name:	Ashley Soon
Project Role:	Research Assistant/Coordinator (Gainesville)
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	5
Contribution to Project:	Ms. Soon has coordinated data collection activities for the Gainesville site, including subject recruitment, travel, reimbursement, tracking, data collection and data entry. In addition, Ms. Soon has coordinated required regulatory submissions for the Gainesville site.
Funding Support:	*n/a*

Name:	Mandeesha Singh
Project Role:	Research Assistant/Coordinator (Richmond)
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	6
Contribution to Project:	Ms. Singh has coordinated data collection activities for the Richmond site, including subject recruitment, travel, reimbursement, tracking, data collection and data entry. In addition, Ms. Singh has coordinated required regulatory submissions for the Richmond site.
Funding Support:	*n/a*

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

There have been some changes to active support for the PI and senior/key since Year 2 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: Research Career Scientist Award
Sponsor: VA RR&D, A9264-S
Veterans Affairs (10P9R) Patricia A. Dorn, Ph.D. Director, Rehab R&D Service 810 Vermont Avenue, NW Washington, DC 20420
Time Commitment: 8 CM (VA APPT) - This award funds Dr. Resnik's VA time and effort as a VA Research Career Scientist which provides salary coverage for effort on VA service and mentoring, as well as VA and OSRI research projects
Period of Performance: 7/1/19-6/30/24
Amount Funded: $1,009,830
Project Goals/Specific Aims: N/A
Overlap: This award will cover Dr. Resnik's time and effort on the proposed project.

Title: Comparative Effectiveness of Upper Limb Prostheses and Component Effects
Sponsor: Department of the Army, W81XWH-19-1-0800
Elena G. Howell Grants Officer
US Army Medical Research Acquisition Activity
820 Chandler Street
Fort Detrick, MD 21702-5014
Time Commitment: 3.0 CM (VA Appt)
Period of Performance: 9/30/19-9/29/22
Amount Funded: $1,493,676
Project Goals/Specific Aims: There are 3 major goals/aims 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.
Overlap: None

Completed

Title: Research Career Scientist Award
Sponsor: VA RR&D, A9264-S

Veterans Affairs (10P9R) Patricia A. Dorn, Ph.D. Director, Rehab R&D Service 810 Vermont Avenue, NW Washington, DC 20420
Time Commitment: 12 CM (VA APPT) - This award funds Dr. Resnik's 8/8th VA time and effort as a VA Research Career Scientist.
Period of Performance: 07/01/14 – 06/30/19
Amount Funded: $915,735
Project Goals/Specific Aims: N/A

Title: Initial Treatment Approaches and Healthcare Utilization among Veterans with Low Back Pain (Schmidt PI)
Sponsor: CoHSTAR
Audrey Kydd
121 S. Main Street
Brown University
Providence, RI 02903
Time Commitment: .12 CM (Brown Univ. Appt)
Period of Performance: 2/15/18-2/14/19
Amount Funded: $25,000
Project Goals/Specific Aims: The objective of this research is to gain a better understanding of the initial intervention approaches and important health and utilization outcomes among Veterans with a new diagnosis of LBP.

Dr. Jill Cancio: The following changes have been made to Dr. Cancio's support*:*
Completed

Title: Development of an Engaging Training Tool to Provide Superior Muscle Computer Interfaces for Rehabilitation of Neuromusculoskeletal Injuries
Sponsor: Clinical and Rehabilitative Medicine Research Program (Hargrove, PI)
Role: Co-Investigator / Site PI
Time Commitment: 2.4CM
Period of Performance: 8/15/2015 -8/14/2018
Award Amount Funded: $1,500,00
Project Goals/Specific Aims: To conduct rehabilitative needs assessment focus groups to determine clinician and amputee preferences for game design and hardware usability

Dr. Melissa Clark: The following changes have been made to Dr. Clark's support*:*
New

Title: Rhode Island Community Wellness and Health Determinants Study
Sponsor: Blue Cross Blue Shield
Role: PI
Time Commitment: 2.40CM
Period of Performance: 12/15/2018 – 12/31/2019
Amount Funded: $151,285
Project Goals/Specific Aims: The goal of this project is to develop an initial survey instrument tool that can be used as a benchmark to measure the five domains of community wellbeing and determinants of health.

Overlap: None

Title: Reducing Hazardous Alcohol Use in Social Networks using Targeted Intervention
Sponsor: Brown University (Barnett, PI)
Role: Co-Investigator
Time Commitment: 1.2 CM
Period of Performance: 09/01/2018-08/31/2021
Amount Funded: $466,217
Project Goals/Specific Aims: The goal of this project is to investigate the efficacy of an individual intervention conducted with selected participants embedded in a social network for reducing alcohol use in other college student network members
Overlap: None

Title: Rhode Island Community Foodbank Survey
Sponsor: RI Food Bank (Vivier, PI)
Role: Co-Investigator
Time Commitment: 0.60 CM
Period of Performance: 12/01/2018 – 11/30/2019
Amount Funded: $61,737
Project Goals/Specific Aims: The Hassenfeld Child Health Innovation Institute will refine and program a data collection instrument and train volunteers to conduct a survey for the Food Bank about food assistance needs in the state of Rhode Island
Overlap: None

Completed

Title: Nursing Home Culture Change: Evaluating Change in Practice and Quality
Sponsor: Brown University/NIH/NIA (Miller, PI)
Role: Co-Investigator
Time Commitment: 1.20 CM
Period of Performance: 09/01/2015 – 03/31/2019
Amount Funded: $127,309
Project Goals/Specific Aims: The long-term goal of this research is to improve NH care and the quality of life within NHs by providing evidence on how culture change implementation impacts quality

Title: Facilitating HIV/AIDS and HIV Testing Literacy for Emergency Department Patients
Sponsor: Rhode Island Hospital/NIH/NINR (Merchant, PI)
Role: Co-Investigator
Time Commitment: 0.60 CM
Period of Performance: 09/01/2015 – 04/30/2019
Amount Funded: $26,035 (sub only
Project Goals/Specific Aims: The goal of this project is to conduct a multi-site randomized controlled longitudinal trial to compare HIV/AIDS and HIV testing knowledge acquisition and retention of English and Spanish-speaking emergency department patients receiving HIV/AIDS and HIV testing knowledge information by video or pictorial brochure

Title: Variations in Needs after Colorectal Cancer Diagnosis (Supplement)
Sponsor: Boston University/NIH/NCI (Boehmer, PI)
Role: Co-Investigator (subcontract PI)
Time Commitment: 0.00 CM
Period of Performance: 09/01/2015 – 06/30/2019
Amount Funded: $21,296 (sub only)
Project Goals/Specific Aims: The overall goal of this project is to understand differences due to sexual orientation in quality of life among colorectal cancer survivors by collecting data from a population-based sample of colorectal cancer survivors of different sexual orientations.

Title: Affordable Senior Housing Project
Sponsor: Jewish Community Housing for the Elderly
Role: Principal Investigator
Time Commitment: 1.20 CM
Period of Performance: 07/01/2018 – 06/30/2019
Amount Funded: $171,965
Project Goals/Specific Aims: The goal of this project is to examine the association between the availability of onsite services and residents' health care utilization and expenditures and to examine the association between the affordable housing and residents' health care utilization and expenditures among residents living in housing properties sponsored by the U.S. Department of Housing and Urban Development

Dr. Jeffrey Heckman: The following changes have been made to Dr. Heckman's support*:*
Completed

Title: 3D Printing Foot Orthosis Outcome Testing (3DP FOOT)
Sponsor: VHA **(**VA Innovators Network Accelerator Program)
Role: Principal Investigator
Time Commitment: 0.6 CM
Period of Performance: 10/1/2017-9/30/2019
Amount Funded: $144,000
Project Goals: The objective of this program is to develop a 3D printed foot orthotic that meets or exceeds current standard practice and improve the timeliness of preventive care for Veterans at high risk for limb loss.

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

Title: Enhanced Auto-Diagnostic Adaptive Precision Trainer for Myoelectric Prosthetic Users (eADAPT-MP)
Sponsor: Design Interactive
Role: Project PI
Period of Performance: 01/23/2019-06/30/2020
Amount Funded: $184,172

Project Goals/Specific Aims: Evaluate a novel training method for users of upper limb myoelectric prostheses and the resulting effects on prosthesis use, return to work, and quality of life
Overlap: None

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

  Nothing to report

8. **SPECIAL REPORTING REQUIREMENTS**

- **COLLABORATIVE AWARDS:**

  Nothing to report, not applicable.

- **QUAD CHARTS:** See attached.

9. **APPENDICES:**

Accepted publication summarizing results from study Aim 1, titled "A National Study of Veterans with major upper limb amputation: Survey methods, participants, and summary findings", "Patient perspectives on benefits and risks of implantable interfaces for upper limb prostheses: a national survey" and "Patient Perspectives on Osseointegration: A National Survey of Veterans with Upper Limb Amputation" are attached to summarize preliminary results from Aim 1.

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: Aim 2 data collection is complete with 585 participants, and Aim 3 visit 1 data collection is complete with 127 participants. 3 manuscripts have been published and 4 manuscripts have been submitted and are under review.

Timeline and Cost

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

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 (NCE Goals) – Data, analysis and dissemination

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

PY3 Budget Expenditure to Date

Projected Expenditure: $2,497,440 (Cumulative, Y1+Y2+Y3 Projected Expenditure)
Actual Expenditure: $1,894,580 as of 09/30/2019 (Cumulative, Y1+Y2+Y3 Actual Expenditure)

PLOS ONE

RESEARCH ARTICLE

A national study of Veterans with major upper limb amputation: Survey methods, participants, and summary findings

Linda Resnik[1,2]*, **Sarah Ekerholm**[1], **Matthew Borgia**[1], **Melissa A. Clark**[3]

1 Research Department, Providence VA Medical Center, Providence, Rhode Island, United States of America, **2** Health Services, Policy and Practice, Brown University, Providence, Rhode Island, United States of America, **3** University of Massachusetts Medical school, Worcester Massachusetts, United States of America

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Citation: Resnik L, Ekerholm S, Borgia M, Clark MA (2019) A national study of Veterans with major upper limb amputation: Survey methods, participants, and summary findings. PLoS ONE 14 (3): e0213578. https://doi.org/10.1371/journal.pone.0213578

Editor: Arezoo Eshraghi, Holland Bloorview Kids Rehabilitation Hospital, CANADA

Received: November 14, 2018

Accepted: February 25, 2019

Published: March 14, 2019

Data Availability Statement: Data are available from the Providence VA Medical Center Institutional Data Access/Ethics Committee for researchers who meet the criteria for access to confidential data. Individually identifiable data, excluding Veterans' name and 38 USC $7332-protected information, will be shared pursuant to a written request and IRB approved waiver of HIPAA authorization, with the approval of the Under Secretary for Health, in accordance with VHA Handbook 1605.1 $13.b(1)(b) or 13.b (1)(c) or

Abstract

Introduction

A comprehensive study to assess quality and outcomes of care for Veterans with upper limb amputation is needed. This paper presents methods and summary findings from a national survey of Veterans with upper limb amputation.

Methods

After completion of a pilot study to develop and refine methods, computer-assisted telephone interviews were conducted with 808 Veterans with upper limb amputation (response rate = 47.7%; cooperation rate = 63.3%).

Results

Respondents were 776 unilateral and 32 bilateral amputees, 97.5% male, mean age 63.3 (sd 14.1). Prostheses were used by 60% unilateral and 91% bilateral, the majority used body powered devices. Prostheses were used ≥8 hours/day by 52% unilateral and 76% bilateral. Prosthetic training was received by 71% unilateral and 59% bilateral. Mean prosthetic satisfaction was 3.9 (sd 0.6) and 3.8 (sd 0.7) as measured by TAPES; and 25.0 (sd 5.1) and 25.7 (sd 4.5) as measured by OPUS CSD for unilateral and bilateral respectively. Mean perceived disability (measured by QuickDASH) scores were 49.5 (sd 20.7) for unilateral and 34.7 (sd 22.0) for bilateral. VR-12 PCS scores were below population norms. The majority reported contralateral limb pain, musculoskeletal conditions, back and neck pain. Phantom limb pain was reported in 83.4% of unilateral and 68.8% of bilateral, and residual limb pain in 65.1% of unilateral and 68.8% of bilateral. Most, (81.8% unilateral, 84.4% bilateral) had been to a Veterans Affairs medical center (VA) for amputation care, while 57% of unilateral and 81.3% of bilateral had been to a VA amputation clinic.

superseding versions of that Handbook. Please contact ValMicucci@va.gov for more information.

Funding: This research was funded by the U.S Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office (W81XWH-16-2-0065 to LR). This research was also funded by the Department of Veterans Affairs Rehabilitation Research and Development (A9264-S to LR). The funder did not play a role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Competing interests: Opinions, interpretations, conclusions and recommendations are those of the author and not necessarily endorsed by the Department of Defense. The authors have declared that no competing interests exist.

Discussion/Conclusion

Veterans with upper limb amputation have moderately impaired physical functioning. Prosthesis use rates were lower than previously reported. Although satisfied with their prostheses, nearly half used them ≤8 hours/day. Rates of musculoskeletal problems, phantom and residual limb pain were higher than previously reported. A substantial proportion never received prosthetic training, or VA amputation care.

1.0—Introduction

Appropriate provision of upper limb prostheses and rehabilitation services can improve satisfaction with the prosthetic limb, reduce device abandonment and improve overall quality of life.[1] Regular use of a prosthesis may also prevent cumulative trauma disorders (CTD) in the sound side limb, as well as back and neck pain related to poor compensatory strategies, common problems of upper limb amputees.[2, 3] Limited research shows that prosthesis use is associated with improved performance in hygiene, grooming and dressing.[4] In contrast, non-use of a prosthesis is associated with development of one-handedness, and limitations in strength, flexibility, endurance, and mobility.[5, 6]

Yet many persons with upper limb amputation abandon or reject their prostheses because they are not satisfied with available prosthetic choices.[7, 8] Studies show that rates of prosthetic rejection vary for different types of prostheses, with rejection of myoelectric hands, body-powered hooks and passive hands, at 39%, 50%, and 53% respectively.[9] Transradial (TR) prosthesis users have the lowest rate of rejection (6%), followed by transhumeral (TH) users (57%), and persons with shoulder disarticulation (SD; 60%).[8]

Currently available prostheses fall short of restoration of full function, which is one reason for high rates of abandonment. Upper limb prosthesis users report that the most challenging activities include household chores (40% of users), sports (30%), hobbies (22%), activities of daily living (19%), social activities (8%), and occupational activities (6%). Upper limb amputees rank improved prosthesis function XXXX as a top design priority.[7]

Over the past decade, the Department of Veterans Affairs (VA) has focused on improving the care of Veterans with amputation. Between 20%-40% of combat amputees in U.S. conflicts in the global war on terror have sustained major upper-extremity amputation.[10, 11] Government reports have raised concerns about VA amputation care. For instance, a 2008 report found that Veterans who received their prosthetic care in the VA were less satisfied than their counterparts who received care in the private sector, suggesting a quality gap in VA care.[12] A 2011 study by the Office of the Inspector General (OIG), which focused solely on combat Veterans from Operation Enduring Freedom (OEF)/Operation Iraqi Freedom (OIF), found that only 69.6% of persons with upper limb amputation were satisfied with their prostheses, leading the OIG to call for efforts to evaluate the needs of Veterans with traumatic upper limb amputations to improve their satisfaction.

A national survey of Veterans with amputation from OEF/OIF and Vietnam reported that rates of prosthetic abandonment were actually lower for OEF/OIF combat amputees (22% overall rejection rates) as compared to 30% in the Vietnam Veteran group.[13] Newer combat Veterans with unilateral upper-limb loss were found to use nearly twice as many prostheses as those from the Vietnam group, and newer combat Veterans used more "high tech" devices, (46% myoelectric and 38% body-powered) as compared to Vietnam Veterans (22% myoelectric, 78% body-powered).[14] Despite continued dissatisfaction with devices, these data

indicate that there may be greater satisfaction with prostheses amongst more recent upper limb amputees, and suggest that lower rates of abandonment may reflect improvements in technology and amputation care over time.

In 2009, the VA reorganized its amputation system of care (ASOC) and made great efforts to improve quality; [15] the full implementation of the new ASOC occurred in 2011. Additionally, the VA and Department of Defense (DoD) collaborated to develop the first evidence-based Clinical Practice Guidelines (CPGs) for the rehabilitation of persons with upper limb amputation.[16] Efforts to disseminate these CPGs (released in 2014) are currently underway system-wide. The CPGs describe care paths to improve outcomes in postoperative pain, physical health, function, psychological support and well-being, patient satisfaction, reintegration, and healthcare utilization, and should, in theory, lead to better prosthetic outcomes. These CPGs may lead to improved care and outcomes across the VA and DoD.

Given major differences in types of prosthetic devices and componentry, research is needed to understand the benefits and drawbacks of currently available devices as well as novel advanced (and expensive) technologies. Therefore, the objective of our overall study was to provide comprehensive cross-sectional and longitudinal data on function, needs, preferences, and satisfaction of Veterans with major upper limb amputation. The purposes of this manuscript are to provide descriptive summary findings and nationally representative estimates of a selection of key measures from the baseline survey for respondents with unilateral and bilateral amputation, and to compare prosthetic satisfaction, and quality of life outcomes of unilateral and bilateral amputees. These data provide prevalence estimates of Veterans with upper limb amputation as well as information about satisfaction and quality of life outcomes to inform approaches to rehabilitative care and investments in technology.

2.0—Methods

The study consisted of development and refinement of survey content and then administration of the survey to a national sample of Veterans at baseline and at 12-month follow-up. This manuscript reports on the cognitive interviews and pretesting for survey refinement as well as baseline data collection efforts. Future reports will address the 12-month follow-up data.

2.1—Survey development and content

The survey instrument was designed to assess demographics, amputation history, prosthesis use, function, quality of life, satisfaction with prosthesis and amputation care, and quality of care. It also included a risk-benefit assessment of technological advances requiring surgical intervention that was developed in conjunction with the Food and Drug Administration (reported elsewhere). Both unilateral and bilateral amputation versions of the survey were developed and tested.

Following instrument development and adaptation, a pilot study was conducted in two phases: cognitive testing to identify problematic items (Phase 1), and pretesting of the full survey (Phase 2). The cognitive interview sample (Phase 1) included 10 participants; 90% male, mean age 56 years, 30% with transradial (TR), 60% with transhumeral (TH), and 10% with shoulder level amputation (SH); 60% were prosthesis users. During the telephone-administered cognitive interviews, we identified several questions that were not understood by participants, were interpreted in multiple ways, or were redundant. These items were revised or dropped from the questionnaire. Second, we identified content areas missing in the initial version of the questionnaire that were important to respondents (e.g., training received on using a prosthesis, impairment experienced on the sound side). Third, we identified some double-barreled items requiring different types of abilities (e.g., use cell phone and take notes; peel and

cut vegetables) and items requiring definitions or specific examples (e.g., heavy objects defined are those over 15 pounds; primary prosthesis is the one used most often; housework such as carrying a laundry basket). Fourth, we noted questions in which additional response options were required (e.g., neurologist, primary care doctor, and no provider were added to an item about which type of providers have been involved in your amputation care in the past 12 months). Finally, we determined that specific items were needed about primary versus secondary (spare) types of prostheses and terminal devices used, and that some questions were not relevant depending on amputation level as well as the number and types of prostheses and terminal devices used. As a result, several additional skip instructions to relevant questions based on prior responses were needed. Therefore, while the initial intention was to have both a self-administered mailed version and a telephone-administered version of the instrument, the final instrument is for telephone administration only due to the complexity of the format.

The pretest sample (Phase 2) included 13 participants; mean age 59 years, 92% male, 38% TR, 46% TH, and 15% SH; 77% were prosthesis users of whom 60% used a body-powered and 40% a myoelectric/hybrid. Based on the pretesting, we continued to refine which items should be asked based on level of amputation as well as how to ask about the number and types of prostheses and terminal devices currently used. We also added additional definitions (e.g., phantom limb, residual limb; driver rehabilitation therapist). Third, we added additional clarification for time frames of some questions. Fourth, in response to continued confusion by respondents in answering questions about difficulty with participation in particular activities, we revised the format to ask respondents about the difficulty of doing a set of activities that typically require two hands without a prosthesis first and then using a primary prosthesis and terminal device (if applicable). Then we asked respondents to think about a set of one-handed activities and asked about the level of difficulty both without and with a prosthesis (if applicable). Finally, based on the timing of the interviews, we determined that a few questions needed to be dropped so that the interview averaged 45 minutes in length. See S2 Appendix for a copy of the instrument.

2.2 –Survey overview

The final baseline survey was comprised of multiple items drawn from the 2008 Survey for Prosthetic Use, [17] previously validated measures, and new items developed and tested for this study. Each component of the survey is described below.

2.2.1—Demographics and amputation type and etiology. The demographics section included items on age, gender, marital status, number of children, gender, race/ethnicity, and employment. The amputation section included items asking about: the side and level of amputation; date, etiology of amputation; surgical history related to the amputation; and hand dominance. When the gender item was not answered at the time of interview, we utilized the gender variable available in the VA Corporate Data Warehouse (CDW).

2.2.2—Prosthesis use. Respondents who reported that they were current prosthesis users were asked to identify their primary device and terminal devices, and if they used more than one type of device or terminal device to indicate which one they considered their secondary or spare device. They were then asked how these prostheses were suspended to their body.

Respondents were asked whether they had ever stopped using a prosthesis, and if abandoned, what type of device(s) they had stopped using, and all reasons for abandonment. Those who were current prosthesis users were asked to report the frequency of prosthesis use, and hours per day of use. Respondents were also asked if they had received prosthetic training, and if so, the number of visits of training, the person who provided the training, and the expertise of the person providing the training.

Additional survey sections asked about the use of prosthesis during daily activities. Finally, items about the frequency of device repairs and the frequency of visits to a prosthetist for adjustments to the socket in the past 12 months were included. Results for these items will be reported elsewhere.

2.2.3—Satisfaction with the prosthesis. Prosthetic satisfaction was addressed using the Trinity Amputation and Prosthetic Experience Scale (TAPES) satisfaction scale, the OPUS Client satisfaction with devices (CSD) scale, as well as items drawn from earlier surveys.[17] The TAPES Satisfaction scale consists of 10 items addressing color, shape, noise, appearance, weight, usefulness, reliability, fit, comfort and overall satisfaction.[18] Items are rated on a 5-point scale (1 = very dissatisfied, 5 = very satisfied). Cronbach alpha for this sample was 0.88. The OPUS CSD contains 11 items relating to prosthesis weight, ease of donning, durability, fit, appearance, comfort, wear and tear from clothes, pain of wearing, skin abrasions, cost of maintenance and cost of repair. Items were rated on a 4-point scale (1 = strongly agree, 4 = strongly disagree). Nine of the items are summed to achieve the final recorded score. The two items related to cost are scored separately. Cronbach alpha for the nine-item scale in this sample was 0.81. The total CSD score was calculated by summing the CSD items. The percentile value of the CSD score (as compared to provisional normative values) was estimated for those without missing values on any items by summing the total of all items and cross-walking to the norm-based values shown on the OPUS Scoring Guide.[19] The survey also included investigator-generated items asking about desire to change devices, inability to wear the prosthesis because of poor socket fit, satisfaction with the way the prostheses and terminal device moves, and unintended movement of the prosthesis.

2.2.4—Function and quality of life. The survey included validated scales and additional items related to function and quality of life. Perceived disability was measured using the 11-item QuickDASH,[20] that assesses difficulty performing activities, amount of limitation, or the extent of interference with activities as well as extent of arm, shoulder and hand pain and tingling. [21, 22] The Cronbach alpha for the QuickDASH in this sample was 0.87. Additional items asked respondents to rate the difficulty of performing 5 common activities (3 two-handed activities, and 2 one-handed activities) with and without using their primary prosthesis and terminal device.

Health Related Quality of Life was assessed using the VR-12 item, a Veteran version of the SF-12 Health Survey that produces the Physical Component Summary (PCS) (Cronbach alpha of 0.86 in this sample) and the Mental Component Summary (MCS) (Cronbach alpha of 0.88 in this sample) scores.[23, 24] Participants were also asked other investigator-generated items including whether or not they needed help from another person to perform daily activities, and if so. how many hours of help they required in a typical day.

The questionnaire included items asking about the presence of pain in the prior 4 weeks in the phantom limb, residual limb, contralateral limb, neck, and back. These items asked about the frequency of each type of pain, and the intensity for those experiencing pain. The questionnaire also included items asking respondents whether they had ever been diagnosed with any of 9 common musculoskeletal conditions in the sound side (e.g. tendinitis of wrist, elbow, finger, thumb, and rotator cuff, carpal tunnel syndrome, and arthritis), residual limb health, and pain. These items were adapted from the Reiber survey.[17] We calculated the proportion of respondents who reported any contralateral limb condition. A detailed analysis of pain and musculoskeletal conditions will be reported in future papers.

Additional items, drawn from prior surveys (results of which will be reported in future papers), pertained to difficulty with activities and participation, and were assessed using items about eating, meal preparation, housework, home maintenance, computer use, lifting and carrying. Our questionnaire also included a single item on the extent of bother from residual limb

sweating in the socket, drawn from the residual limb health subscale of the Prosthetics Evaluation Questionnaire.[25] Other items asked about body image, flashback/nightmares related to the amputation, difficulty concentrating, sense of embodiment of the prosthesis, and confidence using the prosthesis.

2.2.5—Amputation care. The questionnaire included a section on amputation related care and care quality. Investigator-generated items asked about where the respondent had ever gone for amputation-related care, and those who indicated that they had ever gone to a VA Amputation clinic or Department of Defense Amputation clinic were asked the year of most recent visit.

The questionnaire also included the OPUS Client Satisfaction with Services scale (CSS).[26] Respondents were asked a series of investigator generated questions that addressed aspects of clinical practice guidelines for rehabilitation of persons with upper limb amputation. The CSS and the investigator generated items will be described and reported upon in a separate manuscript addressing quality of care.

2.2.6—Risk benefit assessment and technology acceptance. The questionnaire also included a section on risk benefit and technology acceptance of potentially new prosthetic devices, capabilities, and suspension methods. Findings related to these items will be reported in separate manuscripts.

2.3—Survey recruitment and data collection

Our goal was to include a representative sample of Veterans with major upper limb amputation who received care in the VA between 2010–2016, defined in our study as amputation at the forequarter, shoulder disarticulation, transhumeral (TH), elbow disarticulation, transradial (TR), or wrist disarticulation level, The sampling frame was identified from VA CDW sources including Inpatient, Outpatient, and Fee domains; the main source for information regarding VHA Benefit compensation and pension benefits paid to veterans and their beneficiaries; and Veteran's Benefits Administration (VBA) disability ratings. A list of diagnosis and procedure codes used to identify the sample is provided in S1 Appendix.

All non-deceased Veterans with valid addresses and phone numbers were sent an initial recruitment package containing an invitation letter, a study information sheet explaining the study, and a card with stamped envelope to return if they wished to opt out of participation. Veterans who did not opt-out of study participation by returning the postcard or calling the study telephone number within 30 days were contacted by the study interviewers. To maximize study recruitment, up to ten attempts were made to contact potential participants. All participants provided oral informed consent to participate. A waiver of documentation of informed consent was obtained from the VA Central IRB. All surveys were conducted via telephone by trained interviewers and were approximately 45 minutes in length. Separate versions of the survey were administered to unilateral and bilateral amputees. The bilateral version included all questions in the unilateral version but asked collected information on key variables (e.g. amputation etiology, prosthesis use) for both the left and right sides.

2.4—Statistical methods

Response (RR) and cooperation (CR) rates were calculated using American Association of Public Opinion Research guidelines (AAPOR RR4 and CR4).[27] In RR4 and CR4 those with partial interviews are considered as completers. The denominator of eligible subjects in the RR4 includes an estimate for the proportion of cases of unknown eligibly that are actually eligible. The cooperation rate does not include those who could not be reached for the screener or

survey. Using data available in CDW we compared age, gender and year of last encounter at the VA of survey responders and non-responders to assess potential bias in survey respondents. In 3 cases where CDW data differed from self-reported gender, we used the self-report data to categorize gender.

We conducted descriptive analyses to characterize the groups of respondents with unilateral and bilateral amputation. We compared scores for prosthetic satisfaction (TAPES, CSD) for unilateral and bilateral amputees using t-tests and non-parametric Wilcoxon rank sum (WRS) tests. We also compared quality of life outcomes including the Quick-DASH, VR-12 PCS and MCS using t-tests for unilateral versus bilateral amputation. We conducted post-hoc analyses to estimate the magnitude of effect size that we were powered to detect.

3.0—Results

3.1- Sampling frame and response rate

We identified 5639 persons (shown in Fig 1) with a diagnosis of upper limb amputation who had been seen at the VA between 2011 and 2015. We excluded 2080 persons, 1479 of whom were found to be deceased, and 601 who were missing valid addresses and phone numbers. Recruitment materials with opt out cards were sent to the remaining 3559 persons. Two hundred eight persons who responded to the recruitment invitation told us that they did not meet study eligibility criteria. Four hundred eight persons declined participation, and 1050 could not be reached for screening. We screened 1893 persons, 923 were found to be ineligible and 970 found to be eligible. Eight hundred eight (83%) of those screened to be eligible were recruited into the study. The final response rate (RR) and cooperation rate (CR) was 47.7% and 63.3%, respectively [27].

Table 1 compares the 808 survey respondents and the 1620 eligible persons who did not respond. On average, responders were 1.8 years younger (p = 0.0059), more often female (p = 0.0289), and had a more recent year of VA utilization (p = 0.0109).

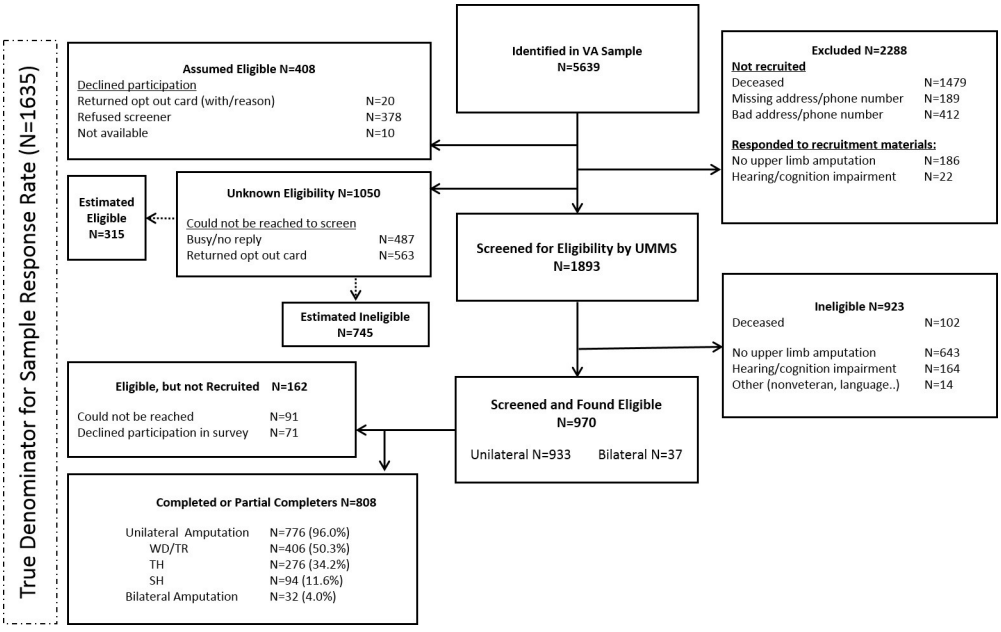

Fig 1. Flow diagram.

https://doi.org/10.1371/journal.pone.0213578.g001

Table 1. Comparison of survey respondents and non-respondents.

	Not Recruited (Eligible or Unknown Eligibility) (N = 1620)	Completers (N = 808)	
	Mean (SD)	**Mean (SD)**	**T-test p**
Age (years)	65.0 (16.0)	63.2 (14.2)	**0.0059**
	N (%)	**N (%)**	**Chisq p**
Gender			**0.0289**
Female	22 (1.4)	21 (2.6)	
Male	1598 (98.6)	787 (97.4)	
Race			0.3211
White	1106 (68.2)	558 (69.1)	
Black	202 (12.5)	82 (10.2)	
Other/Mixed	63 (3.98)	30 (3.7)	
Unknown	250 (15.4)	138 (17.1)	
Last year of VA visit*			**0.0109**
2010	5 (0.3)	1 (0.1)	
2011	15 (0.9)	5 (0.6)	
2012	19 (1.2)	2 (0.3)	
2013	36 (2.2)	7 (0.9)	
2014	30 (1.9)	14 (1.7)	
2015	63 (3.9)	20 (2.5)	
2016	1452 (89.6)	759 (93.9)	

*last year of visit between 1/1/2010-12/31/2016

https://doi.org/10.1371/journal.pone.0213578.t001

3.2—Sample characteristics

Seven hundred eighty-eight persons completed the survey in its entirety, while 20 persons completed at least part of the survey. Table 2 compares demographic data for the sample of 776 unilateral amputees and 32 bilateral amputees. Mean age was 63.3 (sd 14.1), and 787 (97.5%) were male. Seventy-five percent of the sample classified themselves as white, and 8.6% identified themselves as Hispanic or Latino. Only 13% of the sample reported that they were currently working full- or part- time, while 70% were retired. On average, these amputees had lost their limbs 31.4 (sd 18.3) years prior. Among unilateral amputees, the largest amputation level group was transradial (36.1%), followed by above the elbow (30.4%), at the wrist joint (16.2%), at the shoulder (9.2%), at the elbow (5.2%) and forequarter (3.0%). The most common etiologies of amputation (respondents indicated all etiologies that applied) were accident (62.1% unilateral, 62.5% bilateral), "other" (54% unilateral, and 65.6% left side-71.9% right-side bilateral), and combat injury (35.5% unilateral, 28.1% bilateral). Burns were listed as a prevalent cause of amputation for bilateral amputees (40.6% left and right combined).

3.3—Prosthesis use

Sixty percent of unilateral amputees said that they were prosthesis users (Table 3). Ninety-one percent of bilateral amputees used a prosthesis on at least one side. Only 6.8% of unilateral amputees had never used a prosthesis. Fifty percent of unilateral amputees reported that they had ever stopped using a prosthesis, most often a body powered device (36.4%). In contrast 34.4% of bilateral amputees reported that they had ever stopped using a prosthesis, most commonly a body-powered device (28.1%). Amongst unilateral amputees, about 40% had received their most recent prosthesis within the prior 2 years (23.6% within the prior year). However,

Table 2. Demographics characteristics of unilateral and bilateral amputee respondents.

	Unilateral Amputees N = 776	Bilateral Amputees N = 32	All N = 808
	Mean (sd)	**Mean (sd)**	**Mean (sd)**
Age (Years)	63.2 (14.1)	63.6 (15.3)	63.3 (14.1)
Missing (n)	24	0	24
Years since initial amputation (either side)	31.3 (18.4)	32.8 (18.1)	31.4 (18.3)
Years since amputation (second side)	31.3 (18.4)	32.6 (18.3)	31.4 (18.3)
Missing (n)	21	0	21
	n (%)	**n (%)**	**n (%)**
Year of initial amputation			
1940–1949	6 (0.8)	1 (3.1)	7 (0.9)
1950–1959	20 (2.7)	2 (6.3)	22 (2.8)
1960–1969	182 (24.1)	4 (12.5)	186 (23.6)
1970–1979	136 (18.0)	6 (18.8)	142 (18.0)
1980–1989	83 (11.0)	6 (18.8)	89 (11.3)
1990–1999	76 (10.1)	5 (15.6)	81 (10.3)
2000–2003	44 (5.8)	2 (6.3)	46 (5.8)
2004–2006	51 (6.8)	1 (3.1)	52 (6.6)
2007–2009	46 (6.1)	1 (3.1)	47 (6.0)
2010–2013	84 (11.1)	4 (12.5)	88 (11.2)
2014–2016	27 (3.6)	0 (0.0)	27 (3.4)
Missing (n)	21	0	21
Gender			
Male	755 (97.3)	32 (100.0)	787 (97.5)
Female	21 (2.7)	0 (0.0)	21 (2.6)
Missing (n)	24	0	24
Race			
White	583 (77.5)	22 (68.8)	605 (74.9)
Black	86 (11.4)	3 (9.4)	89 (11.0)
Native American	5 (0.7)	0 (0.0)	5 (0.6)
Other (including mixed race)	30 (4.0)	4 (12.5)	34 (4.2)
Unknown	48 (6.4)	3 (9.4)	75 (9.3)
Missing (n)	24	0	24
Hispanic or Latino			
Yes	62 (8.2)	5 (15.6)	67 (8.6)
No	678 (90.2)	26 (81.3)	704 (89.8)
Unknown	12 (1.6)	1 (3.1)	13 (1.7)
Missing (n)	24	0	24
Employment			
Employed full-time	73 (9.7)	1 (3.1)	74 (9.4)
Employed part-time	31 (4.1)	13 (40.6)	31 (4.0)
Student	20 (2.7)	0 (0.0)	20 (2.6)
Retired, but employed after amputation	373 (49.6)	13 (40.6)	386 (49.2)
Retired, but not employed after amputation	152 (20.2)	5 (15.6)	165 (21.1)
On medical leave	9 (1.2)	0 (0.0)	9 (1.2)
Other	93 (12.4)	0 (0.0)	98 (12.5)
Unknown	1 (0.1)	0 (0.0)	1 (0.1)
Missing (n)	24	0	24

(*Continued*)

Table 2. (Continued)

	Unilateral Amputees N = 776	Bilateral Amputees N = 32		All N = 808
	Mean (sd)	Mean (sd)		Mean (sd)
Laterality of amputation				
Unilateral Right	370 (47.7)	0 (0.0)		370 (45.8)
Unilateral left	406 (52.3)	0 (0.0)		406 (50.3)
Bilateral	0 (0.0)	32 (100.)		32 (4.0)
Amputation level				
		Left	Right	
Forequarter	23 (3.0)	1 (3.1)	0 (0.0)	
At the shoulder joint	71 (9.2)	1 (3.1)	1 (3.1)	
Above the elbow	236 (30.4)	5 (15.6)	4 (12.5)	
At the elbow	40 (5.2)	14 (43.8)	1 (3.1)	
Below the elbow	280 (36.1)	10 (31.3)	20 (62.5)	
At the wrist joint	126 (16.2)	0 (0.0)	6 (18.8)	
Through the hand	0 (0.0)	1 (3.1)	0 (0.0)	
Etiology of amputation (may be more than one)				
Combat injury	275 (35.5)	9 (28.1)	9 (28.1)	
Accident	481 (62.1)	20 (62.5)	20 (62.5)	
Burn	81 (10.5)	13 (40.6)	13 (40.6)	
Cancer	30 (3.9)	0 (0.0)	0 (0.0)	
Diabetes	11 (1.4)	0 (0.0)	1 (3.1)	
Infection	86 (11.1)	9 (28.1)	8 (25.0)	
Other	417 (54.0)	21 (65.6)	23 (71.9)	
Missing (n)	3	0	0	
Amputation of lower limb				
Yes	94 (12.1)	8 (25.0)		
No	682 (87.9)	24 (75.0)		
Amputation of lowerlimb	N = 94	N = 8		
Right Side	39 (41.5)	1 (12.5)		
Left Side	23 (24.5)	1 (12.5)		
Both Sides	32 (34.0)	6 (75.0)		

https://doi.org/10.1371/journal.pone.0213578.t002

32.8% reported that they received their most recent device more than 4 years prior. In contrast 41% of bilateral amputees had received at least one of their devices within the past 2 years (21% within the prior year). Thirty seven percent of unilateral amputees reported that they used 2 or more prostheses, and 24% of bilateral amputees used 2 or more prostheses for at least one side. Body powered devices were the most common primary prosthesis type used (70.9% unilateral amputees, 79% bilateral left and right sides).

Forty-three percent of unilateral amputees reported that they used two or more types of terminal devices, as compared to about 14% of bilateral amputees who used two or more terminal devices on at least one side. The most common types of primary terminal devices were body powered hooks (unilateral: 62%, bilateral: 72% left, 74.0% right. Multi-degree of freedom terminal devices (including the I-limb, Michaelangelo Hand and Bebionic) were used by 10.8% of unilateral amputees and 0% of bilateral amputees. The most prevalent suspension methods were self-suspending (75.2% unilateral, 84.0% left and 81.5% right bilateral), followed by gel or

Table 3. Type of prostheses, terminal devices and suspension methods: Comparison of unilateral and bilateral amputees.

	Unilateral Amputees N = 776	Bilateral Amputees N = 32	
		Left	Right
	n (%)	n (%)	
Currently use a prosthesis			
Yes	461 (60.0)	25 (78.1)	27 (84.4)
No	254 (33.0)	7 (21.9)	5 (15.8)
*Never Used Prosthesis	52 (6.8)	0 (0.0)	0 (0.0)
Unknown	2 (0.3)	0 (0.0)	0 (0.0)
Missing (n)	7	0	
Have you ever stopped using a prosthesis?			
Yes	379 (49.9)	11 (34.4)	
No	327 (43.1)	21 (65.6)	
*Never Used Prosthesis	52 (6.9)	0 (0.0)	
Unknown	1 (0.1)	0 (0.0)	
Missing (n)	17	0	
Were any of the prostheses that you stopped using?			
Body powered	276 (36.4)	9 (28.1)	
Myoelectric	135 (17.8)	3 (9.4)	
Hybrid	26 (3.4)	0 (0.0)	
*Never Used Prosthesis	52 (6.9)	0 (0.0)	
*Never stopped using ANY prosthesis	327 (43.1)	21 (65.6)	
Unknown	21 (2.8)	0 (0.0)	
Missing (n)	18	0	
Prosthesis users	**Unilateral N = 461**	**Left N = 25**	**Right N = 27**
Prosthesis users: most recent prosthesis received			
< 3 months	29 (6.3)	2 (8.0)	4 (14.8)
3–6 months	42 (9.1)	2 (8.0)	3 (11.1)
6–12 months	38 (8.2)	4 (16.0)	4 (14.8)
12–24 months	90 (19.5)	6 (24.0)	6 (22.2)
2–4 years	109 (23.6)	6 (24.0)	6 (22.2)
4 + years	151 (32.8)	5 (20.0)	4 (14.8)
Unknown	2 (0.4)	0 (0.0)	0 (0.0)
Number of prostheses used			
One	291 (63.1)	21 (84.0)	20 (74.1)
Two or more	170 (36.9)	4 (16.0)	7 (25.9)
Primary type of prosthesis used			
Body powered	326 (70.9)	19 (76.0)	21 (77.8)
Myoelectric	96 (20.9)	3 (12.0)	4 (14.8)
Hybrid	6 (1.3)	0 (0.0)	0 (0.0)
Cosmetic	22 (4.8)	3 (12.0)	2 (7.4)
Sports/recreation	6 (1.3)	0 (0.0)	0 (0.0)
Unknown	4 (0.9)	0 (0.0)	0 (0.0)
Missing (n)	1	0	0
Suspension type for primary prosthesis			
Suction	156 (34.0)	5 (20.0)	8 (29.6)
Gel or silicone liner with pin	91 (19.8)	2 (8.0)	2 (7.4)

(*Continued*)

Table 3. (Continued)

Vacuum	51 (11.1)	2 (9.0)	5 (18.5)
Self-suspending because of the socket shape	172 (37.5)	11 (44.0)	11 (40.7)
Harnessing	345 (75.2)	21 (84.0)	22 (81.5)
External strap	62 (13.5)	4 (16.0)	3 (11.1)
Unsure	1 (0.2)	0 (0.0)	0 (0.0)
Missing (n)	2	0	0
Number of terminal devices used			
One	259 (56.4)	23 (92.0)	23 (85.2)
Two or more	195 (42.5)	2 (8.0)	4 (14.8)
Unknown	5 (1.1)	0 (0.0)	0 (0.0)
Missing (n)	2	0	0
Users of one or more terminal devices	**Unilateral N = 454**	**Left N = 25**	**Right N = 27**
Primary type of terminal device used			
Body-powered hook	281 (62.2)	18 (72.0)	20 (74.1)
Greiffer	6 (1.3)	0 (0.0)	0 (0.0)
Power hook (ETD)	17 (3.8)	0 (0.0)	4 (14.8)
Sensor Speed Hand	11 (2.4)	2 (8.0)	0 (0.0)
I-Limb	14 (3.1)	0 (0.0)	0 (0.0)
Michaelangelo hand	7 (1.6)	0 (0.0)	0 (0.0)
Bebionic hand	28 (6.2)	0 (0.0)	0 (0.0)
Other	77 (17.0)	5 (20.0)	3 (11.1)
Unknown	11 (2.4)	0 (0.0)	0 (0.0)
Missing (n)	4	0	0
Prosthetic users with two or more prostheses	**Unilateral N = 170**	**Left N = 4**	**Right N = 7**
Secondary type of prosthesis used			
Body powered	74 (43.8)	2 (50.0)	3 (42.9)
Myoelectric	63 (37.3)	2 (50.0)	3 (42.9)
Hybrid	3 (1.8)	0 (0.0)	0 (0.0)
Cosmetic	5 (3.0)	0 (0.0)	1 (14.3)
Sports/recreation	20 (11.8)	0 (0.0)	0 (0.0)
Unknown	4 (2.4)	0 (0.0)	0 (0.0)
Missing (n)	1	0	0

https://doi.org/10.1371/journal.pone.0213578.t003

silicone liners with pin (37.5% unilateral, 44.0% left and 40.7% right bilateral), and suction (34.0% unilateral, 20% left and 29.6% right bilateral).

The reasons reported for abandoning each type of device is shown in Fig 2. For unilateral amputees, the most common reasons for abandoning all types of devices were lack of function, too much fuss, fit/comfort and heaviness/fatigue. There were differences in reasons for abandonment by prosthesis type, for example, 50.0% of myoelectric abandoners reported that the device was broken or unreliable, as compared to 38.0% of hybrid abandoners and 30.1% of body powered abandoners. A greater proportion of myoelectric and hybrid device abandoners cited too much fuss, lack of function, and heavy/fatiguing as compared to body powered users. For the 11 bilateral amputees who abandoned a device (Fig 3), the most common reasons were broken/unreliable devices, fit/comfort, and other reasons. Body-powered users listed too much fuss, lack of function, and other reasons more often than myoelectric users.

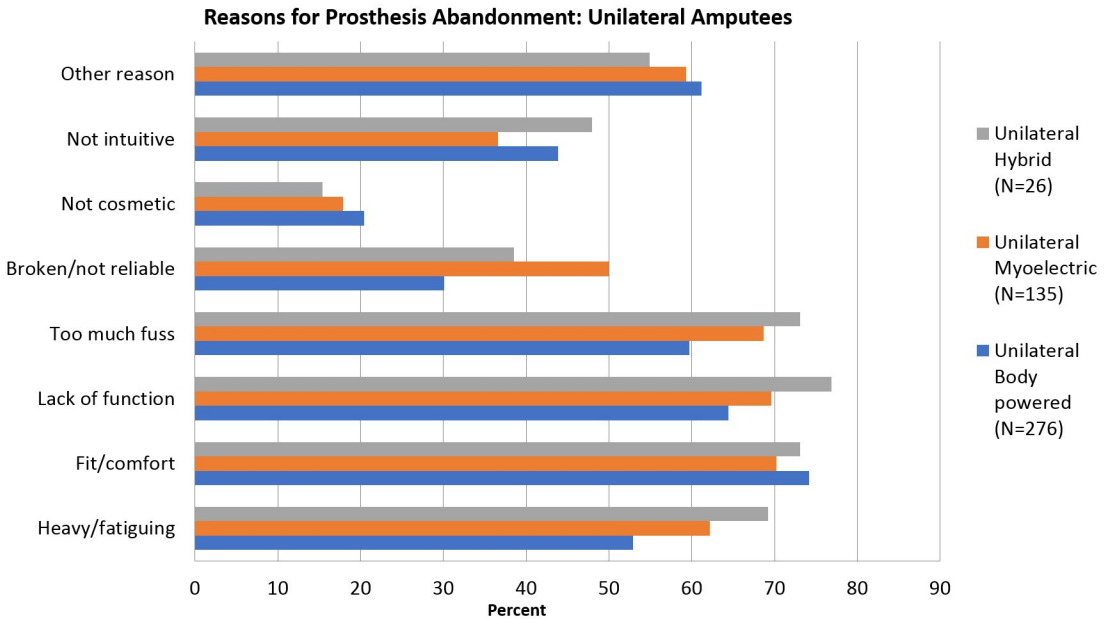

Fig 2. Reasons for prosthesis abandonment by type of device: Unilateral amputees.

https://doi.org/10.1371/journal.pone.0213578.g002

Hours of use of the prosthesis are compared graphically in Fig 4. Seventy seven percent of unilateral amputees used their devices daily, and 52% reported that they used their devices 8 or more hours per day. (Fig 5). Nineteen percent used their devices less than 2 hours per day. One hundred percent of bilateral amputees used at least one prosthesis daily, and 76% used at least one of their prostheses 8 hours per day or more, while about 7% used at least one less than 2 hours per day. (Fig 5)

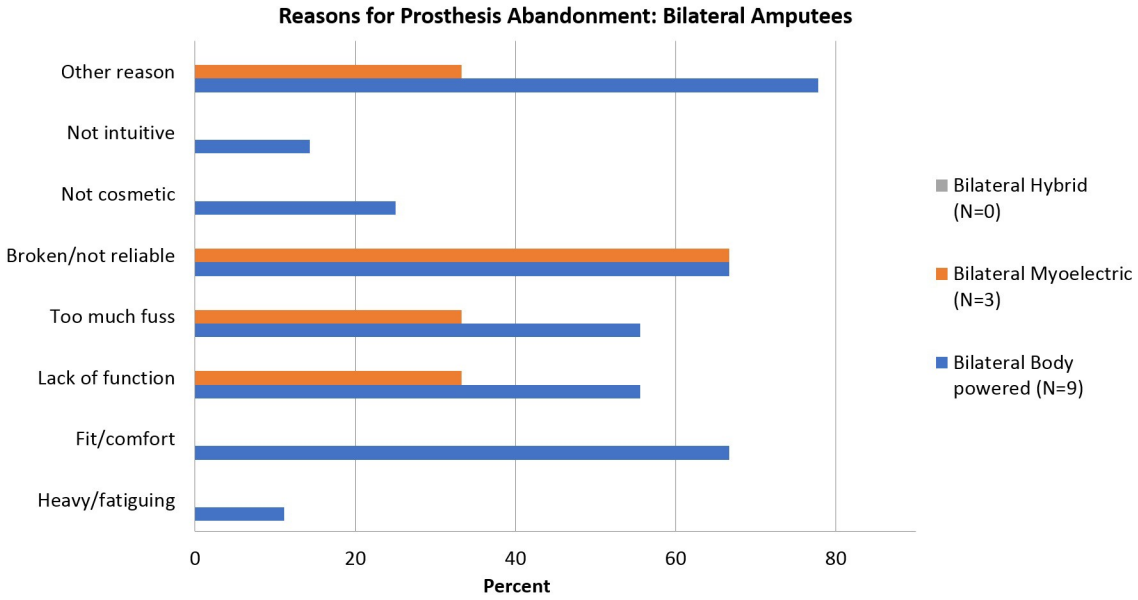

Fig 3. Reasons for prosthesis abandonment by type of device: Bilateral amputees.

https://doi.org/10.1371/journal.pone.0213578.g003

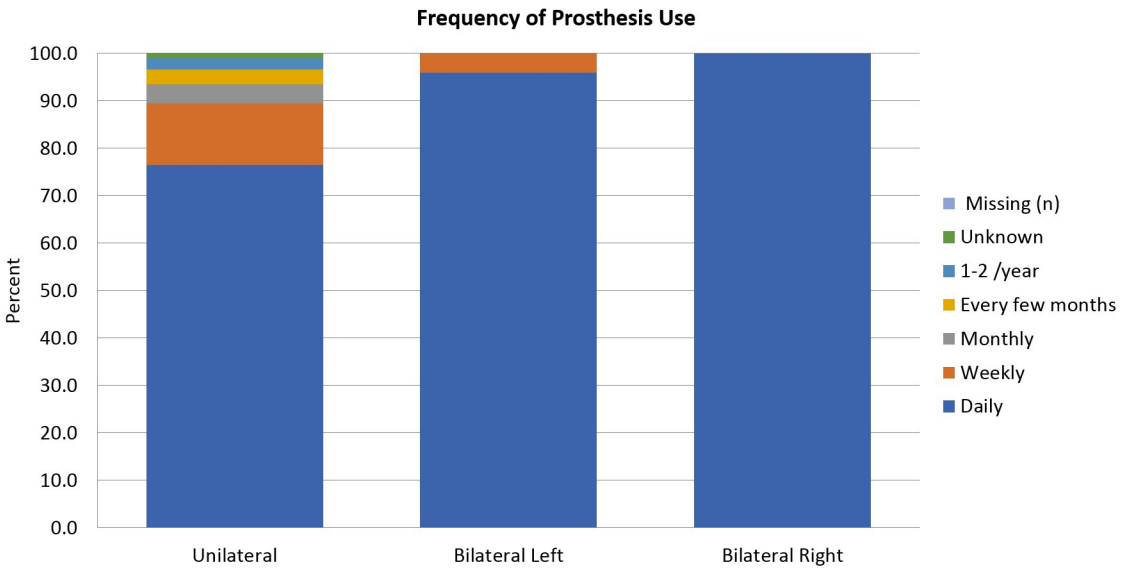

Fig 4. Frequency of prosthesis use.

https://doi.org/10.1371/journal.pone.0213578.g004

3.4—Prosthesis training

Seventy one percent of unilateral amputees and 59% of bilateral amputees had received training to use their first prosthesis. A slightly lower proportion (66% unilateral, 48.0% left and 55.6% right bilateral) had received training to use their current primary prosthesis. The distribution of training visits is shown in Table 4. Overall, 28% of unilateral amputees received 1–3 training visits. Twenty one percent of bilateral amputees had received 1–3 training visits for the prosthesis they used on their left side, and 14.8% received this amount of training for the prosthesis that they used on their right side. At the other extreme, 14.8% of unilateral amputees received more than 30 training visits. Seventeen percent of bilateral amputees received more than 30 hours of training for their left side, and 30% received it for their right side. Prosthetic

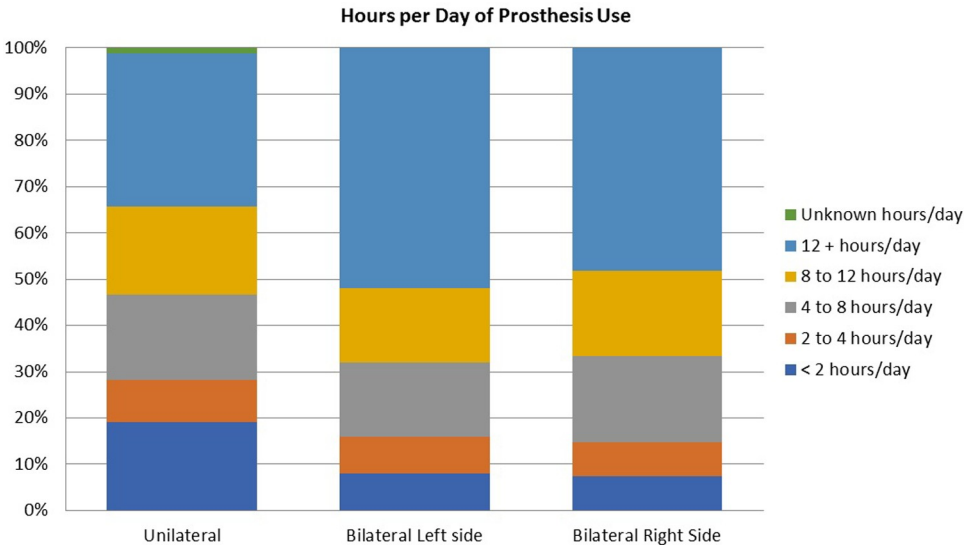

Fig 5. Hours of prosthesis use per day.

https://doi.org/10.1371/journal.pone.0213578.g005

Table 4. Prosthesis training.

	Unilateral Amputees N = 776	Bilateral Amputees N = 32	
	N (%)	N (%)	N (%)
Received training to use first prosthesis			
Yes	545 (70.9)	19 (59.4)	
No	165 (21.5)	13 (40.6)	
Never Used Prosthesis	52 (6.8)	0 (0.0)	
Unknown	7 (0.91)	0 (0.0)	
Missing (n)	7	0	
Prosthesis users	**Unilateral N = 461**	**Left N = 25**	**Right N = 27**
Received training to use current prosthesis			
Yes	301 (66.0)	12 (48.0)	15 (55.6)
No	153 (33.6)	12 (48.0)	12 (44.4)
Unknown	2 (0.4)	1 (4.0)	0 (0.0)
Missing (n)	5	0	0
Number of training visits			
1 to 3	127 (28.0)	5 (20.8)	4 (14.8)
4 to 10	53 (11.7)	1 (4.2)	2 (7.4)
11 to 20	22 (4.9)	1 (4.2)	1 (3.7)
21 to 30	21 (4.6)	0 (0.0)	0 (0.0)
More than 30	67 (14.8)	4 (16.7)	8 (29.6)
No Training	153 (33.7)	12 (50.0)	12 (44.4)
Unknown	11 (2.4)	1 (4.2)	0 (0.0)
Missing (n)	7	0	0
Received training	**Unilateral N = 301**	**Left N = 12**	**Right N = 15**
Who conducted prosthetic training			
Prosthetist	123 (40.9)	4 (33.3)	4 (26.7)
PT/OT	164 (54.5)	5 (41.7)	9 (60.0)
Other	6 (2.0)	3 (25.0)	2 (13.3)
Unknown	8 (2.7)	0 (0.0)	0 (0.0)
Rating of trainer skill level			
Not at all skilled	6 (2.0)	0 (0.0)	0 (0.0)
Adequately skilled	69 (22.9)	3 (25.0)	4 (26.7)
Highly skilled	217 (72.1)	9 (75.0)	10 (66.7)
Unknown	9 (3.0)	0 (0.0)	1 (6.7)

https://doi.org/10.1371/journal.pone.0213578.t004

training visits were conducted most often by a PT or OT (54.5% unilateral, 41.7% for bilateral left and 60.0% for bilateral right), and less frequently by a prosthetist (unilateral: 40.9%; bilateral 33.3%on left, 26.7% on right). Respondents rated the skill level of their trainers high, with only 2% of unilateral and 0% of bilateral amputees stating that their trainers were "not at all skilled."

3.5—Satisfaction with the prosthesis, health function and quality of life

Prosthetic satisfaction ratings are shown in Table 5. The overall TAPES scores

indicated that both unilateral and bilateral amputees were somewhat satisfied with their prostheses: unilateral amputees mean scores 3.9 (0.6), bilateral mean scores 3.8 (0.7).

Table 5. Satisfaction with primary prosthesis (prosthesis users only).

		Unilateral N = 461		Bilateral ^ N = 29	t test	WRS+
Prosthesis users only		**Mean (sd)**		**Mean (sd)**	**p-value**	**p-value**
TAPES satisfaction scale#						
Color	449	4.0 (0.8)	28	4.0 (0.6)	0.8094	0.7292
Shape	449	4.0 (0.8)	29	4.1 (0.6)	0.5243	0.6541
Noise	430	4.0 (0.8)	28	3.9 (1.0)	0.2594	0.4042
Appearance	450	3.9 (0.9)	29	3.8 (0.9)	0.7412	0.6473
Weight	453	3.8 (1.0)	29	3.7 (1.1)	0.7128	0.7608
Usefulness	450	3.8 (1.1)	29	3.9 (1.0)	0.7302	0.7342
Reliability	449	3.9 (1.0)	29	3.8 (1.0)	0.6469	0.5302
Fit	449	3.9 (1.0)	29	3.8 (1.0)	0.4279	0.3013
Comfort	450	3.6 (1.1)	29	3.5 (1.1)	0.5423	0.4997
Overall Satisfaction	447	4.0 (0.9)	29	3.9 (0.8)	0.8240	0.6416
Average total TAPES satisfaction score	453	3.9 (0.6)	29	3.8 (0.7)	0.6654	0.5858
OPUS Client satisfaction with devices (CSD) *						
My prosthesis fits well	448	1.9 (0.8)	29	2.1 (0.8)	0.2709	0.2171
The weight of my prosthesis is manageable	451	1.8 (0.6)	29	1.8 (0.4)	0.7660	0.4701
My prosthesis is comfortable throughout the day	448	2.2 (0.8)	28	2.1 (0.5)	0.4699	0.5055
It is easy to put on my prosthesis	450	1.8 (0.7)	29	1.9 (0.5)	0.5586	0.3979
My prosthesis looks good	443	2.0 (0.7)	27	2.0 (0.6)	0.8022	0.5823
My prosthesis is durable	447	1.9 (0.7)	29	2.1 (0.7)	0.6820	0.1106
My clothes are free of wear and tear from my prosthesis	449	2.8 (0.9)	29	3.1 (0.8)	0.0547	0.0760
My skin is free of abrasions and irritations	448	2.3 (0.8)	29	2.3 (0.7)	0.5921	0.6293
My prosthesis is pain-free to wear	444	2.2 (0.8)	28	2.3 (0.6)	0.9401	0.9803
I can afford out-of-pocket expenses to purchase and maintain prosthesis	385	3.0 (0.9)	24	3.0 (0.9)	0.7722	0.7881
I can afford to repair or replace my prosthesis as soon as needed	386	2.9 (0.9)	23	3.2 (0.8)	0.2140	0.2578
OPUS CSD total score	347	25.0 (5.1)	20	25.7 (4.5)	0.5694	0.6412
OPUS CSD crosswalk estimated percentile score	347	49.6 (10.2)	20	51.2 (7.7)	0.4871	0.6412
Additional satisfaction related items						0.5123
My terminal device is appropriately sized for me	318	1.8 (0.6)	22	1.9 (0.4)	0.4626	0.2994
Overall, my prosthetic device is appropriately sized	318	1.8 (0.6)	22	2.0 (0.5)	0.1362	0.0987
I am self-conscious about wearing my prosthesis	447	2.9 (0.9)	29	2.9 (0.8)	0.8906	0.8983
Desire to change devices	435	2.7 (0.9)	28	2.8 (0.8)	0.4553	0.5123
Inability to wear the prosthesis due to fit	446	3.1 (0.8)	28	3.1 (0.6)	0.9362	0.6520
Satisfaction with prosthesis/terminal device movement	452	1.8 (0.8)	29	1.9 (0.7)	0.9074	0.9276
Unintended movement	447	2.5 (0.9)	29	2.4 (0.8)	0.4878	0.4861

^Satisfaction with dominant side

#Response categories for TAPES: 1 = very dissatisfied, 2 = dissatisfied, 3 = neither satisfied nor dissatisfied, 4 = satisfied, 5 = very satisfied

*Response categories for CSD and additional satisfaction related items: * 1 = Strongly Agree, 2 = Agree, 3 = Disagree 4 = Strongly Disagree

+WSR = Wilcoxon rank sum test.

https://doi.org/10.1371/journal.pone.0213578.t005

Comfort was the lowest rated individual item, but was still in the neither satisfied nor dissatisfied range. The total CSD scores were 25.0 (5.1) and 25.7 (4.5) for unilateral and bilateral amputees, respectively. The cross-walked scores were 49.6 (10.2) for unilateral and 51.2 (7.7) for bilateral amputees. The items rated most highly pertained to fit and durability of the prosthesis. The items rated most poorly pertained to self-consciousness, clothing wear and tear, and device costs. The only differences between unilateral and bilateral amputees related to

CSD items was in the item "my clothes are free from wear and tear," bilateral amputees disagreed more with this statement, however the difference was small and did not reach statistical significance (P = 0.054). In general, participants did not want to change their prosthesis to another type, could wear their prosthesis because of fit, were satisfied with prosthesis/terminal device movement but indicated that their prosthesis sometimes moved in unintended ways.

Table 6 shows the comparisons of disability and quality of life ratings for unilateral and bilateral amputees. Bilateral amputees were more disabled as measured by the QuickDASH as compared to unilateral amputees ((mean 49.5(20.7) vs. 34.7(22.0), P = 0.053)); while the t-test was not statistically significant, the Wilcoxon rank sum test indicated strong statistical significance. Scores of the VR 12 PCS and MCS did not differ by group, but PCS were lower than population norms. There were no other statistically significant differences between unilateral and bilateral amputees. Seventy one percent of unilateral amputees reported contralateral limb pain (Fig 6), and 51.2% reported at least one of the musculoskeletal conditions we asked about. In terms of pain, 72.5% of unilateral and 65.6% of bilateral amputees reported any back pain, while 60.1% of unilateral and 71.9% of bilateral amputees reported any neck pain. Phantom and residual limb pain were prevalent with 73.4% of unilateral and 68.8% of bilateral amputees reporting phantom pain and 65.0% of unilateral and 68.8% of bilateral amputees reporting any residual limb pain.

3.6—Amputation care

The majority of respondents had been to a VA medical center for their amputation related care (81.8% unilateral, 84.4% bilateral) (Table 7). Fifty-seven percent of unilateral amputees and 81.3% of bilateral amputees had been to a VA amputation clinic at some time. Sixty-six percent of unilateral amputees who were prosthesis users and 80% of bilateral amputees who were prosthesis users had been to a VA amputee clinic between 2015 and the time of survey.

4.0—Discussion

We conducted the first-of-its-kind national study of Veterans with major upper limb loss. Our study was by far the largest study of Veterans with upper limb amputation conducted to date, and its sampling strategy and analytical methods make the results generalizable to Veterans with upper limb amputation who were seen at the VA for care. We characterized amputation

Table 6. Disability and quality of life.

Full sample		Unilateral		Bilateral	T-test	WRS+
	N	Mean (sd)	N	Mean (sd)	p-value	p-value
QuickDASH	743	34.7 (22.0)	32	49.5 (20.7)	0.0529	**0.0048**
VR-12 PCS	727	45.1 (8.7)	31	44.6 (9.7)	0.7648	0.7128
VR-12 MCS	727	49.6 (13.4)	31	50.6 (13.4)	0.6857	0.5727
Pain and musculoskeletal conditions	**N**	**N (%)**	**N**	**N (%)**	**Chisq p**	**Fisher's Exact p**
Any contralateral limb pain (unilateral only)	757	538 (71.1)				
Any problem of sound side (U_B9)	771	395 (51.2)				
Any back pain	760	551 (72.5)	32	21 (65.6)	0.3950	0.4215
Any neck pain	760	457 (60.1)	32	23 (71.9)	0.1829	0.2011
Any Phantom limb pain	756	555 (73.4)	32	22 (68.8)	0.5596	0.5453
Those with amputations distal to shoulder		Unilateral		Bilateral		
Any Residual limb pain	663	431 (65.0)	32	22 (68.8)	0.6643	0.7091

+WRS = Wilcoxon rank sum test

https://doi.org/10.1371/journal.pone.0213578.t006

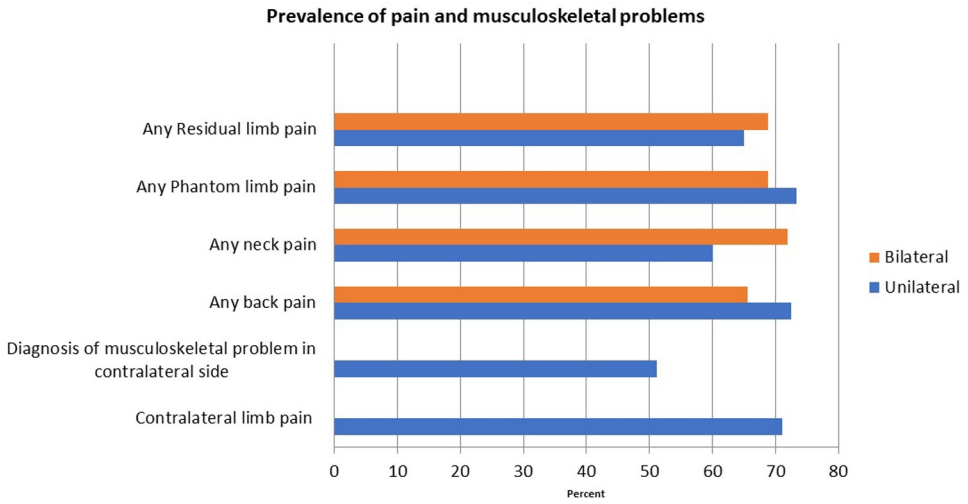

Fig 6. Prevalence of pain and musculoskeletal problems.

https://doi.org/10.1371/journal.pone.0213578.g006

level and etiology, prosthesis and terminal device types used, prosthesis suspension methods, as well amount and frequency of prosthesis use and prosthesis training receipt. For persons who had abandoned using a prosthesis, we also described the reasons for abandonment by device type. Additionally, we compared prosthetic satisfaction, and several measures of health-related quality of life of unilateral and bilateral amputees.

Sixty percent of unilateral amputees in our study were prosthesis users, fewer than that reported for combat Veterans in earlier studies (72% Vietnam and 76% OEF/OIF).[17] We found that 84% of our respondents with bilateral amputation were prosthesis users, a similar prevalence to that reported in OEF/OIF combat amputees with bilateral upper limb amputation (85.7%).[17] We also found that 6.8% of unilateral amputees had never received a prosthesis, a slighter higher prevalence than reported in combat amputees.[17] Differences in prevalence of prosthesis use in our sample compared to earlier reports may be related to amputation level of respondents as well as etiology of amputation. Twelve percent of our sample were amputees with shoulder or forequarter amputation (107 persons) (compared to 4.4% in the earlier study), and included 55 persons with elbow disarticulation, and 132 persons with wrist disarticulation (higher proportions in our sample than in the earlier study). Elbow disarticulation and wrist disarticulation may be particularly challenging to fit with prostheses. Our sample included amputees with any type of etiology (only 35% were combat amputees). These factors may explain differences in prosthesis use. Future analyses of our data will explore these and additional factors that may be associated with prosthesis use and abandonment.

The majority of prosthesis users in our study used body powered devices (70.9% of unilateral amputees, and 77.8% of bilateral amputees) as their primary device. This finding is consistent with earlier reports that only 8% of unilateral combat amputees from Vietnam had ever received a myoelectric device. We found that 42% of unilateral amputees used more than one type of terminal device. Only 10.9% of unilateral amputees and no bilateral amputees used a multi-degree of freedom powered terminal device as their primary terminal devices. We plan to explore the relationship between type of devices used and functional abilities in future analyses.

A majority of respondents had abandoned a prosthesis at some point, and the most common reasons for abandonment were lack of function, problems with fit/comfort and too much fuss. There were some differences between reasons for abandonment of devices by unilateral

Table 7. Amputation care.

	Unilateral N = 776	Bilateral N = 32
	N (%)	N (%)
Location of amputation-related care (ever) (all that apply)		
VA medical center	617 (81.8)	27 (84.4)
Local prosthetist office	462 (61.3)	23 (71.9)
Non-VA health care center or hospital	280 (37.1)	17 (53.1)
Department of Defense medical center	147 (19.5)	10 (31.3)
Someplace else	94 (12.5)	5 (15.6)
Missing (n)	22	0
Ever been to VA Amputation Clinic?		
Yes	428 (56.8)	26 (81.3)
No	280 (37.1)	5 (15.6)
Unknown	46 (6.1)	1 (3.1)
Missing (n)	22	0
Ever been to DoD Amputation Clinic?		
Yes	109 (14.5)	7 (21.9)
No	601 (79.8)	21 (65.6)
Unknown	43 (5.7)	4 (12.5)
Missing (n)	22	0
Among those who have been to VA Amputation Clinic (n = 384)	**Unilateral N = 428**	**Bilateral N = 26**
Year of last visit to VA Amputation clinic		
2008 or before	63 (16.4)	1 (4.0)
2009	2 (0.5)	0 (0.0.)
2010	10 (2.6)	0 (0.0.)
2011	5 (1.3)	0 (0.0.)
2012	14 (3.7)	1 (4.0)
2013	12 (3.1)	1 (4.0)
2014	24 (6.3)	1 (4.0)
2015	40 (10.4)	7 (28.0)
2016	78 (20.3)	2 (8.0)
2017	127 (33.1)	1 (44.0)
2018	9 (2.3)	0 (0.0.)
Missing (n)	44	1

https://doi.org/10.1371/journal.pone.0213578.t007

and bilateral amputees. No bilateral amputees reported abandoning a body powered device because it was too heavy or fatiguing.

Almost 30% of unilateral amputees and 41% of bilateral amputees who had ever used a prosthesis had not received any training to use their first prosthesis, and 34% of unilateral and 48.0% (on left) and 44.4% (on right) of bilateral amputees had not received training to use their current prosthesis. The amount of prosthetic training received varied considerably, with a greater proportion of bilateral amputees having had 30 or more training visits. To our knowledge, ours is the first study that has examined receipt of prosthetic training. Prosthetic training is considered critical for maximizing functional capabilities with the prosthesis. [28–30] The impact of prosthetic training receipt on function and disability, and prosthesis abandonment has not been fully examined, and is another area that we plan to explore using our survey data.

We quantified the hours of prosthesis use per day and found that 28.2% of unilateral amputees used their devices four hours or less per day, and only 52.1% used them 8 hours or more. In contrast, 76% bilateral amputees used at least one of their prosthesis 8 hours per day or more. Historically, some have defined full time prosthesis use as use of at least 8 hours per day. [4] Our findings on prosthesis use point to the need for future studies to examine the relationship between prosthesis satisfaction and hours of use, and between self-rated disability and hours of prosthesis use. These analyses will be possible in future studies using our data.

Generally, Veterans responses indicated that they were neutral or somewhat satisfied with their prostheses as measured by the TAPES satisfaction measure and the OPUS CSD scores. Items with the lowest satisfaction ratings included comfort (TAPES), and self-consciousness about the prosthesis, wear and tear of clothing and device costs (OPUS). The unilateral values for the CSD in our sample fall between the 64-71st percentile, while the bilateral values fall between the 71-78th percentile of reported provisional normative scores [19], which indicates lower than average satisfaction with devices in our sample. It is difficult to make other direction comparisons between our findings on prosthesis satisfaction and those reported in prior studies of combat amputees that employed modified scales and used dichotomous scoring. [17, 31] The OIG reported that 69.6% of traumatic upper limb amputees in their study were satisfied were their prostheses.

The QuickDASH measure of self-reported disability showed that Veterans with upper limb amputation have significant disability as compared to normative values. [32] Not surprisingly, bilateral amputees rated themselves as more disabled as compared to unilateral amputees (49.5 vs 34.7), (WSR $P<0.01$) Scores for unilateral amputees were comparable to those reported in a prior OIG report of OEF/OIF combat Veterans with upper limb amputation, (mean 36.6, 95 percent CI: 31.6, 41.6).[31] Future analyses from our data will examine the impact of QuickDASH scores, amputation and prosthesis characteristics on the need for and amount of help with daily activities.

The VR-12 PCS scores in our sample were approximately 0.5 standard deviation below population means (for non-disabled), indicating moderately impaired physical functioning, with no large differences between unilateral and bilateral amputee groups. In contrast, the VR-12 MCS scores were at the population mean, indicating normal mental/emotional functioning. These findings are consistent with prior reports of lower physical functioning, and greater pain [33] and equivalent mental health for upper limb amputees. [34]

We found that the majority (71%) of unilateral amputees reported that they had at least one type of musculoskeletal condition of the contralateral limb, and that the majority of respondents reported back and neck pain. These prevalence rates are higher than reported in Norwegian upper limb amputees. [35, 36] In the Norwegian sample, the prevalence rate of musculoskeletal conditions in persons with upper limb amputation was about twice that of the general population; we do not have comparable data to know how prevalence of back and neck pain in our sample compare to an age-matched Veteran population. In addition, the relationship between contralateral limb pain, back and neck pain and years of prosthesis use as well as type of prosthesis used is not known. These relationships can be explored in future research using our data.

Phantom and residual limb pain were also prevalent in Veterans with upper limb amputation. Phantom limb pain impacted almost three quarters of unilateral amputees and 69% of bilateral amputees, while residual limb pain was reported by approximately two thirds of respondents. These rates are higher than reported in prior literature (42.6% phantom pain, 43% residual limb pain).[37] Future studies will examine the factors associated with prevalent phantom and residual limb pain.

Given that the sampling frame was drawn from Veterans who had received some type of care at the VA, it is not surprising that the majority of respondents had been to the VA for amputation related care, with a higher proportion of bilateral amputees (81.3%) as compared to unilateral amputees (57%) having gone to a VA amputation clinic. This finding makes some sense, given the greater complexity in meeting the needs of bilateral amputees. While the vast majority of prosthesis users had their last visit to a VA amputation clinic since 2015, about 26.3% of unilateral and 16% of bilateral had not been to an amputation clinic in the previous 5 years. Further study is needed to understand the impact of site of amputation care on prosthetic satisfaction and other important outcomes.

4.1—Limitations

We observed minor differences in survey respondents and non-respondents. Respondents were an average of 1.8 years younger than non-respondents, females were more likely to respond then males, and a slightly higher proportion of respondents had been seen at the VA in the years 2015 and 2016. We believe that these differences are small, and given the strong overall response rate, our findings are generalizable to Veterans with upper limb amputation who received care in the VA between 2011-2015.The results may have limited generalizability to Veterans who received care only after 2015 (and thus were not identified in our original sampling frame), and to the overall civilian population with limb loss. Our sampling frame was generated from VA medical record data, using inclusive criteria for identifying upper limb amputees (any instance of a diagnosis). We found that 829 persons, about 15% of the sample were not upper limb amputees, as identified through opt outs and after screening. We can assume that a similar proportion of persons with unknown eligibility were also not amputees (157 persons). Thus, the total estimate of persons without amputation would be 986, or approximately 17% of the original sampling frame. Our study response rate was calculated using the American Association of Public Opinion Research methodology. [27] Using this methodology, we estimated a proportion of non-respondents as being ineligible; if we considered them all to be eligible, the response rate would be 33%.

We do not believe that misclassification errors from medical records are unique to the diagnosis of upper limb amputation, but we do not have any comparative data. Given the possibility of medical coding errors, it is possible that there were additional Veterans with major upper limb amputation who were not coded as such and thus did not appear in our sampling frame. However, we have no visibility into the prevalence of missing amputation diagnosis codes.

Our survey instrument was long, and it is possible that some respondents became fatigued during interviews, however we have no way of knowing to what extent this may have influenced accuracy of data collection. We had very few interviews that were cut short. Although we compared outcomes of unilateral and bilateral amputees statistically, our sample of bilateral amputees was small (N = 32). This sample size limited us in detecting minor differences as statistically significant when they may have existed. That said, we were adequately powered to detect moderate differences between unilateral and bilateral amputee groups. We conducted a post-hoc power analysis for each outcome measure that we compared, utilizing the standard deviations of the measure and the sample size for each group. We had at least 80% power to detect moderate differences in group means of approximately 0.5 sd (effect sizes 0.51–0.65) for the QuickDASH, VR12 MCS and PCS, TAPES, and OPUS CSD. It is possible that smaller differences between groups actually existed, but that we are underpowered to detect them.

Although we attempted to compare OPUS CSD findings to normative values reported in 2010 to assist in interpreting the scores, these comparisons must be interpreted cautiously.

Normative values for the OPUS were drawn from work with predominantly lower limb amputees and most of the data were from international samples. Therefore, we are unsure how our OPUS CSD results would compare to those from upper limb amputees in the U.S and/or who were non-Veterans. Further, we are unable to compare our prosthetic satisfaction results to those reported for Vietnam and OEF/OIF combat amputees because prior analyses used modified satisfaction items, created a new satisfaction scale, and dichotomized responses of individual items.

5.0—Conclusions

This paper reports summary findings from the first ever nationally representative study of Veterans with all cause upper limb amputation, and one of the largest studies to describe upper limb amputees, their prosthesis use, satisfaction with devices, health-related quality of life and care receipt. We found that rates of prosthesis use were lower than reported in samples of combat Veterans.[13] Body powered devices were used by 70.9% of unilateral and 76.0% (on left) and 77.8% (on right) of bilateral amputees. Multi-degree of freedom terminal devices, used by 11% of unilateral amputees, were not used by any bilateral amputees. Overall, we found that Veterans who were prosthesis users were somewhat satisfied with their devices, although only 52% utilized their devices at least 8 hours per day and substantial proportion used them less than 2 hours per day. A substantial proportion of respondents had not received any training to use either their initial prostheses, or their current prostheses.

Veterans with upper limb amputation rated themselves as disabled on the QuickDASH, and were found to have moderately impaired physical functioning as measured by the VR-12. Musculoskeletal problems, phantom limb and residual limb pain affected the majority, with rates of phantom and residual limb pain higher than previously reported. [37] A substantial proportion of Veterans did not receive amputation related care at the VA amputation care and many had never been to a VA amputation clinic, suggesting an opportunity to increase access to care.

Supporting information

S1 Appendix. Amputation codes.
(DOCX)

S2 Appendix. Copy of survey instrument.
(DOCX)

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Project administration: Linda Resnik, Sarah Ekerholm.

Supervision: Linda Resnik, Melissa A. Clark.

Writing – original draft: Linda Resnik, Matthew Borgia, Melissa A. Clark.

Writing – review & editing: Sarah Ekerholm, Matthew Borgia.

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Expert Review of Medical Devices

ISSN: 1743-4440 (Print) 1745-2422 (Online) Journal homepage: https://www.tandfonline.com/loi/ierd20

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

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To cite this article: Linda Resnik, Heather Benz, Matthew Borgia & Melissa A. Clark (2019) Patient perspectives on benefits and risks of implantable interfaces for upper limb prostheses: a national survey, Expert Review of Medical Devices, 16:6, 515-540, DOI: 10.1080/17434440.2019.1619453

To link to this article: https://doi.org/10.1080/17434440.2019.1619453

Accepted author version posted online: 15 May 2019.
Published online: 30 May 2019.

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

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ORIGINAL RESEARCH

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

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ABSTRACT

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

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

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

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

ARTICLE HISTORY
Received 17 January 2019
Accepted 13 May 2019

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

1. Background

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

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

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

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

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Article highlights

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

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

2. Methods

2.1. Development and pilot testing of the patient perspective survey

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

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

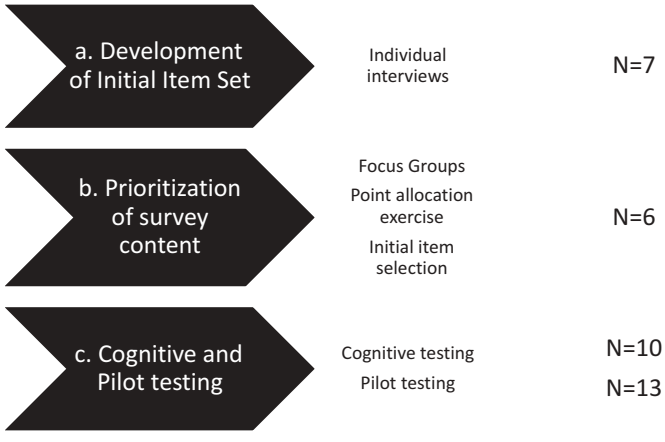

Figure 1. Benefit factor ratings for those who would consider surgery to have a prosthesis that could restore a sense of touch (yes/maybe): unilateral and bilateral amputees.

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

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

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

2.2. Recruitment

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

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

2.3. Data collection

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

2.4. Data analyses

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

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

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

3. Results

3.1. Sampling frame and response rate

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

3.2. Demographic, amputation-related and prosthetic use characteristics

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

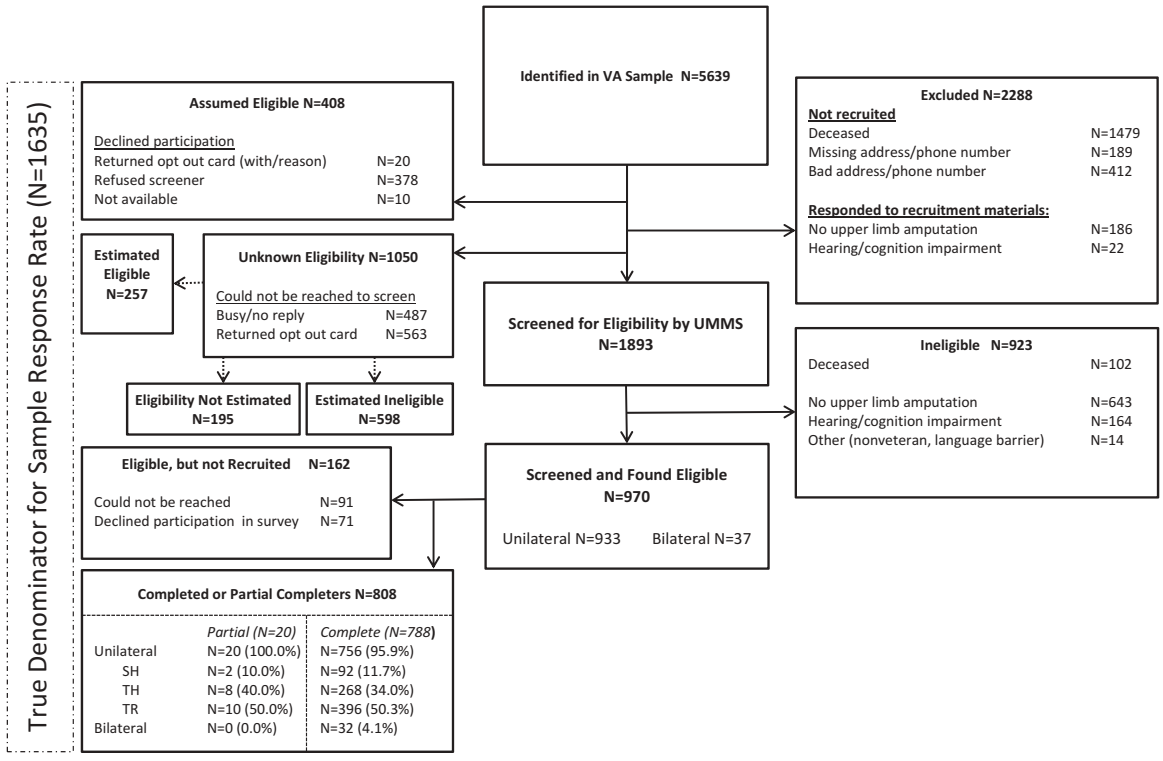

Figure 2. Benefit factor ratings for those who would consider surgery to have a prosthesis that gives more control over finger movements, grasps or wrist motions (yes/maybe): unilateral and bilateral amputee.

3.3. Willingness to undergo surgery

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

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

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

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

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

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

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

Table 1. Characteristics of unilateral and bilateral amputee respondents.

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

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

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

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

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

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

3.6. Willingness to accept surgical risks

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

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

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

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

3.7. Acceptable risk and benefit importance

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

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

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

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

3.8. Amputation levels and importance ratings

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

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

3.9. Prosthesis use and importance ratings

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

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

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

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

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

4. Discussion

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

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

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

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

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

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

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

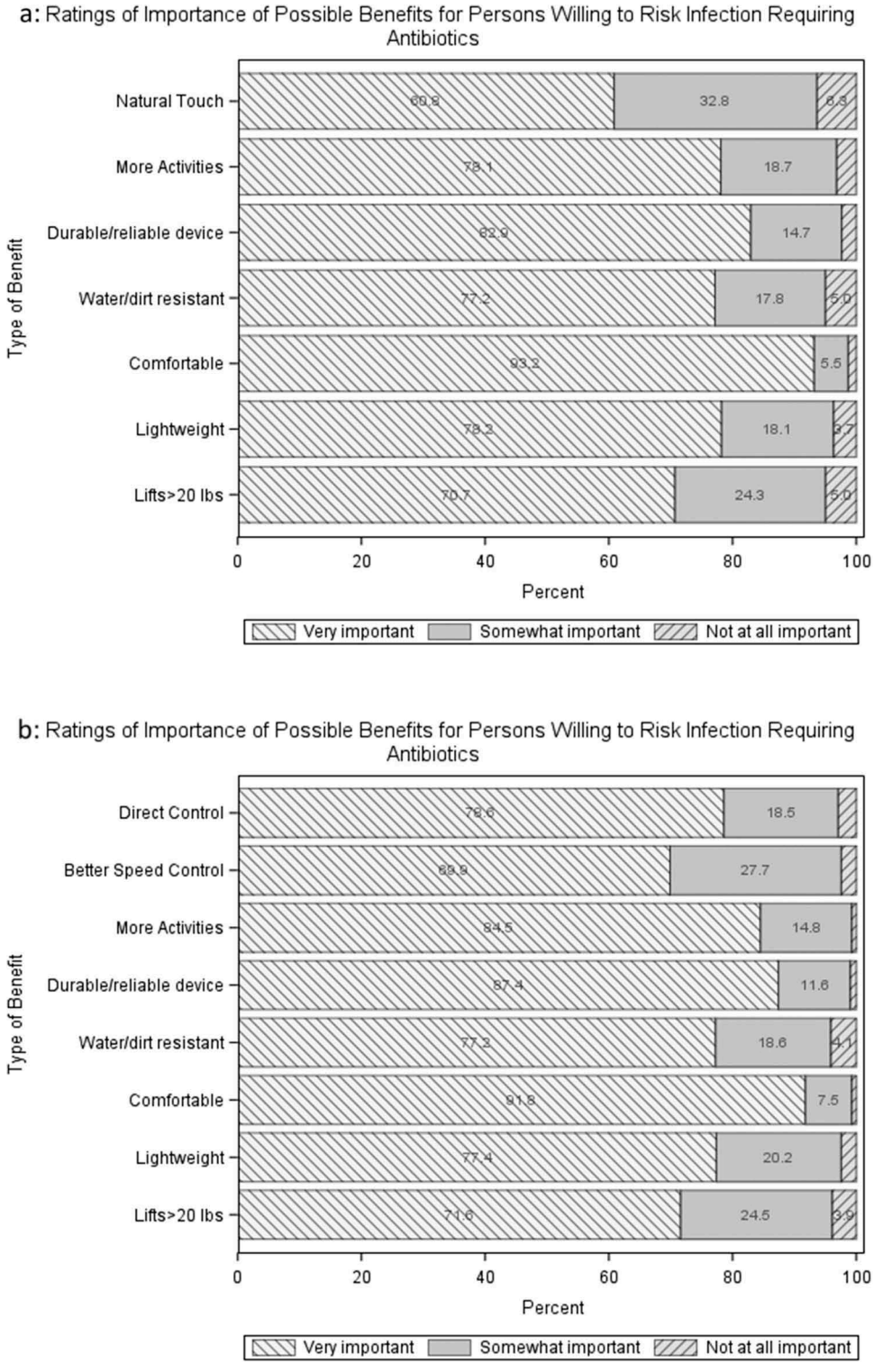

Figure 3. Sub-group comparisons of importance of factors for those who were willing to undertake specific risks (yes/maybe) in order to obtain a prosthesis that could restore a sense of touch by amputation level.

*significant at $p < 0.05$

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

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

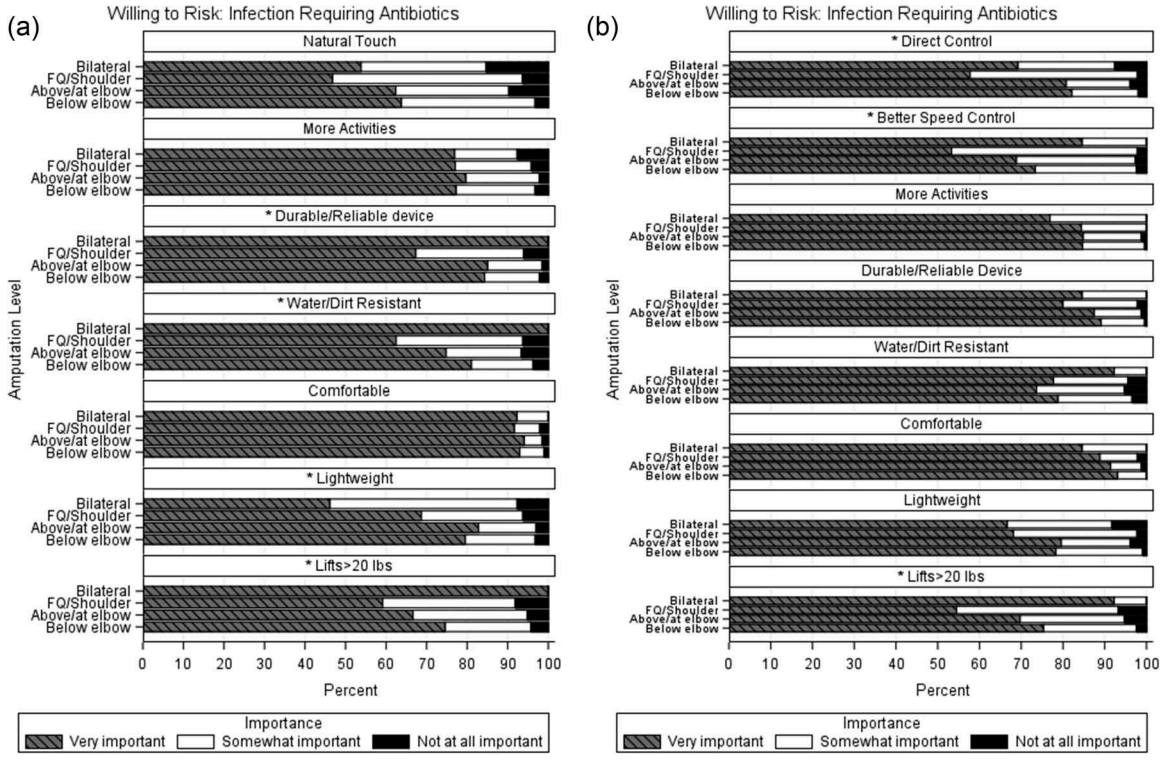

Figure 4. Sub-group comparisons of importance of factors for those who were willing to undertake specific risks (yes/maybe) in order to obtain a prosthesis that could restore better movement control by amputation level.

*significant at $p < 0.05$

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

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

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

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

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

5. Limitations

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

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

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

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

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

6. Conclusions

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

7. Expert opinion

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

Author contributions

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

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

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

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

Funding

This paper was funded by the Office of the Assistant Secretary of Defense for Health Affairs, through the Orthotics and Prosthetics Outcomes Research Program Prosthetics Outcomes Research Award (W81XWH-16-2-0065) and the U.S Department of Veterans Affairs (VA RR&D, A2707-I and VA RR&D A9264A-S).

Declaration of interest

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

Reviewer disclosures

Peer reviewers on this manuscript have no relevant financial or other relationships to disclose

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Appendix A

Benefit-Risk Questions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Appendix B

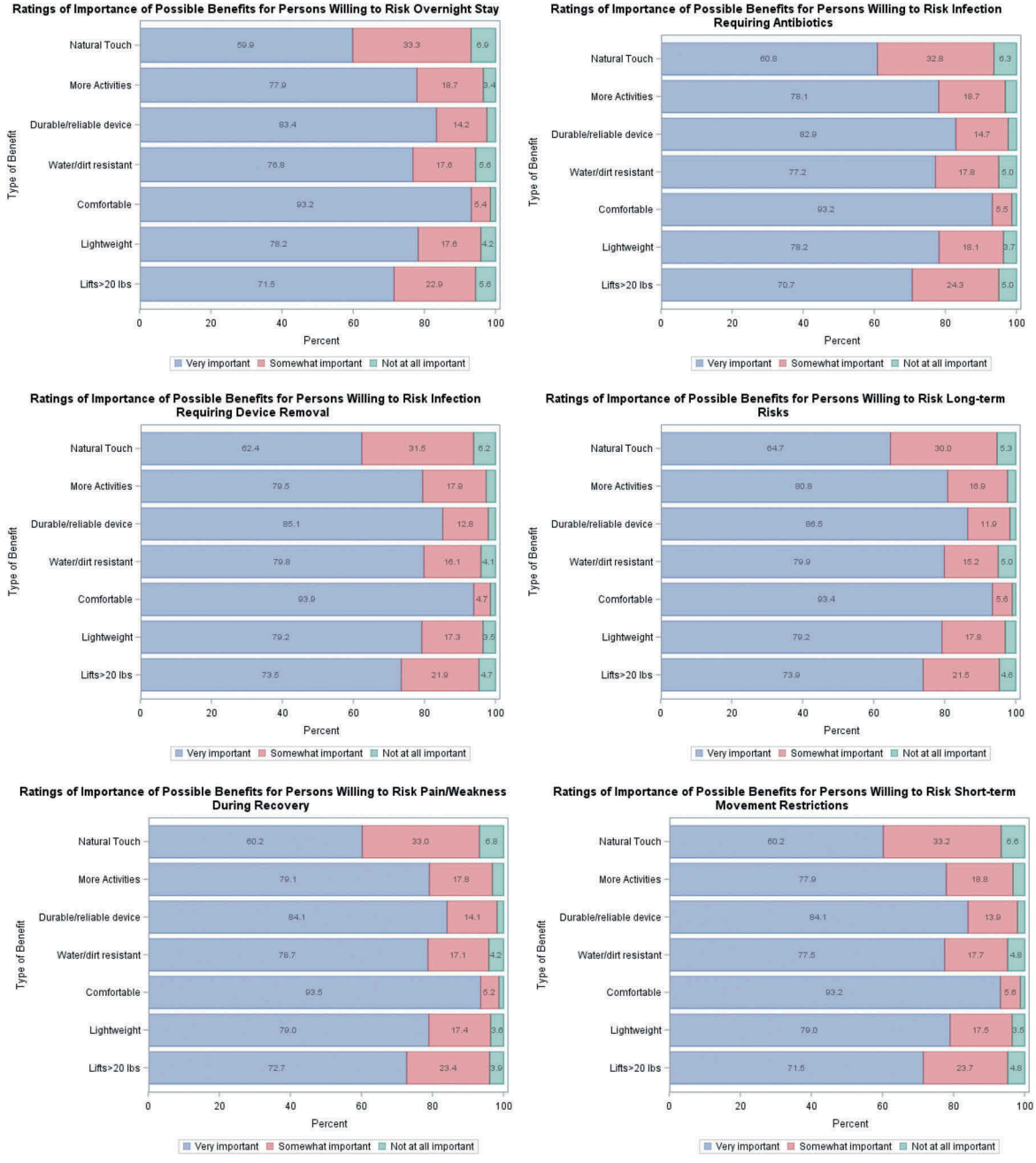

Figure 1A. Benefit factor ratings for those who would consider surgery to have a prosthesis that could restore a sense of touch (yes/maybe): unilateral and bilateral amputees.

*significant at $p < 0.05$

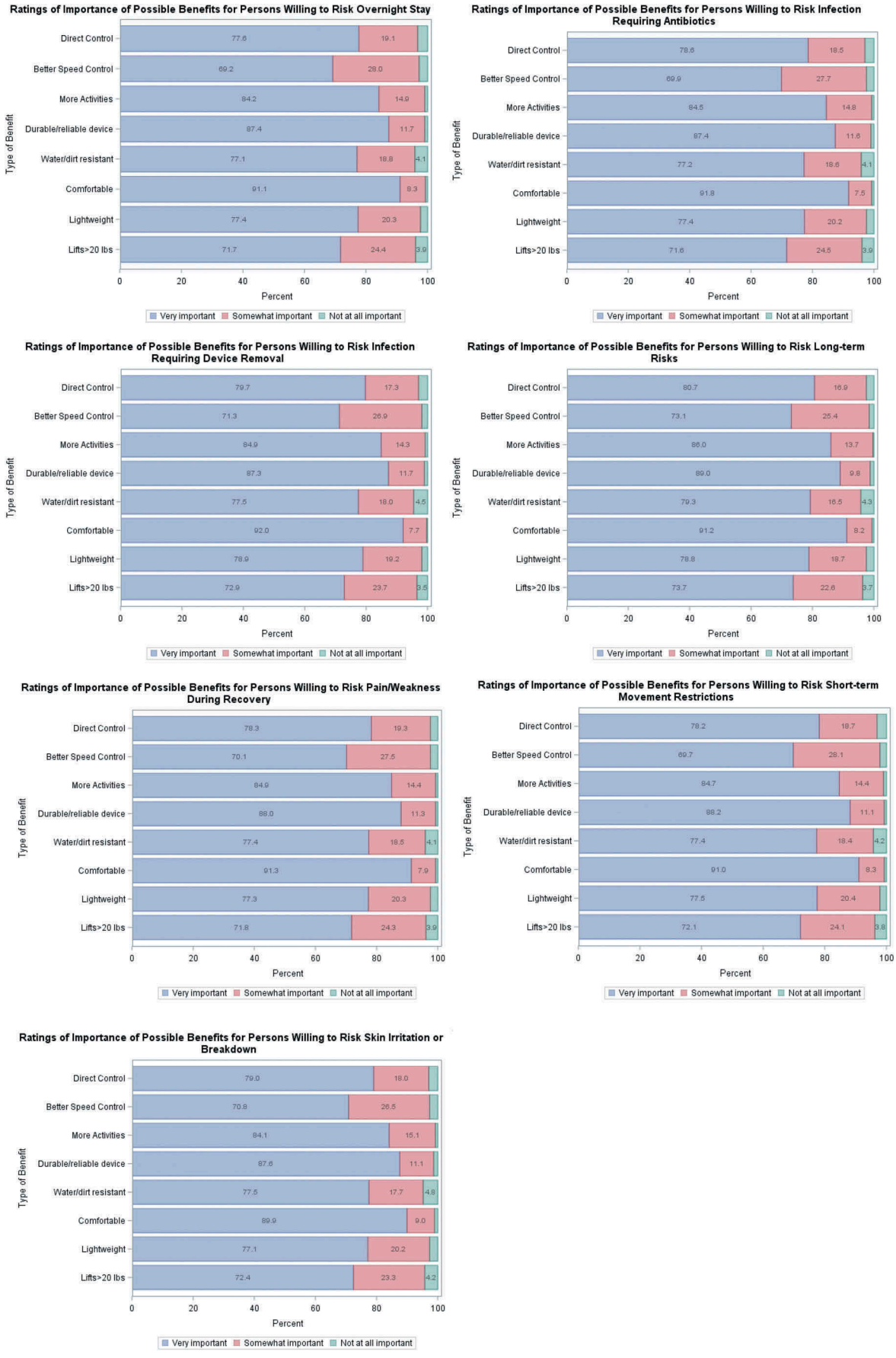

Figure 2A. Benefit factor ratings for those who would consider surgery to have a prosthesis that gives more control over finger movements, grasps or wrist motions (yes/maybe): unilateral and bilateral amputee.

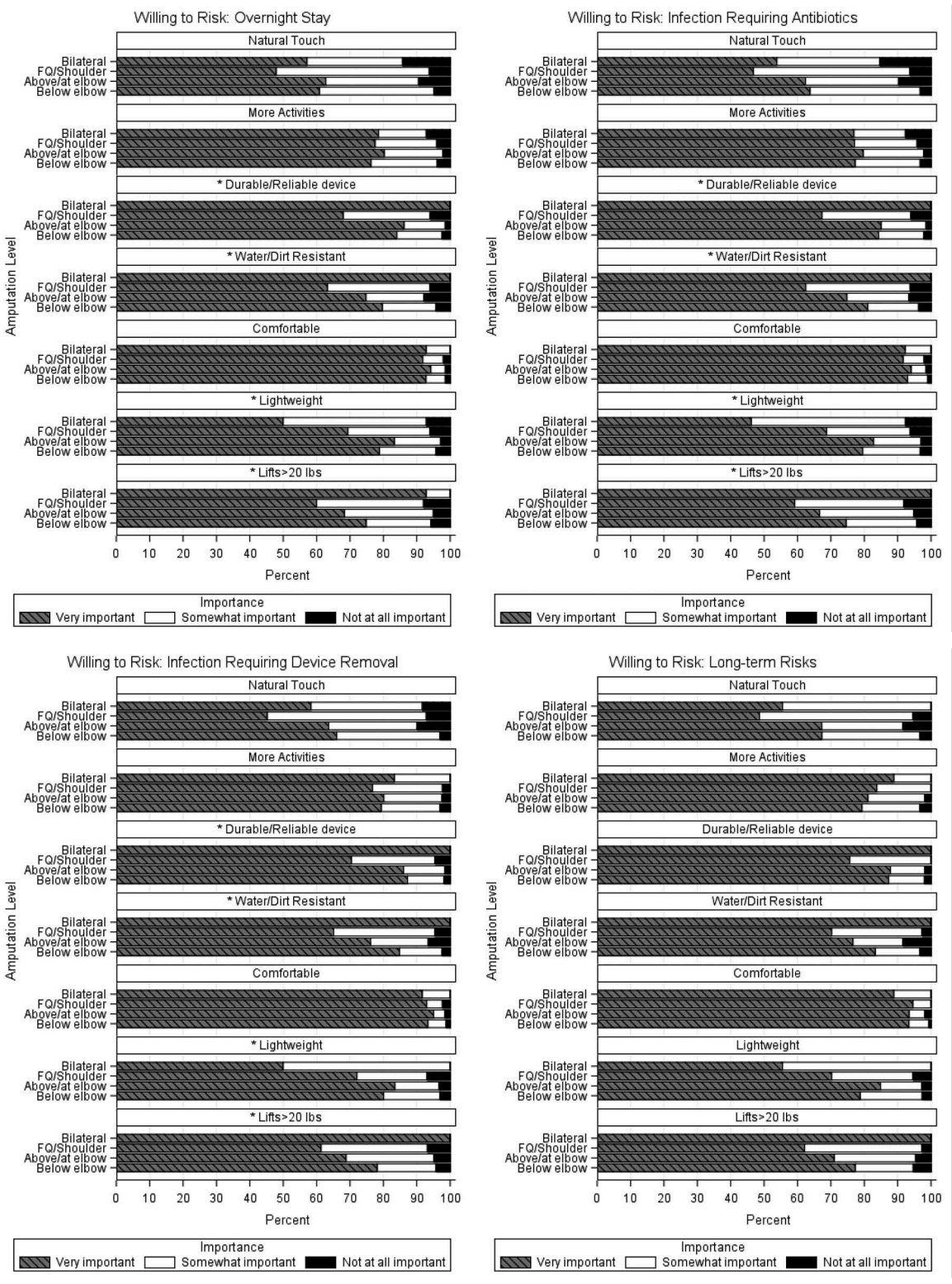

Figure 3A. Sub-group comparisons of importance of factors for those who were willing to undertake specific risks (yes/maybe) in order to obtain a prosthesis that could restore a sense of touch by amputation level.

*significant at $p < 0.05$

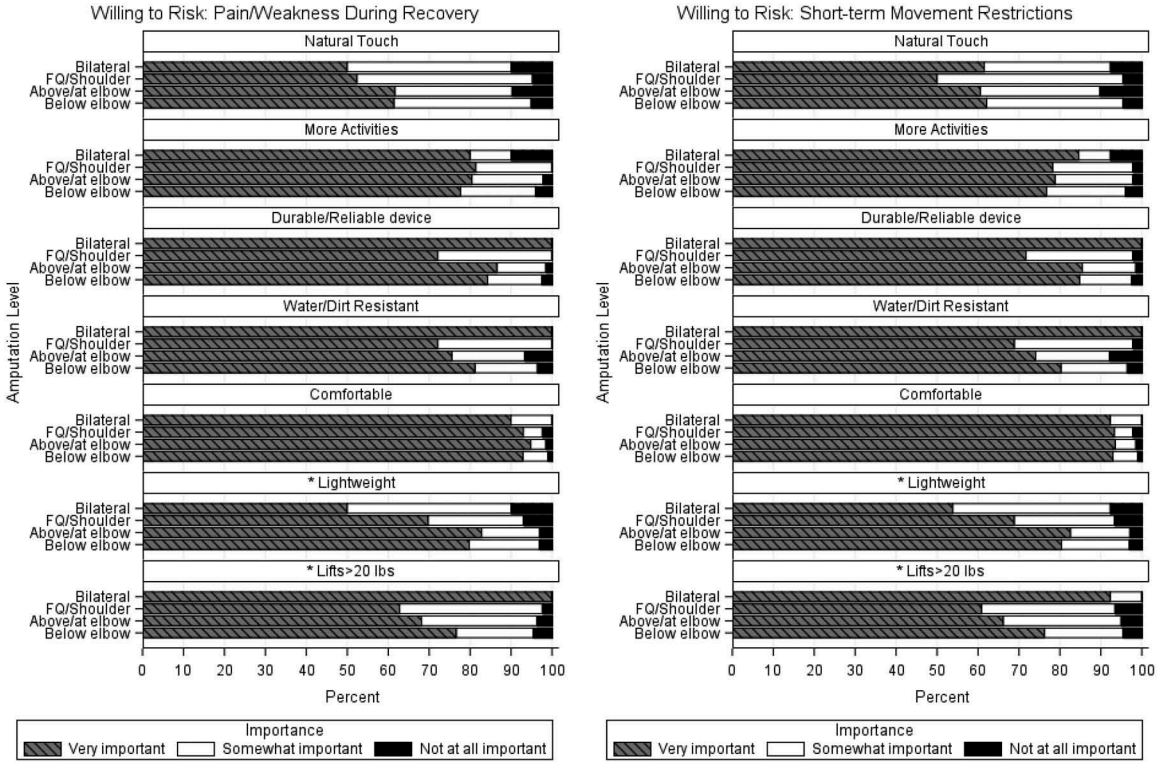

Figure 3A. (Continued).

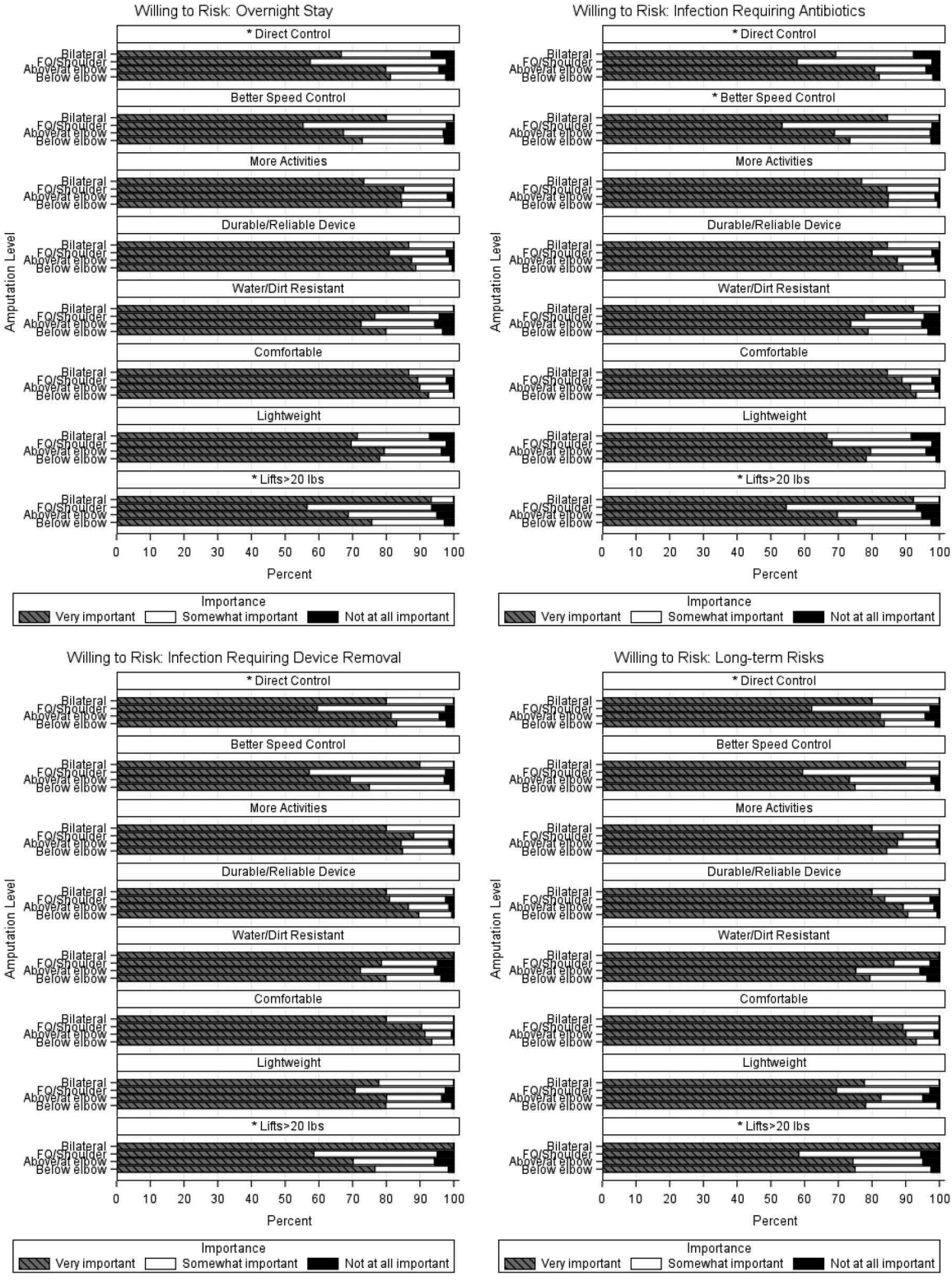

Figure 4A. Sub-group comparisons of importance of factors for those who were willing to undertake specific risks (yes/maybe) in order to obtain a prosthesis that could restore better movement control by amputation level.

*significant at $p < 0.05$

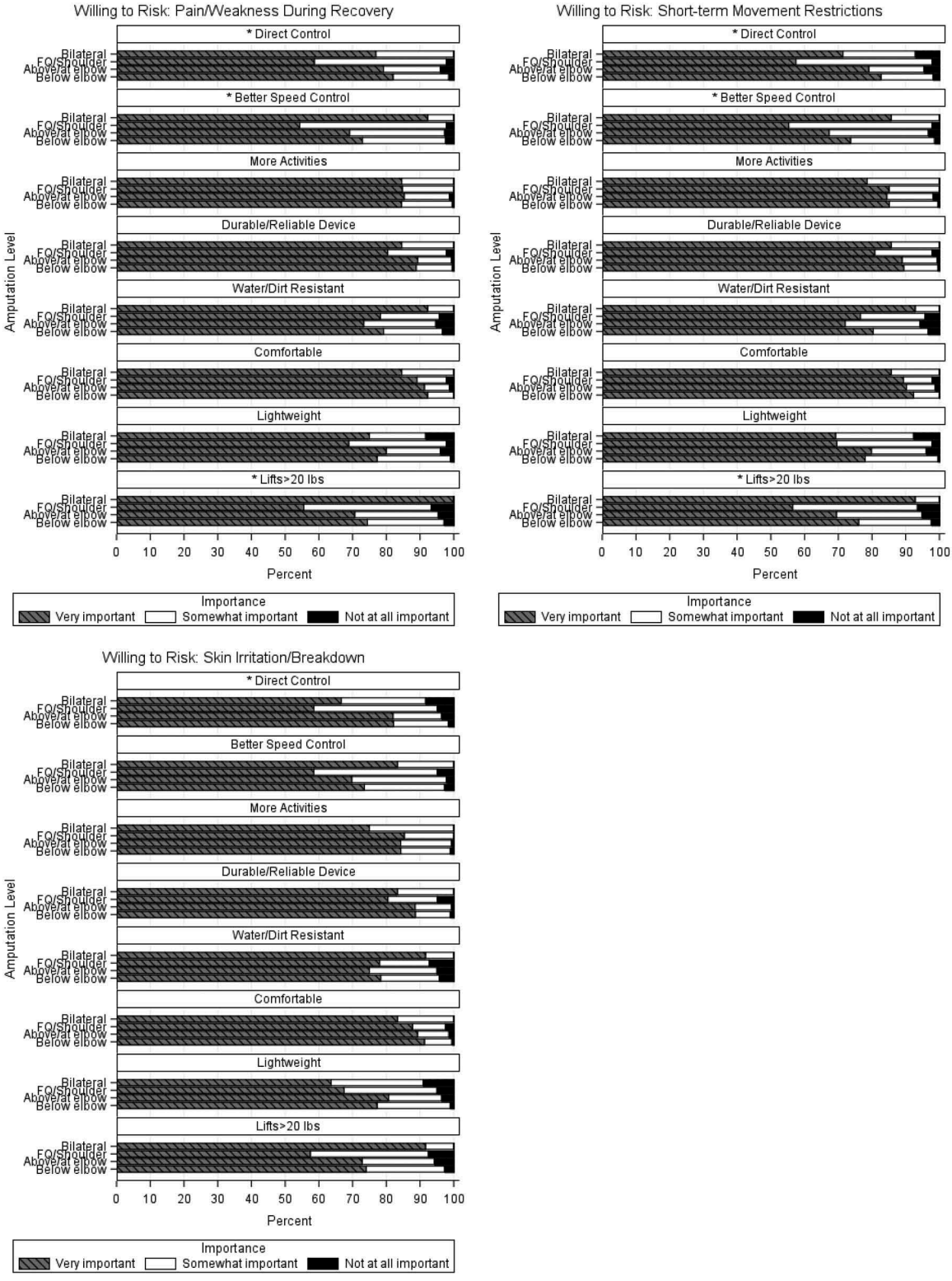

Figure 4A. (Continued).

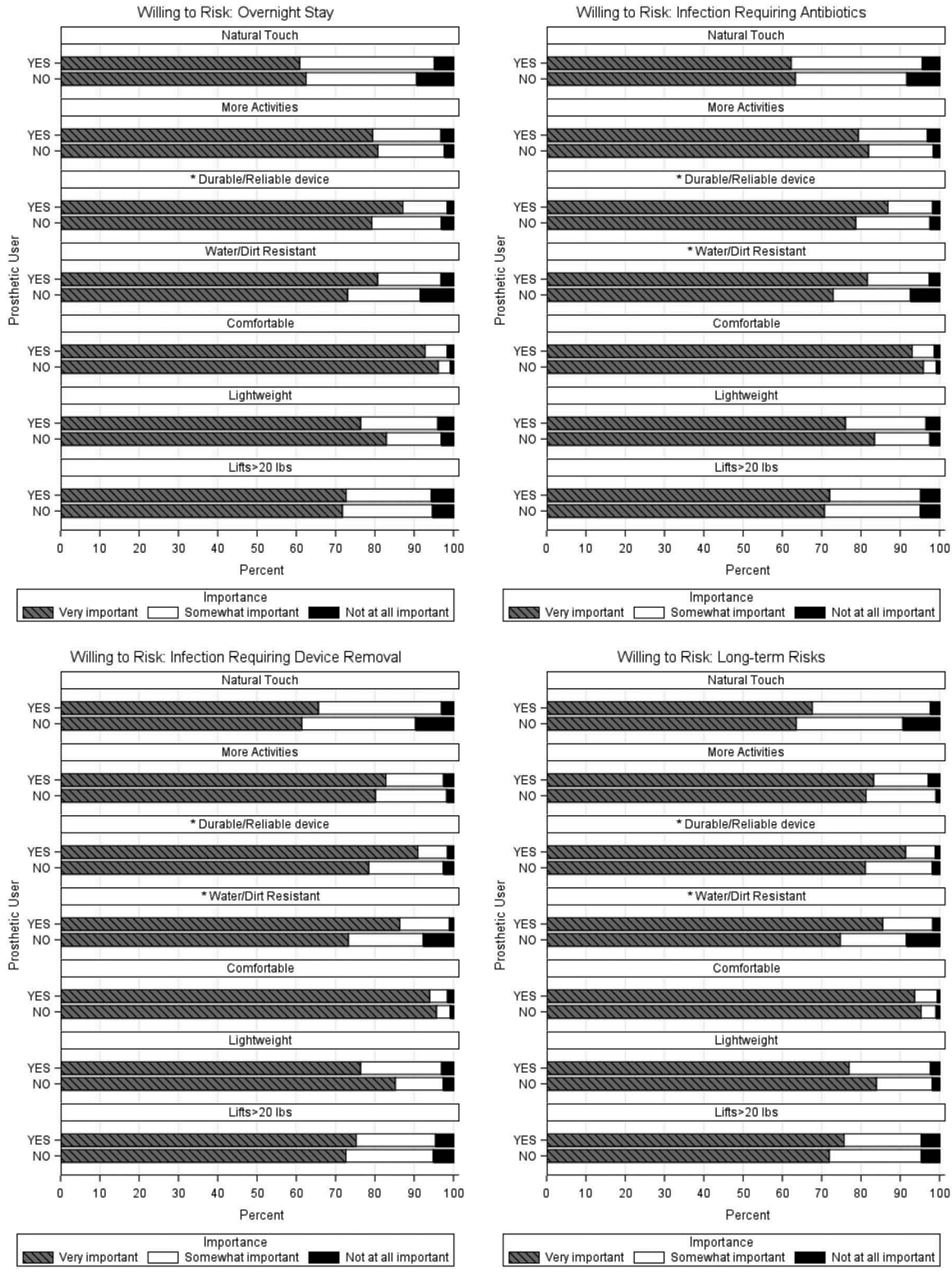

Figure 5A. Sub-group comparisons of importance of factors for those who were willing to undertake specific risks a (yes/maybe) in order to obtain a prosthesis that could restore a sense of touch by amputation level.

*significant at $p < 0.05$

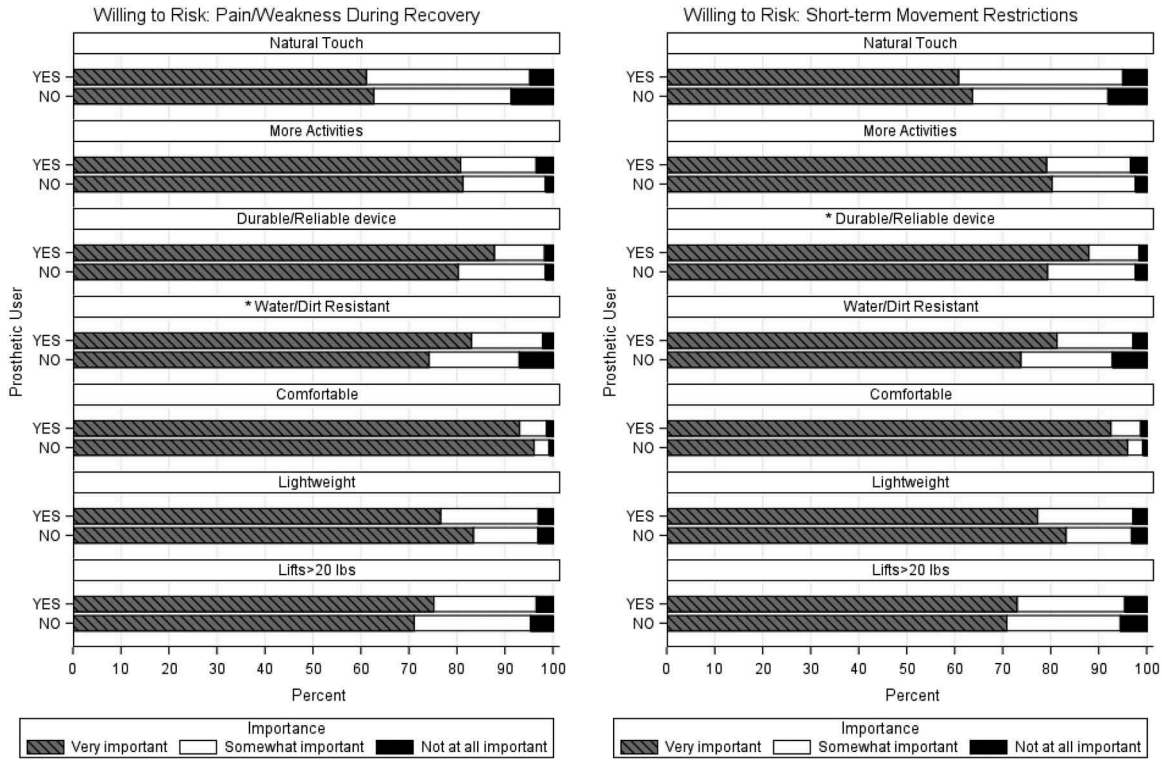

Figure 5A. (Continued).

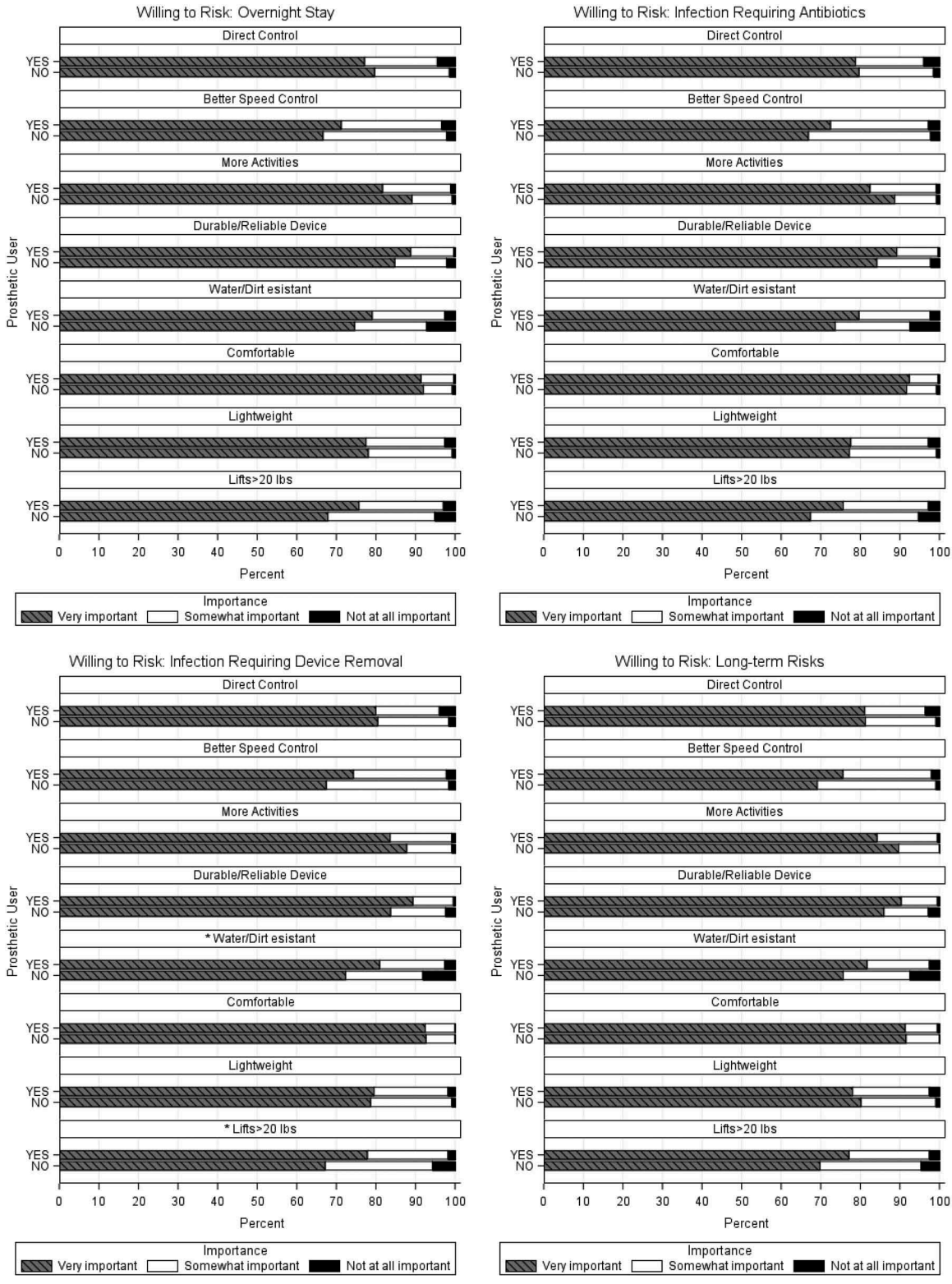

Figure 6A. Sub-group comparisons of importance of factors for those who were willing to undertake specific risks a (yes/maybe) in order to obtain a prosthesis that could restore better movement control by amputation level.

*significant at $p < 0.05$

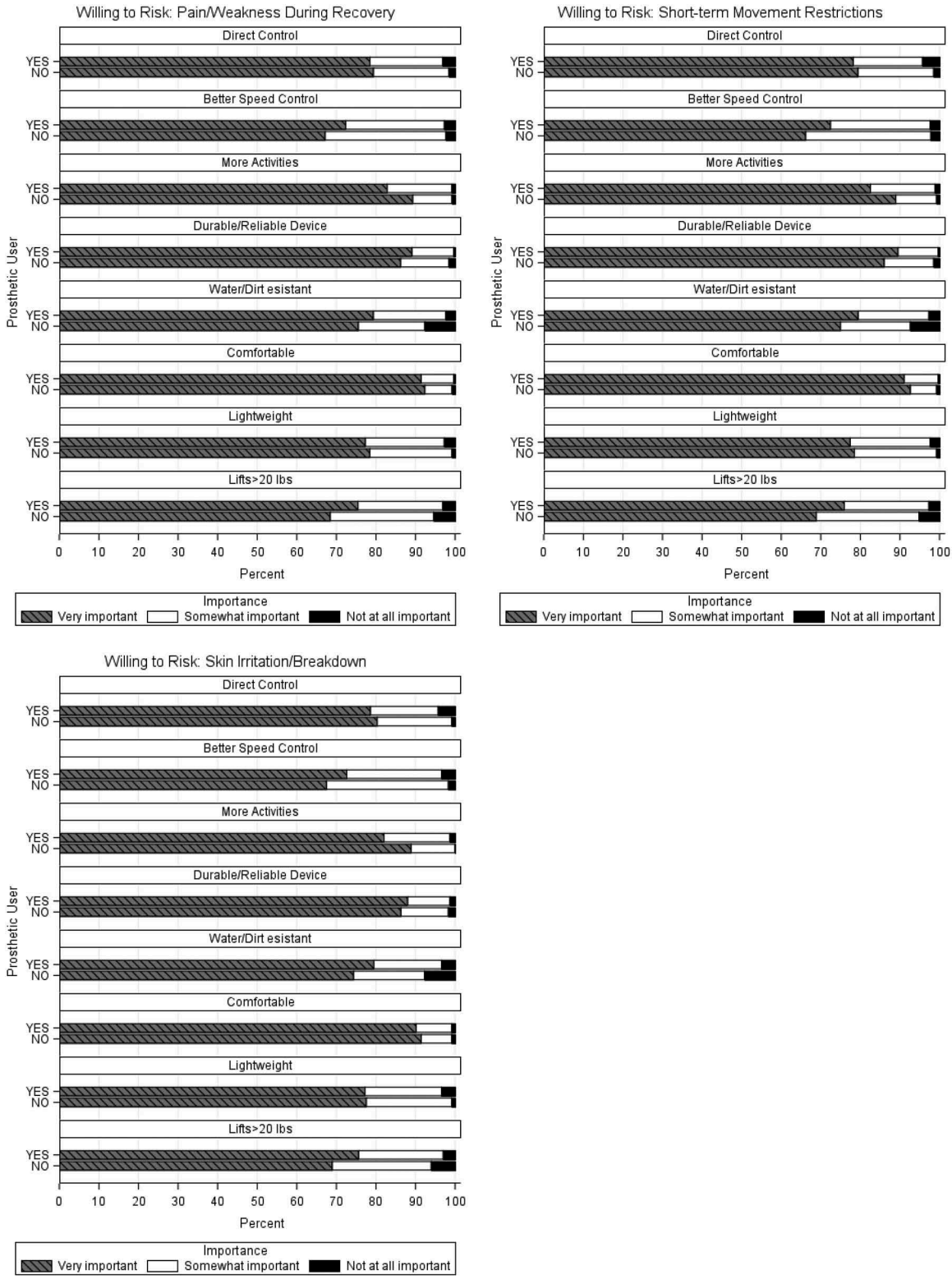

Figure 6A. (Continued).

PM R xx (2019) 1-11

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Original Research

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

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

Abstract

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

Introduction

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

https://dx.doi.org/10.1002/pmrj.12147

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

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

Methods

Patient Perspective Survey Development and Pilot Testing

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

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

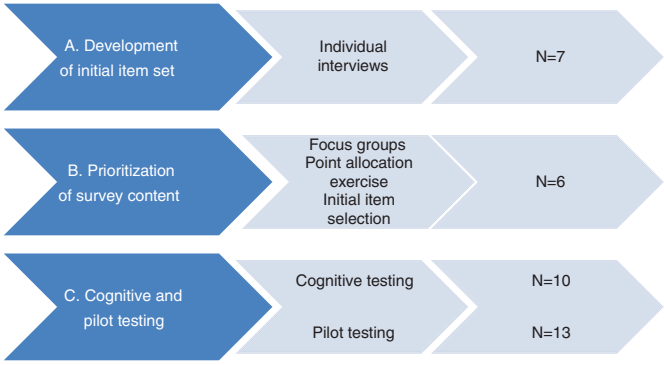

Figure 1. Stages of benefit–risk survey development.

Recruitment

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

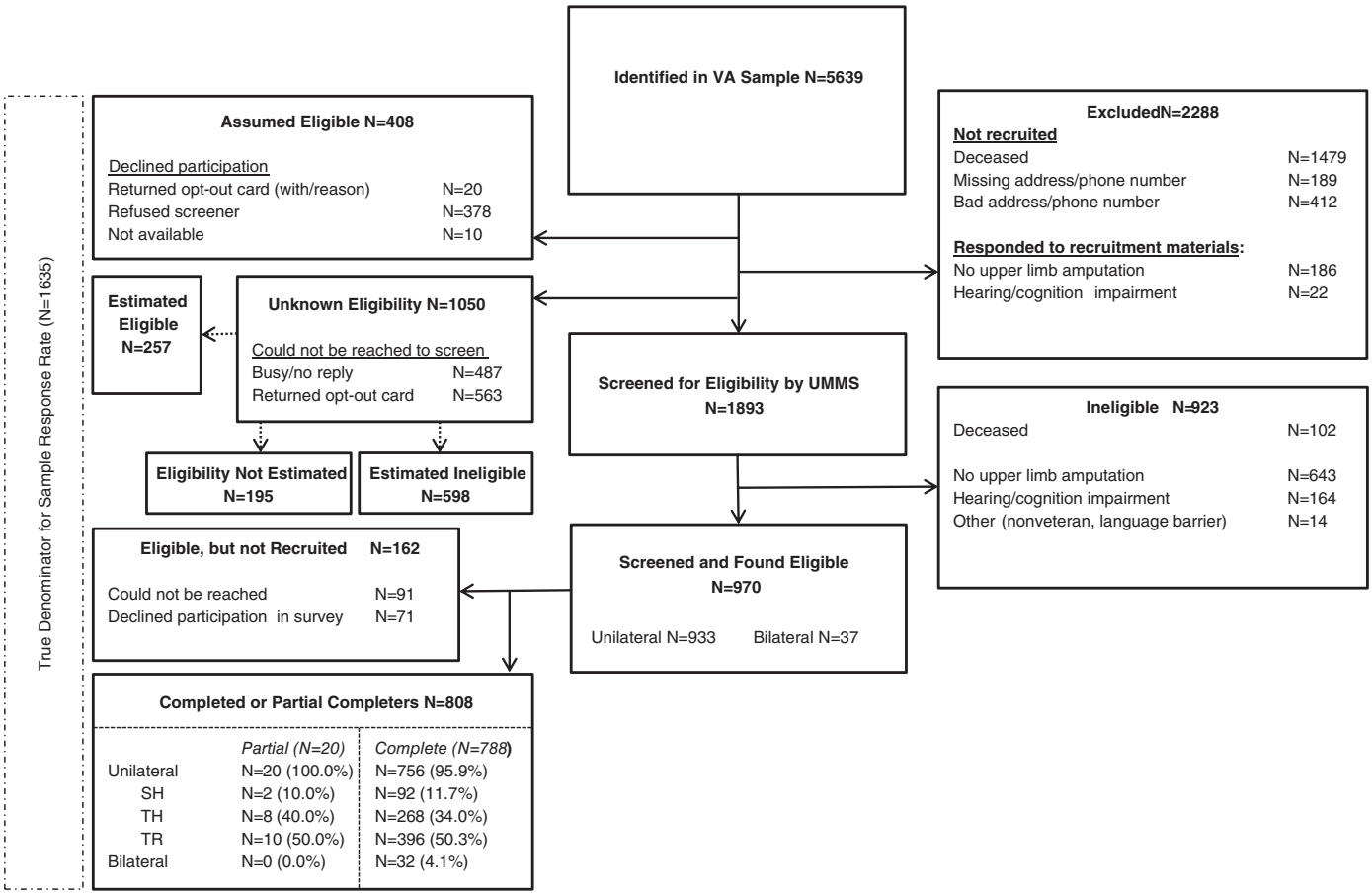

Figure 2. Flow diagram.

Data Collection

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

Data Analyses

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

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

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

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

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

Results

Sampling Frame and Response Rate

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

Demographic, Amputation-Related, and Prosthetic Use Characteristics

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

Willingness to Undergo Surgery

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

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

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

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

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

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

Table 1
Characteristics of unilateral and bilateral amputee respondents

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

Table 2
Proportion of participants willing to consider osseointegration

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

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

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

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

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

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

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

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

Table 4
Multivariable logistic regressions predicting willingness to consider osseointegration

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

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

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

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

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

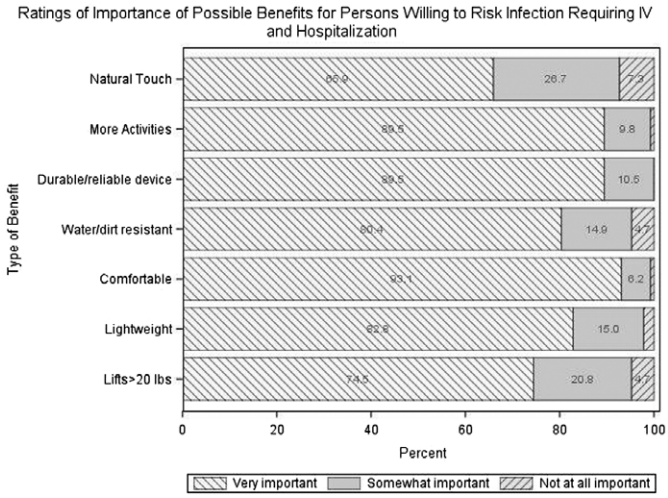

Figure 3. Benefit factor ratings for those who would consider osseointegration surgery (yes/maybe): Example figure using those willing to risk infection requiring IV antibiotics and hospitalization).

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

Discussion

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

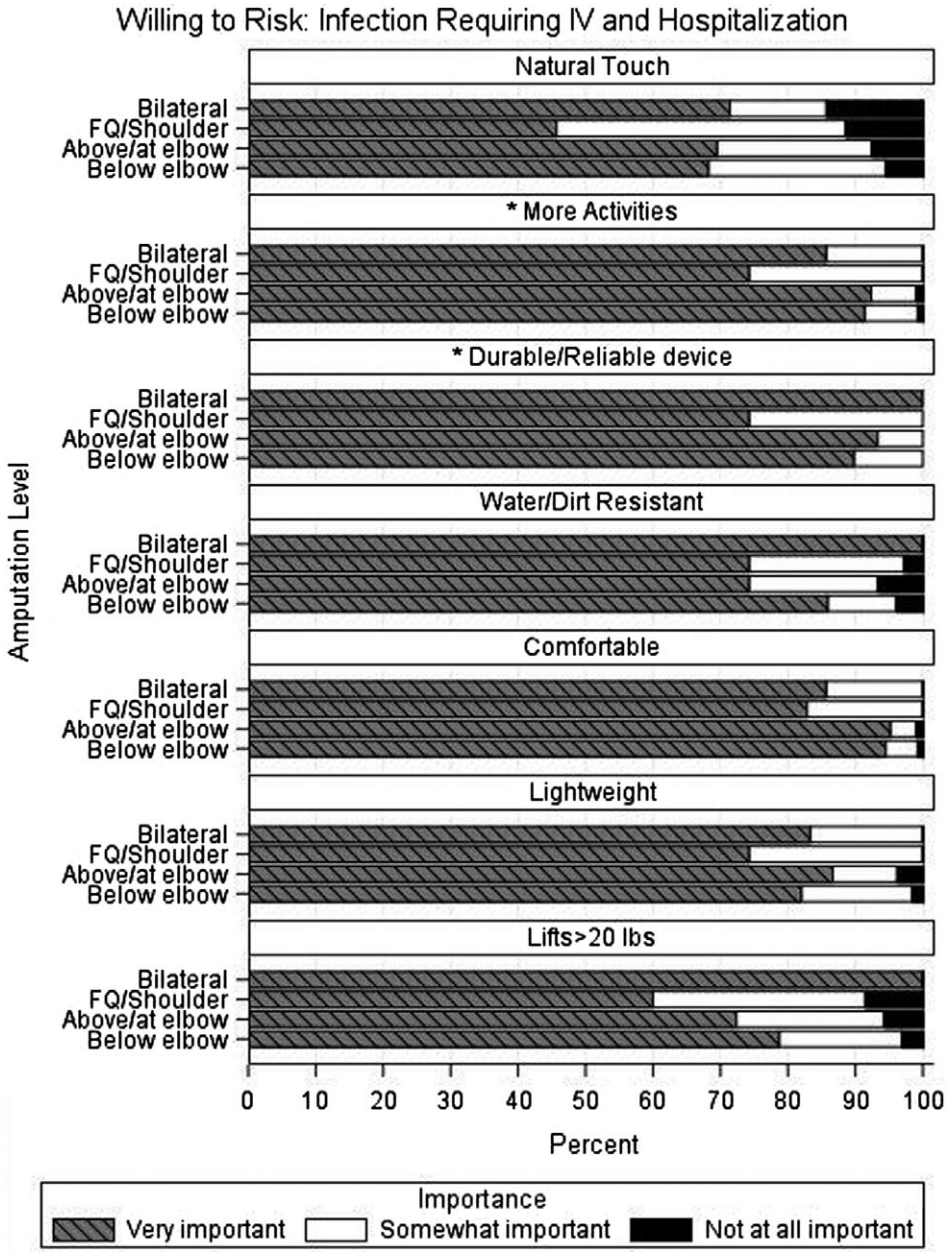

Figure 4. Subgroup comparisons of importance of factors for those who were willing to risks infection requiring antibiotics in order to obtain an osseointegrated prosthesis by amputation level.
*significant at $P < .05$
FQ=Forequarter

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

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

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

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

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

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

Limitations

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

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

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

Conclusions

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

Acknowledgments

This work was supported by the Office of the Assistant Secretary of Defense for Health Affairs, through the Orthotics and Prosthetics Outcomes Research Program Prosthetics Outcomes Research Award under Award No. W81XWH-16-0794 and through VA RR&D A9265-S. Opinions, interpretations, conclusions, and recommendations are those of the author and not necessarily endorsed by the Department of Veterans Affairs or the Department of Defense.

Supporting Information

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

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Disclosure

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Disclosure: none

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Disclosure: none

Funding Sources: U.S Army Medical Research Acquisition Activity W81XWH-16-2-0065
VA RR&D A9264-S

Submitted for publication December 5, 2018; accepted February 12, 2019.